

ACHILLION PHARMACEUTICALS INC  
Form 10-Q  
May 15, 2009  
Table of Contents

**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, 2009

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 000-33095

**ACHILLION PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>52-2113479</b> (I.R.S. Employer Identification No.)
<b>300 George Street, New Haven, CT</b> (Address of principal executive offices)	<b>06511</b> (Zip Code)
<b>(203) 624-7000</b> (Registrant's telephone number, including area code)	

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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

As of April 30, 2009, the registrant had 26,398,527 shares of Common Stock, \$0.001 par value per share, outstanding.

**Table of Contents**

**INDEX**

	<b>PAGE NUMBER</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>ITEM 1. FINANCIAL STATEMENTS</u></b>	
<u>Balance Sheets at March 31, 2009 and December 31, 2008 (unaudited)</u>	3
<u>Statements of Operations for the Three Months Ended March 31, 2009 and 2008 (unaudited)</u>	4
<u>Statements of Cash Flows for the Three Months Ended March 31, 2009 and 2008 (unaudited)</u>	5
<u>Notes to Financial Statements</u>	6
<b><u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	
	12
<b><u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	
	21
<b><u>ITEM 4. CONTROLS AND PROCEDURES</u></b>	
	21
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>ITEM 1A. RISK FACTORS</u></b>	
	22
<b><u>ITEM 6. EXHIBITS</u></b>	
	38

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****Achillion Pharmaceuticals, Inc.****Balance Sheets****(in thousands, except per share amounts)****(Unaudited)**

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,972	\$ 11,060
Marketable securities	18,099	24,297
Prepaid expenses and other current assets	991	1,181
Total current assets	28,062	36,538
Fixed assets, net	1,612	1,770
Deferred financing costs	87	100
Restricted cash	153	153
Total assets	\$ 29,914	\$ 38,561
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,403	\$ 2,544
Accrued expenses	2,052	2,260
Deferred revenue		1,128
Current portion of long-term debt	5,255	6,247
Total current liabilities	8,710	12,179
Deferred revenue	2,489	1,361
Total liabilities	11,199	13,540
Commitments and contingencies		
Stockholders Equity:		
Common Stock, \$.001 par value; 100,000 shares authorized: 26,399 shares issued and outstanding	26	26
Additional paid-in capital	205,346	204,861
Accumulated deficit	(186,705)	(179,981)
Accumulated other comprehensive income	48	115
Total stockholders equity	18,715	25,021
Total liabilities and stockholders equity	\$ 29,914	\$ 38,561

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

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Revenue	\$ (293)	\$ 627
Operating expenses		
Research and development	4,777	4,998
General and administrative	1,603	1,689
<b>Total operating expenses</b>	<b>6,380</b>	<b>6,687</b>
Loss from operations	(6,673)	(6,060)
Other income (expense)		
Interest income	92	291
Interest expense	(183)	(251)
Net loss before tax benefit	(6,764)	(6,020)
Tax benefit	40	22
Net loss	(6,724)	(5,998)
Basic and diluted net loss per share (Note 3)	\$ (0.25)	\$ (0.38)
Weighted average shares used in computing basic and diluted net loss per share	26,399	15,638

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (6,724)	\$ (5,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	206	208
Noncash stock-based compensation	485	566
Noncash interest expense	27	32
Amortization of premium (discount) on marketable securities	63	(173)
Changes in operating assets and liabilities:		
Accounts receivable		(38)
Prepaid expenses and other current assets	190	258
Accounts payable	(1,141)	142
Accrued expenses	(208)	(635)
Deferred revenue		(453)
Net cash used in operating activities	(7,102)	(6,091)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(34)	(6)
Purchase of available for sale marketable securities	(1,432)	(11,118)
Maturities of marketable securities	7,500	15,764
Net cash provided by investing activities	6,034	4,640
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options		6
Borrowings under notes payable		5,000
Repayments of notes payable	(1,020)	(1,018)
Payment of deferred financing costs		(100)
Net cash provided by (used in) financing activities	(1,020)	3,888
Net increase (decrease) in cash and cash equivalents	(2,088)	2,437
Cash and cash equivalents, beginning of period	11,060	8,971
Cash and cash equivalents, end of period	\$ 8,972	\$ 11,408
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 152	\$ 178
Cash received from tax credits	\$	\$ 176
<b>Supplemental disclosure of noncash financing activities</b>		
Issuance of warrants in connection with debt financing	\$	\$ 155

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





**Table of Contents**

**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 \$172,843 from inception through March 31, 2009 and had an accumulated deficit of \$186,705 through March 31, 2009. 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 its collaboration partner, Gilead Sciences, Inc. (Gilead).

The Company believes that its existing cash and cash equivalents will be sufficient to support its current operating plan through at least the twelve months following March 31, 2009. However, its operating plan may change as a result of many factors, including:

the costs involved in the clinical development, manufacturing and formulation of ACH-1625;

the outcome of the Company's discussions with Gilead regarding revisions to the license and collaboration agreement and the costs associated with the appropriate clinical path for ACH-1095;

the outcome of the Company's strategic and development assessment of ACH-702;

the Company's ability to enter into corporate collaborations and the terms and success of these collaborations; 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.

In the event that the Company is unable to secure additional funding within the twelve months following March 31, 2009, the Company has developed a contingency plan which provides for changes in its operations. The Company believes that this plan would reduce its operating expenses and believes that implementation of this contingency plan, if necessary, would permit it to conduct its operations for at least the next twelve months.

The Company expects to incur substantial and increasing losses for at least the next several years and will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which the Company 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 funding will be available on terms favorable to the Company, if at all.

In addition to the normal risks associated with early-stage companies, there can be no assurance that the Company will successfully complete its research and development, obtain adequate patent protection for its technology, obtain necessary government regulatory approval for drug candidates the Company develops or that any approved drug candidates will be commercially viable. In addition, the Company may not be profitable even if it succeeds in commercializing any of its drug candidates.

**2. Basis of Presentation**

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

The accompanying unaudited condensed 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, 2008 included in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2009. 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.

**Table of Contents**

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.

**3. Earnings (Loss) Per Share ( EPS )**

Basic EPS is calculated in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 128, *Earnings per Share*, or SFAS No. 128, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated in accordance with SFAS No. 128 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, 2009 and 2008 (prior to consideration of the treasury stock method):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Options	2,713	1,847
Warrants	6,711	354
<b>Total potentially dilutive securities outstanding</b>	<b>9,424</b>	<b>2,201</b>

**4. Collaboration Arrangements*****Gilead Sciences, Inc.***

In November 2004, the Company entered into a collaboration arrangement with Gilead (the Gilead Arrangement ) to jointly develop and commercialize compounds for use in treating hepatitis C infection which inhibit viral replication through a specified novel mechanism of action. Commercialization efforts will commence only if such compounds are found to be commercially viable and all appropriate regulatory approvals have been obtained. In connection with this arrangement, Gilead paid the Company \$10,000 as payment for both a non-refundable upfront license fee and 2,300 shares of the Company's Series C-1 Convertible Preferred Stock ( Series C-1 ).

Under the Gilead Arrangement, the Company and Gilead are working together to develop one or more compounds for use in treating hepatitis C infection until proof-of-concept in one compound, as defined in the Gilead Arrangement, is achieved (the Research Period ). Subsequent to the achievement of proof-of-concept, the Company has no further obligation to continue providing services to Gilead but, at Gilead's request, the Company may elect to extend the Research Period for up to an additional two years after proof-of-concept is established, based upon good faith negotiations at that point in time. Further, if it is agreed that potential back-up compounds should continue to be researched, good faith negotiations would also be conducted to determine the specifics of any arrangement to continue to research backup compounds.

