

CURIS INC
Form 10-Q
April 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 MARCH 31, 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
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 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, 2008, there were 63,314,836 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**PART I FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****CURIS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	March 31, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 16,241,439	\$ 17,396,599
Marketable securities	18,990,208	24,062,577
Accounts receivable	221,132	230,467
Prepaid expenses and other current assets	415,500	349,453
Total current assets	35,868,279	42,039,096
Property and equipment, net	2,355,664	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
	\$ 47,423,930	\$ 53,816,685
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Debt, current portion	\$ 93,483	\$ 403,832
Accounts payable	1,892,001	3,222,091
Accrued liabilities	880,632	1,150,931
Deferred revenue, current portion		1,852,518
Total current liabilities	2,866,116	6,629,372
Other long-term liabilities	299,907	342,750
Total liabilities	3,166,023	6,972,122
Commitments		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 64,362,543 and 63,314,836 shares issued and outstanding, respectively, at March 31, 2008 and 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007	643,625	642,888
Additional paid-in capital	743,728,173	742,903,399
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(51,793)	(46,286)
Accumulated deficit	(699,278,405)	(695,847,738)
Accumulated other comprehensive income	107,581	83,574
Total stockholders equity	44,257,907	46,844,563

\$ 47,423,930 \$ 53,816,685

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,	
	2008	2007
REVENUES:		
Research and development contracts	\$ 215,065	\$ 1,282,873
License fees	1,852,518	1,079,913
Total Revenues	2,067,583	2,362,786
COSTS AND EXPENSES:		
Research and development	3,475,812	3,295,615
General and administrative	2,415,494	2,951,585
Total costs and expenses	5,891,306	6,247,200
Loss from operations	(3,823,723)	(3,884,414)
OTHER INCOME (EXPENSE):		
Interest income	390,735	365,352
Other income	6,131	11,264
Interest expense	(3,810)	(32,975)
Total other income, net	393,056	343,641
Net loss	\$ (3,430,667)	\$ (3,540,773)
Net loss per common share (basic and diluted)	\$ (0.05)	\$ (0.07)
Weighted average common shares (basic and diluted)	63,245,538	49,354,125
Net loss	\$ (3,430,667)	\$ (3,540,773)
Unrealized (loss) gain on marketable securities	24,007	(2,520)
Comprehensive loss	\$ (3,406,660)	\$ (3,543,293)

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,	
	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,430,667)	\$ (3,540,773)
Adjustments to reconcile net loss to net cash used in operating activities-		
Depreciation and amortization	256,091	475,506
Stock-based compensation expense	752,304	915,263
Gain on sale of assets		(68,329)
Unrealized foreign currency exchange gain		(11,264)
Changes in operating assets and liabilities:		
Accounts receivable	9,335	24,652
Prepaid expenses and other assets	(66,047)	56,738
Accounts payable and accrued liabilities	(1,645,248)	(217,922)
Deferred revenue	(1,852,518)	(1,257,572)
Total adjustments	(2,546,083)	(82,928)
Net cash used in operating activities	(5,976,750)	(3,623,701)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(5,004,484)	(5,459,103)
Sale of marketable securities	10,100,860	7,041,796
Purchases of property and equipment	(34,153)	(20,769)
Net proceeds from the sale of assets		196,688
Net cash provided by investing activities	5,062,223	1,758,612
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	67,700	44,252
Repayments of obligations under notes payable	(308,333)	(509,962)
Net cash used in financing activities	(240,633)	(465,710)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,155,160)	(2,330,799)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,396,599	18,829,332
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 16,241,439	\$ 16,498,533

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 in the field of cancer 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 grow its business and obtain adequate financing to fund this growth.

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 March 31, 2008 and the results of operations and cash flows for the three-month periods ended March 31, 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 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 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 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

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deferred revenue. As of March 31, 2008, the Company has no remaining short- and long-term deferred revenue related to its collaborations.

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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 three months ended March 31, 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. As such, and 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.

5. 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 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 March 7, 2008, Wyeth provided the Company with written notice that it will terminate this license agreement effective May 6, 2008. On the termination date, the licenses granted by the Company to Wyeth terminate and all terminated license rights revert 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 is 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 February 2004 through February 2008.

The Company recorded revenue under this collaboration of \$252,000 and \$530,000 during the three-month periods ended March 31, 2008 and 2007, respectively. Of this amount, approximately \$103,000 and \$76,000 was

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attributed to the amortization of the \$1,362,000 up-front license fee and is included in License fees within the Revenues section of the Consolidated Statements of Operations for the three-month periods ended March 31, 2008 and 2007, respectively. Of the remaining amounts, \$134,000 and \$395,000 were related to research services performed by the Company's full-time equivalents for the three months ended March 31, 2008 and 2007, respectively, and \$15,000 and \$59,000 for the three months ended March 31, 2008 and 2007, respectively, related to expenses incurred on behalf of Wyeth by the Company for which Wyeth is obligated to reimburse the Company and have met the revenue recognition provisions of EITF 99-19. These amounts are included within the Research and development contracts line item within the Revenues section of the Consolidated Statements of Operations.

6. Fair Value Measurements

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*, (SFAS No. 157) and SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, (SFAS No. 159) for its financial assets and liabilities. The adoption of SFAS No. 157 did not have 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, until January 1, 2009. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

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.

SFAS No. 157 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. SFAS No. 157 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 and cash equivalents, investments in marketable securities, and a long-term restricted investment. As of March 31, 2008, the Company held cash and cash equivalents and marketable securities of \$16,241,000 and \$18,990,000, 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, 2008 was solely comprised of a one-year 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, 2008.
- 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, 2008.

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The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable, common stock in privately-held companies, accounts payable and debt obligations. Short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. While the Company believes its valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

7. Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2008	December 31, 2007
Accrued compensation	\$ 397,000	\$ 708,000
Professional fees	106,000	73,000
Facility-related costs	187,000	192,000
Other	191,000	178,000
Total	\$ 881,000	\$ 1,151,000

8. Debt

Short-term debt, including accrued interest, consists of the following at March 31, 2008 and December 31, 2007:

	March 31, 2008	December 31, 2007
Notes payable to financing agencies for capital purchases	\$ 93,000	\$ 404,000
Less current portion	(93,000)	(404,000)
Total long-term debt obligations	\$	\$