ACHILLION PHARMACEUTICALS INC
Form 10-Q
May 04, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ 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 x

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

As of May 1, 2011, the registrant had 58,412,552 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Achillion Pharmaceuticals, Inc.

Balance Sheets

(in thousands, except per share amounts)

(Unaudited)

	March 31, 2011	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 28,721	$ 25,373
Marketable securities	17,691	29,827
Accounts receivable	93	246
Prepaid expenses and other current assets	2,741	2,052
Total current assets	49,246	57,498
Fixed assets, net	406	468
Deferred financing costs	138	117
Restricted cash	152	152
Total assets	$ 49,942	$ 58,235
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 3,895	$ 2,672
Accrued expenses	2,460	2,061
Current portion of long-term debt		469
Total current liabilities	6,355	5,202
Deferred revenue	2,489	2,489
Total liabilities	8,844	7,691
Commitments and contingencies		
Stockholders Equity:		
Common Stock, $.001 par value; 100,000 shares authorized: 58,400 and 58,376 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	58	58
Additional paid-in capital	282,567	281,878
Accumulated deficit	(241,527)	(231,394)
Accumulated other comprehensive income		2
Total stockholders equity	41,098	50,544
Total liabilities and stockholders equity	$ 49,942	$ 58,235

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

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Achillion Pharmaceuticals, Inc.

Statements of Operations

(in thousands, except per share amounts)

(Unaudited)

	For the Three Months Ended March 31,	
	2011	**2010**
Revenue	$ 65	$ 74
Operating expenses		
Research and development	7,993	3,960
General and administrative	2,223	1,667
Total operating expenses	10,216	5,627
Loss from operations	(10,151)	(5,553)
Other income (expense)		
Interest income	40	10
Interest expense	(22)	(94)
Net loss	(10,133)	(5,637)
Basic and diluted net loss per share (Note 4)	$ (0.17)	$ (0.16)
Weighted average shares used in computing basic and diluted net loss per share	58,389	35,576

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

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Achillion Pharmaceuticals, Inc.

Statements of Cash Flows

(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (10,133)	$ (5,637)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74	194
Noncash stock-based compensation	648	471
Noncash interest expense	9	13
Loss on disposal of equipment		4
Amortization of premium on marketable securities	110	32
Changes in operating assets and liabilities:		
Accounts receivable	153	(18)
Prepaid expenses and other assets	(707)	(204)
Accounts payable	1,223	(275)
Accrued expenses	399	(1,273)
Net cash used in operating activities	(8,224)	(6,693)
Cash flows from investing activities		
Purchases of fixed assets	(5)	(18)
Purchases of marketable securities	(10,220)	(5,665)
Maturities of marketable securities	22,244	
Net cash provided by (used in) by investing activities	12,019	(5,683)
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs		22,628
Proceeds from exercise of stock options	41	
Payment of deferred financing costs	(10)	
Repayments of debt	(478)	(567)
Net cash (used in) provided by financing activities	(447)	22,061
Net increase in cash and cash equivalents	3,348	9,685
Cash and cash equivalents, beginning of period	25,373	9,712
Cash and cash equivalents, end of period	$ 28,721	$ 19,397
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 11	$ 76

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

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

(Unaudited)

1. Nature of the Business

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

The Company incurred losses of $227,665 from inception through March 31, 2011 and had an accumulated deficit of $241,527 at March 31, 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 March 31, 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 protease inhibitors, ACH-1625 and ACH-2684, and our NS5A inhibitors, ACH-2928 and related compounds;
- the Company s ability to enter into corporate collaborations for its HCV candidates and the terms and success of these collaborations;
- any partnership opportunities that may arise for elvucitabine, ACH-702 or ACH-2881 that the Company determines to pursue; and
- 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.

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.

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.

