CURIS INC
Form 10-Q
May 10, 2012
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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, 2012

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). x 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 May 2, 2012, there were 79,013,330 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, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 14,687,247	$ 15,119,730
Marketable securities	30,352,199	22,597,845
Accounts receivable	339,802	42,067
Prepaid expenses and other current assets	351,333	743,799
Total current assets	45,730,581	38,503,441
Property and equipment, net	435,858	455,730
Long-term investment restricted	194,282	235,914
Goodwill	8,982,000	8,982,000
Other assets	2,980	2,980
Total assets	$ 55,345,701	$ 48,180,065
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,636,240	$ 2,364,437
Accrued liabilities	1,132,083	1,422,107
Total current liabilities	3,768,323	3,786,544
Warrants	3,809,581	4,361,168
Other long-term liabilities	169,093	156,396
Total liabilities	7,746,997	8,304,108
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 79,728,447 shares issued and 78,680,740 shares outstanding at March 31, 2012; and 78,165,360 shares issued and 77,117,653 shares outstanding at December 31, 2011	797,284	781,654
Additional paid-in capital	777,502,097	772,039,254
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Accumulated deficit	(729,861,905)	(732,087,642)
Accumulated other comprehensive income	52,502	33,965
Total stockholders equity	47,598,704	39,875,957

Total liabilities and stockholders equity	$ 55,345,701	$ 48,180,065

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(unaudited)

	Three Months Ended March 31,	
	2012	**2011**
Revenues:		
Research and development	$ 85,630	$ 133,538
Royalties	270,622	
License fees	10,000,000	
Total Revenues	10,356,252	133,538
Costs and Expenses:		
Cost of royalty revenues	113,531	
Research and development	5,241,949	3,058,499
General and administrative	2,801,077	2,407,349
Total costs and expenses	8,156,557	5,465,848
Income (loss) from operations	2,199,695	(5,332,310)
Other Income (Expense):		
Interest income	18,101	33,569
Change in fair value of warrant liability	7,941	(1,501,410)
Total other income (expense), net	26,042	(1,467,841)
Net income (loss)	$ 2,225,737	$ (6,800,151)
Basic net income (loss) per common share	$ 0.03	$ (0.09)
Diluted net income (loss) per common share	$ 0.03	$ (0.09)
Basic weighted average common shares	77,556,366	75,825,801
Diluted weighted average common shares	83,336,695	75,825,801
Total comprehensive income (loss)	$ 2,244,274	$ (6,794,684)

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,	
	2012	**2011**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income/(loss)	$ 2,225,737	$ (6,800,151)
Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities:		
Depreciation and amortization	30,380	21,020
Stock-based compensation expense	1,022,676	677,713
Issuance of common stock to licensees	964,000	
Change in fair value of warrant liability	(7,941)	1,501,410
Non-cash interest (income)/expense	(58,858)	102,602
Net gain on sale of assets		(31,225)
Changes in operating assets and liabilities:		
Accounts receivable	(297,735)	10,358
Prepaid expenses and other assets	440,422	37,690
Accounts payable and accrued liabilities	(5,524)	(147,790)
Total adjustments	2,087,420	2,171,778
Net cash provided by/(used in) operating activities	4,313,157	(4,628,373)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(21,742,568)	(18,864,743)
Sale of marketable securities	14,065,609	25,972,812
Purchases of property and equipment	(10,508)	(39,588)
Proceeds from sale of assets		31,225
Decrease in restricted cash	41,632	219,458
Net cash (used in)/provided by investing activities	(7,645,835)	7,319,164
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Company s share-based compensation plans and warrant exercises	2,900,195	601,905
Net cash provided by financing activities	2,900,195	601,905
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(432,483)	3,292,696
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	15,119,730	7,826,549
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 14,687,247	$ 11,119,245

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 and development 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. In January 2012, the Erivedge capsule was approved by the FDA and became commercially available in February 2012 (see Note 4).