Gilead has agreed to make milestone payments to the Company upon the achievement of various defined clinical, regulatory and commercial milestones, such as regulatory approval in the United States, the European Union or Japan. The Company could receive up to \$157,500 in development, regulatory and sales milestone payments, assuming the successful simultaneous development of a lead and back-up compound, and annual sales in excess of \$600,000. The Company could also receive royalties on net sales of products if commercialization is achieved.

The up-front payment of \$10,000, received in 2004, was first allocated to the fair value of the Series C-1, in which each share of the Series C-1 was determined to be worth \$0.88 per share, or approximately \$2,000 in aggregate. The remaining \$8,000 balance of the \$10,000 is being accounted for as a non-refundable up-front license fee. Due to certain provisions contained within the Gilead Arrangement relating to services to be performed on both the primary and backup compounds, as defined in the Gilead Arrangement, the non-refundable up-front license fee of \$8,000, as well as a \$2,000 milestone achieved during the Research Period, is being accounted for under the proportionate performance model. Future milestones, if any, will occur after the Research Period and are not accounted for under the proportionate performance model. Revenue recognized under the proportionate performance model is limited by the aggregate cash received or receivable to date by the Company. Milestones achieved, if any, after the termination of the Research Period, will be recognized when the milestone is achieved as the Company has no further research or development obligations after the Research Period.



---

**Table of Contents**

Under the Gilead Arrangement, through March 31, 2007, agreed upon research or development expenses, including internal full-time equivalent ( FTE ) costs and external costs, incurred by both companies during the period up to proof-of-concept were borne equally by both parties. Prior to March 31, 2007, the Company was incurring the majority of those expenses and, therefore, was the net receiver of funds under this cost-sharing portion of the arrangement. Effective April 1, 2007, internal FTE costs are no longer subject to this cost-sharing arrangement. Instead, each party bears its own internal costs, including FTE costs. External costs continue to be shared equally by both parties. In March 2007, the Company and Gilead also revised their joint research program to focus on next-generation NS4A antagonists, after discontinuing clinical trials for ACH-806, an NS4A antagonist the Company was previously evaluating. In addition, the Company also revised its joint research program with Gilead in the first quarter of 2009 to include a more complete series of preclinical studies, thereby increasing its total estimated efforts under the collaboration and extending the estimated period over which the Company's remaining obligations under the arrangement would be completed to the second half of 2010. Generally under collaboration arrangements, payments received during the period of performance may 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, but will be limited by the aggregate cash received or receivable to date by the Company.

At a meeting of the joint research committee in May 2009, the Company and Gilead arrived at different opinions on the appropriate further progression of GS 9525, also known as ACH-1095, based on their respective scientific assessments of the therapeutic index for GS 9525 from various preclinical studies. Gilead indicated that it does not intend to initiate clinical development of GS 9525, while Achillion believes that the compound should be advanced. Gilead and Achillion are in discussions regarding a proposal for a restructuring of the existing license and collaboration agreement. Achillion has proposed that it continue to develop ACH-1095, while the parties would jointly continue to advance additional compounds also operating by the NS4A mechanism of action. It has been proposed that future costs related to clinical development of ACH-1095 would be borne by Achillion, while costs associated with any additional compounds would be borne by the parties jointly. There can be no assurance, however, that the parties will reach a definitive agreement regarding this revision to the license and collaboration agreement.

Gilead has the right to terminate the agreement without cause upon 120 days written notice to the Company. Upon termination of the Gilead Arrangement for any reason, all cost share amounts due and payable through the date of termination shall be paid by the appropriate party and no previously paid amounts will be refundable. In addition to Gilead's rights to unilaterally terminate this agreement, each party has the right to terminate for material breach; however, the Company may terminate for Gilead's breach only on a market-by-market basis, and, if applicable, a product-by-product basis.

During the three months ended March 31, 2009 and 2008, the Company recognized revenue of \$(293) and \$627, respectively, under the Gilead Arrangement, of which \$0 and \$453, respectively, related to the recognition of the non-refundable upfront fee, a pre-proof-of-concept milestone and FTE reimbursements recognized under the proportionate performance model. As result of the May 2009 announcement, for the three months ended March 31, 2009, the Company recognized no amortization of this deferred revenue as it currently is unable to accurately estimate its total performance obligations under the collaboration. The Company will determine if it is able to estimate its remaining total performance obligations in the future following the outcome of discussions with Gilead regarding compounds to be developed. The remaining \$(293) and \$174 recognized during the three months ended March 31, 2009 and 2008, related to external costs billed by the Company to Gilead, net of Gilead billings to the Company of \$362 and \$26 for the three months ended March 31, 2009 and 2008, respectively. Payments to Gilead under this collaboration are recognized as a reduction in revenue. Recognition of external costs incurred by Gilead exceeded amounts recognized under the proportionate performance model, resulting in negative revenue for the current quarter.

Included in the accompanying balance sheets as of March 31, 2009 and December 31, 2008 are \$293 and \$260, respectively, of accrued expenses 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.

**Table of Contents****5. Marketable Securities**

The Company applies the provisions of SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, for financial assets and liabilities measured on a recurring basis. SFAS No. 157 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 securities of \$18,099 as of March 31, 2009 is valued based on level 2 inputs as defined in SFAS No. 157. The Company classifies its entire investment portfolio as available for sale as defined in SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. As of March 31, 2009 and December 31, 2008, the Company's investment portfolio consisted of U.S. government and agency securities and government sponsored bond obligations and corporate debt securities held by a major banking institution. The maturities of all marketable securities held at March 31, 2009 and December 31, 2008 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 from marketable securities was \$48 and \$115 at March 31, 2009 and December 31, 2008, respectively.

As of March 31, 2009 and December 31, 2008, none of the Company's investments were determined to be other than temporarily impaired.

**6. Accrued Expenses**

Accrued expenses consist of the following:

	March 31, 2009	December 31, 2008
Accrued compensation	\$ 627	\$ 472
Accrued research and development expenses	972	1,233
Accrued professional fees	251	355
Other accrued expenses	202	200
<b>Total</b>	<b>\$ 2,052</b>	<b>\$ 2,260</b>

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.

**7. Debt**

Debt consists of the following:

	March 31, 2009	December 31, 2008
CII Term Loan, payable in monthly installments of \$13 through September 2010 with a final balloon payment of \$686, with interest at 7.5% per annum	\$ 821	\$ 844
2003 Credit Facility, payable in monthly installments as the individual notes mature through December 2010, with interest ranging from 7.75% to 9.06% per annum	326	394
2008 Credit Facility, payable in monthly installments as notes mature through March 2011, with interest of 9.97% to 11.58% per annum	4,108	5,009
<b>Total long-term debt</b>	<b>5,255</b>	<b>6,247</b>
<b>Less: current portion</b>	<b>(5,255)</b>	<b>(6,247)</b>

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

Total long-term debt, net of current portion	\$	\$
--	----	----

Each of the Company's debt agreements contains certain subjective acceleration clauses, such that upon the occurrence of a material adverse change in the financial condition, business or operations of the Company in the view of the lenders (Material Adverse Change), amounts outstanding under the agreement may become immediately due and payable. As stated in Note 1, the Company will need additional financing to fund operations which the Company will seek to raise through public or private equity

**Table of Contents**

or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funding will be available on terms favorable to the Company, if at all. As such funding cannot be assured, the Company's debt balances have been classified as short term at March 31, 2009. The Company has no indication that it is in default of any such clauses and none of the Company's lenders have accelerated scheduled loan payments as a result of these provisions.

**8. 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 637 shares available to be granted under the 2006 Plan as of March 31, 2009.

