

CURIS INC
Form 10-Q
May 05, 2009
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

04-3505116
(I.R.S. Employer
Identification No.)

45 Moulton Street

Cambridge, Massachusetts
(Address of Principal Executive Offices)

02138
(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. 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

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 No

As of April 28, 2009, there were 63,653,698 shares of the registrant's common stock outstanding.

Table of Contents

CURIS, INC. AND SUBSIDIARIES
QUARTERLY REPORT ON FORM 10-Q
INDEX

	Page Number
PART I. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Unaudited Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three Months ended March 31, 2009 and 2008</u>	4
<u>Consolidated Statements of Cash Flows for the Three Months ended March 31, 2009 and 2008</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
PART II. <u>OTHER INFORMATION</u>	
Item 1A. <u>Risk Factors</u>	21
Item 6. <u>Exhibits</u>	37
<u>SIGNATURE</u>	38

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****CURIS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	March 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 9,790,497	\$ 10,158,795
Marketable securities	20,212,139	18,694,200
Accounts receivable	37,127	107,341
Prepaid expenses and other current assets	482,600	373,373
Total current assets	30,522,363	29,333,709
Property and equipment, net	1,264,479	1,448,176
Long-term investment restricted	210,007	210,007
Goodwill	8,982,000	8,982,000
Other assets	7,980	7,980
	\$ 40,986,829	\$ 39,981,872
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,275,119	\$ 1,961,439
Accrued liabilities	677,993	624,462
Total current liabilities	1,953,112	2,585,901
Other long-term liabilities	128,531	171,375
Total liabilities	2,081,643	2,757,276
Commitments		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 64,701,405 and 63,653,698 shares issued and outstanding at March 31, 2009 and at December 31, 2008	647,014	647,014
Additional paid-in capital	745,966,031	745,360,736
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(18,607)	(12,550)
Accumulated deficit	(706,845,777)	(707,970,836)
Accumulated other comprehensive income	47,799	91,506
Total stockholders equity	38,905,186	37,224,596
	\$ 40,986,829	\$ 39,981,872

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

Table of Contents**CURIS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(unaudited)**

	Three Months Ended March 31,	
	2009	2008
REVENUES:		
Research and development contracts	\$ 37,127	\$ 215,065
License fees	6,000,000	1,852,518
Total Revenues	6,037,127	2,067,583
COSTS AND EXPENSES:		
Research and development	2,916,059	3,475,812
General and administrative	2,095,074	2,415,494
Total costs and expenses	5,011,133	5,891,306
Income (loss) from operations	1,025,994	(3,823,723)
OTHER INCOME (EXPENSE):		
Interest income	99,065	390,735
Other income		6,131
Interest expense		(3,810)
Total other income, net	99,065	393,056
Net income (loss)	\$ 1,125,059	\$ (3,430,667)
Net income (loss) per common share (basic and diluted)	\$ 0.02	\$ (0.05)
Basic weighted average common shares	63,595,755	63,245,538
Diluted weighted average common shares	68,455,453	63,245,538
Net income (loss)	\$ 1,125,059	\$ (3,430,667)
Unrealized (loss) gain on marketable securities	(43,707)	24,007
Comprehensive gain (loss)	\$ 1,081,352	\$ (3,406,660)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Three Months Ended March 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 1,125,059	\$ (3,430,667)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities-		
Depreciation and amortization	191,168	256,091
Stock-based compensation expense	599,238	752,304
Changes in operating assets and liabilities:		
Accounts receivable	70,214	9,335
Prepaid expenses and other assets	(109,227)	(66,047)
Accounts payable and accrued liabilities	(675,633)	(1,645,248)
Deferred revenue		(1,852,518)
Total adjustments	75,760	(2,546,083)
Net cash provided by (used in) operating activities	1,200,819	(5,976,750)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(12,242,875)	(5,004,484)
Sale of marketable securities	10,681,229	10,100,860
Purchases of property and equipment	(7,471)	(34,153)
Net cash provided by (used in) investing activities	(1,569,117)	5,062,223
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock		67,700
Repayments of obligations under notes payable		(308,333)
Net cash used in financing activities		(240,633)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(368,298)	(1,155,160)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,158,795	17,396,599
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 9,790,497	\$ 16,241,439

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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 targeted cancer therapies. In expanding the Company's drug development efforts with respect to these targeted cancer programs, Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog pathway. Curis seeks to conduct 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 and preclinical stage drug candidates in its internally funded programs, unproven technologies and drug development approaches, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company's technologies, its ability to comply with FDA government regulations and approval requirements as well as its ability to execute on its business strategies and obtain adequate financing to fund its operations through corporate collaborations, sales of equity or otherwise.

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, 2009 should enable it to maintain current and planned operations into the second half of 2010. The Company's ability to continue funding its planned operations is dependent upon, among other things, the success of its collaborations with Genentech, its ability to control the cash burn rate and its ability to raise additional funds through equity, debt, entry into 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, 2008, as filed with the Securities and Exchange Commission on February 26, 2009.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company's financial position at March 31, 2009 and the results of operations and cash flows for the three-month periods ended March 31, 2009 and 2008. 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

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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

Table of Contents

candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, contingent cash payments based upon achievement of clinical development and regulatory objectives and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. 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 February 26, 2009.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the twelve-month period ended March 31, 2009 are classified as long-term deferred revenue. As of March 31, 2009 and December 31, 2008, the Company had no deferred revenue related to its collaborations.

