

ACHILLION PHARMACEUTICALS INC

Form 10-Q

May 10, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2010

OR

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

For the transition period from _____ to _____

Commission File Number 001-33095

ACHILLION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer or a smaller reporting company. See 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 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 May 7, 2010, the registrant had 38,521,896 shares of Common Stock, \$0.001 par value per share, outstanding.

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

	March 31, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 19,397	\$ 9,712
Marketable securities	5,626	
Accounts receivable	83	65
Prepaid expenses and other current assets	1,018	768
Total current assets	26,124	10,545
Fixed assets, net	707	876
Deferred financing costs	40	149
Restricted cash	152	100
Total assets	\$ 27,023	\$ 11,670
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,002	\$ 2,277
Accrued expenses	1,325	2,598
Current portion of long-term debt	2,730	2,867
Total current liabilities	6,057	7,742
Deferred revenue	2,489	2,489
Long term debt		417
Total liabilities	8,546	10,648
Commitments and contingencies		
Stockholders' Equity:		
Common Stock, \$.001 par value; 100,000 shares authorized: 38,522 and 26,706 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	39	27
Additional paid-in capital	229,995	206,908
Accumulated deficit	(211,550)	(205,913)
Accumulated other comprehensive income	(7)	
Total stockholders' equity	18,477	1,022
Total liabilities and stockholders' equity	\$ 27,023	\$ 11,670

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)**

	For the Three Months Ended March 31,	
	2010	2009
Revenue	\$ 74	\$ (293)
Operating expenses		
Research and development	3,960	4,737
General and administrative	1,667	1,603
Total operating expenses	5,627	6,340
Loss from operations	(5,553)	(6,633)
Other income (expense)		
Interest income	10	92
Interest expense	(94)	(183)
Net loss	(5,637)	(6,724)
Basic and diluted net loss per share (Note 4)	\$ (0.16)	\$ (0.25)
Weighted average shares used in computing basic and diluted net loss per share	35,576	26,399

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

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

	Three Months Ended March 31,	
	2010	2009
Cash flows from operating activities		
Net loss	\$ (5,637)	\$ (6,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	194	206
Noncash stock-based compensation	471	485
Noncash interest expense	13	27
Loss on disposal of equipment	4	
Amortization of premium on marketable securities	32	63
Changes in operating assets and liabilities:		
Accounts receivable	(18)	
Prepaid expenses and other current assets	(204)	190
Accounts payable	(275)	(1,141)
Accrued expenses	(1,273)	(208)
Net cash used in operating activities	(6,693)	(7,102)
Cash flows from investing activities		
Purchase of property and equipment	(18)	(34)
Purchase of available for sale marketable securities	(5,665)	(1,432)
Maturities of marketable securities		7,500
Net cash (used in) provided by investing activities	(5,683)	6,034
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs	22,628	
Repayments of notes payable	(567)	(1,020)
Net cash provided by (used in) financing activities	22,061	(1,020)
Net increase (decrease) in cash and cash equivalents	9,685	(2,088)
Cash and cash equivalents, beginning of period	9,712	11,060
Cash and cash equivalents, end of period	\$ 19,397	\$ 8,972
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 76	\$ 152

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

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

(Unaudited)

1. Nature of the Business

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

The Company incurred losses of \$197,688 from inception through March 31, 2010 and had an accumulated deficit of \$211,550 through March 31, 2010. 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, cash equivalents and marketable securities, as potentially augmented by its Standby Equity Distribution Agreement ("SEDA"), with YA Global Master SPV Ltd. ("YA Global") (see Note 3) or additional financing activities, will be sufficient to support its current operating plan through at least December 31, 2010. However, the Company's 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 costs associated with the investigational new drug application ("IND") preparation, including the required chemical manufacturing and control ("CMC") work, related to ACH-1095;

the costs associated with the preclinical development and manufacturing of ACH-2684;

the potential therapeutic uses and resulting partnership opportunities for ACH-702 that the Company may pursue;

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 January 2010, the Company issued 10,275 shares of its common stock in an underwritten public offering. In February 2010, the Company issued an additional 1,541 shares of common stock in connection with the underwriters' exercise of an over-allotment option. The Company received net proceeds of \$22,628.

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 may 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.

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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, find and maintain partners for certain drug candidates 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.

Certain prior period amounts have been reclassified to conform to the current year's presentation. State research and development credit carryforwards that were exchanged for cash of \$40 were reclassified from income tax benefit to a reduction of research and development expenditures for the three months ended March 31, 2009.

