CURIS INC
Form 10-Q
August 04, 2011
Table of Contents

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.

Table of Contents

CURIS, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q

INDEX

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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,

7

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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

11

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 response rate, progression-free survival, overall survival, and duration of response in all evaluable patients, including locally advanced BCC or metastatic BCC patients. In addition, absence of residual BCC in patients was assessed by sampling biopsies in patients with locally advanced BCC. Genentech had previously reported Phase I clinical trial results in the *New England Journal of Medicine* in which an investigator-assessed response rate of 55% was observed in 33 patients with advanced BCC treated with vismodegib, including those with locally advanced BCC or metastatic BCC. In the pivotal Phase II trial, study investigators assessed the overall response rate to be 55%, with 60% in the locally advanced BCC cohort, and 46% in metastatic BCC cohort. The overall response rate in the pivotal Phase II trial as assessed by an independent review facility showed vismodegib substantially shrank tumors or healed visible lesions, with observed response rates of 43% of patients in the laBCC cohort and 30% of patients in the metastatic BCC cohort. The clinical benefit rate (defined as patients who experienced response as well as those who experienced prolonged stable disease for more than 24 weeks) showed vismodegib shrank tumors or healed visible lesions, or prevented them from growing any further in 75% of patients with locally advanced BCC and 76% of patients with metastatic BCC, as assessed by independent review. The median duration of progression-free survival by independent review for both metastatic and locally advanced BCC patients was 9.5 months. The median duration of response by independent review was 7.6 months for both metastatic and locally advanced BCC patients. The median duration of response as assessed by study investigators was 12.9 and 7.6 months for metastatic BCC and locally advanced BCC patients, respectively. There was no residual BCC in sampling biopsies of 54% of locally advanced BCC patients. As of the November 26, 2010, data cutoff date,

Table of Contents

there were 19 (57.6%) metastatic BCC and 32 (45.1%) locally advanced BCC patients remaining on treatment. The median duration on treatment as of this date was 10 and 9.7 months for metastatic BCC and locally advanced BCC patients, respectively.

The most common adverse events observed in the study (observed in greater than 20% of patients) included muscle spasms, hair loss, altered taste sensation, weight loss, fatigue, nausea, decreased appetite, and diarrhea. Serious adverse events were observed in 26 patients (25%). Four of these patients (4%) had serious adverse events that were considered to be related to vismodegib, including one case each of: blocked bile flow from the liver (cholestasis), dehydration with loss of consciousness (syncope), pneumonia accompanied by an inability of the heart to pump enough blood (cardiac failure) and a sudden arterial blockage in the lung (pulmonary embolism). Fatal events were reported in seven patients (7%); none were considered by investigators to be related to vismodegib. In all fatalities, pre-existing risk factors and comorbid conditions were present.

The pivotal phase II clinical trial is an international, single-arm, multi-center, two-cohort, open-label phase II study that enrolled 104 patients with advanced BCC, including metastatic (33) and/or locally advanced BCC (71), defined as patients whose lesions are inappropriate for surgery (inoperable, or for whom surgery would result in substantial deformity) and for which radiotherapy was unsuccessful or contraindicated. metastatic BCC was defined as BCC that had spread to other parts of the body, including the lymph nodes, lung, bones and/or internal organs. The study was conducted at 31 sites in the United States, Australia and Europe. Study participants received 150mg vismodegib orally, once daily until disease progression or intolerable toxicity. Tumor responses for metastatic BCC were measured by RECIST criteria and for locally advanced BCC by a novel composite endpoint which included reduction of size of lesions of at least 30% in longest dimension and/or complete resolution of locally advanced BCC ulceration.

Genentech is also conducting a separate phase II clinical trial of vismodegib in patients with operable nodular basal cell carcinoma, 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 study was initiated by Genentech in October 2010 to test vismodegib as a single-agent therapy in approximately 50 patients with operable nodular BCC in a US-based, open label, two-cohort clinical trial. All patients will receive a 150 mg daily oral dose of vismodegib for 12 weeks. The primary outcome measure for the first cohort is the rate of complete histological clearance of target nodular BCC lesions at the time of tumor excision (which may occur up to 12 weeks 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).

In addition to the BCC clinical trials being conducted directly by Genentech and Roche, vismodegib 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, including in treating BCC in patients with basal cell nevus syndrome (Gorlin syndrome), medulloblastoma, sarcoma and glioblastoma multiforme, as well as in pancreatic, small cell lung, gastroesophageal junction, gastric, breast, and prostate cancers, among others.