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4. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common 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 months ended March 31, 2011 and 2010:

	Three Months Ended March 31,	
	2011	2010
Options	5,848	3,340
Warrants	9,664	2,785
Total potentially dilutive securities outstanding	15,512	6,125

5. 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 back-up activities, which includes 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 unless Gilead chooses not to opt back in on ACH-1095 development. 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 Series C-1. 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 months ended March 31, 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 March 31, 2011 and 2010, the Company recognized revenue of $65 and $74, 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 March 31, 2011 and December 31, 2010 are $65 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.

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GCA Therapeutics, Ltd.

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

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine. There was no financial impact upon the signing of the agreement. The Company will be eligible to receive development milestones and royalties on net sales in those territories.

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

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

6. Marketable Securities

The Company applies the provisions of 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 statement 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 $17,691 and $29,827 as of March 31, 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 March 31, 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.

The unrealized gain (loss) from marketable securities was $0 and $2 at March 31, 2011 and December 31, 2010, respectively.

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

7. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2011	December 31, 2010
Accrued compensation	$ 831	$ 978
Accrued research and development expenses	1,008	676
Accrued professional fees	401	317

Other accrued expenses	220	90
Total	$ 2,460	$ 2,061

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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.

8. Debt

Debt consists of the following:

	March 31, 2011	December 31, 2010
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		469
Less: current portion		(469)
Total long-term debt, net of current portion	$	$

In March 2011, the Company entered into a Master Security Agreement for a $2,000 Capital Expenditure Line of Credit, (the 2011 Credit Facility) with Webster Bank. Under the 2011 Credit Facility, the Company may take equipment loan advances for the purchase of new laboratory equipment through March 2012. As of March 31, 2011, there were no advances under the 2011 Credit Facility.

9. 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 1,157 shares available to be granted under the 2006 Plan as of March 31, 2011.

A summary of the status of the Company s stock option activity for the three months ended March 31, 2011 is presented in the table and narrative below:

	Options	Weighted Average Exercise Price
Outstanding at January 1, 2011	5,860	$ 3.67
Granted	18	5.93
Exercised	(25)	1.67
Cancelled/Forfeited	(5)	1.53
Outstanding at March 31, 2011	5,848	$ 3.68
Options exercisable at March 31, 2011	2,479	$ 4.66
Weighted-average fair value of options granted during the period		$ 4.38

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 Three Months Ended	
	March 31, 2011	**March 31, 2010**
Expected term of option	5.0 - 6.1 years	6.1 years
Expected volatility	87%	86%
Risk free interest rate	2.57%	2.92%
Expected dividend yield	0%	0%

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Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $597 and $458 for the three months ended March 31, 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 March 31, 2011, the intrinsic value of the options outstanding was $22,956, of which $8,860 related to vested options and $14,096 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 March 31, 2011, the total compensation cost related to unvested options not yet recognized in the financial statements is approximately $6,149, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.77 years.

10. Standby Equity Distribution Agreement

On July 1, 2009, the Company entered into a SEDA with YA Global pursuant to which the Company may, at its sole and exclusive option, periodically sell to YA Global shares of its common stock, $0.001 par value per share for total proceeds of up to $15,000. Each advance under the SEDA shall not exceed the greater of $300 or the average daily trading volume of the Company s common stock for the five consecutive trading days prior to the notice date. Advance notices may be given to YA Global once every five trading days. For each share of common stock purchased pursuant to an advance under the SEDA, YA Global will pay to the Company ninety-five percent of the lowest volume-weighted average price of the common stock on the NASDAQ Global Market during the five consecutive trading days following delivery by the Company of an advance notice. Additionally, in no event shall the number of shares of common stock issued under the SEDA cause YA Global to own more than 9.99% of the Company s common stock as of July 1, 2009 (5,292,427 shares), unless the Company obtains stockholder approval or obtains a written opinion from counsel that such approval is not required. The Company is not obligated to utilize any of the $15,000 available under the SEDA and there are no minimum commitments or minimum use penalties. The Company issued YA Global 191 shares of its common stock as a commitment fee in connection with the transaction and also paid a due diligence and structuring fee of $25. These shares of common stock, as well as any additional shares of common stock the Company may issue pursuant to the SEDA in the future, have been registered on a registration statement that was declared effective on September 21, 2009. The SEDA has two year term and may be terminated by the Company at any time. The Company capitalized $98 of issuance costs related to the SEDA. As of March 31, 2011, there were no advances under the SEDA.

