CURIS INC
Form 10-Q
August 04, 2011
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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 JUNE 30, 2011

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 July 27, 2011, there were 76,545,631 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)

	June 30, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,791,800	$ 7,826,549
Marketable securities	25,934,612	32,553,269
Short-term investment restricted		219,458
Accounts receivable	99,524	92,371
Prepaid expenses and other current assets	475,066	392,249
Total current assets	33,301,002	41,083,896
Property and equipment, net	504,010	302,721
Long-term investment restricted	277,546	277,546
Goodwill	8,982,000	8,982,000
Other assets	2,980	2,980
Total assets	$ 43,067,538	$ 50,649,143
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,685,967	$ 2,620,968
Accrued liabilities	701,105	854,605
Total current liabilities	3,387,072	3,475,573
Warrants	3,426,592	1,604,742
Other long-term liabilities	126,912	51,171
Total liabilities	6,940,576	5,131,486
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 77,527,811 shares issued and 76,480,104 shares outstanding at June 30, 2011; and 76,803,868 shares issued and 75,756,161 shares outstanding at December 31, 2010	775,278	768,039
Additional paid-in capital	770,152,216	767,825,232
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation		(955)
Accumulated deficit	(733,942,962)	(722,228,747)
Accumulated other comprehensive income	33,704	45,362
Total stockholders equity	36,126,962	45,517,657
Total liabilities and stockholders equity	$ 43,067,538	$ 50,649,143

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS)/INCOME (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
REVENUES:				
Research and development	$ 92,867	$ 98,634	$ 226,405	$ 181,135
License fees	300,000		300,000	12,475,833
Total revenues	392,867	98,634	526,405	12,656,968
COSTS AND EXPENSES:				
Research and development	3,144,050	2,244,742	6,202,549	4,712,546
General and administrative	1,867,782	1,780,377	4,275,131	6,206,822
Total costs and expenses	5,011,832	4,025,119	10,477,680	10,919,368
(Loss)/income from operations	(4,618,965)	(3,926,485)	(9,951,275)	1,737,600
OTHER INCOME:				
Interest income	25,341	31,254	58,910	58,043
Change in fair value of warrant liability	(320,440)	1,797,244	(1,821,850)	890,635
Total other (expense)/income	(295,099)	1,828,498	(1,762,940)	948,678
Net (loss)/income	$ (4,914,064)	$ (2,097,987)	$ (11,714,215)	$ 2,686,278
Basic net (loss)/income per common share	$ (0.06)	$ (0.03)	$ (0.15)	$ 0.04
Diluted net (loss)/income per common share	$ (0.06)	$ (0.03)	$ (0.15)	$ 0.03
Basic weighted average common shares	76,378,369	75,617,858	76,103,611	74,261,033
Diluted weighted average common shares	76,378,369	75,617,858	76,103,611	77,979,738
Net (loss)/income	$ (4,914,064)	$ (2,097,987)	$ (11,714,215)	$ 2,686,278
Unrealized (loss)/income on marketable securities	(17,125)	39,790	(11,658)	22,786
Comprehensive (loss)/income	$ (4,931,189)	$ (2,058,197)	$ (11,725,873)	$ 2,709,064

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	Six Months Ended June 30, 2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)/income	$ (11,714,215)	$ 2,686,278
Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities:		
Depreciation and amortization	45,089	361,300
Stock-based compensation expense	1,039,558	1,346,662
Change in fair value of warrant liability	1,821,850	(890,635)
Non-cash interest expense (income)	120,363	(74,906)
Net gain on sale of assets	(36,446)	
Changes in operating assets and liabilities:		
Accounts receivable	(7,153)	471,246
Prepaid expenses and other assets	22,183	312,761
Accounts payable and accrued liabilities	(117,760)	(816,334)
Deferred revenue		(475,833)
Total adjustments	2,887,684	234,261
Net cash (used in)/provided by operating activities	(8,826,531)	2,920,539
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(25,611,178)	(34,673,435)
Sales of marketable securities	32,097,814	18,540,620
Purchases of property and equipment	(246,378)	(39,450)
Proceeds from sale of assets	36,446	
Decrease in restricted cash	219,458	
Net cash provided by/(used in) investing activities	6,496,162	(16,172,265)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from registered direct offering of common stock and warrants, net of issuance costs of $1,310,000		14,942,317
Proceeds from other issuances of common stock and exercise of warrants	1,295,620	1,939,819
Net cash provided by financing activities	1,295,620	16,882,136
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,034,749)	3,630,410
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	7,826,549	7,275,433
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 6,791,800	$ 10,905,843