Promising interim data from an investigator-sponsored study in basal cell nevus syndrome, or BCNS, was presented in April at the American Association for Cancer Research 2011 annual meeting. This phase II double blind, randomized placebo-controlled, two arm multicenter clinical study of vismodegib enrolled 41 BCNS patients from September 2009 to January 2011. It is designed to assess the safety and efficacy of a 150 mg dose of daily oral vismodegib versus a placebo. A Data Safety Monitoring Board, or DSMB, tasked with reviewing the unblinded results from an interim analysis of 29 patients who completed an average of six months of drug treatment, subsequently recommended to end the placebo arm of the trial due to statistically significant differences between the two groups, in order for all of the patients enrolled in the trial to receive vismodegib treatment. The DSMB s analysis revealed that vismodegib reduced the rate of new BCCs from an average of 1.74 BCCs per month in the placebo group to 0.07 in the vismodegib group ($p<0.0001$). Vismodegib also reduced the size of existing BCCs (-24 cm vs. 3 cm placebo, cumulative diameter, $p=0.006$). Some patients achieved near complete remission with no BCC developing resistance during this period of time on trial. Observations related to vismodegib s safety were similar to what has been reported in previous clinical studies, including grade 1-2 taste loss, muscle cramps, hair loss and weight loss when compared to placebo were common. There were two grade 3-4 adverse events observed, including one grade 3 muscle cramp and one grade 4 depression. Overall, 28% of patients taking vismodegib discontinued participation due to adverse events.

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 and believe that our approach

Table of Contents

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 since our drug candidates are being designed to disrupt multiple targets in the cancer network environment as compared to most other cancer drugs.

CUDC-101. Our lead candidate from these programs is CUDC-101, a first-in-class small molecule compound designed to simultaneously target histone deacetylase, or HDAC, epidermal growth factor receptor, or EGFR, and human epidermal growth factor receptor 2, or Her2, all of which are validated cancer targets. A significant amount of our capital resources are focused on the ongoing clinical development of this molecule. To date, we have completed a phase I dose escalation clinical trial of this molecule in 25 patients with advanced, refractory solid tumors and initiated a phase I expansion trial to test CUDC-101 in approximately 50 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. We have enrolled 45 patients in this study to-date and expect to complete enrollment in the phase I study and report full data from this study during the second half of 2011. The phase I expansion trial is designed as an open-label study in which patients are 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 are to compare the safety and tolerability of CUDC-101 in subjects with these specific advanced solid tumors when the drug is administered 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).

The safety profile observed to-date for both dosing schedules appears to be consistent with that observed in the phase I dose escalation study. In addition, we have observed stable disease in several patients in this study. Most notably, we have observed stable disease in four patients with advanced liver cancer. Two patients have been treated with CUDC-101 for over six months, one of which remains on study drug following ten months of treatment, while two additional patients achieved stable disease for approximately four months prior to disease progression. Based on these observations, we are evaluating various options for further testing of CUDC-101 in the liver cancer setting.

During the second quarter of 2011, we initiated a phase I clinical trial of CUDC-101 in advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. We are currently recruiting patients for this study and anticipate that we will enroll the first patient during the third quarter of 2011. The primary objective of this study is 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 the 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 and durability of cisplatin and radiation therapy in this patient population.

We are also working on an oral formulation of CUDC-101, which we believe will make CUDC-101 more competitive in certain cancers such as non-small cell lung cancer where patients are generally on therapy for several months and there are competing commercially available molecules that are orally administered. Pending the successful completion of ongoing formulation and preclinical development work, we intend to file the appropriate regulatory documents to test an oral formulation of CUDC-101 in clinical trials in late 2011.

CUDC-907. In January 2011, we selected development candidate CUDC-907, an orally bioavailable, network-targeted small molecule that is designed to inhibit HDAC and phosphatidylinositol-3-kinase, or PI3K. Our scientists are developing CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction against cancer cells. 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 agents. Pending the successful completion of ongoing formulation and preclinical development work, we expect to file an investigational new drug application, or IND, with the FDA to test an oral formulation of CUDC-907 in early 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 suffering from advanced solid tumors.