A summary of the status of the Company's stock option activity for the three months ended March 31, 2009 is presented in the table and narrative below:

	Options	Weighted Average Exercise Price
Outstanding at January 1, 2009	2,596	\$ 4.45
Granted	125	0.92
Exercised		
Cancelled/Forfeited	(8)	4.85
Outstanding at March 31, 2009	2,713	\$ 4.29
Options exercisable at March 31, 2009	1,230	\$ 5.09
Weighted-average fair value of options granted during the period		\$ 0.63

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, 2009	March 31, 2008
Expected term of option	6.1 years	6.1 years
Expected volatility	79%	64%
Risk free interest rate	1.97%	2.67%
Expected dividend yield	0%	0%

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees for the three months ended March 31, 2009 and 2008 was \$473 and \$533, 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, 2009, the intrinsic value of the options outstanding was \$479, of which \$19 related to vested options and \$460 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, 2009, the total compensation cost related to unvested options not yet recognized in the financial statements is approximately \$3,382, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.24 years.



**9. Comprehensive Income (Loss)**

The Company reports and presents comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes standards for reporting and display of comprehensive loss and its components in a full set of general

**Table of Contents**

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 gains (losses) on marketable securities.

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net loss	\$ (6,724)	\$ (5,998)
Change in unrealized gain (loss) on marketable securities	(67)	26
<b>Total comprehensive loss</b>	<b>\$ (6,791)</b>	<b>\$ (5,972)</b>

**10. Recently Issued Accounting Pronouncements**

In December 2007, the EITF reached a consensus on EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF No. 07-01. EITF No. 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. EITF No. 07-01 is effective for the Company's collaborations existing after January 1, 2009. There was no impact to the Company's financial statements upon adoption.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, or SFAS No. 141R, which changes the accounting for business acquisitions. SFAS No. 141R requires the acquiring entity in a business combination to recognize all the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination, including contingent consideration; exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS No. 141R is effective for business combinations and adjustments to an acquired entity's deferred tax asset and liability balances occurring after December 31, 2008. The Company's adoption of SFAS No. 141R did not have an impact on its financial statements but will have a material impact on the Company's financial position and results of operations in the event that the Company enters into a business combination that falls within the scope of this pronouncement.

**11. Subsequent Event**

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

As disclosed within the Company's Form 10-K, the Company believed that it was entitled to a larger cash refund for tax credit carryovers from the State of Connecticut for certain prior years. The Company filed complaints with the Superior Court for the tax year 2003 seeking cash refunds of certain unused research and development tax credits that the Company alleged were wrongfully disallowed by the State of Connecticut. Additionally, the Company filed appeals for this matter to keep the statute of limitations open for subsequent periods. In May 2009, the Superior Court affirmed the judgment of the trial court and concluded that the Company may only exchange research and development tax credits for a credit refund during the year in which the Company qualified and earned the credit. Accordingly, the Company is not eligible to receive additional money from the state as part of this exchange program for the years in question. The Company had not recorded a receivable related to this pending judgment, therefore no adjustment to the amounts disclosed within the financial statements is necessary.

---

**Table of Contents**

**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 advancing two late-stage preclinical candidates: ACH-1095, a NS4A antagonist for the treatment of chronic hepatitis C, which has been developed in collaboration with Gilead Sciences, Inc., or Gilead, and ACH-1625, a protease inhibitor also for the treatment of chronic hepatitis C. We are currently in discussions with Gilead to restructure our existing license and collaboration agreement to allow us to continue the development of ACH-1095. In addition, we have established a pipeline of certain other product candidates for which we are currently seeking appropriate collaborative partners or for which we are considering whether to seek appropriate collaborative partners, but to which we are not devoting significant resources at this time. These product candidates include elvucitabine for the treatment of HIV infection, and ACH-702 for the treatment of serious bacterial infections.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of \$173 million from inception through March 31, 2009 and had an accumulated deficit of \$187 million through March 31, 2009. Our net losses were \$6.7 million and \$6.0 million for the three months ended March 31, 2009 and 2008, respectively. We have funded our operations primarily through:

proceeds of \$192.4 million from the sale of equity securities, including our initial public offering in October 2006 and a private placement of our common stock in August 2008;

borrowings of \$22.1 million from debt facilities; and

receipts of \$10.0 million from up-front and milestone payments, as well as \$9.1 million in cost-sharing receipts, from our collaboration partner, Gilead.

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

initiate clinical testing of ACH-1625;

determine the appropriate clinical path for ACH-1095 and continue clinical development of this compound;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; and

progress additional drug candidates.

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

We will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available on terms favorable to us, if at all. In addition to the normal 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 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, 2009 and 2008 we recognized \$(293,000) and \$627,000, respectively, under this collaboration agreement.

---

**Table of Contents**

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.

Effective April 1, 2007, each party provides for the costs of their own full-time equivalents. External research costs continue to be shared equally by both parties. Through March 31, 2007 research and development expenses under our collaboration with Gilead, including internal full-time equivalent costs and external research costs, incurred by both companies prior to proof-of-concept, were borne equally by both parties. As we were providing the majority of those services and were incurring the majority of those expenses, we were the net recipient of funds under this cost-sharing portion of the arrangement and therefore recognized the reimbursed costs as revenue rather than research expense. For the quarter ended March 31, 2009, Gilead incurred a greater amount of external costs, therefore we were the net payor of funds to Gilead under this portion of the arrangement.

***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 expect that our research and development expenses will remain substantially unchanged from the first quarter for the remainder of the year.

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

**ACH-1095, a NS4A Antagonist for Chronic Hepatitis C Infection.** We are evaluating ACH-1095 (also known as GS 9525) for the treatment of chronic hepatitis C. In preclinical and clinical studies, NS4A antagonists studied demonstrate potent inhibition of the replication of HCV, the virus that causes hepatitis C, by targeting a non-structural, or NS, viral protein called 4A. We believe these NS4A antagonists may offer several potential advantages compared to currently available treatments, including greater potency, a novel mechanism of action, lack of cross resistance and the potential for oral administration. We believe these compounds could be used in combination with the current standard of care, or with other therapies in development, to significantly improve treatment outcomes. Since November 2004, we have collaborated with Gilead under an exclusive license and collaboration agreement for the research, development and commercialization of compounds operating by this mechanism of action. Our first drug candidate under this program, ACH-806 (also known as GS 9132), demonstrated positive antiviral effect in a proof-of-concept clinical trial in HCV infected patients, but also elevated serum creatinine levels, a marker of kidney function. As a result, we discontinued further clinical development of ACH-806 in favor of a next-generation back-up compound, ACH-1095, which is currently in late-stage preclinical studies. At a meeting of the joint research committee in May 2009, Gilead and Achillion arrived at different opinions on the appropriate further progression of GS 9525, also known as ACH-1095, based on their respective scientific assessments of the therapeutic index for GS 9525 from various preclinical studies. Gilead indicated that it does not intend to initiate clinical development of GS 9525, while we believe that the compound should be advanced. We are in discussions with Gilead regarding a proposal for a restructuring of the existing license and collaboration agreement. We have proposed that we continue to develop ACH-1095, while the parties jointly continue to advance additional compounds also operating by the NS4A mechanism of action. If Gilead agrees that we can advance ACH-1095 on our own, we anticipate requesting a pre-IND consultation with the FDA to discuss the most appropriate clinical development path for the compound.

**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. ACH-1625 has demonstrated strong in vitro potency and a good safety profile in preclinical studies. We have completed preclinical studies with this compound and we anticipate entering clinical trials for this compound in the first half of 2009.

**ACH-702 for Drug Resistant Bacterial Infections.** ACH-702 is a preclinical candidate with potency against a broad spectrum of bacterial pathogens including methicillin-resistant staphylococcus aureus, or MRSA. We recently

**Table of Contents**

completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the Division of Special Pathogen and Transplant Products, or the DSPTP. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner.

