

CURIS INC
Form 10-Q
July 30, 2008
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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 JUNE 30, 2008

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

04-3505116
(I.R.S. Employer

Incorporation or Organization)

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 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.

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 July 28, 2008, there were 63,433,660 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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Table of Contents**Item 1. FINANCIAL STATEMENTS****CURIS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	June 30, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 9,298,426	\$ 17,396,599
Marketable securities	24,615,973	24,062,577
Accounts receivable	209,514	230,467
Prepaid expenses and other current assets	190,074	349,453
Total current assets	34,313,987	42,039,096
Property and equipment, net	2,117,262	2,577,602
Long-term investment restricted	210,007	210,007
Goodwill	8,982,000	8,982,000
Other assets, net	7,980	7,980
	\$ 45,631,236	\$ 53,816,685
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Debt, current portion	\$	\$ 403,832
Accounts payable	1,474,678	3,222,091
Accrued liabilities	1,081,543	1,150,931
Deferred revenue, current portion		1,852,518
Total current liabilities	2,556,221	6,629,372
Other long-term liabilities	257,063	342,750
Total liabilities	2,813,284	6,972,122
Commitments		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 64,477,867 and 63,430,160 shares issued and outstanding, respectively, at June 30, 2008 and 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007	644,779	642,888
Additional paid-in capital	744,349,682	742,903,399
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(44,871)	(46,286)
Accumulated deficit	(701,242,961)	(695,847,738)
Accumulated other comprehensive income	2,597	83,574
Total stockholders equity	42,817,952	46,844,563
	\$ 45,631,236	\$ 53,816,685

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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 June 30, 2008	2007	Six Months Ended June 30, 2008	2007
REVENUES:				
Research and development contracts	\$ 107,810	\$ 682,281	\$ 322,875	\$ 1,965,154
License fees	3,000,000	546,443	4,852,518	1,626,356
Total revenues	3,107,810	1,228,724	5,175,393	3,591,510
COSTS AND EXPENSES:				
Research and development	3,200,683	3,046,824	6,676,495	6,342,439
General and administrative	2,124,809	2,359,186	4,540,303	5,310,771
Total costs and expenses	5,325,492	5,406,010	11,216,798	11,653,210
Loss from operations	(2,217,682)	(4,177,286)	(6,041,405)	(8,061,700)
OTHER INCOME (EXPENSE):				
Interest income	250,374	328,957	641,109	694,309
Other income (expense)	2,796	(125,075)	8,927	(113,811)
Interest expense	(44)	(24,140)	(3,854)	(57,115)
Total other income, net	253,126	179,742	646,182	523,383
Net loss	\$ (1,964,556)	\$ (3,997,544)	\$ (5,395,223)	\$ (7,538,317)
Net loss per common share (basic and diluted)	\$ (0.03)	\$ (0.08)	\$ (0.09)	\$ (0.15)
Weighted average common shares (basic and diluted)	63,337,647	49,408,100	63,291,592	49,381,508
Net loss	\$ (1,964,556)	\$ (3,997,544)	\$ (5,395,223)	\$ (7,538,317)
Unrealized gain (loss) on marketable securities	(104,984)	7,990	(80,977)	5,470
Comprehensive loss	\$ (2,069,540)	\$ (3,989,554)	\$ (5,476,200)	\$ (7,532,847)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**CURIS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)**

	Six Months Ended June 30,	
	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (5,395,223)	\$ (7,538,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	509,831	786,593
Stock-based compensation expense	1,280,403	1,798,373
Gain on sale of assets		(68,329)
Impairment of investments		145,000
Impairment of assets		318,380
Realized foreign currency exchange gain		(26,935)
Changes in operating assets and liabilities:		
Accounts receivable	20,953	1,058,928
Prepaid expenses and other assets	159,379	321,269
Accounts payable and accrued liabilities	(1,905,107)	(724,194)
Deferred revenue	(1,852,518)	(1,988,899)
Total adjustments	(1,787,059)	1,620,186
Net cash used in operating activities	(7,182,282)	(5,918,131)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(19,432,567)	(14,085,990)
Sales of marketable securities	18,798,194	16,857,069
Purchases of property and equipment	(49,491)	(49,276)
Net proceeds from sale of assets		196,689
Net cash (used in) provided by investing activities	(683,864)	2,918,492
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	169,186	155,740
Repayments of principal obligations under note payable	(401,213)	(818,296)
Net cash used in financing activities	(232,027)	(662,556)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,098,173)	(3,662,195)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,396,599	18,829,332
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 9,298,426	\$ 15,167,137

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 create new medicines, primarily for cancer. In expanding the Company's drug development efforts through its targeted cancer drug development platform, Curis is building upon its past experiences in targeting signaling pathways for the development of next generation targeted cancer therapies.