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 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, 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 the Company s 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 June 30, 2011 should enable the Company to maintain its current and planned operations into the fourth quarter of 2012. The Company s ability to continue funding its planned operations into and beyond the fourth quarter of 2012 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.

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, 2010, as filed with the Securities and Exchange Commission on March 8, 2011.

In the opinion of management, 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 June 30, 2011, the results of operations for the three- and six-month periods ended June 30, 2011 and 2010 and cash flows for the six month periods ended June 30, 2011 and 2010. 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, including the value of its warrant liability. 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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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 equity investments in the Company, 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 March 8, 2011.

4. Debiopharm Hsp90 Inhibitor License Agreement

In August 2009, the Company granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell its heat shock protein 90, or Hsp90, inhibitor technology to Debiopharm S.A. The Company amortized this payment over its estimated performance period of this agreement, which concluded during the first quarter of 2010, resulting in the recognition of $333,000 in license fee revenue during the six month period ended June 30, 2010. In addition, under the terms of this agreement, in March 2010, the Company received a payment of $8,000,000 from Debiopharm upon acceptance by French regulatory authorities of Debiopharm s clinical trial application for Hsp90 inhibitor Debio 0932. The Company has recorded these amounts, which totaled $8,333,000 as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the six months ended June 30, 2010 because the Company has no ongoing material performance obligations under the agreement.

5. Micromet Settlement

On February 4, 2010, the Company entered into a settlement, mutual release and termination agreement with Micromet, Inc. to resolve a claim filed by the Company relating to a June 2001 Agreement associated with the Company s Single Chain Peptide technology between the Company and Micromet s wholly owned subsidiary Micromet AG. Under the June 2001 agreement, Micromet AG acquired from the Company certain intellectual property assets relating to single chain antibodies, including patents and license agreements. Pursuant to the settlement agreement, Micromet has made a final payment of $4,000,000 to the Company in order to settle the dispute and discharge and terminate all future payment obligations that would have arisen under the June 2001 agreement. The Company has recorded the $4,000,000 within the License fee revenue line item in the Consolidated Statement of Operations for the six months ended June 30, 2010. During the first quarter of 2010, the Company incurred approximately $1,525,000 in related legal fees and expenses through the settlement date. These costs are included within the General and administrative expense line item of the Consolidated Statement of Operations for the six months ended June 30, 2010.

6. Fair Value Measurements

The Company discloses fair value measurements based on a framework outlined by generally accepted accounting principles, or 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.

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. The Company s Level 1 assets include cash equivalents, investments in marketable securities, and restricted investments. The Company held cash equivalents and marketable securities of $5,384,000 and $25,935,000,

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respectively, as of June 30, 2011, and $6,193,000 and $32,553,000, respectively, as of December 31, 2010. The Company s marketable securities are investments with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and consist of commercial paper 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 and U.S. Treasury securities.

The Company also had a long-term restricted investment of $278,000 as of June 30, 2011 and December 31, 2010 that was solely comprised of a certificate of deposit pursuant to the requirements of the Company s property lease. The restriction on a prior short-term restricted investment of $219,000 at December 31, 2010 was lifted on January 31, 2011.

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 June 30, 2011.

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 7, and is therefore classified as Level 3.