**Elvucitabine for HIV Infection.** Elvucitabine is an antiviral we are developing for the treatment of HIV infection. We have evaluated elvucitabine in phase II clinical trials to further explore its safety and efficacy in HIV-infected patients over 48 and 96-weeks of treatment, and the open-label extension of one trial remains on-going through 2010. We currently retain full development and marketing rights to elvucitabine. However, we are currently seeking to enter a collaboration arrangement for elvucitabine and do not plan to advance elvucitabine into Phase III clinical trials without a collaboration partner.

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.

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
<b>Clinical candidate direct external costs:</b>		
NS4A antagonists (including ACH-1095 and ACH-806)	\$ 96	\$ 157
ACH-1625	1,161	362
ACH-702	13	92
Elvucitabine	327	1,022
	1,597	1,633
<b>Direct internal personnel costs</b>	<b>1,754</b>	<b>2,038</b>
<b>Sub-total direct costs</b>	<b>3,351</b>	<b>3,671</b>
<b>Indirect costs and overhead</b>	<b>1,426</b>	<b>1,327</b>
<b>Total research and development</b>	<b>\$ 4,777</b>	<b>\$ 4,998</b>

Currently, we are initiating clinical studies for ACH-1625 and completing the open-label extension phases of two phase II clinical trials for elvucitabine. We are in discussions with Gilead regarding the future of our collaboration and the appropriate clinical path for ACH-1095. From inception through March 31, 2009, we incurred approximately \$29.7 million in total costs for our NS4A antagonist program, including both ACH-1095 and ACH-806, approximately \$13.7 million for ACH-1625, approximately \$19.8 million in total costs for ACH-702 and approximately \$49.9 million in total costs for elvucitabine. These figures include our internal research and development personnel costs and related facilities overhead.

We estimate that the expense associated with early clinical development through proof-of-concept of ACH-1095, our next generation NS4A antagonist, will total approximately \$3.0 million, exclusive of internal personnel costs. Following the May 2009 meeting of the joint research committee, we have proposed a revision to the license and collaboration agreement which would allow future costs related to clinical development of ACH-1095 to be borne by Achillion, while costs associated with any additional compounds would be borne by the parties jointly. There can be no assurance, however, that the parties will reach a definitive agreement regarding this revision to the license and collaboration agreement.

We estimate that the costs associated with early clinical development of ACH-1625, our HCV protease inhibitor, will be approximately \$3.0 million, exclusive of internal personnel costs. We are currently assessing our strategic and development plans for ACH-702 and considering whether to undertake such development independently or with a collaborative partner. We currently estimate that the clinical trial costs for two phase III clinical trials of elvucitabine in different HIV populations will be approximately \$50.0 million, exclusive of the internal personnel costs associated with conducting these trials; however, we currently do not plan to undertake these two Phase III trials for elvucitabine unless or until

we enter into a collaboration agreement.



---

**Table of Contents*****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. We expect that general and administrative expenses will remain substantially unchanged for the remainder of the year.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations set forth below are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition, research and development costs, stock-based compensation, accrued expenses and income taxes. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect management's more significant judgments and estimates used in the preparation of our financial statements:

***Revenue Recognition***

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB No. 104, and Financial Accounting Standards Board, or FASB, Emerging Issue Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF No. 00-21. Revenue-generating research and development collaborations are often multiple element arrangements, providing for a license as well as research and development services. Such arrangements are analyzed to determine whether the deliverables, including research and development services, can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF No. 00-21. We recognize upfront license payments as revenue upon delivery of the license only if the license has standalone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have standalone value or (ii) have standalone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the upfront license payments are recognized as revenue over the estimated period of when our performance obligations are performed.

When we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue related to upfront license payments will be recognized. Revenue will be recognized using either a proportionate performance or straight-line method. We recognize revenue using the proportionate performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Under the proportionate performance method, periodic revenue related to up-front license 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. Actual effort is generally determined based upon actual direct labor hours or full-time equivalents incurred and include research and development activities performed by internal scientists. Total expected effort is generally based upon the total direct labor hours of full-time equivalents incorporated into the detailed budget and project plan that is agreed to by both parties to the collaboration. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we expect to complete the related performance obligations. For example, under our arrangement with Gilead Sciences, the joint research committee periodically reviews and updates the project plan. In the event that a change in estimate occurs, the change will be accounted for using the cumulative catch-up method which provides for an adjustment to revenue in the current period. Estimates of our level of effort may change in the future, resulting in a material change in the amount of revenue recognized in future periods, including negative revenue in some periods. We revised our joint research program with Gilead in the first quarter of 2007 to focus on next-generation NS4A antagonists. At that time, we extended the period over which our remaining obligations under the arrangement would be completed. We and Gilead also agreed to continue to equally share external costs, but effective April 1, 2007, internal full-time equivalents are no longer subject to a cost sharing arrangement. Instead, each party bears the costs

**Table of Contents**

of their respective full-time equivalents. In addition, we also revised our joint research program with Gilead in the first quarter of 2009 to include a more complete series of preclinical studies, thereby increasing our total estimated efforts under the collaboration and extending the estimated period over which our remaining obligations under the arrangement would be completed to the second half of 2010.

At a meeting of the joint research committee in May 2009, we and Gilead arrived at different opinions on the appropriate further progression of GS 9525, also known as ACH-1095, based on their respective scientific assessments of the therapeutic index for GS 9525 from various preclinical studies. Gilead indicated that it does not intend to initiate clinical development of GS 9525, while Achillion believes that the compound should be advanced. Gilead and Achillion are in discussions regarding a proposal for a restructuring of the existing license and collaboration agreement. Achillion has proposed that it continue to develop ACH-1095, while the parties would jointly continue to advance additional compounds also operating by the NS4A mechanism of action. It has been proposed that future costs related to clinical development of ACH-1095 would be borne by Achillion, while costs associated with any additional compounds would be borne by the parties jointly. There can be no assurance, however, that the parties will reach a definitive agreement regarding this revision to the license and collaboration agreement. As a result of the ongoing discussions regarding a revision to the license and collaboration agreement, for the three months ended March 31, 2009, we did not recognize any revenue related to the amortization of the upfront, milestone and FTE fees previously received under the collaboration as we are currently unable to estimate our remaining performance obligations under the collaboration. We will determine if we are able to estimate our remaining total performance obligations in the future following the outcome of discussions with Gilead regarding compounds to be developed.

Generally under collaboration arrangements, payments received during the period of performance may 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, but will be limited by the aggregate cash received or receivable to date by us.

Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: (1) the milestone payments are non-refundable, (2) achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone and (5) a reasonable amount of time passes between the upfront license payment and the first milestone payment as well as between each subsequent milestone payment.

Reimbursement of costs is recognized as revenue provided the provisions of EITF Issue No. 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent*, are met, the amounts are determinable and collection of the related receivable is reasonably assured.

***Stock-Based Compensation Employee Stock-Based Awards***

We apply the Statement of Financial Accounting Standards No. 123 as revised in 2004, *Share-Based Payment*, or SFAS No. 123R, which requires measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and employee stock purchases under our 2006 ESPP Plan based on estimated fair values. In December 2007, the SEC issued Staff Accounting Bulletin No. 110, or SAB No. 110, which extended the use of the simplified method in developing an estimate of the expected term of plain vanilla share options beyond December 31, 2007. We utilize the provisions of SAB No. 110 in our application of SFAS No. 123R.

We primarily grant qualified stock options for a fixed number of shares to employees with an exercise price equal to the market value of the shares at the date of grant. To the extent that the amount of the aggregate fair market value of qualified stock options that become exercisable for an individual exceeds \$100,000 during any tax year, those stock options are treated as non qualified stock options. Under the fair value recognition provisions of SFAS No. 123R, stock-based compensation cost is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized during the three months ended March 31, 2009 and 2008 includes compensation expense for stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the fair value on the grant date estimated in accordance with the pro forma provisions of SFAS No. 123. Compensation expense also includes amounts related to the stock-based awards granted subsequent to December 31, 2005, based on the fair value on the grant date, estimated in accordance with the provisions of SFAS No. 123R.