2. Basis of Presentation

The accompanying unaudited financial statements of the Company should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2009 included in the Company's Annual Report on Form 10-K filed with the SEC on March 11, 2010. 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

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements Continued

(in thousands, except per share amounts)

(Unaudited)

instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

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

3. Financing Activities

Public Offering

On January 22, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC, Noble Financial Capital Markets and National Securities Corporation, as underwriters (the "Underwriters"), related to a public offering of shares of the Company's common stock, par value \$.001 per share, at a price of \$2.08 per share less underwriting discounts and commissions (the "Offering"). The Company issued 10,275 shares of common stock in connection with the Offering on January 27, 2010.

On February 2, 2010, the Company closed on the sale of an additional 1,541 shares of common stock in connection with the exercise of the over-allotment option that was granted to the underwriters in the Underwriting Agreement.

The Offering resulted in net proceeds to the Company of \$22,628. The Company intends to use the net proceeds for general corporate purposes, research and development expenses, including clinical trial costs, general and administrative expenses and products and technologies that complement its business. The Company has invested the net proceeds in investment-grade, interest bearing securities.

Standby Equity Distribution Agreement

On July 1, 2009, the Company entered into a SEDA with YA Global pursuant to which the Company may, at its sole and exclusive option, periodically sell to YA Global shares of its common stock, \$0.001 par value per share for total proceeds of up to \$15,000. Each advance under the SEDA shall not exceed the greater of \$300 or the average daily trading volume of the Company's common stock for the five consecutive trading days prior to the notice date. Advance notices may be given to YA Global once every five trading days. For each share of common stock purchased pursuant to an advance under the SEDA, YA Global will pay to the Company ninety-five percent of the lowest volume-weighted average price of the common stock on the NASDAQ Global Market during the five consecutive trading days following delivery by the Company of an advance notice. Additionally, in no event shall the number of shares of common stock issued under the SEDA cause YA Global to own more than 9.99% of the Company's common stock as of July 1, 2009 (5,292,427 shares), unless the Company obtains stockholder approval or obtains a written opinion from counsel that such approval is not required. The Company is not obligated to utilize any of the \$15,000 available under the SEDA and there are no minimum commitments or minimum use penalties. The Company issued YA Global 191 shares of its common stock as a commitment fee in connection with the transaction and also paid a due diligence and structuring fee of \$25. These shares of common stock, as well as any additional shares of common stock the Company may issue pursuant to the SEDA in the future, have been registered on a registration statement that was declared effective on September 21, 2009. The SEDA has two year term and may be terminated by the Company at any time. The Company capitalized \$98 of issuance costs related to the SEDA. As of March 31, 2010, there were no advances under the SEDA.

4. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities,

Table of Contents**Achillion Pharmaceuticals, Inc.****Notes to Financial Statements Continued****(in thousands, except per share amounts)****(Unaudited)**

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, 2010 and 2009 (prior to consideration of the treasury stock method):

	Three Months Ended	
	March 31,	
	2010	2009
Options	3,340	2,713
Warrants	2,785	6,711
Total potentially dilutive securities outstanding	6,125	9,424

5. Collaboration Arrangement***Gilead Sciences, Inc.***

In November 2004, the Company entered into a research collaboration and license agreement with Gilead Sciences, Inc. pursuant to which the Company agreed to collaborate exclusively with Gilead throughout the world to develop and commercialize compounds for the treatment of chronic hepatitis C and which inhibit HCV replication through a novel mechanism of action targeting the HCV NS4A protein. In May 2009, Gilead informed the Company that they did not intend to pursue development of its lead compound ACH-1095. The Company believes the compound should be advanced and therefore in September 2009, the Company and Gilead amended the collaboration arrangement so that the Company may continue to develop ACH-1095 independently during an Interim Period, while Gilead may rejoin in the development of ACH-1095 at clinical proof-of-concept, as defined. The Company will bear all costs associated with ACH-1095 development during this Interim Period. If Gilead elects to regain rights to ACH-1095, Gilead will reimburse the Company for all ACH-1095 development costs incurred during the Interim Period, and all original milestone and royalty payments described in the license agreement will again apply to ACH-1095. Gilead is under no obligation to exercise any rights with respect to ACH-1095. If Gilead elects not to exercise its rights to ACH-1095 within forty-five (45) days after proof-of-concept, the Company shall gain all rights to ACH-1095, and Gilead will then have the right to designate a new lead compound under the license agreement.