4. Genentech, Inc. Hedgehog Pathway Inhibitor Collaboration

In the first quarter of 2009, the Company received a payment of \$6,000,000 from Genentech under the parties' June 2003 Hedgehog pathway inhibitor collaboration upon Genentech's initiation of a pivotal Phase II clinical trial of GDC-0449, an orally-administered small molecule Hedgehog pathway inhibitor, as a single-agent therapy for patients with metastatic or locally advanced basal cell carcinoma. GDC-0449 is the lead drug candidate in development under this collaboration. The Company has recorded this amount as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the three months ended March 31, 2009 because the Company has no ongoing material performance obligations under the collaboration.

5. Fair Value Measurements

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*, (SFAS No. 157) for its financial assets and liabilities. The adoption of SFAS No. 157 has not had a material impact on the Company's financial position or results of operations. As permitted by FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, the Company elected to defer the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis.

SFAS No. 157 provides a framework for measuring fair value under U.S. GAAP and requires expanded disclosures regarding fair value measurements. SFAS No. 157 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.

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 a long-term restricted investment. As of March 31, 2009, the Company held cash equivalents and marketable securities of \$7,494,000 and \$20,136,000, respectively. The Company's marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, 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, U.S. Treasury securities, U.S. Treasury money market funds and interest bearing bank accounts.

The long-term restricted investment of \$210,000 as of March 31, 2009 was solely comprised of a certificate of deposit.

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, 2009.

Table of Contents

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 has no material Level 3 assets or liabilities at March 31, 2009.

6. Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2009	December 31, 2008
Accrued compensation	\$ 225,000	\$ 111,000
Professional fees	111,000	137,000
Facility-related costs	234,000	262,000
Other	108,000	114,000
Total	\$ 678,000	\$ 624,000

7. Accounting for Stock-Based Compensation

As of March 31, 2009, the Company had three shareholder-approved, share-based compensation plans: the 2000 Stock Incentive Plan (the 2000 Plan), the 2000 Director Stock Option Plan (the 2000 Director Plan) and the 2000 Employee Stock Purchase Plan (the ESPP). For a complete discussion of the Company's share-based compensation plans, see Note 5 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission on February 26, 2009.

During the quarter ended March 31, 2009, the Company's board of directors granted options to purchase 1,010,000 shares of the Company's common stock to officers and employees of the Company under the 2000 Plan. These options vest over a four-year period and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date.

During the quarter ended March 31, 2009, the Company's board of directors also granted options to its non-employee directors to purchase 175,000 shares of common stock under the 2000 Plan and options to purchase 45,000 shares of common stock under the 2000 Director Plan. All of these options were fully vested on the February 5, 2009 grant date and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on this date of grant.

Employee and Director Grants

The Company recorded a total of \$539,000 and \$711,000 in compensation expense for the quarters ended March 31, 2009 and 2008, respectively, related to the employee and director stock option grants. In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model when applying the provisions of Statement of Financial Accounting Standards 123(R), Share-Based Payment (SFAS 123(R)). The Company calculated the Black-Scholes value of employee options awarded during the quarters ended March 31, 2009 and 2008 based on the assumptions noted in the following table:

	Three Months Ended March 31,	
	2009	2008
Expected life (years) - employees	6	6
Expected life (years) - directors	6	7
Risk-free interest rate	2.1-2.3%	2.97-3.2%
Volatility	82%	90.4-93.4%
Dividends	None	None

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The stock price volatility and expected terms utilized in the calculation involve management's best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, accordingly, the expense that is to be recognized over the life of the option. In determining the expense recorded in the Company's Consolidated Statements of Operations, the Company has applied an estimated forfeiture rate to the remaining unvested awards based on historical experience, as adjusted. This estimate is evaluated quarterly and the forfeiture rate is adjusted as necessary. If the actual number of forfeitures differs from management's estimates, additional adjustments to compensation expense may be required in future periods.

Table of Contents

The aggregate intrinsic value of employee options outstanding at March 31, 2009 was \$797,000, of which \$252,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the quarters ended March 31, 2009 and 2008 were \$0.76 and \$1.09, respectively. As of March 31, 2009, there was approximately \$3,198,000, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 2.93 years. The intrinsic values of employee stock options exercised during the quarter ended March 31, 2008 was \$34,000. No stock options were exercised during the quarter ended March 31, 2009. The total fair values of vested stock options for the quarters ended March 31, 2009 and 2008 were \$716,000 and \$543,000, respectively.

The Company recorded a total of \$17,000 and \$13,000 in compensation expense for the quarters ended March 31, 2009 and 2008, respectively, related to the ESPP. The Company calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model with the following assumptions:

	For the three months ended March 31,	
	2009	2008
Expected term	6 months	6 months
Risk-free interest rate	0%	3.28%
Volatility	85.5%	63.5%
Dividends	None	None

The Company also recorded \$15,000 in compensation expense for the quarter ended March 31, 2009, related to a restricted stock award that was issued in October 2008 and which is vesting over a one-year period ending in October 2009. The Company did not incur compensation expense related to restricted stock awards in the first quarter of 2008.

Stock-based compensation for employees, including expense related to the ESPP, for the three months ended March 31, 2009 and 2008 was calculated using the above assumptions and has been included in the Company's results of operations. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is not probable that the net deferred tax asset will be realized.

Non-Employee Grants

The Company has historically granted stock options to consultants for services. These options were issued at or above their fair market value on the date of grant and have various vesting dates from date of grant, ranging from 3.5 months to 4 years. Should the Company or the consultants terminate the consulting agreements, any unvested options will be cancelled. Options issued to non-employees are marked-to-market until they vest, which means that as the Company's stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of \$28,000 related to non-employee stock options for each of the quarters ended March 31, 2009 and 2008. As of March 31, 2009, the Company had recorded \$19,000 in deferred compensation related to unvested non-employee options.

Total Stock-Based Compensation Expense

For the three