We utilize 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. Determining the



## **Table of Contents**

fair value of stock-based awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock and expected dividends. In addition, we previously accounted for forfeitures as they occurred. In accordance with SFAS No. 123R, we are required to estimate forfeitures at the grant date and recognize compensation costs for only those awards that are expected to vest. Judgment is required in estimating the amount of stock-based awards that are expected to be forfeited.

If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods, the compensation expense that we record under SFAS No. 123R may differ significantly from what we have recorded in the current period. Therefore, we believe it is important for investors to be aware of the degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. There is risk that our estimates of the fair values of our share-based compensation awards on the grant dates may differ from the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. Although the fair value of employee share-based awards is determined in accordance with SFAS No. 123R and SAB No. 110 using an option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

### ***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. Some of our service providers require upfront or milestone payments. If our estimate of services performed is less than the upfront or milestone payments, the difference is accounted for as a prepaid expense. In the event that we do not identify costs that have been incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon facts and circumstances known to us in accordance with U.S. GAAP.

### ***Income Taxes***

We use an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is more likely than not that all or a portion of deferred tax assets will not be realized.

We apply the provisions of Financial Accounting Standards Board ( FASB ) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. Under FIN 48, the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

We do not have any unrecognized tax benefits as of March 31, 2009. We review all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

### **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.



**Table of Contents****Comparison of Three Months Ended March 31, 2009 and 2008**

*Revenue.* Revenue was \$(293,000) and \$627,000 for the three months ended March 31, 2009 and 2008, respectively. The decrease in revenue in 2009 is substantially due to the fact that there was no recognition of revenue in the current quarter related to the non-refundable upfront fee, pre proof-of-concept milestone and FTE reimbursement under the collaboration arrangement with Gilead coupled with net payments to Gilead of \$293,000 for shared external costs. At a meeting of the joint research committee in May 2009, we and Gilead arrived at different opinions on the appropriate further progression of GS 9525, also known as ACH-1095, based on their respective scientific assessments of the therapeutic index for GS 9525 from various preclinical studies. Gilead indicated that it does not intend to initiate clinical development of GS 9525, while Achillion believes that the compound should be advanced. Gilead and Achillion are in discussions regarding a proposal for a restructuring of the existing license and collaboration agreement. Achillion has proposed that it continue to develop ACH-1095, while the parties would jointly continue to advance additional compounds also operating by the NS4A mechanism of action. There can be no assurance, however, that the parties will reach a definitive agreement regarding a revision to the license and collaboration agreement.

As such, we have ceased recognizing revenue related to upfront, milestone and FTE payments previously received until we can reasonably estimate our total future performance obligations. We will determine if we are able to estimate the collaboration's remaining total performance obligations in the future following the outcome of discussions with Gilead regarding compounds to be developed. 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 equally by both parties and payments made by us to Gilead in connection with this collaboration are recognized as a reduction of revenue. External costs incurred by Gilead exceeded external costs incurred by us, resulting in a net payable of \$293,000 from us to Gilead during the quarter. Recognition of external costs incurred by Gilead exceeded amounts recognized under the proportionate performance model, resulting in negative revenue for the current quarter.

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>Change</b>
	<b>(in thousands)</b>		
Gilead collaboration revenue	\$ (293)	\$ 627	(920)
Total revenue	\$ (293)	\$ 627	(920)

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

*Research and Development Expenses.* Research and development expenses were \$4.8 million and \$5.0 million for the three months ended March 31, 2009 and 2008, respectively. The decrease for the three months ended March 31, 2009 was primarily due to lower personnel and stock based compensation costs, offset by increased costs associated with ACH-1625 preclinical studies. We expect that research and development expenses during the remainder of 2009 will remain substantially unchanged. Research and development expenses for the three months ended March 31, 2009 and 2008 are comprised as follows:

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>Change</b>
	<b>(in thousands)</b>		
Personnel costs	\$ 1,566	\$ 1,749	\$ (183)
Stock based compensation	189	298	(109)
Outsourced research and supplies	1,812	1,633	179
Professional and consulting fees	474	542	(68)
Facilities costs	698	723	(25)
Travel and other costs	38	53	(15)
Total	\$ 4,777	\$ 4,998	\$ (221)



**Table of Contents**

*General and Administrative Expenses.* General and administrative expenses were \$1.6 million and \$1.7 million for the three months ended March 31, 2009 and 2008, respectively. The slight decrease for the three months ended March 31, 2009 was primarily due to a decrease in accounting and audit related fees. We expect that general and administrative expenses will remain substantially unchanged for the remainder of the year. General and administrative expenses for the three months ended March 31, 2009 and 2008 are comprised as follows:

	<b>Three Months Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>Change</b>
	<b>(in thousands)</b>		
Personnel costs	\$ 552	\$ 537	\$ 15
Stock based compensation	297	268	29
Professional and consulting fees	333	431	(98)
Facilities costs	278	294	(16)
Travel and other costs	143	159	(16)
<b>Total</b>	<b>\$ 1,603</b>	<b>\$ 1,689</b>	<b>\$ (86)</b>

*Other Income (Expense).* Interest income was \$92,000 and \$291,000 for three months ended March 31, 2009 and 2008, respectively. The decrease was primarily due to decreased average cash balances combined with lower interest rates. Interest expense was \$183,000 and \$251,000 for the three months ended March 31, 2009 and 2008, respectively. The decrease was primarily due to lower debt balances in 2009.

*Tax Benefit.* The State of Connecticut provides companies with the opportunity to forego certain research and development tax credit carryforwards in exchange for cash. The program provides for such exchange of the research and development credits at a rate of 65% of the annual incremental and non-incremental research and development credits, as defined. The amount of tax benefit we recognized in connection with this exchange program was \$40,000 and \$22,000 for the three months ended March 31, 2009 and 2008, respectively. The increase from 2008 to 2009 was primarily due to a reduction to the final 2007 tax return amount during the three months ending March 31, 2008.

**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, 2009, we had received approximately \$192.4 million in aggregate net proceeds from stock issuances, including convertible preferred stock, our initial public offering and our private placement, \$19.1 million from Gilead under our collaboration agreement with them and approximately \$22.1 million under debt facilities. As of March 31, 2009, the following debt facilities remain outstanding:

<b>Lender</b>	<b>Date</b>	<b>Interest Rate (per annum)</b>	<b>Principal Amount</b>	<b>Maturity Date</b>
Connecticut Innovations, Inc.	November 2000	7.50%	\$ 1,400,000	September 2010
Webster Bank	May 2003	6.72 - 9.27	972,185	June 2006-Dec 2009
Oxford Finance Corporation	May 2006	11.56	2,500,000	April 2009
General Electric Capital Corporation	May 2006	11.56	2,500,000	April 2009
Oxford Finance Corporation	June 2007	11.58	400,000	June 2010
General Electric Capital Corporation	June 2007	11.58	400,000	June 2010
Webster Bank	December 2007	7.46	414,623	December 2010
Oxford Finance Corporation	February 2008	9.97	2,500,000	March 2011
General Electric Capital Corporation	February 2008	9.97%	\$ 2,500,000	March 2011

The amounts reflected above represent original maturities under our debt agreements. As of March 31, 2009, our debt balance due to borrowings was \$5.3 million with a weighted average interest rate of 9.87%.