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 its 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, 2012 should enable the Company to maintain its current and planned operations into the first half of 2014. The Company s ability to continue funding its planned operations into and beyond the first half of 2014 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. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company cannot assure that it will attain any further revenue under any collaborations or licensing arrangements. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

2. Basis of Presentation

The accompanying condensed 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, 2011, as filed with the Securities and Exchange Commission on February 29, 2012.

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, 2012 and the results of operations and cash flows for the three-month periods ended March 31, 2012 and 2011. The preparation of the Company s Condensed 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, management assumptions used in its calculations of stock-based compensation expense, and the value of certain investments and liabilities, including the value of its warrant liability. Actual results may differ from such estimates.

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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 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 February 29, 2012.

4. Collaboration Agreements

(a) Genentech, Inc. June 2003 Collaboration

In January 2012, the U.S. Food and Drug Administration (FDA) approved Genentech s New Drug Application for the Erivedge capsule for the treatment of adults with basal cell carcinoma that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and commercialized by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between the Company and Genentech. As a result of the FDA s approval of Erivedge in this indication, the Company earned a $10,000,000 milestone payment from Genentech and is also entitled to receive royalties on future sales of the product. The Company is eligible to receive up to an aggregate of $115,000,000 in contingent cash payments under the collaboration for the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this aggregate amount, the Company has received $42,000,000 as of March 31, 2012.

During the first quarter of 2012, the Company recognized the $10,000,000 milestone payment as license revenue in its Condensed Consolidated Statement of Comprehensive Income (Loss) for the three months ended March 31, 2012, as the Company does not have any further performance obligations under the collaboration. In addition, the Company recorded research and development expenses related to the FDA s approval of Erivedge of $1,464,000 during the three months ended March 31, 2012 which represents the Company s obligations to university licensors. Of this amount, $964,000 represents the fair value of a one-time issuance of an aggregate of 200,000 shares of the Company s common stock to two university licensors in connection with the FDA-approval of Erivedge. The remaining $500,000 represents sublicense fees the Company paid to these same licensors, upon receipt of the $10,000,000 milestone payment in the first quarter of 2012.

The Company also recognized $270,622 of royalty revenue from Genentech s net sales of Erivedge during the quarter ended March 31, 2012. The Company recorded costs of royalty revenues within the costs and expenses section of its Condensed Consolidated Statements of Comprehensive Income (Loss) of $113,531, including a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and $13,531 paid to two university licensors, which represents 5% of the royalties earned by the Company with respect to Erivedge during the first quarter of 2012.

(b) The Leukemia & Lymphoma Society Agreement

In November 2011, the Company entered into an agreement with The Leukemia & Lymphoma Society (LLS) under which LLS will support the Company s ongoing development of CUDC-907 for patients with B-cell lymphoma and multiple myeloma. Under the agreement, LLS will fund approximately 50% of the direct costs of the development of CUDC-907, up to $4,000,000. Under certain conditions associated with the successful partnering and/or commercialization of CUDC-907 in these indications, the Company may be obligated to make payments to LLS up to a maximum of $10,000,000. The Company has not received any payments under this agreement to date and expects that the first milestone could be achieved in the second half of 2012 as CUDC-907 nears IND filing. Additional milestones would be earned as the Company progresses CUDC-907 into a phase Ia clinical trial.

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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.

Financial Accounting Standards Board (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.
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.
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.