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.

Details relating to unrealized gains and losses and other comprehensive loss are as follows:

	For the Three Months Ended March 31,	
	2011	**2010**
Net loss	$ (10,133)	$ (5,637)
Change in unrealized loss on marketable securities	(2)	(7)
Total comprehensive loss	$ (10,135)	$ (5,644)

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12. Stockholders Equity

Changes in stockholders equity for the three months ended March 31, 2011 and 2010 were as follows:

	For the Three Months Ended March 31,	
	2011	2010
Balance at December 31, 2010 and 2009	$ 50,544	$ 1,022
Net loss	(10,133)	(5,637)
Stock based compensation	648	471
Exercise of stock options	41	
Change in unrealized loss on marketable securities	(2)	(7)
Issuance of common stock		22,628
Balance at March 31, 2011 and 2010	$ 41,098	$ 18,477

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

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we believe, expect, anticipate, plan, target, intend and similar expressions should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed in this section and elsewhere in this quarterly report on Form 10-Q, including those discussed in 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 three HCV drug candidates for the treatment of chronic hepatitis C: ACH-1625, a protease inhibitor for the treatment of chronic hepatitis C, currently being tested in an on-going phase IIa clinical trial, ACH-2684, a pangenotypic protease inhibitor for which we have recently filed an investigational new drug, or IND, application, and ACH-2928, a NS5A inhibitor for which we have recently filed an IND application. 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 $228 million from inception through March 31, 2011 and had an accumulated deficit of $242 million at March 31, 2011, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $10.1 million and $5.6 million for the three months ended March 31, 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 a public offering of our common stock in January 2010;
- 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 underwriter s 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.

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;

initiate clinical testing of ACH-2684 and ACH-2928; and

identify and progress additional drug candidates.

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

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

Financial Operations Overview

Revenue

To date, we have not generated revenue from the sale of any drugs. The majority of our revenue recognized to date has been derived from our collaboration with Gilead to develop compounds for use in treating chronic hepatitis C. During the three months ended March 31, 2011 and 2010, we recognized $65,000 and $74,000, 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 being 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 three months ended March 31, 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 Hepatitis C Infection. We are evaluating ACH-1625, a protease inhibitor for the treatment of chronic hepatitis C, in a phase IIa clinical trial to assess the compound s safety, tolerability, pharmacokinetic properties and efficacy in HCV-infected subjects. We are currently conducting a phase IIa clinical trial in both the United States and Europe. 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 600mg once daily. Preliminary results from the first 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 (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 segment of this phase IIa trial is on-going.

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ACH-2684, a High-Potency Protease Inhibitor for Chronic Hepatitis C Infection. We are evaluating 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 the hepatitis C virus, 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. ACH-2684 can be used in combination with other HCV inhibitors, and *in vitro* is synergistic with NS5B nucleoside polymerase inhibitors. We have completed IND-enabling preclinical testing for ACH-2684 and filed an IND in March 2011.

ACH-2928, a NS5A Inhibitor for Chronic Hepatitis C 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. In early preclinical studies, ACH-2928 demonstrated excellent potency against HCV RNA replication, as well as good pharmacokinetic and safety profiles. The compound is highly active and is potent against HCV genotypes 1a and 1b, as well as across other genotypes. We believe its high potency, in the picomolar range, and its 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 completed IND-enabling preclinical testing for ACH-2928 and filed an IND in April 2011.