We had \$27.1 million and \$35.4 million in cash, cash equivalents and marketable securities as of March 31, 2009 and December 31, 2008, respectively. We regularly review our investments and monitor the financial markets. The recent distress in the financial markets has not had a significant impact on our financial position. As of March 31, 2009, our cash, cash equivalents and marketable securities included high-quality financial instruments, primarily money market funds, government sponsored bond obligations and corporate debt securities which we believe are



subject to limited credit risk.

## Table of Contents

Cash used in operating activities was \$7.1 million for the three months ended March 31, 2009 and was primarily attributable to our \$6.7 million net loss and a decrease in accounts payable primarily offset by non-cash charges related to depreciation, amortization and non-cash stock based compensation. Cash used in operating activities was \$6.1 million for the three months ended March 31, 2008 and was primarily attributable to our \$6.0 million net loss and decreases in deferred revenue and accrued expenses, offset by others decreases in working capital and non-cash charges related to depreciation, amortization and non-cash stock based compensation.

Cash provided by investing activities was \$6.0 million for the three months ended March 31, 2009 and was primarily attributable to the maturities of marketable securities partially offset by purchases of marketable securities. Cash provided by investing activities was \$4.6 million for the three months ended March 31, 2008 and was primarily attributable to the maturities of marketable securities offset by purchases of marketable securities.

Cash used in financing activities was \$1.0 million for the three months ended March 31, 2009 and was primarily attributable to repayments of debt. Cash provided by financing activities was \$3.9 million for the three months ended March 31, 2008 and was primarily attributable to \$5.0 million in borrowing under our 2008 credit facility, 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:

initiate clinical testing of ACH-1625;

determine the appropriate clinical path for ACH-1095 and continue clinical development of this compound;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; 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 being able to market any drug candidates, to, among other things, 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) through other sources of financing.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for at least the twelve months following March 31, 2009. 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;

the outcome of our discussions with Gilead regarding revisions to the license and collaboration agreement and the costs associated with the appropriate clinical path for ACH-1095;

the outcome of our strategic and development assessment of ACH-702;

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;

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

competing technological and market developments currently unknown to us.

We intend to augment our cash balance in 2009 through financing transactions, including the issuance of debt or equity securities, and/or further corporate alliances. No arrangements have been entered into for any future financing and 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 during 2009, we will be required to:

delay, reduce the scope of or eliminate our research and development programs;

reduce our planned commercialization efforts;

---

## **Table of Contents**

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.

Additionally, any future equity funding may dilute the ownership of our equity investors.

We have developed a contingency plan which provides for changes in our operations in the event that we are unable to secure additional funding within the next twelve months. We believe that this plan would reduce its operating expenses and believe that implementation of this contingency plan, if necessary, would permit us to conduct our operations for at least the twelve months following March 31, 2009.

### **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 Pronouncements**

In December 2007, the EITF reached a consensus on EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF No. 07-01. EITF No. 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis within expenses when certain characteristics exist in the collaboration relationship. EITF No. 07-01 is effective for our collaborations existing after January 1, 2009. There was no material impact to our financial statements upon adoption.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*, which changes the accounting for business acquisitions. SFAS No. 141R requires the acquiring entity in a business combination to recognize all the assets acquired and liabilities assumed in the transaction and establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed in a business combination. Certain provisions of this standard will, among other things, impact the determination of acquisition-date fair value of consideration paid in a business combination, including contingent consideration; exclude transaction costs from acquisition accounting; and change accounting practices for acquired contingencies, acquisition-related restructuring costs, in-process research and development, indemnification assets, and tax benefits. SFAS No. 141R is effective for business combinations and adjustments to an acquired entity's deferred tax asset and liability balances occurring after December 31, 2008. Our adoption of SFAS No. 141R did not have an impact on our financial statements but will likely have a material impact on our financial position and results of operations in the event that we enter into a business combination that falls within the scope of this pronouncement.

### **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 do not believe the recent distress in the financial markets has had a significant impact on our financial position. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and corporate debt securities, with the effective duration of the portfolio less than six months and no security with an effective duration in excess of 12 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, 2009. 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

## **Table of Contents**

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, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2009 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 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, 2009, our accumulated deficit was approximately \$187 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase substantially over the next several years as we expand our research, development and commercialization efforts, including as we:

initiate clinical testing of ACH-1625;

complete discussions with Gilead regarding revisions to our license and collaboration agreement and determine the appropriate clinical path for ACH-1095;

complete the open-label extension phases of our phase II clinical trials for elvucitabine; and

progress additional drug candidates.

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

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

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

We believe that our existing cash and cash equivalents will be sufficient to support our current operating plan through at least the twelve months following March 31, 2009. Our operating plan may change as a result of many factors, including:

the costs involved in the clinical development, manufacturing and formulation of ACH-1625;

the outcome of our discussions with Gilead regarding revisions to our license and collaboration agreement and the costs associated with the appropriate clinical path for ACH-1095;

the outcome of our strategic and development assessment of ACH-702;

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;

**Table of Contents**

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; or

delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our drug candidates, if approved for sale.

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. For example, in August 2008, we issued in a private placement 10,714,655 shares of our common stock, plus common stock warrants to purchase a total of 2,678,644 additional shares of stock, resulting in gross proceeds to us of \$31.1 million but which substantially diluted our existing stockholders. We also issued warrants in the private placement, which if exercised in full would generate approximately \$10.4 million in additional proceeds. However, there can be no assurance that the investors will exercise their warrants. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance 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.

**We depend on the success of our HCV drug candidates, ACH-1095 and ACH-1625, which are still under development.**

We have invested a significant portion of our efforts and financial resources in the development of our HCV candidates, ACH-1095 and ACH-1625, for the treatment of chronic hepatitis C. 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;

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



## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of the drugs, whether alone or in collaboration with others; and

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

If Gilead allows us to advance ACH-1095 on our own, we anticipate requesting a pre-IND consultation with the FDA to discuss the most appropriate clinical development path for the compound. There can be no assurance that we will gain the agency's approval for the future clinical advancement of ACH-1095, and if we are not able to advance ACH-1095 our business may be significantly harmed. Even if successful in gaining FDA approval to advance to human clinical trials, the clinical development timelines and costs may be greater than anticipated.

We plan to enter human clinical trials for our HCV candidate ACH-1625 in 2009. 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

**Table of Contents**

industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed preclinical studies 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 may not be successful in our currently on-going negotiations with our collaboration partner, Gilead Sciences, to advance ACH-1095. If unsuccessful, we will not be able to advance ACH-1095 into human clinical development, and the program may be terminated.**

At a meeting of the joint research committee in May 2009, Gilead and Achillion arrived at different opinions on the appropriate further progression of GS 9525, also known as ACH-1095, based on their respective scientific assessments of the therapeutic index for GS 9525 from various preclinical studies. Gilead indicated that it does not intend to initiate clinical development of GS 9525, while Achillion believes that the compound should be advanced. Gilead and Achillion are in discussions regarding a proposal for a restructuring of the existing license and collaboration agreement. Achillion has proposed that it continue to develop ACH-1095, while the parties would jointly continue to advance additional compounds also operating by the NS4A mechanism of action. It has been proposed that future costs related to clinical development of ACH-1095 would be borne by Achillion, while costs associated with any additional compounds would be borne by the parties jointly. There can be no assurance that the parties will reach a definitive agreement regarding this revision to the license and collaboration agreement. Even if successful in entering a definitive revision to the agreement, the terms may not be favorable to us and there can be no assurance that ACH-1095 will demonstrate efficacy, safety and tolerability in human clinical trials. In addition, there can be no assurance that we will be able to identify or progress additional candidates that operate by the NS4A mechanism of action.