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In accordance with the fair value hierarchy, the following table shows the fair value as of March 31, 2012 and December 31, 2011 of those financial assets and liabilities 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 or liabilities are measured at fair value on a nonrecurring basis at March 31, 2012 and December 31, 2011.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of March 31, 2012:				
Cash equivalents				
Money market funds	$ 5,721,949	$	$	$ 5,721,949
Corporate commercial paper, stock, bonds and notes	1,749,930	2,864,879		4,614,809
Municipal bonds		2,145,000		2,145,000
Investments				
US government obligations		1,033,069		1,033,069
Corporate commercial paper, stock, bonds and notes	10,485,559	18,833,571		29,319,130
Total assets at fair value	$ 17,957,438	$ 24,876,519	$	$ 42,833,957
Warrants			3,809,581	3,809,581
Total liabilities at fair value	$	$	$ 3,809,581	$ 3,809,581
As of December 31, 2011:				
Cash equivalents				
Money market funds	$ 5,366,747	$	$	$ 5,366,747
Municipal bonds	2,375,000			2,375,000
Investments				
US government obligations		3,808,704		3,808,704
Corporate commercial paper, stock, bonds and notes	7,365,841	11,423,300		18,789,141
Total assets at fair value	$ 15,107,588	$ 15,232,004	$	$ 30,339,592
Warrants			4,361,168	4,361,168
Total liabilities at fair value	$	$	$ 4,361,168	$ 4,361,168

The following table rolls forward the fair value of the Company s warrant liability, the fair value of which is determined by Level 3 inputs for the three months ended March 31, 2011 and 2012:

Balance at December 31, 2010	$ 1,604,742
Change in fair value for the three months ended March 31, 2011	1,501,410
Balance at March 31, 2011	$ 3,106,152
Balance at December 31, 2011	$ 4,361,168

Change in fair value of warrants exercised during the three months ended March 31, 2012	(543,646)
Change in fair value for the three months ended March 31, 2012	(7,941)
Balance at March 31, 2012	$ 3,809,581

6. Common Stock and Warrant Liability

On January 27, 2010, the Company completed a registered direct offering of 6,449,288 units with each unit consisting of (i) one share of the Company s common stock and (ii) one warrant to purchase 0.25 of one share of common stock at a purchase price of $2.52 per unit. The Company received net proceeds from the sale of the units, after deducting offering expenses, of approximately $14,942,000.

In connection with this offering, the Company issued warrants to purchase an aggregate of 1,612,322 shares of common stock. As of March 31, 2012, warrants to purchase 214,004 shares of the Company s common stock have been exercised. The warrants have an initial exercise price of $3.55 per share and a five-year term. The warrants contain

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antidilution adjustment provisions that will result in a decrease in the price and an increase in the number of shares of common stock issuable upon exercise of such warrants in the event of certain issuances of common stock by the Company at prices below $3.55 per share. The warrants also included a cash-settlement option in the event of a change of control that expired on January 27, 2012. Due to the terms, the warrants are deemed to be a liability and, therefore, the fair value of the warrants was recorded as a liability in the Consolidated Balance Sheets as of March 31, 2012 and December 31, 2011.

The Company has estimated the fair value of the warrants using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants, with updated assumptions at each reporting date. The Company estimated that the fair value of the warrants at March 31, 2012 was $3,809,581, using the following assumptions: expected volatility of 77.2%, risk free interest rate of 0.5%, expected life of 2.8 years, and no dividends. The Company estimated that the fair value of the warrants at March 31, 2011 was $3,106,152 using the following assumptions assigned to the varying outcomes: expected volatilities of 78.5% and 90.8%, risk free interest rates ranging from 1.2% to 1.7%, expected lives of three to four years, and no dividends. The warrants are revalued at each reporting period and the resulting change in fair value of the warrant liability will be recognized in the Consolidated Statement of Operations. The Company recorded other income of $7,941 due to changes in fair value and a decrease to the warrant liability with an offsetting increase to additional paid-in-capital of $543,656 as a result of the exercise of warrants to purchase 212,500 shares of the Company s common stock during the three months ended March 31, 2012. The Company recorded other expense of $1,501,410 for the three months ended March 31, 2011, as a result of a change in the fair value of the warrant liability that was primarily due to an increase in the Company s stock price during the prior year period.

7. Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2012	December 31, 2011
Accrued compensation	$ 781,930	$ 1,065,570
Professional fees	157,625	190,500
Other	192,528	166,037
Total	$ 1,132,083	$ 1,422,107

8. Related Party Transaction

License Agreement

On February 24, 2012, the Company entered into a Drug Development Partnership and License Agreement for CU-906 and CU-908 (the License Agreement) with Guangzhou BeBetter Medicine Technology Company Ltd., a company organized under the laws of the People s Republic of China (GBMT). Dr. Changgeng Qian, the Company s former Senior Vice President, Discovery and Preclinical Development, is the founder, owner, and legal representative of GBMT.

Pursuant to the license agreement, the Company has granted to GBMT an exclusive royalty-free license, with the right to grant sublicenses subject to certain conditions, to develop, manufacture, market and sell any product containing CU-906 or CU-908 in the GBMT Territory (China, Macau, Taiwan and Hong Kong). In addition, the Company has granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CU-906 or CU-908 or any product containing CU-906 or CU-908 outside of the GBMT Territory solely to import the compounds or products into the GBMT Territory. Pursuant to the terms of the license agreement, the Company has retained rights, including the right to grant sublicenses, to develop, manufacture, market and sell any product containing CU-906 or CU-908 worldwide excluding the GBMT Territory. The Company also has certain specified rights to any GBMT technology developed under the license agreement as well as certain specified rights to GBMT s interest in joint technology developed under the license agreement. Furthermore, the Company has a right of first negotiation to obtain a license to CU-906 or CU-908 for the GBMT Territory from GBMT.

The Company has agreed to transfer to GBMT know how, information and materials necessary for GBMT to continue the development of products in accordance with the development plan outlined in the license agreement and has agreed not to assert certain Company patents against GMBT, its affiliates or sublicensee so that such party may manufacture, market and sell any product containing CU-906 or CU-908 in the GBMT Territory. Furthermore, the Company will provide GBMT with up to $400,000 in financial support for specified CU-908 pre-clinical activities related to enabling the filing by the Company of an initial new drug application, or IND, with the FDA, provided that

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GMBT completes such CU-908 IND-enabling activities in accordance with specified criteria and delivers a U.S. IND package for CU-908 to the Company within prescribed timeframes as specified in the License Agreement. All costs incurred under this agreement will be expensed as incurred. As of March 31, 2012, the Company had not incurred any expenses under this agreement.

GBMT will assume all future development responsibility and incur all future costs related to the development, registration and commercialization of products in the GMBT Territory under the license agreement. Pursuant to the terms of the license agreement, GBMT has agreed to undertake reasonable commercial efforts, and to use qualified third party service providers approved by the Company, to implement the development plan in the timeframes described in the license agreement in order to develop, register and commercialize the products in the GBMT Territory and will be solely responsible for all the costs relating thereto. The Company and GBMT must agree to any changes to the development plan and such revised development plan is subject to review and approval by the joint steering committee.

The license agreement is effective as of February 24, 2012, and, unless terminated earlier in accordance with the terms of the license agreement, will expire on the later of (i) the expiration of the last-to-expire valid claim of the Company patents and the Company non-assert patents relating to the products, and (ii) such time as none of GBMT, its affiliates and sublicensees is commercializing any compound or product in the GBMT Territory. Pursuant to the license agreement, either party can terminate the license agreement upon notice under prescribed circumstances, and the license agreement specifies the consequences to each party for such early termination.

The License Agreement also sets forth customary terms regarding each party s intellectual property ownership rights, representations and warranties, indemnification obligations, confidentiality rights and obligations, and patent prosecution, maintenance, enforcement and defense rights and obligations.

Severance Agreement

On February 16, 2012, the Company and Dr. Qian entered into a severance agreement that became binding and effective on February 24, 2012. The severance agreement provides that Dr. Qian, in exchange for his execution and nonrevocation of a general release of claims in favor of the Company as set forth in the severance agreement, will be provided certain severance benefits, including a lump-sum payment equivalent to one-half times his base annual salary rate in effect as of his termination date to be paid out in September 2012. As a result, the Company had accrued $137,500 related to Dr. Qian s severance in the accrued liabilities section of the Company s Condensed Consolidated Balance Sheets as of March 31, 2012. The severance agreement also provides for the engagement of Dr. Qian as a consultant pursuant to the terms of a consulting agreement.

