ACHILLION PHARMACEUTICALS INC
Form 10-Q
May 07, 2013
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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, 2013

OR

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

For the transition period from to

Commission File Number 001-33095

ACHILLION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2113479**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
300 George Street, New Haven, CT	**06511**
(Address of principal executive offices)	**(Zip Code)**

(203) 624-7000

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨

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

As of May 1, 2013, the registrant had 96,556,639 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Achillion Pharmaceuticals, Inc.

Balance Sheets

(in thousands, except per share amounts)

(Unaudited)

	March 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 39,398	$ 18,526
Marketable securities	105,595	46,884
Accounts and other receivables	589	277
Prepaid expenses and other current assets	3,775	2,180
Total current assets	149,357	67,867
Marketable securities	54,946	12,008
Fixed assets, net	1,301	1,247
Deferred financing costs	79	256
Restricted cash	152	152
Total assets	$ 205,835	$ 81,530
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 5,193	$ 4,276
Accrued expenses	5,031	4,510
Current portion of long-term debt	356	350
Total current liabilities	10,580	9,136
Long-term debt	255	347
Total liabilities	10,835	9,483
Commitments and contingencies		
Stockholders Equity:		
Common Stock, $.001 par value; 200,000 shares authorized: 96,557 and 79,626 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	97	80
Additional paid-in capital	529,399	394,675
Accumulated deficit	(334,465)	(322,727)
Accumulated other comprehensive income	(31)	19
Total stockholders equity	195,000	72,047
Total liabilities and stockholders equity	$ 205,835	$ 81,530

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

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Achillion Pharmaceuticals, Inc.

Statements of Comprehensive Loss

(in thousands, except per share amounts)

(Unaudited)

	For the Three Months Ended March 31,	
	2013	2012
Revenue	$	$ 2,489
Operating expenses		
Research and development	8,719	8,942
General and administrative	3,074	2,739
Total operating expenses	11,793	11,681
Loss from operations	(11,793)	(9,192)
Other income (expense)		
Interest income	77	65
Interest expense	(22)	(14)
Net loss	(11,738)	(9,141)
Total comprehensive loss (Note 11)	(11,788)	(9,093)
Basic and diluted net loss per share (Note 5)	$ (0.14)	$ (0.13)
Weighted average number of shares used in computing basic and diluted net loss per share	85,850	70,411

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

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Achillion Pharmaceuticals, Inc.

Statements of Cash Flows

(in thousands)

(Unaudited)

	Three Months Ended March 31, 2013	2012
Cash flows from operating activities		
Net loss	$ (11,738)	$ (9,141)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	98	100
Noncash stock-based compensation	1,423	920
(Premium) on purchase of marketable securities	(2,901)	(207)
Amortization of premium on marketable securities	249	98
Changes in operating assets and liabilities:		
Accounts and other receivables	(312)	86
Prepaid expenses and other assets	(1,427)	(957)
Accounts payable	917	101
Accrued expenses	521	161
Deferred revenue		(2,489)
Net cash used in operating activities	(13,170)	(11,328)
Cash flows from investing activities		
Purchases of fixed assets	(143)	(475)
Purchases of marketable securities	(119,747)	(26,500)
Maturities of marketable securities	20,700	49,950
Net cash (used in) provided by investing activities	(99,190)	22,975
Cash flows from financing activities		
Proceeds from the issuance of common stock in connection with the public offering, net of issuance costs	133,211	
Proceeds from exercise of stock options	107	1,158
Borrowings of debt		609
Repayments of debt	(86)	(35)
Net cash provided by financing activities	133,232	1,732
Net increase in cash and cash equivalents	20,872	13,379
Cash and cash equivalents, beginning of period	18,526	16,110
Cash and cash equivalents, end of period	$ 39,398	$ 29,489
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 14	$ 9
Supplemental disclosure of noncash financing activities		
Cashless exercise of warrants		$ 2,051

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 $320,603 from inception through March 31, 2013 and had an accumulated deficit of $334,465 at March 31, 2013, which includes preferred stock dividends recognized until the Company s initial public offering in 2006. The Company has funded its operations primarily through the sale of equity securities.