**If we are not successful in forming an alliance for the commercialization of elvucitabine, or are significantly delayed in doing so, our business may be harmed.**

We currently plan to enter into an alliance for the phase III development and commercialization of elvucitabine. Given the limited number of global pharmaceutical companies which currently develop and market drugs for the treatment of HIV, and the strategic need for elvucitabine to be suitable for co-formulation with drugs already marketed or under development by a potential partner, the number of potential partners is relatively small. To date, we have been unsuccessful in partnering with the major pharmaceutical companies with whom we have had on-going discussions. We are continuing partnering efforts with regional companies and institutions, including those in Asia, South America and elsewhere. If we are not successful in forming an alliance before the completion of the currently ongoing trial extensions, we do not plan to enter phase III clinical trials and would not independently pursue further development or commercialization of elvucitabine.

**If we are not able to determine the most appropriate therapeutic use for ACH-702, or determine and execute a successful business strategy pursuant to that use, our business may be harmed.**

Following preclinical studies, we completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the DSTPP. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms, use in ophthalmic infections and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete our strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner. Even if we elect to seek a collaboration partner, we may be unable to find an appropriate collaboration partner to advance the program.

**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, serious hospital-based bacterial infections and HIV infection. We would expect ACH-1095, ACH-1625, ACH-702 and elvucitabine to compete with the following approved drugs and drug candidates currently under development:

**Table of Contents**

*ACH-1095 and ACH-1625.* If approved, our NS4A antagonist, ACH-1095, and our protease inhibitor, ACH-1625, would compete with drugs currently approved for the treatment of hepatitis C, the interferon-alpha based products from Roche (Pegasys and Roferon-A) or Schering-Plough (Intron-A or Peg-Intron) and the ribavirin based products from Schering- Plough (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 are also under development for the treatment of hepatitis C by companies such as Abbott, Anadys, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Human Genome Sciences, Intermune, Johnson & Johnson, Medivir, Merck, Novartis, Pfizer, Pharmasset, Roche, Schering-Plough, Valeant and Vertex.

*ACH-702.* ACH-702, if approved, would compete with drugs currently marketed for the treatment of serious gram-positive nosocomial infections including: vancomycin (multiple generic forms), Cubicin (daptomycin) by Cubist Pharmaceuticals, Zyvox (linezolid) by Pfizer and Synercid (dalbopristin + quinupristin) by King Pharmaceuticals. In addition, ACH-702 may compete with other drugs currently under development for the treatment of nosocomial gram-positive infections including: dalbavancin in development by Pfizer, telavancin from Theravance, oritavancin by Intermune, doripenem by Johnson & Johnson, ceftobiprole by Basilea and Johnson & Johnson, iclaprim by Arpida and garenoxacin by Schering-Plough. In addition, ACH-702 may compete with other drugs currently marketed or under development for the treatment of topical skin infections including Altabax by GlaxoSmithKline and XOMA-629 by Xoma Therapeutics Ltd. We may also compete with the following companies that have a strategic interest in the discovery, development and marketing of drugs for the treatment of bacterial infections: Abbott, Aventis, Bristol-Myers Squibb, Cubist, GlaxoSmithKline, Merck, Novartis, Roche and Wyeth.

*Elvucitabine.* If approved, elvucitabine would compete with the NRTIs currently marketed for treatment of HIV infection, including: Epivir (lamivudine), Retrovir (AZT), Ziagen (abacavir), Combivir (lamivudine + AZT), Trizivir (lamivudine + AZT + abacavir) and Epzicom (lamivudine + abacavir) from GlaxoSmithKline, Hivid (ddC) from Hoffman-La Roche, Emtriva (FTC), Viread (tenofovir) and Truvada (FTC + tenofovir) from Gilead and Videx EC, Videx (ddI) and Zerit (d4T) from Bristol-Myers Squibb. In addition, elvucitabine may compete with other NRTIs currently under development for HIV by companies such as Avexa, Medivir, Pharmasset and Koronis. Other drugs in other classes recently approved for treatment of HIV infection include Selzentry (maraviroc, an entry inhibitor) from Pfizer and Isentress (raltegravir, an integrase inhibitor) from Merck. In addition, there are other classes of drugs under development for the treatment of HIV infection by companies such as Abbott, Boehringer Ingelheim, Johnson & Johnson, Myriad, Roche, Schering-Plough and.

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.



## **Table of Contents**

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

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

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs. We currently have clinical trial insurance in an amount equal to up to \$10.0 million in the aggregate and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a successful claim. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

### **We may grow through additional acquisitions, which could dilute our existing shareholders and could involve substantial integration risks.**

As part of our business strategy, we may acquire other businesses and/or technologies in the future. We may issue equity securities as consideration for future acquisitions that would dilute our existing stockholders, perhaps significantly depending on the terms of the acquisition. We may also incur additional debt in connection with future acquisitions, which, if available at all, may place additional restrictions on our ability to operate our business. Acquisitions may involve a number of risks, including:

difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;

potential disruption of our ongoing business and distraction of management;

potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;

difficulty in incorporating acquired technology and rights into our products and technology;

unanticipated expenses and delays in completing acquired development projects and technology integration;

management of geographically remote units both in the United States and internationally;

impairment of relationships with partners;

entering markets or types of businesses in which we have limited experience;

potential loss of key employees of the acquired company; and

inaccurate assumptions of acquired company's product quality and/or product reliability.

As a result of these and other risks, we may not realize anticipated benefits from any acquisitions. Any failure to achieve these benefits or failure to successfully integrate acquired businesses and technologies could seriously harm our business.

## **Table of Contents**

### **Risks Relating to Our Common Stock**

**We may be required to dilute our existing stockholders further in connection with capital raising activities and certain purchasers may beneficially own significant blocks of our common stock. 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, upon the closing of our private placement on August 12, 2008, we issued to a group of institutional investors a total of 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. We also issued these investors additional unit warrants which represent the right to purchase 3,679,078 units, consisting of 3,679,078 shares of common stock and common stock warrants to purchase 919,770 shares of our common stock. The issuance of these shares and warrants resulted in substantial dilution to stockholders who held our common stock prior to the private placement.

Pursuant to our obligations under a registration rights agreement for the private placement, on October 6, 2008 we filed a registration statement with the SEC, covering the resale of the 10,714,655 shares of common stock issued in the private placement and the 2,678,664 shares of common stock issuable upon exercise of the warrants which was declared effective on October 30, 2008, making such shares 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 April 1, 2009, 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 86% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

delaying, deferring or preventing a change in control of our company;

entrenching our management and/or board;

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

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

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

The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. During the period from January 1, 2007 to March 31, 2009, our closing 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 preclinical studies and planned clinical trials of ACH-1625;

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

the outcome of the Company's discussions with Gilead regarding the future of its collaboration and the determination of the appropriate clinical path for ACH-1095;

the results of our currently on-going phase II trial extensions for elvucitabine;

the entry into, or termination of, key agreements, in particular our collaboration agreement with Gilead or our sublicense agreement with Vion Pharmaceuticals, or any new collaboration agreement we may enter for elvucitabine;

the results of regulatory reviews relating to the approval of 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;



**Table of Contents**

the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

the failure or discontinuation of any of our research programs;

issues in manufacturing our drug candidates or any approved products;

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

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

future sales of our common stock;

changes in the structure of health care payment systems;

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

low trading volume of our common stock.

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

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

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

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

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

At March 31, 2009, we had \$9.0 million in cash and cash equivalents and \$18.1 million in marketable securities consisting of U.S. government and agency securities and FDIC guaranteed commercial paper held by a major banking institution.

There is a possibility that our stock price may decline, due in part to the volatility of the stock market and the general economic downturn.

