CURIS INC
Form 10-Q
October 29, 2009
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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 SEPTEMBER 30, 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)

Delaware	04-3505116
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

45 Moulton Street

Cambridge, Massachusetts	02138
(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 x

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 October 26, 2009, there were 66,568,005 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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Item 1. FINANCIAL STATEMENTS

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,803,801	$ 10,158,795
Marketable securities	20,411,153	18,694,200
Accounts receivable	226,979	107,341
Prepaid expenses and other current assets	432,027	373,373
Total current assets	27,873,960	29,333,709
Property and equipment, net	889,597	1,448,176
Long-term investment restricted	216,002	210,007
Goodwill	8,982,000	8,982,000
Other assets	7,980	7,980
	$ 37,969,539	$ 39,981,872
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,287,653	$ 1,961,439
Accrued liabilities	751,082	624,462
Deferred revenue	1,458,334	
Total current liabilities	3,497,069	2,585,901
Other long-term liabilities	42,843	171,375
Total liabilities	3,539,912	2,757,276
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 66,514,255 shares outstanding at September 30, 2009 and 63,653,698 shares outstanding at December 31, 2008	675,620	647,014
Additional paid-in capital	749,736,303	745,360,736
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(16,843)	(12,550)
Accumulated deficit	(715,087,459)	(707,970,836)
Accumulated other comprehensive income	13,280	91,506
Total stockholders equity	34,429,627	37,224,596
	$ 37,969,539	$ 39,981,872

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
REVENUES:				
License fees	$ 666,666	$	$ 6,666,666	$ 4,852,518
Research and development contracts	98,647	86,721	199,037	409,596
Total revenues	765,313	86,721	6,865,703	5,262,114
COSTS AND EXPENSES:				
Research and development	2,295,997	3,000,266	7,493,123	9,676,761
General and administrative	2,566,475	1,861,971	6,691,403	6,402,274
Total costs and expenses	4,862,472	4,862,237	14,184,526	16,079,035
Loss from operations	(4,097,159)	(4,775,516)	(7,318,823)	(10,816,921)
OTHER INCOME (EXPENSE):				
Interest income	36,863	203,210	202,200	844,319
Other income (expense)		855		9,782
Interest expense				(3,854)
Total other income, net	36,863	204,065	202,200	850,247
Net loss	$ (4,060,296)	$ (4,571,451)	$ (7,116,623)	$ (9,966,674)
Net loss per common share (basic and diluted)	$ (0.06)	$ (0.07)	$ (0.11)	$ (0.16)
Weighted average common shares (basic and diluted)	66,270,778	63,435,070	64,516,816	63,339,767
Net loss	$ (4,060,296)	$ (4,571,451)	$ (7,116,623)	$ (9,966,674)
Unrealized gain (loss) on marketable securities	(6,199)	18,447	(78,226)	(62,530)
Comprehensive loss	$ (4,066,495)	$ (4,553,004)	$ (7,194,849)	$ (10,029,204)

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,116,623)	$ (9,966,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	566,050	762,916
Stock-based compensation expense	1,484,748	1,774,031
Changes in current assets and liabilities:		
Accounts receivable	(119,638)	154,250
Prepaid expenses and other assets	(58,654)	(92,369)
Accounts payable and accrued liabilities	(675,698)	(1,965,992)
Deferred revenue	1,458,334	(1,852,518)
Total adjustments	2,655,142	(1,219,682)
Net cash used in operating activities	(4,461,481)	(11,186,356)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(28,843,925)	(27,328,912)
Sale of marketable securities	27,048,746	26,767,978
Increase in restricted cash	(5,995)	
Purchases of property and equipment	(7,471)	(60,547)
Net cash used in investing activities	(1,808,645)	(621,481)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	2,915,132	180,501
Repayments of notes payable		(401,213)
Net cash provided by (used in) financing activities	2,915,132	(220,712)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(3,354,994)	(12,028,549)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,158,795	17,396,599
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 6,803,801	$ 5,368,050

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 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 its corporate collaborator Genentech and its licensee Debiopharm S.A., a Swiss corporation, (Debiopharm), to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA, or foreign equivalent, 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 September 30, 2009 should enable it to maintain current and planned operations through the fourth quarter of 2010. The Company s ability to continue funding its planned operations beyond 2010 is dependent upon, among other things, anticipated near-term payments from its licensee Debiopharm, which include a payment upon the acceptance by regulatory authorities of Debiopharm s application to begin a phase I clinical trial and upon Debiopharm s treatment of the fifth patient in the first phase I clinical trial; payments that it may receive from Genentech upon the achievement of development and regulatory approval objectives, if any; its ability to manage its expenses; 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 September 30, 2009 and the results of operations and cash flows for the three- and nine-month periods ended September 30, 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 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.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

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 may provide for the Company s licensees and collaborators to agree to make non-refundable license fees, 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 February 26, 2009.

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the accompanying Consolidated Balance Sheets. Amounts not expected to be recognized during the twelve-month period ended September 30, 2010 would be classified as long-term deferred revenue. As of September 30, 2009, the Company had $1,458,000 in short-term deferred revenue primarily related to its license agreement with Debiopharm (see Note 5).

4. Genentech, Inc. Hedgehog Pathway Inhibitor Collaboration

In March 2009 and in May 2008, the Company received payments of $6,000,000 and $3,000,000, respectively, from Genentech under the parties June 2003 Hedgehog pathway inhibitor collaboration for the achievement of certain clinical development objectives related to GDC-0449, which is the lead drug candidate in development under this collaboration. The Company has recorded these amounts as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the nine months ended September 30, 2009 and 2008, respectively, because the Company has no ongoing material performance obligations under the collaboration.