9. Accounting for Stock-Based Compensation

As of March 31, 2012, the Company had two shareholder-approved, share-based compensation plans: the 2010 Stock Incentive Plan and the 2010 Employee Stock Purchase Plan. These plans were adopted by the board of directors in April 2010 and approved by shareholders in June 2010. In the first quarter of 2010, the Company s 2000 Stock Incentive Plan expired in accordance with its terms and its 2000 Director Stock Option Plan had no available shares remaining under the plan. No additional awards will be made under these plans, although all outstanding awards under these plans will remain in effect until they are exercised or they expire in accordance with their terms. 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, 2011, as previously filed with the Securities and Exchange Commission on February 29, 2012.

During the quarter ended March 31, 2012, the Company s board of directors granted options to purchase 1,174,000 shares of the Company s common stock to officers and employees of the Company under the 2010 Stock Incentive 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, 2012, the Company s board of directors also granted options to its non-employee directors to purchase 470,000 shares of common stock under the 2010 Stock Incentive Plan. These options will vest monthly over a one-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.

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Employee and Director Grants

In determining the fair value of stock options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee and director options awarded during the quarters ended March 31, 2012 and 2011 based on the assumptions noted in the following table:

		Three Months Ended March 31,	
		2012	2011
Expected life (years)	employees	6	6
Expected life (years)	directors	6	6
Risk-free interest rate		1.2%	2.4-2.5%
Volatility		76%	73-74%
Dividends		None	None

The expected volatility is based on the annualized daily historical volatility of the Company s stock price through the grant date for a time period consistent with the expected term of a grant. Management believes that the historical volatility of the Company s stock price best represents the volatility of the stock price. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company does not anticipate declaring dividends in the foreseeable future.

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, ultimately, the expense that will be recognized over the life of the option. GAAP also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

The aggregate intrinsic value of employee options outstanding at March 31, 2012 was $26,503,000, of which $22,073,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the quarters ended March 31, 2012 and 2011 were $2.99 and $1.43, respectively. As of March 31, 2012, there was approximately $6,757,000, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the Company s 2000 and 2010 Stock Incentive Plans that is expected to be recognized as expense over a weighted average period of 2.6 years. The intrinsic values of employee stock options exercised during the quarters ended March 31, 2012 and 2011 was $3,176,000 and $687,000, respectively. The total fair values of vested stock options for the quarters ended March 31, 2012 and 2011 were $710,000 and $825,000, respectively.

The Company recorded a total of $816,228 and $662,997 in compensation expense for the quarters ended March 31, 2012 and 2011, respectively, related to employee and director stock option grants.

Non-Employee Grants

The Company has periodically granted stock options and unrestricted stock awards to consultants for services, pursuant to the Company s stock plans at the fair market value on the respective dates of grant. Should the Company terminate any of its consulting agreements, the unvested options underlying the agreements would also be cancelled. For the three months ended March 31, 2012 and 2011, the Company recognized expense related to non-employee stock options of $206,448 and $14,716, respectively.