**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.**

Prior to our initial public offering in 2006, as a private company with limited resources, we maintained a small finance and accounting staff. 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 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, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

---

## **Table of Contents**

**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 in 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 a collaboration arrangement with Gilead for the development and commercialization of certain of our HCV compounds involving NS4A antagonism, and we may enter into additional collaborative arrangements in the future. For example, we currently plan to enter into an alliance for the phase III development and commercialization of elvucitabine. Given the limited number of global pharmaceutical companies which currently develop and market drugs for the treatment of HIV, and the strategic need for elvucitabine to be suitable for co-formulation with drugs already marketed or under development by a potential partner, the number of potential partners is relatively small. To date we have been unsuccessful in partnering with the major pharmaceutical companies with whom we have had on-going discussions. We are continuing partnering efforts with regional companies and institutions, including those in Asia, South America and elsewhere. If we are not successful in forming an alliance before the completion of the currently ongoing trial extensions, we do not plan to enter phase III clinical trials and would not independently pursue further development or commercialization of elvucitabine. In addition, as we continue to assess our strategic and development options for ACH-702, at this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not significantly invest in the future development of this compound without a collaboration partner. 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.

**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 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 May 2009, Gilead notified us that they do not intend to initiate clinical development of GS-9525 and if we are unable to pursue the development of ACH-1095 on our own, our business may be 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 120 days notice. If Gilead were to exercise this right, the development and commercialization of our HCV compounds would be adversely affected.

In addition, under our current collaboration arrangement research and development activities prior to proof-of-concept are overseen by a research committee comprised of equal numbers of our representatives and representatives from Gilead. The joint research committee assigns research and development tasks, agrees upon a budget for the research program, and shares equally in the related costs. The parties may agree at any time to increase or decrease the research budget. Prior to proof-of-concept, any disputes within the joint research committee that cannot be resolved between designated executives of each party will be resolved by Gilead. Future collaboration arrangements may be differently structured.

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



---

## Table of Contents

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, our collaborator for our chronic hepatitis C program, currently is developing other products for the treatment of chronic hepatitis C, and the results of its development efforts could affect its commitment to our drug candidate. For example, Gilead has informed us that they do not intend to develop GS 9525 and we are currently in discussions with Gilead for a revision to the license and collaboration agreement. Achillion has proposed that it continue to develop ACH-1095, while the parties would jointly continue to advance additional compounds also operating by the NS4A mechanism of action. It has been proposed that future costs related to clinical development of ACH-1095 would be borne by Achillion, while costs associated with any additional compounds would be borne by the parties jointly. If Gilead pursues the development of a backup compound or another product for chronic hepatitis C, its development efforts could affect our ability to pursue ACH-1095. 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. Accordingly, these third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

### **We currently depend on third-party manufacturers to produce our preclinical and clinical drug supplies and intend to rely upon third-party manufacturers to produce commercial supplies of any approved drug candidates. 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 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. 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.

## **Table of Contents**

We currently rely on a single manufacturer for the preclinical and clinical supplies of each of our drug candidates and do not currently have relationships for redundant supply or a second source for any of our drug candidates. To date, our third-party manufacturers have met our 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 manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contract manufacturers cannot perform as agreed, we may be required to replace them. Although we believe that there are a number of potential replacements given our manufacturing processes are not manufacturer 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 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 and test 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 most advanced drug candidate is elvucitabine, which is currently in phase II clinical trials. 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 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; and

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

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. For example, in February 2007, we



**Table of Contents**

announced that we discontinued further clinical development of ACH-806 (also known as GS 9132) which was determined to have positive antiviral effect in a proof-of-concept clinical trial in HCV infected patients, but also to elevate serum creatinine levels, a marker of kidney function. There can be no assurance that we have identified the source of the serum creatinine elevation and that we will not see a similar outcome in human clinical trials with that program's successor compound, ACH-1095 (also known as GS 9525) or that observations in preclinical studies of ACH-1095 in one species may not limit or even preclude its clinical use. Accordingly, there can be no assurance that this, or another type of toxicity, will not arise in future clinical trials.

Additionally, the results from the completed preclinical studies and clinical trials and ongoing clinical trials for elvicitabine, ACH-702, ACH-1625 and our other drug candidates may not be predictive of the results we may obtain in later stage trials. In addition, we have not yet made a final determination regarding the most appropriate therapeutic application or clinical development plan for ACH-702. We continue to assess our strategic and development options for ACH-702 for topical administration and other potential applications including use in medical biofilms, use in ophthalmic infections and for use against tuberculosis. At this time, we do not anticipate moving into clinical development of ACH-702 until we complete this strategic assessment, and even then, we may not invest significantly in the future development of this compound without a collaboration partner. We do not expect any of our drug candidates to be commercially available for several years.

**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-1095, ACH-1625, ACH-702, elvicitabine 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; and

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

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. In particular, we recently completed a pre-IND consultation with the FDA on the most appropriate clinical development program for ACH-702. Given the complexity of the mechanism of action of ACH-702, which operates via a three-part target including gyrase, topoisomerase IV and primase, the complexity of the preclinical results noted with ACH-702, and the evolving regulatory climate for antibacterials, we decided our development strategy for this compound should be further discussed with the FDA before initiating human clinical studies. While the FDA provided guidance on an appropriate path toward regulatory approval for topical administration for ACH-702, the Division of Anti-Infective and Ophthalmology Products referred our request for additional guidance on systemic administration of ACH-702 to the Division of Special Pathogen and Transplant Products (the DSPTP). We are currently assessing our strategic and development plans for ACH-702 for topical administration and other potential applications including use in medical biofilms and for use against tuberculosis. Even after receiving guidance from the DSPTP, if any, there can be no assurance that the FDA will approve our IND application once filed. Furthermore, 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

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

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.

## **Table of Contents**

**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;

the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

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. For example, we experienced delays in patient enrollment in connection with our phase II trial of elvucitabine in HIV infected patients who have failed a HAART regimen which included Efavirenz (lamivudine) due to the strict entry criteria for this trial. As a result, we expanded the number of sites at which the trial was conducted and changed the protocol of the trial to include additional treatment with elvucitabine after the initial 14 days of treatment. 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 or IRBs 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.

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.

## Edgar Filing: ACHILLION PHARMACEUTICALS INC - Form 10-Q

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

---

## **Table of Contents**

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 bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

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

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposing of these materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. In addition, though we have environmental liability insurance, such coverage may not provide for all related losses. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

### **Risks Related to 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.

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

Even if ACH-1095, ACH-1625, ACH-702, elvucitabine 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;

**Table of Contents**

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 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.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

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



---

## **Table of Contents**

**Federal legislation has increased the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.**

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changes the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

### **Risks Related to Patents and Licenses**

**If we are unable to adequately protect our drug candidates, or if we infringe the rights of others, our ability to successfully commercialize our drug candidates will be harmed.**

As of March 31, 2009, our patent portfolio included a total of 230 patents and patent applications worldwide. We own or hold exclusive licenses to a total of 13 U.S. issued patents and 27 U.S. pending provisional and non-provisional patent applications, as well as 190 pending PCT applications and associated non-US patents and patent applications. Our success depends in part on our ability to obtain 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. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as anti-infective drugs. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The 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.

**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



---

## **Table of Contents**

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.

**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, Emory and Gilead have the primary right, but not an obligation, to bring actions against an infringing third party. However, if Gilead or Emory elects not to bring an action, we may bring an action against the infringing party.

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

the patentability of our inventions relating to our drug candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

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

incur substantial monetary damages;

encounter significant delays in bringing our drug candidates to market; and/or

be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

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

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

proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

**Table of Contents**

**ITEM 6. EXHIBITS**

- 31.1 Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
  
- 31.2 Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
  
- 32.1 Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
  
- 32.2 Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.

**Table of Contents**

**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.

Date: May 15, 2009

ACHILLION PHARMACEUTICALS, INC.

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

Date: May 15, 2009

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

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Exhibit</b>
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.