The Company had no transfers between the three levels during the three- and six-month periods ending June 30, 2011 and 2010. In accordance with the fair value hierarchy, the following table shows the fair value as of June 30, 2011 and December 31, 2010, of those financial assets 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 are measured at fair value on a nonrecurring basis at June 30, 2011 and December 31, 2010.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of June 30, 2011:				
Cash equivalents				
Money market funds	$ 3,409,000	$	$	$ 3,409,000
Municipal bonds	1,975,000			1,975,000
Marketable securities				
US government obligations	5,321,000			5,321,000
Corporate commercial paper, bonds and notes	20,614,000			20,614,000
Restricted investment (certificate of deposit)	278,000			278,000
Total assets at fair value	$ 31,597,000	$	$	$ 31,597,000
As of December 31, 2010:				
Cash equivalents				
Money market funds	$ 3,863,000	$	$	$ 3,863,000
Municipal bonds	2,330,000			2,330,000
Marketable securities				
US government obligations	3,600,000			3,600,000
Corporate commercial paper, bonds and notes	28,953,000			28,953,000
Restricted investments (certificates of deposit)	497,000			497,000
Total assets at fair value	$ 39,243,000	$	$	$ 39,243,000

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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 June 30, 2010 and 2011:

Balance at December 31, 2009	$
Issuance of warrants	2,181,000
Change in fair value for the six months ended June 30, 2010	(891,000)
Balance at June 30, 2010	$ 1,290,000
Balance at December 31, 2010	$ 1,605,000
Change in fair value for the six months ended June 30, 2011	1,822,000
Balance at June 30, 2011	$ 3,427,000

7. Common Stock and Warrant Liability

2011 At Market Issuance Sales Agreement

On June 13, 2011, the Company entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which the Company may issue and sell from time to time through MLV shares of its common stock, $0.01 par value per share, with an aggregate offering price of up to $20,000,000. Upon delivery of a placement notice and subject to the terms and conditions of the ATM agreement, MLV may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 of the Securities Act of 1933, including sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker. With the Company s prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. The Company or MLV may suspend or terminate the offering of common stock upon notice and subject to other conditions. MLV will act as sales agent on a commercially reasonable best efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ. The Company will pay MLV a commission equal to 3.0% of the gross sales price per share sold. The Company has agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. As of June 30, 2011, the Company had not delivered a placement notice and had not sold any common shares under the ATM agreement. Total offering expenses incurred related to the ATM agreement through June 30, 2011 were approximately $105,000. The Company has capitalized this amount in the Prepaid expenses and other current assets line item of its Consolidated Balance Sheet as of June 30, 2011. In July 2011, the Company delivered a placement notice to MLV and sold shares under the ATM agreement resulting in proceeds of $255,000, which is net of MLV s commission.

2010 Registered Direct Offering

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. The warrants have an initial exercise price of $3.55 per share and a five-year term. The warrants include certain protective features for the benefit of the warrantholder, including an anti-dilution adjustment clause and a possible cash-settlement option in the event of a change of control until the later to occur of (i) two years from the date of original issuance of the warrant and (ii) the date upon which Genentech or Roche submits a new drug application (NDA) for vismodegib. Due to these terms, the warrants were deemed to be a liability and, therefore, the fair value of the warrants was recorded as a liability in the Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010. The Company estimated that the fair value of the warrants at issuance was $2,181,000 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 the following assumptions assigned to the varying outcomes: expected volatilities of 69.8% and 80%, risk free interest rates ranging from 1.42% to 2.38%, expected lives of three to five years, and no dividends.

The Company estimated that the fair value of the warrants at June 30, 2011 was $3,427,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatility of 80%, risk free interest rates ranging from 0.8% to 1.1%, expected lives of three to four years, and no dividends. The Company estimated that the fair value of the warrants at June 30, 2010 was $1,290,000 using the following assumptions assigned to the

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varying outcomes: expected volatilities of 78.4% and 97.8%, risk free interest rates ranging from 0.9% to 2.4%, expected lives of three to five years, and no dividends. The warrants will be revalued each reporting period with updated assumptions, and the resulting change in fair value of the warrant liability will be recognized in the Consolidated Statement of Operations.