16

Table of Contents

Liquidity

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, the private and public placement of our equity securities and debt financings and the monetization of certain royalty rights. We have never been profitable and have an accumulated deficit of $733,943,000 as of June 30, 2011. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our research and development programs. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We believe that near term key drivers to our success will include:

- Genentech s ability to successfully submit regulatory submissions to the FDA and EMA seeking the approval to commercialize vismodegib in advanced BCC and to have such filings approved by the respective regulatory agency;
- Debiopharm s ability to successfully complete its ongoing phase I clinical testing and advance Debio 0932 into later stages of clinical development;
- our ability to continue to successfully enroll and treat patients in our phase I expansion trial for CUDC-101;
- our ability to successfully enroll and treat patients in our phase I clinical trial for CUDC-101 in combination with radiation and cisplatin in head and neck cancer patients;
- our ability to plan, finance and complete clinical trials for CUDC-101 in indications other than head and neck cancers;
- our ability to successfully advance development candidates CUDC-907 and CUDC-101 (oral formulation) through formulation and manufacturing processes and IND-enabling studies and successfully initiate phase I testing for these candidates;
- our ability to successfully enter into a material license or collaboration agreement for any of our proprietary drug candidates; and
- our ability to advance the research of other small molecule cancer drug candidates that we are developing under our proprietary pipeline of network-targeted cancer programs.

In the longer term, a key driver to our success will be our ability, and the ability of any current or future collaborator or licensee, to successfully commercialize drugs based upon our proprietary technologies.

Collaboration Agreements

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog pathway inhibitor technologies, and an August 2009 license agreement with Debiopharm relating to our Hsp90 inhibitor technology. Our past and current collaborations have generally provided for research, development and commercialization programs to be wholly or majority-funded by our collaborators and provide us with the opportunity to receive additional contingent cash payments if specified development and regulatory approval objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaborations. We are currently not receiving any research funding and we do not expect to receive such funding in the future from Genentech or Debiopharm under our current agreements with these parties. We currently expect to incur only nominal research and development costs under our collaborations with Genentech related to the maintenance of licenses. In addition, as a result of our licensing agreements with various universities, we are obligated to make payments to these university licensors when we receive certain payments from Genentech. As of June 30, 2011, we have paid an aggregate of approximately $940,000 related to ongoing agreements, of which $900,000 relates to payments that we received from Genentech. We also expect to incur general and administrative costs associated with our share of intellectual property costs under our June 2003 collaboration with Genentech. We

do not expect to incur any material costs related to our Hsp90 technologies under development by Debiopharm under our August 2009 license agreement with Debiopharm.

Financial Operations Overview

General. Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments, if any, from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. We anticipate

Table of Contents

that existing capital resources as of June 30, 2011 should enable us to maintain current and planned operations into the fourth quarter of 2012. Our ability to continue funding our planned operations into and beyond the fourth quarter of 2012 is dependent on future contingent payments that we may receive from Debiopharm or Genentech upon the achievement of development and regulatory approval objectives, our ability to manage our expenses and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under Part II, Item 1A Risk Factors.

Revenue. We do not expect to generate any revenue from our direct sale of products for several years, if ever. Substantially all of our revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees.

We currently receive no research funding for our programs under our collaborations with Genentech and Debiopharm and we do not expect to receive such funding in the future under these collaborations. Accordingly, our only source of revenues and/or cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of clinical development and regulatory objectives, if any are met, under new collaborations or our existing collaborations with Genentech and Debiopharm, and royalty payments that are contingent upon the successful commercialization of any products based upon these collaborations. Our ability to enter into new collaborations and our receipt of additional payments under our existing collaborations with Genentech and Debiopharm cannot be assured, nor can we predict the timing of any such arrangements or payments, as the case may be.

Research and Development. Research and development expense consists of costs incurred to discover, research and develop our drug candidates. These expenses consist primarily of: (1) salaries and related expenses for personnel including stock-based compensation expense; (2) outside service costs including clinical research organizations, medicinal chemistry and sublicense payments; and (3) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We are currently incurring only nominal research and development expenses under our Hedgehog pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. For each contingent payment, if any, received under the Hedgehog pathway inhibitor collaboration, we would be obligated to make payments to certain third-party licensors and recognize the related expense.