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Total Stock-Based Compensation Expense

For the three months ended March 31, 2012 and 2011, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss, including expense related to its 2010 Employee Stock Purchase Plan:

	Three Months Ended March 31,	
	2012	2011
Research and development expenses	$ 399,155	$ 165,053
General and administrative expenses	623,521	512,660
Total stock-based compensation expense	$ 1,022,676	$ 677,713

The table below summarizes options outstanding and exercisable at March 31, 2012:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number of Shares	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
$ 0.79 - $ 1.39	3,084,941	4.91	$ 1.19	2,845,065	$ 1.20
1.43 - 1.57	2,001,819	4.18	1.50	2,000,819	1.50
1.67 - 2.27	1,937,734	7.32	2.17	961,170	2.15
2.43 - 3.98	2,061,233	4.02	3.22	1,486,795	3.07
4.03 - 4.56	2,201,864	7.92	4.51	636,195	4.48
4.75 - 5.60	261,000	1.68	5.04	261,000	5.04
	11,548,591	5.53	$ 2.49	8,191,044	$ 2.10

10. Income (Loss) Per Common Share

The Company applies ASC Topic 260 *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic income (loss) per common share is computed using the weighted-average number of shares outstanding during the period. Diluted income per common share is computed using the weighted-average number of shares outstanding during the period plus the incremental shares outstanding assuming the exercise of dilutive stock options, restricted stock and outstanding warrants.

The following summarizes the effect of dilutive securities on diluted income per common share for the three months ended March 31, 2012:

	Three Months Ended March 31, 2012
Weighted average shares for basic EPS	77,556,366
Dilutive effect:	
Shares to be issued under the Company s stock plan	5,407,251
Warrants	373,078

Subtotal of dilutive securities	5,780,329
Weighted average shares for diluted EPS	83,336,695

The weighted-average diluted shares outstanding for the quarter ended March 31, 2012 excludes the approximately 261,000 shares of common stock underlying stock options since such options have an exercise price in excess of the average market value of the Company s common stock during the period and would, therefore, be anti-dilutive.

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Diluted net loss per common share is the same as basic net loss per common share for the three months ended March 31, 2011, as the effect of the potential common stock equivalents is antidilutive due to the Company s net loss position for this period. Antidilutive securities consist of stock options and warrants outstanding as of March 31, 2011 as follows:

	Three Months Ended March 31, 2011
Stock options outstanding	12,002,955
Warrants outstanding	1,612,322
Total antidilutive securities	13,615,277

11. Subsequent Events

In May 2012, Roche announce that it has submitted an application for marketing registration for Erivedge to Australia s Therapeutic Goods Administration (TGA). The application is currently under review by the TGA for the treatment of adults with advanced BCC for whom surgery is inappropriate. As a result of the submission of this application to the TGA, the Company earned a $4,000,000 milestone payment. If Roche receives approval to commercialize Erivedge in Australia, the Company will also be entitled to receive an additional milestone payment as well as royalties on any future net sales of Erivedge in Australia.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes appearing elsewhere in this report.

Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. We are building upon our experience in modulating signaling pathways, including the Hedgehog signaling pathway, in our effort to develop network-targeted cancer therapies. We conduct our research and development programs both internally and through strategic collaborations.

Hedgehog Pathway Inhibitor Program (Erivedge)

Erivedge (vismodegib) capsule. Our most advanced program is our Hedgehog pathway inhibitor program under collaboration with Genentech, Inc., a member of the Roche Group. The lead drug candidate being developed under this program is Erivedge, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor, which is also referred to as vismodegib. Erivedge is designed to selectively inhibit signaling in the Hedgehog pathway by targeting a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. However, mutations in the pathway that reactivate Hedgehog signaling are seen in certain cancers, including basal cell carcinoma, or BCC. Abnormal signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

In January 2012, the U.S. Food and Drug Administration (FDA) approved Genentech s new drug application, or NDA, for the Erivedge capsule for the treatment of adults with BCC that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and commercialized by Roche and Genentech. As a result of the FDA s approval of Erivedge in this indication, we earned a $10,000,000 payment from Genentech and we are also entitled to receive royalties on future sales of the product. During the first quarter of 2012, we recognized the $10,000,000 milestone payment as license revenue for the three months ended March 31, 2012. In addition, we recorded research and development expenses related to the FDA s approval of Erivedge of $1,464,000 during the three months ended March 31, 2012 which represents our obligations to university licensors. Of this amount, $964,000 represents the fair value of a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors in connection with the FDA-approval of Erivedge. The remaining $500,000 represents sublicense fees we paid to these same licensors, upon receipt of the $10,000,000 milestone payment in the first quarter of 2012.