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.

	Three Months Ended March 31,	
	2011	2010
	(in thousands)	
Clinical candidate direct external costs:		
ACH-1625 (and related compounds)	$ 3,412	$ 1,131
ACH-2684 (and related compounds)	642	120
ACH-2928 (and related compounds)	990	
ACH-1095 (and related compounds)	1	36
ACH-702, ACH-2881 (and related compounds)	36	11
Elvucitabine	19	
	5,100	1,298
Direct internal personnel costs	1,894	1,689
Sub-total direct costs	6,994	2,987
Indirect costs and overhead	1,032	1,003
Research and development tax credit	(33)	(30)
Total research and development	$ 7,993	$ 3,960

We are currently conducting a phase IIa clinical trial of ACH-1625, and are initiating phase I clinical studies 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

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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.

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 three 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 Months Ended March 31, 2011 and 2010

Revenue. Revenue recognized during the three months ended March 31, 2011 and 2010 consists of amounts billed by us to Gilead for shared external costs under our collaboration arrangement.

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 months ended March 31, 2011 and 2010 is comprised as follows:

	Three Months Ended March 31,		
	2011	2010	Change
	(in thousands)		
Gilead collaboration revenue	$ 65	$ 74	(9)
Total revenue	$ 65	$ 74	(9)

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.

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Research and Development Expenses. Research and development expenses were $8.0 million and $4.0 million for the three months ended March 31, 2011 and 2010, respectively. The increase for the three months ended March 31, 2011 was primarily due to increased expenses related to clinical testing of ACH-1625, combined with increased preclinical costs for ACH-2684 and ACH-2928. We expect that research and development expenses during the remainder of the year will remain consistent with the first quarter of 2011, as we continue clinical testing of ACH-1625 and initiate clinical testing of ACH-2684 and ACH-2928. Research and development expenses for the three months ended March 31, 2011 and 2010 are comprised as follows:

	Three Months Ended March 31,		
	2011	2010	Change
	(in thousands)		
Personnel costs	$ 1,628	$ 1,502	$ 126
Stock based compensation	266	190	76
Outsourced research and supplies	4,941	1,295	3,646
Professional and consulting fees	653	370	283
Facilities costs	473	600	(127)
Travel and other costs	65	33	32
Research and development tax credit	(33)	(30)	(3)
Total	$ 7,993	$ 3,960	$ 4,033

General and Administrative Expenses. General and administrative expenses were $2.2 million and $1.7 million for the three months ended March 31, 2011 and 2010, respectively. The increase for the three months ended March 31, 2011 was primarily due to an increase in business development consulting fees, Board of Directors compensation and non-cash charges related to stock based compensation. We expect that general and administrative expenses will be consistent for the remainder of the year. General and administrative expenses for the three months ended March 31, 2011 and 2010 are comprised as follows:

	Three Months Ended March 31,		
	2011	2010	Change
	(in thousands)		
Personnel costs	$ 765	$ 644	$ 121
Stock based compensation	382	281	101
Professional and consulting fees	567	297	270
Facilities costs	234	238	(4)
Travel and other costs	275	207	68
Total	$ 2,223	$ 1,667	$ 556

Other Income (Expense). Interest income was $40,000 and $10,000 for three months ended March 31, 2011 and 2010, respectively. The decrease was primarily due to increased average cash balances. Interest expense was $22,000 and $94,000 for the three months ended March 31, 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 March 31, 2011, we have received approximately $267.0 million in aggregate net proceeds from stock issuances, including convertible preferred stock, our initial public offering, our 2008 and 2010 private placements and our 2010 public offering, $19.3 million from Gilead under our collaboration agreement and approximately $22.1 million under debt facilities. As of March 31, 2011, there were no outstanding debt balances.

We had $46.4 million and $55.2 million in cash, cash equivalents and marketable securities as of March 31, 2011 and December 31, 2010, respectively. We regularly review our investments and monitor the financial markets. As of March 31, 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.

