CURIS INC
Form 10-Q
April 28, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2011

OR

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

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3505116**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4 Maguire Road	
Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant s Telephone Number, Including Area Code: (617) 503-6500

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. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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, a 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 ¨	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 x No

As of April 25, 2011, there were 76,349,956 shares of the registrant s common stock outstanding.

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CURIS, INC. AND SUBSIDIARIES

QUARTERLY REPORT ON FORM 10-Q

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PART I FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	March 31, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,119,245	$ 7,826,549
Marketable securities	25,348,065	32,553,269
Short-term investment restricted		219,458
Accounts receivable	82,013	92,371
Prepaid expenses and other current assets	866,652	392,249
Total current assets	37,415,975	41,083,896
Property and equipment, net	321,289	302,721
Long-term investment restricted	277,546	277,546
Goodwill	8,982,000	8,982,000
Other assets	2,980	2,980
Total assets	$ 46,999,790	$ 50,649,143
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,608,194	$ 2,620,968
Accrued liabilities	658,589	854,605
Total current liabilities	3,266,783	3,475,573
Warrants	3,106,152	1,604,742
Other long-term liabilities	112,171	51,171
Total liabilities	6,485,106	5,131,486
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 77,397,663 shares issued and 76,349,956 shares outstanding at March 31, 2011; and 76,803,868 shares issued and 75,756,161 shares outstanding at December 31, 2010	773,977	768,039
Additional paid-in capital	769,610,050	767,825,232
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation		(955)
Accumulated deficit	(729,028,898)	(722,228,747)
Accumulated other comprehensive income	50,829	45,362
Total stockholders equity	40,514,684	45,517,657

Total liabilities and stockholders equity	$ 46,999,790	$ 50,649,143

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

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS)/INCOME

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
REVENUES:		
Research and development	$ 133,538	$ 82,501
License fees		12,475,833
Total Revenues	133,538	12,558,334
COSTS AND EXPENSES:		
Research and development	3,058,499	2,467,804
General and administrative	2,407,349	4,426,445
Total costs and expenses	5,465,848	6,894,249
(Loss)/income from operations	(5,332,310)	5,664,085
OTHER INCOME (EXPENSE):		
Interest income	33,569	26,789
Change in fair value of warrant liability	(1,501,410)	(906,609)
Total other expense, net	(1,467,841)	(879,820)
Net (loss)/income	$ (6,800,151)	$ 4,784,265
Basic net (loss)/income per common share	$ (0.09)	$ 0.07
Diluted net (loss)/income per common share	$ (0.09)	$ 0.06
Basic weighted average common shares	75,825,801	72,889,133
Diluted weighted average common shares	75,825,801	76,282,898
Net (loss)/income	$ (6,800,151)	$ 4,784,265
Unrealized gain/(loss) on marketable securities	5,467	(17,004)
Comprehensive (loss)/income	$ (6,794,684)	$ 4,767,261

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)/income	$ (6,800,151)	$ 4,784,265
Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities-		
Depreciation and amortization	21,020	180,799
Stock-based compensation expense	677,713	1,069,565
Change in fair value of warrant liability	1,501,410	906,609
Non-cash interest income	102,602	
Net gain on sale of assets	(31,225)	
Changes in operating assets and liabilities:		
Accounts receivable	10,358	458,404
Prepaid expenses and other assets	37,690	340,960
Accounts payable and accrued liabilities	(147,790)	(402,533)
Deferred revenue		(475,833)
Total adjustments	2,171,778	2,077,971
Net cash (used in)/provided by operating activities	(4,628,373)	6,862,236
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(18,864,743)	(27,484,583)
Sale of marketable securities	25,972,812	7,967,260
Purchases of property and equipment	(39,588)	
Proceeds from sale of assets	31,225	
Decrease in restricted cash	219,458	
Net cash provided by/(used in) investing activities	7,319,164	(19,517,323)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from registered direct offering of common stock and warrants, net of issuance costs of $1,310,000		14,942,317
Proceeds from other issuances of common stock and exercise of warrants	601,905	1,910,721
Net cash provided by financing activities	601,905	16,853,038
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,292,696	4,197,951
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	7,826,549	7,275,433
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 11,119,245	$ 11,473,384