We also recognized $271,000 of royalty revenue from Genentech s net sales of Erivedge during the quarter ended March 31, 2012. We recorded costs of royalty revenues of $114,000 during the three months ended March 31, 2012, including a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and $14,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the first quarter of 2012.

During the fourth quarter of 2011, Roche submitted a Marketing Authorization Application, or MAA, for Erivedge to the European Medicines Agency, or EMA, for which we earned a $6,000,000 milestone payment. Roche has indicated that it anticipates potential EMA approval for Erivedge during the second half of 2012 or the first half of 2013. Roche has also filed new drug applications in 2012 for marketing registration with Australian, Canadian and Swiss health agencies seeking approval for Erivedge in advanced BCC. In May 2012 we earned a $4,000,000 milestone payment in connection with Roche s filing in Australia. Genentech s FDA approval and Roche s regulatory submissions in Europe, Australia, Canada and Switzerland are based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive additional milestone payments if Erivedge receives EMA marketing authorization or approval in Australia. We are also entitled to receive royalties on future net sales in all territories where Erivedge is sold.

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In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge.

Genentech is also conducting a separate phase II clinical trial of Erivedge in patients with operable nodular BCC, which is a less severe form of the disease and accounts for a significant percentage of the approximately two million BCCs diagnosed annually in the United States. This phase II trial is the first study to assess the ability of Erivedge to provide complete histological clearance of tumor, an important first step in determining the efficacy of Erivedge in less severe forms of BCC, where BCC lesions are generally treated surgically. This trial is designed to test Erivedge as a single-agent therapy in approximately 75 patients with operable nodular BCC in a US-based, open label, three-cohort clinical trial. Patients in the first and second cohorts receive a 150 mg daily oral dose of Erivedge for 12 weeks, while patients in the third cohort receive 16 weeks of daily dosing, with two eight-week dosing cycles surrounding a four-week period in which patients will not receive Erivedge. The primary outcome measure for the first and third cohorts is the rate of complete histological clearance of the target nodular BCC lesions at the time of tumor excision (which may occur up to 12 or 20 weeks, respectively, following initiation of treatment) while the primary outcome measure for the second cohort is the rate of durable complete clearance of target nodular BCC lesions at the time of excision (which may occur up to 36 weeks following initiation of treatment).

Data from the first cohort was published in April 2012 in the *Journal of Investigative Dermatology* and will be presented at the Society of Investigative Dermatology Annual Meeting in May 2012. This first cohort evaluated the safety and efficacy of 12 weeks of daily 150 mg dosing of Erivedge in 24 patients with newly diagnosed nodular, operable BCC. Patients then underwent Mohs surgery with independent pathology review. Clinical complete and partial responses were reported for 23 (96%) patients, including pathologically confirmed complete clearance in 10 (42%) patients. The most frequent adverse events (AEs) were similar to those observed in previous studies with Erivedge and included muscle spasms (79%), ageusia/dysgeusia (79%), alopecia (33%), fatigue (21%) and nausea (21%). Most AEs were Grade 1-2; seven patients (29%) reported Grade 3 AEs, including four patients with muscle spasm; no serious AEs were reported. Eight (33%) patients discontinued from the study, including two due to AEs. Accrual to cohorts two and three is ongoing with full study results expected in first half of 2013.

In addition to the BCC clinical trials being conducted directly by Genentech and Roche, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the U.S. National Cancer Institute, or NCI.

Network-Targeted Cancer Programs

Our internal drug development efforts are focused on our network-targeted cancer programs, in which we are seeking to design single novel small molecule drug candidates that inhibit multiple signaling pathways that are believed to play roles in cancer cell proliferation. We refer to this approach as cancer network disruption. We believe that our approach of targeting multiple nodes in cancer signaling pathway networks may provide a better therapeutic effect than many of the cancer drugs currently marketed or in development which are designed to disrupt only one target.