The Company recorded other expense of approximately $320,000 and $1,822,000 for the three and six months ended June 30, 2011, respectively, and other income of approximately $1,797,000 and $891,000 for the three and six months ended June 30, 2010, respectively, as a result of the change in the fair value of the warrant liability. These changes are primarily due to the changes in the Company s stock price during the respective reporting periods.

8. Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2011	December 31, 2010
Accrued compensation	$ 338,000	$ 539,000
Professional fees	142,000	143,000
Facility-related costs	96,000	34,000
Other	125,000	139,000
Total	$ 701,000	$ 855,000

9. Accounting for Stock-Based Compensation

As of June 30, 2011, 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, 2010, as previously filed with the Securities and Exchange Commission on March 8, 2011.

During the six months ended June 30, 2011 and consistent with past practices, the Company s board of directors granted options to purchase 859,000 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 six months ended June 30, 2011, the Company s board of directors also granted options to its non-employee directors to purchase 235,000 shares of common stock under the 2010 Stock Incentive Plan. All of these options were fully vested on the January 7, 2011 grant date and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date.

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 options awarded during the six months ended June 30, 2011 and 2010 based on the assumptions noted in the following table:

		Six Months Ended June 30,	
		2011	2010
Expected life (years)	employees	6	6
Expected life (years)	directors	6	6
Risk-free interest rate		2.4-2.5%	2.6-2.8%
Volatility		73-74%	69%
Dividends		None	None

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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 an award. The Company 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, the Company 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 June 30, 2011 was $18,329,000, of which $14,606,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the six months ended June 30, 2011 and 2010 were $1.43 and $1.46, respectively. As of June 30, 2011, there was approximately $2,482,000, 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 2.4 years. The intrinsic values of employee stock options exercised during the six months ended June 30, 2011 and 2010 were $826,000 and $197,000, respectively. The total fair values of vested stock options for the six months ended June 30, 2011 and 2010 were $1,050,000 and $1,785,000, respectively.

The Company recorded $349,000 and $1,012,000 in compensation expense for the three and six months ended June 30, 2011, respectively, and $295,000 and $1,363,000 in compensation expense for the three and six months ended June 30, 2010, respectively, related to employee and director stock option grants. Certain stock options to purchase a total of 816,500 shares of the Company s common stock were issued to employees of the Company in 2008 and 2007 in which vesting was tied to a performance condition, which was achieved in March 2010. This resulted in the immediate vesting of these options and the Company recorded approximately $485,000 in additional stock compensation expense during the six months ended June 30, 2010.

Non-Employee Grants

The Company has periodically granted stock options and unrestricted stock awards to consultants for services, and issued 25,000 options to the chairman of the Company s Clinical and Scientific Advisory Board during the six months ended June 30, 2011. These options were issued pursuant to the 2010 Stock Incentive Plan at their fair market value on the date of grant and will vest over a four-year period from the date of grant. Should the Company terminate the consulting agreement, any unvested options will be cancelled. Unvested non-employee options are marked-to-market, which means that as the Company s stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of $13,000 and $28,000 related to non-employee stock options for the three and six months ended June 30, 2011, respectively. The Company reversed expense of $18,000 and $16,000 related to non-employee stock options for the three and six months ended June 30, 2010, respectively, as a result of a decline in the Company s stock price during the period.