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Business

Curis, Inc. (the Company or Curis) is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog signaling pathway, in its efforts to develop network-targeted cancer therapies. Curis conducts research programs both internally and through strategic collaborations.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to: development by its competitors of new or better technological innovations; dependence on key personnel; its ability to protect proprietary technology; its ability to successfully advance discovery, preclinical and clinical stage drug candidates in its internally funded programs; unproven technologies and drug development approaches; reliance on corporate collaborators and licensees to successfully research, develop and commercialize products based on the Company s technologies; its ability to comply with FDA regulations and approval requirements; its ability to execute on its business strategies; and its ability to obtain adequate financing to fund its operations.

The Company s future operating results will largely depend on the magnitude of payments from its current and potential future corporate collaborators and the progress of drug candidates currently in its research and development pipeline. The results of the Company s operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of its entry into new collaborations, if any, the timing of the receipt of payments from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. The Company anticipates that existing capital resources at March 31, 2011 should enable the Company to maintain its current and planned operations into the fourth quarter of 2012. The Company s ability to continue funding its planned operations into and beyond the fourth quarter of 2012 is dependent upon, among other things, the success of its collaborations with Genentech and Debiopharm and receipt of additional cash payments under these collaborations, its ability to control expenses and its ability to raise additional funds through equity or debt financings, new collaborations or other sources of financing.

2. Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the United States of America for complete financial statements and should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the Securities and Exchange Commission on March 8, 2011.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary for a fair statement of the Company s financial position at March 31, 2011 and the results of operations and cash flows for the three-month periods ended March 31, 2011 and 2010. The preparation of the Company s consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure in the financial statements. Such estimates include revenue recognition, the collectability of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities. Actual results may differ from such estimates.

These interim results are not necessarily indicative of results to be expected for a full year or subsequent interim periods.

3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of these agreements may

provide for the Company s licensees and collaborators to agree to make

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non-refundable license fee payments, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 8, 2011.

4. Debiopharm License Agreement

In August 2009, the Company granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell its heat shock protein 90, or Hsp90, inhibitor technology to Debiopharm S.A. The Company amortized this payment over its estimated performance period of this agreement, which concluded during the first quarter of 2010, resulting in the recognition of $333,000 in license fee revenue during the period ended March 31, 2010. In addition, under the terms of this agreement, in March 2010, the Company received a payment of $8,000,000 from Debiopharm upon acceptance by French regulatory authorities of Debiopharm s clinical trial application for Hsp90 inhibitor, Debio 0932. The Company has recorded these amounts, which totaled $8,333,000 as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the three months ended March 31, 2010 because the Company has no ongoing material performance obligations under the agreement.

5. Fair Value Measurements

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP also defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

FASB Codification Topic 820, *Fair Value Measurements and Disclosures,* requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company s Level 1 assets include cash equivalents, investments in marketable securities, and restricted investments. The Company held cash equivalents and marketable securities of $9,975,000 and $25,348,000, respectively, as of March 31, 2011, and $6,193,000 and $32,553,000, respectively, as of December 31, 2010. The Company s marketable securities are investments with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and consist of commercial paper and government obligations. These amounts are invested directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings and U.S. Treasury securities.

The Company also had a long-term restricted investment of $278,000 as of March 31, 2011 and December 31, 2010 that was solely comprised of a certificate of deposit pursuant to the requirements of the Company s property lease. The restriction on a prior short-term restricted investment of $219,000 at December 31, 2010 was lifted on January 31, 2011.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company has no Level 2 assets or liabilities at March 31, 2011.

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Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company s warrant liability was valued using a probability-weighted Black-Scholes model, discussed further in Note 6, and is therefore classified as Level 3.

In accordance with the fair value hierarchy, the following table shows the fair value as of March 31, 2011 and December 31, 2010, of those financial assets that are measured at fair value on a recurring basis, according to the valuation techniques the Company used to determine their fair market value. No financial assets are measured at fair value on a nonrecurring basis at March 31, 2011 and December 31, 2010.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of March 31, 2011:				