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Cash used in operating activities was $8.2 million for the three months ended March 31, 2011 and was primarily attributable to our $10.1 million net loss and increase in prepaid expenses, offset primarily by non-cash stock-based compensation, combined with increases in accounts payable and accrued expenses. Cash used in operating activities was $6.7 million for the three months ended March 31, 2010 and was primarily attributable to our $5.6 million net loss and decreases in accounts payable and accrued expenses, offset primarily by non-cash charges related to depreciation, amortization and non-cash stock-based compensation.

Cash provided by investing activities was $12.0 million for the three months ended March 31, 2011 and was primarily attributable to the maturities of marketable securities, offset by purchases of marketable securities. Cash used in investing activities was $5.7 million for the three months ended March 31, 2010 and was primarily attributable to the purchase of marketable securities.

Cash used in financing activities was $0.5 million for the three months ended March 31, 2011 and was primarily attributable to repayments of debt. Cash provided by financing activities was $22.1 million for the three months ended March 31, 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;
- initiate clinical testing of ACH-2684 and ACH-2928; and
- identify and progress additional drug candidates.

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

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements through at least March 31, 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 and market developments currently unknown to us.

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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.

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 March 31, 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 March 31, 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.

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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 March 31, 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 hepatitis C 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. We filed IND applications for ACH-2684 and ACH-2928 in March 2011 and April 2011, respectively, and are preparing to initiate clinical testing of both of these compounds. 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 March 31, 2011, our accumulated deficit was approximately $242 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.

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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 segments of the pharmaceutical industry that are 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. 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 hepatitis C. 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 hepatitis C, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron) and the ribavirin based products from Merck (Rebetrol), Roche (Copegus) or generic versions sold by various companies. 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. Other products in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors, toll-like receptors and cyclophilin inhibitors are also under development for the treatment of hepatitis C 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. The first of these competing DAAs, telaprevir by Vertex and boceprevir by Merck, are currently being reviewed for approval by the FDA. Each of these compounds were recently unanimously recommended for approval by the FDA s Antiviral Drugs Advisory Committee, and may be approved during 2011, potentially leading to substantive sales in 2012.

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.

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.

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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 one year. 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 and the terms and success of these collaborations;
- the costs involved in obtaining regulatory approvals for our drug candidates;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- our ability to raise incremental debt or equity capital, including any changes in the credit market that may impact our ability to obtain capital in the future;
- our acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to us.

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 your 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 42,306,006 shares of our common stock in two private placements and one public offering 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.

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.

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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. New therapies, including telaprevir and boceprevir are being reviewed by FDA and if approved, 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.

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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;

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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 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 ACH-1625 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, the FDA has required us to establish predetermined stopping rules, as well as a Data Safety Monitoring Board (DSMB) in order to monitor and ensure patient safety. Any interruption of the Phase IIa clinical trial currently underway, whether a result of ACH-1625 or co-administration of the standard of care, 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 an untitled letter or 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

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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 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 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 September 30, 2010, October 16, 2009 and October 30, 2008, making such shares available for immediate resale in the public market.

We also entered into a Standby Equity Distribution Agreement, or SEDA, with YA Global Master SPV Ltd. on July 1, 2009 whereby we have the option, at our sole discretion, to sell up to $15.0 million of common stock to YA Global. The sale of shares of our common stock pursuant to the SEDA will have a dilutive impact on our stockholders and may cause the market price of our common stock to decline. As of March 31, 2011, there were no advances under the SEDA.

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 May 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 72% 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

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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 May 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.

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

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

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

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

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

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

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

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

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.

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If a collaborative partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our drug candidates could be delayed or terminated.