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 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, 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.

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 product 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 June 30, 2008, should enable it to maintain current and planned operations into the fourth quarter of 2009. 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, 2007, as filed with the Securities and Exchange Commission on March 14, 2008.

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 June 30, 2008 and the results of operations and cash flows for the three- and six-month periods ended June 30, 2008 and 2007. 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 of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility 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 the agreements

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typically include non-refundable license fees, funding of research and development, contingent cash payments based upon achievement of clinical development and sales objectives and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission's Staff

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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 March 14, 2008.

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the consolidated balance sheets.

4. June 2003 Collaboration with Genentech

In May 2008, the Company received a payment of \$3,000,000 from Genentech for the achievement of a phase II clinical development objective under the parties' June 2003 Hedgehog antagonist collaboration agreement. This development objective related to Genentech's initiation of a phase II clinical trial in metastatic colorectal cancer. The Company has recorded this amount as revenue within *License Fees* in the Revenues section of its Consolidated Statement of Operations for the three and six months ended June 30, 2008 because the Company has no ongoing material performance obligations under the collaboration.

5. Stryker Corporation

On December 27, 2007, the Company completed a transaction with Stryker Corporation, in which Stryker paid the Company \$1,750,000 in cash in exchange for the sale and assignment of all of the Company's remaining BMP assets. As a result of the transaction, Stryker has assumed all future BMP costs subsequent to the December 27, 2007 effective date, including those related to future development and maintenance and prosecution of the patent portfolio. As of December 31, 2007, the Company recorded the \$1,750,000 received as short-term deferred revenue because the Company had not delivered all of the assets to Stryker as required by the agreement as of that date. The Company completed the transfer of all assets during the first quarter of 2008, at which time no material ongoing performance obligations remained under the agreement. Accordingly, the Company recorded \$1,750,000 as license revenue within the Revenues section of the Consolidated Statement of Operations for the six months ended June 30, 2008.

Under the terms of the agreement, the Company is entitled to contingent cash payments related to certain clinical development and sales objectives, if such objectives are achieved by Stryker. The Company believes that these contingent payments would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. However, because the Company has no future deliverables under the agreement, the Company intends to recognize such contingent payments as revenue in *License Fees* within the Revenues section of the Consolidated Statement of Operations if and when any such objectives are achieved and the related contingent cash payment from Stryker is reasonably assured.

6. Termination of January 2004 Wyeth Collaboration

On January 12, 2004, the Company licensed its Hedgehog proteins and small molecule Hedgehog pathway agonists to Wyeth Pharmaceuticals, or Wyeth, for therapeutic applications in the treatment of neurological and other disorders. Pursuant to the collaboration agreement, Wyeth agreed to make specified cash payments, including up-front payments of \$3,000,000, which consisted of a \$1,362,000 non-refundable license fee payment and \$1,638,000 in exchange for 315,524 shares of the Company's common stock.

The Company applied the provisions of EITF 00-21 and determined that its performance obligations under this collaboration should be accounted for as a single unit of accounting. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company's level of effort required to complete its performance obligations, the Company estimated that Wyeth would elect twice to extend the research and development service period and related funding, each in one-year increments, for a total of four years. The agreement also provided for a one-year evaluation period immediately following the end of the research term, during which time the Company could have been obligated to serve on a steering committee that oversees the program and could have been required, at Wyeth's expense, to perform additional research and development services. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term plus the one-year evaluation period. In developing this estimate, the Company assumed that Wyeth

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would maintain its initially elected number of eight full-time equivalents throughout the five-year period. The steering committee effort was also expected to be consistent over the five-year period. On November 3, 2006, Wyeth agreed to extend the research funding term by one year through February 9, 2008 but elected to fund only five researchers working on the program through the research term. Accordingly, the Company revised its estimated level of effort over the remaining performance period. In December 2007, Wyeth informed the Company that it would not extend the current contractual research funding term beyond February 2008. As a result, the Company changed its estimated performance period to coincide with the conclusion of the research term from its original estimate of February 2009.

On May 6, 2008 the agreement terminated. On the termination date, the licenses granted by the Company to Wyeth terminated and all terminated license rights reverted to the Company. The Company intends to seek to license this technology to a third party collaborator.

The \$1,362,000 up-front license fee plus \$7,250,000, which was the total amount of research funding the Company received for providing an average of 7.25 full-time equivalents over the four-year performance period at a rate of \$250,000 each, was attributed to the research services. Revenue was recognized as the research services were provided over the performance period of