Regardless of Gilead's election to exercise its rights with respect to ACH-1095, during the Interim Period the parties retain their rights to compounds which were identified under the collaboration prior to the effective date of the Amendment. The terms of the original License Agreement, including milestone, royalty and cost-sharing provisions, shall apply to the development of such other compounds. New lead compounds under the collaboration can be identified by mutual agreement of the parties.

Gilead has the right to terminate the agreement without cause upon 30 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.

If Gilead elects to exercise its rights with respect to development of ACH-1095 or if the Company and Gilead pursue a back-up compound, research and development activities prior to proof-of-concept will be overseen by a research committee comprised of equal numbers of the Company's representatives and representatives from Gilead. The joint research committee assigns research and development tasks, agrees upon a

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budget for the research program, and shares equally in the related costs. In addition, 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.

The Company continues to be responsible for back-up activities, which includes preclinical assessment of a limited number of other NS4A antagonists until such time as proof-of-concept is achieved. Gilead will otherwise be responsible for all manufacturing, formulation and commercialization activities associated with such compounds, if nominated, including all regulatory filings and clinical trials after proof-of-concept unless Gilead chooses not to opt back in on ACH-1095 development. Gilead has agreed under the agreement to use reasonably diligent efforts to develop and commercialize at least one compound in each of the United States, Japan, Germany, France, Italy, Spain and the United Kingdom.

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements Continued

(in thousands, except per share amounts)

(Unaudited)

The Company received \$10,000 from Gilead upon the execution of the license agreement, consisting of license fees and an equity investment, and 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 may 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 back-up 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 period prior to achievement of proof-of-concept (the Research Period), is being accounted for under the proportionate performance model. Future milestones, if any, will occur after the Research Period, are not accounted for under the proportionate performance model and will be recognized when the milestone is achieved as the Company has no further research or development obligations after the Research Period.

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

In the first quarter of 2009, the Company and Gilead revised their joint research program to increase total estimated efforts under the collaboration and extended the estimated period over which the Company's remaining obligations under the arrangement would be completed. At this time, the Company cannot accurately estimate its future obligations under the collaboration as it has not identified a new lead compound that will be developed jointly. Therefore, during the three months ended March 31, 2010 and 2009, the Company did not recognize revenue from upfront, milestone and FTE fees previously received under the collaboration. The Company will determine its remaining obligations if and when a new lead compound is identified.

During the three months ended March 31, 2010 and 2009, the Company recognized revenue of \$74 and \$(293), respectively, under the Gilead Arrangement, all of which related to external costs billed by the Company to Gilead, net of Gilead billings to the Company of \$0 and \$362 for the three months ended March 31, 2010 and 2009, 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 three months ended March 31, 2009.

Included in the accompanying balance sheets as of March 31, 2010 and December 31, 2009 are \$74 and \$61 respectively, of accounts receivable resulting from this collaboration agreement and \$2,489 and \$2,489, respectively, of deferred revenue resulting from the up-front fee, a milestone payment, and FTE costs.

GCA Therapeutics, Ltd.

On February 1, 2010, the Company entered into a license agreement (the Agreement) with GCA Therapeutics, Ltd. (GCAT) for elvucitabine, the Company's nucleoside reverse transcriptase inhibitor for the treatment of both hepatitis B virus (HBV) infection and human immunodeficiency virus (HIV) infection. The Agreement was amended and restated on March 8, 2010. The exclusive license grants GCAT the right, through a Chinese joint venture with Tianjing Institute of Pharmaceutical Research, to clinically develop and commercialize elvucitabine in mainland China, Hong Kong and Taiwan.

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine, and the Company will be eligible to receive development

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milestones and royalties on net sales in those territories.

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

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

6. Marketable Securities

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

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

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

Level 3: Unobservable inputs.

The fair value of the Company's securities of \$5,626 as of March 31, 2010 is valued based on level 2 inputs. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. As of March 31, 2010 and December 31, 2009, the Company's investment portfolio consisted of U.S. government and agency securities and government sponsored bond obligations and government backed corporate debt securities held by a major banking institution. The maturities of all marketable securities held at March 31, 2010 and December 31, 2009 are less than one year. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders' equity.

The unrealized gain (loss) from marketable securities was \$(7) and \$0 at March 31, 2010 and December 31, 2009, respectively.

As of March 31, 2010 and December 31, 2009, none of the Company's investments were determined to be other than temporarily impaired.

7. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2010	December 31, 2009
Accrued compensation	\$ 613	\$