If Gilead, GCAT or another future collaborative partner does not devote sufficient time and resources to collaboration arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. For example, in 2009, Gilead notified us that they did not intend to initiate clinical development of ACH-1095, and we subsequently amended our collaboration so that we may continue to develop ACH-1095, subject to certain rights of Gilead. Had we not come to an agreed upon arrangement, the program may have been terminated, and our business may have been significantly harmed.

In addition, if any existing or future collaboration partner were to breach or terminate its arrangements with us, the development and commercialization of the affected drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on our own. Under our collaboration agreement with Gilead, Gilead may terminate the collaboration for any reason at any time upon 30 days notice. If Gilead were to exercise this right, the development and commercialization of our NS4A compounds for HCV infection would be adversely affected. We recently made the strategic decision not to advance ACH-1095 into clinical trials at this time. Gilead maintains the right to continue the collaboration by advancing certain backup compounds also operating by the NS4A antagonism; however, we and Gilead may not elect to advance any backup compounds under the collaboration.

Much of the potential revenue from our existing and future collaborations will consist of contingent payments, such as payments for achieving development milestones and royalties payable on sales of drugs developed. The milestone and royalty revenues that we may receive under these collaborations will depend upon our collaborator s ability to successfully develop, introduce, market and sell new products. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases we will not be involved in these processes and accordingly will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize products using our products or technologies because they:

- decide not to devote the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or
- cannot obtain the necessary regulatory approvals.

In addition, a collaborator may decide to pursue a competitive drug candidate developed outside of the collaboration. In particular, Gilead is currently developing other products for the treatment of chronic hepatitis C, and the results of its development efforts could affect its commitment to our drug candidates, including Gilead s desire to continue research of NS4A antagonists. If a collaboration partner fails to develop or effectively commercialize drug candidates or drugs for any of these reasons, we may not be able to replace the collaboration partner with another partner to develop and commercialize a drug candidate or drugs under the terms of the collaboration. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a drug candidate.

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.

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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.

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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. The current standard of care for HCV infection includes immunomodulatory therapy with pegylated interferon and ribavirin. No DAAs are currently approved for treatment of chronic HCV infection.

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. Two DAAs developed by our competitors, telaprevir by Vertex and boceprevir by Merck, are currently being reviewed for approval by the FDA. Each of these compounds were recently unanimously recommended by the FDA s Antiviral Drugs Advisory Committee, and may be approved during 2011. We cannot currently predict with any certainty the impact of the potential commercial launch of one or both of these compounds on the HCV market.

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;
- 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

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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.

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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 lags 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 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

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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.

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In addition, under the Bayh-Dole Act, the federal government has certain rights to the technology licensed 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 BMS and Gilead have applications that are broadly directed to HCV inhibitors. Such claims, 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;

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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

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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.

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ITEM 6. EXHIBITS

10.1(1)	Second Amended and Restated Employment Agreement and Supplemental Severance Agreement, dated as of March 9, 2010, and Supplemental Terms of Compensation, dated as of April 5, 2011, entered into by the Company and Milind S. Deshpande, Ph.D.
10.2(1)	Second Amended and restated Employment Agreement and Supplemental Severance Agreement, dated as of March 9, 2010, and Supplemental Terms of Compensation, dated as of April 5, 2011, entered into by the Company and Mary Kay Fenton.
10.3(1)	Employment Agreement entered into by the Company and Michael D. Kishbauch, dated April 5, 2011.
10.4(1)	Employment Agreement entered into by the Company and Elizabeth A. Olek, B.S. Pharm., D.O., M.P.H., dated April 5, 2011.
10.5(1)	Employment Agreement entered into by the Company and Gautam Shah, Ph.D., dated April 5, 2011.
10.6(1)	Employment Agreement entered into by the Company and Joseph Truitt, dated April 5, 2011.
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.

(1) Incorporated herein by reference to our Current Report on Form 8-K filed on April 8, 2011.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHILLION PHARMACEUTICALS, INC.

Date: May 4, 2011

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

Date: May 4, 2011

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

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