Total Stock-Based Compensation Expense

For the three and six months ended June 30, 2011 and 2010, 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:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2011	2010	2011	2010
Research and development expenses	$ 179,000	$ 107,000	$ 344,000	$ 384,000
General and administrative expenses	183,000	170,000	696,000	963,000
Total stock-based compensation expense	$ 362,000	$ 277,000	$ 1,040,000	$ 1,347,000

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The table below summarizes options outstanding and exercisable at June 30, 2011:

	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 $1.35	2,085,726	6.64	$ 1.05	1,611,904	$ 1.04
1.39 1.43	2,550,446	6.19	1.41	2,370,003	1.40
1.50 2.15	2,945,242	6.16	1.81	1,994,867	1.66
2.27 2.43	2,036,813	5.38	2.35	1,416,088	2.38
2.48 4.83	1,982,000	2.71	4.04	1,926,750	4.07
4.95 5.89	228,000	2.40	5.11	228,000	5.11
	11,828,227	5.46	$ 2.12	9,547,612	$ 2.17

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.

Diluted net loss per common share is the same as basic net loss per common share for the three and six months ended June 30, 2011, as well as for the three months ended June 30, 2010, 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 June 30, 2011 as follows:

	For the Three and Six Months Ended June 30, 2011	For the Three Months Ended June 30, 2010
Stock options outstanding	11,828,227	12,107,562
Warrants outstanding	1,610,818	1,612,322
Total antidilutive securities	13,439,045	13,719,884

The following summarizes the effect of dilutive securities on diluted income per common share for the six months ended June 30, 2010:

	For the Six Months Ended June 30, 2010
Weighted average shares for basic EPS	74,261,033
Dilutive securities:	
Warrants	266,035
Stock options	3,452,670
Subtotal of dilutive securities	3,718,705
Weighted average shares for diluted EPS	77,979,738

The weighted-average diluted shares outstanding for the six months ended June 30, 2010 excludes the dilutive effect of approximately 2,938,045 shares of common stock underlying stock options and 1,612,322 shares of common stock underlying warrants since such options and warrants have an exercise price in excess of the average market value of the Company s common stock during the respective period.

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11. Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued an amendment to the accounting guidance for presentation of comprehensive income. Under the amended guidance, a company may present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In either case, a company is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. Regardless of choice in presentation, the company is required to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income in the statement(s) where the components of net income and the components of other comprehensive income are presented. For public companies, the amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and shall be applied retrospectively. Early adoption is permitted. Other than a change in presentation, the adoption of this update is not expected to have a material impact on the Company s consolidated financial statements.

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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

Vismodegib. 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 vismodegib, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor, which is also referred to as GDC-0449 and RG3616.

Vismodegib 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 several different types of cancer. Abnormal signaling in the Hedgehog pathway is implicated in the majority of basal cell carcinoma, or BCC, cases.

In March 2011, Genentech and Roche notified us of a positive outcome in a pivotal phase II clinical trial of vismodegib in advanced BCC, and in June 2011, Genentech presented detailed results from this study at the Seventh European Association of Dermato-Oncology, or EADO, Congress in Nantes, France. The study met its primary endpoint showing that vismodegib substantially shrank tumors or healed visible lesions, with observed response rates of 43% of patients in the locally advanced BCC cohort and 30% of patients in the metastatic BCC cohort as assessed by an independent review facility. Advanced BCC is a severe form of the disease that includes cutaneous BCCs that are considered inoperable by the treating physician as well as BCCs that have metastasized to other tissues and organs. Based on the results of this study, Roche has indicated that it anticipates filing a new drug application, or NDA, with the United States Food and Drug Administration, or FDA, in 2011 to seek approval to commercialize vismodegib in the U.S. The filing timeline for a European regulatory submission seeking to commercialize the drug in Europe is dependent on planned discussions with the European Medicines Agency, or EMA. Assuming that submissions are filed by Roche and accepted by the applicable regulatory agencies, we will be eligible to receive milestone payments for the U.S. and European territories. We are eligible for additional milestone payments upon regulatory approval as well as royalties on any future sales of vismodegib.

The primary endpoint of the study is overall response rate as assessed by an independent review facility, with secondary endpoints including investigator-assessed overall