CUDC-101. Our lead candidate from these programs is CUDC-101, a first-in-class small molecule compound designed to simultaneously target epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and histone deacetylase, or HDAC, all of which are validated cancer targets. A significant amount of our capital resources are focused on the ongoing clinical and preclinical development of this molecule. To date, we have completed a phase I dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase I expansion trial to test CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The phase I expansion trial was designed as an open-label study in which patients were treated with CUDC-101 at the maximum tolerated dose, which was determined in the phase I dose escalation study to be 275 milligrams per meter^2. The primary objectives of this study were to compare the safety and tolerability of CUDC-101 in subjects with these specific advanced solid tumors when the drug was administered via one-hour intravenous infusion either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off).

In 2011, we initiated a phase I clinical trial of CUDC-101 in locally advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. We have treated four patients in this trial as of May 3, 2012. The primary objectives of this study are to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Upon determination of the maximum tolerated dose and assuming the otherwise successful completion of this phase I trial, we intend to conduct a randomized phase II two-arm clinical trial in which head and neck cancer patients will receive cisplatin and radiation plus or minus CUDC-101. The phase II study would seek to evaluate whether the addition of CUDC-101 can improve the efficacy of cisplatin and radiation therapy in this patient population. We currently estimate initiating this phase II study in the first half of 2013.

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We are also working on an oral formulation of CUDC-101, which we believe has the potential to make CUDC-101 more competitive in certain cancers such as non-small cell lung cancer or in other cancers where there are investigational or competing commercially available molecules that are orally administered. Pending the successful completion of ongoing formulation and preclinical development work, we intend to file an investigational new drug application, or IND, with the FDA and begin a phase I study of an oral formulation of CUDC-101 in the second half of 2012.

CUDC-907. In 2011, we selected development candidate CUDC-907, an orally bioavailable, network-targeted small molecule that is designed to inhibit phosphatidylinositol-3-kinase, or PI3K, and HDAC. Our scientists are developing CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction in certain preclinical cancer models. We believe that this synergistic mechanism of cancer signaling network disruption, which demonstrated efficacy and a favorable safety profile in a number of preclinical xenograft models, could translate into clinical advantages over single targeted agents.

In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will provide a portion of the funding of the development of CUDC-907 if we succeed in advancing this development candidate into a clinical trial for patients with B-cell lymphoma and multiple myeloma. Pending the successful completion of ongoing formulation and preclinical development work, we expect to file an IND with the FDA and begin a phase I study of CUDC-907 during the second half of 2012.

In addition to our development-stage programs, we continue to progress additional proprietary preclinical research programs and expect that we will select additional small molecule inhibitors from our preclinical portfolio in the future.

Hsp90 Program

Debio 0932. Our heat shock protein 90, or Hsp90, program is being developed by Debiopharm, a Swiss pharmaceutical development company, under an August 2009 license agreement between Curis and Debiopharm. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. In April 2010, Debiopharm treated the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of the phase I study. Debio 0932 was generally well tolerated, with no evidence of ocular or liver toxicity, and showed promising signs of efficacy in patients with advanced solid tumors in this study. The recommended dose for further study was determined by Debiopharm to be 1000mg daily. Debiopharm has indicated that it expects to present data from this phase I study at the annual meeting of the American Society of Clinical Oncolgoy (ASCO) to be held in Chicago, Illinois in June 2012.

Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study in the beginning of 2012. The primary objectives of this portion of the study are to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 and to make a preliminary assessment of anti-tumor activity. Debiopharm expects that approximately 30 patients with advanced solid tumors will be treated in this portion of the study, including patients with non-small cell lung cancer (NSCLC).

Debiopharm has also indicated that it expects to initiate a combination Phase I/II study in NSCLC patients in the second quarter of 2