The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to support its current operating plan through at least March 31, 2014. However, the Company s operating plan may change as a result of many factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of sovaprevir, ACH-3102 and ACH-2684;
- the scope of and costs associated with entering into cooperative study arrangements, or CSAs, if any, for the collaborative development of its drug candidates in combination with others drug candidates;
- the costs involved in obtaining regulatory approvals for the Company s drug candidates;
- the scope, prioritization and number of programs the Company pursues;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the Company s ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact its ability to obtain capital in the future;
- the Company s acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to the Company.

Certain prior period amounts have been reclassified to conform to the current year s presentation. The premiums paid on the purchase of marketable securities were reclassified from investing activities to operating activities on the Statement of Cash Flows for three months ended March 31, 2012.

2. Accounting Standards Updates

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-02, Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. This standard requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income (AOCI). This ASU is effective for reporting periods beginning after December 15, 2012. The Company evaluated this pronouncement effective January 1, 2013 and determined the further breakout of accumulated other comprehensive income is immaterial to the Company s financial statements.

3. Basis of Presentation

The accompanying unaudited financial statements of the Company should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2012 included in the Company s Annual Report on Form 10-K filed with the SEC on February 20, 2013. The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

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

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4. Financing Activities

Public Offering

In February 2013, the Company entered into an underwriting agreement (the Underwriting Agreement) with Citigroup Global Markets, Inc. and Leerink Swann LLC as representatives of the several underwriters named therein (the Underwriters), related to a public offering of shares of the Company s common stock, par value $.001 per share, at a price of $8.40 per share less underwriting discounts and commissions (the Offering). The Company issued and sold to the Underwriters an aggregate of 16,894 shares of common stock in connection with the Offering. The Offering resulted in net proceeds to the Company of $133,211.

5. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated in accordance with ASC 260, *Earnings Per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. Potentially dilutive securities were as follows during the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
Stock Options:		
Weighted average number, in thousands	7,083	6,248
Warrants:		
Weighted average number, in thousands	5,358	9,254

Potentially dilutive securities outstanding as of March 31, 2013 and 2012 are as follows:

	March 31,	
	2013	2012
Options, in thousands	7,076	6,144
Warrants, in thousands	5,358	9,069
Total potentially dilutive securities outstanding, in thousands	12,434	15,213

6. Collaboration Arrangements

GCA Therapeutics, Ltd.

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

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine. The Company did not receive any payment upon the signing of the agreement. Upon the first commercial sale of a licensed product GCAT is obligated to pay $100 to the Company. Further, the Company will be eligible to receive royalties up to 15% of net sales in those territories.

The Company does not believe that the milestone specified under the Agreement is substantive as achievement of the milestone is based solely on the performance of GCAT and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Agreement, it intends to recognize revenue related to the milestone payment upon achievement of the milestone by GCAT. However, there can be no assurance that GCAT will achieve the milestone or that the Company will receive the related revenue. This Agreement shall be effective, unless earlier terminated, until the expiration of the last to expire royalty term.

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Ora, Inc.

In October 2012, the Company entered into a license and development agreement (the Ora Agreement) with Ora, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. The Ora Agreement was amended in April 2013. Under the terms of the Ora Agreement, Ora will assume development and regulatory responsibility and associated costs for ACH-702. Upon initiation of the agreement, the Company received a one-time license fee of $100, which was recognized as revenue upon the completion of the technology transfer by the Company. The Company is eligible to receive up to $4,000 in development milestones and up to $7,000 in commercialization milestones as well as royalties up to 3.5% of net sales. The Company has no further obligations under the Ora Agreement.

The Ora Agreement includes the right to sublicense any or all of the licensed rights, subject to the Company s approval. Ora shall pay the Company15% of all up-front licensing payments and any other payment allocated to or received by Ora pursuant to any sublicense agreement granted by Ora under this agreement; provided that such payment is not a royalty on net sales and not a development or commercial milestone already due to Achillion. In December 2012, Ora entered into a sublicense agreement with Taejoon Pharmaceutical Co. for the development of ACH-702.

The Company does not believe that the milestones specified under the Ora Agreement are substantive as achievement of the milestones is based solely on the performance of Ora and its sublicensee(s) and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Ora Agreement, it intends to recognize revenue related to the milestone payments upon achievement of the milestone by Ora or its sublicensee(s). The Ora Agreement shall be effective and, unless earlier terminated, will continue until the last sale of each and every licensed product to an unrelated third party by Ora, its affiliate or sublicensee.

7. Marketable Securities

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

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

Level 2: Inputs other than quoted prices included within Level 1