Table of Contents

Our research and development programs, both internal and under collaboration, are summarized in the following table:

Product Candidate	Primary Disease	Collaborator/Licensee	Status
Hedgehog Pathway Inhibitor			
- Vismodegib (GDC-0449; RG3616)	Advanced BCC	Genentech	NDA submission preparation
- Vismodegib (GDC-0449; RG3616)	Operable Nodular BCC	Genentech	Phase II
Network-targeted Cancer Programs			
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I expansion
- CUDC-101 intravenous formulation (HDAC, EGFR, Her2 inhibitor)	Advanced head and neck cancer	Internal development	Phase I
- CUDC-101 oral formulation (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Development candidate
- CUDC-907 (HDAC, PI3K inhibitor)	Cancer	Internal development	Development candidate
- Other network-targeted cancer programs	Cancer	Internal development	Preclinical
- Debio 0932 (formerly CUDC-305) (Hsp90 inhibitor)	Cancer	Debiopharm	Phase I

In the chart above, NDA submission preparation means that Genentech is currently preparing to file an NDA with the FDA in 2011 and, pending planned discussions with EMA, submit a regulatory filing seeking approval of vismodegib in advanced BCC in Europe. Phase II means that Genentech is currently treating human patients in a phase II clinical trial, the primary objective of which is a therapeutic response in the patient population. Phase I expansion means that we are currently treating human patients with specific tumor types in an extension of our phase I dose escalation trial, at the maximum tolerated dose from such trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. Phase I means that we and Debiopharm are currently treating human patients in separate phase I clinical trials, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. Development candidate means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an IND application with the FDA seeking to commence a phase I clinical trial. Preclinical means that we are seeking to obtain evidence of therapeutic efficacy and safety in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

Because of the early stages of development of these programs, our ability and that of our collaborators and licensees to successfully complete preclinical studies and clinical trials of these drug candidates, and the timing of completion of such programs, is highly uncertain. There are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators future results, including:

- the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;
- the results of future preclinical studies and clinical trials;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our drug candidates and any products that we may develop;

the effect of competing technological and market developments; and

the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Table of Contents

We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our drug candidates. Any failure to complete the development of our drug candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

A further discussion of some of the risks and uncertainties associated with completing our research and development programs on schedule, or at all, and some consequences of failing to do so, are set forth below in Part II, Item 1A Risk Factors.

General and Administrative. General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by us.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosures in the financial statements. Such estimates and judgments include the assumptions underlying the valuation of our warrant liability, carrying value of property and equipment and intangible assets, revenue recognition, the collectability of receivables and the value of certain investments and liabilities. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes to the probabilities underlying the assumptions used in valuing our warrant liability could materially impact our financial statements. Actual results may differ from these estimates under different assumptions or conditions. We set forth our critical accounting policies and estimates in our Annual Report on Form 10-K for the year ended December 31, 2010, which is on file with the SEC. There have been no material changes at June 30, 2011.

Recently Issued Accounting Standards

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 our consolidated financial statements.

Table of Contents

Results of Operations

Three-Month Periods Ended June 30, 2011 and June 30, 2010

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)
	2011	2010	
REVENUES:			
Research and development			
Genentech	$ 87,000	$ 85,000	2%
Other	6,000	14,000	(57%)
Subtotal	93,000	99,000	(6%)
License fees			
Other	300,000		100%
Total revenues	$ 393,000	$ 99,000	297%

Total revenues increased by $294,000, or 297%, to $393,000 for the three months ended June 30, 2010 as compared to $99,000 for the same period in the prior year, primarily as a result of the receipt of a $300,000 license fee payment during the second quarter of 2011. Research and development revenues are limited to expenses that we incur under our collaborations, primarily Genentech, for which our collaborators are obligated to reimburse us.

Research and Development Expenses. Research and development expenses are summarized as follows:

	For the Three Months Ended June 30,		Percentage Increase/
Research and Development Program	**2011**	**2010**	**(Decrease)**
Hedgehog pathway inhibitor	$ 48,000	$ 48,000	%
CUDC-101	1,123,000	369,000	204%
CUDC-907	659,000		100%
Debio 0932	17,000	2,000	750%
Other network-targeted cancer programs	1,108,000	1,751,000	(37%)
Sublicense fees	15,000		100%
Gain on sale of assets	(5,000)	(32,000)	(84%)
Stock-based compensation	179,000	107,000	67%
Total research and development expense	$ 3,144,000	$ 2,245,000	40%

Our research and development expenses increased by $899,000, or 40%, to $3,144,000 for the three months ended June 30, 2011 as compared to $2,245,000 for the same period in the prior year. The increase in research and development expenses is the result of a $754,000 increase in spending related to our CUDC-101 program. This increase primarily relates to outside services and clinical costs associated with several of our programs for CUDC-101, including our phase I expansion trial that is ongoing, initial costs related to a phase I trial in advanced head and neck cancers and manufacturing costs related to an oral formulation of CUDC-101. In addition, CUDC-907 was selected as a development candidate in January 2011and we have incurred costs of $659,000 related to this program during the three months ended June 30, 2011. Spending on our other network-targeted cancer programs decreased $643,000 when compared to the prior year period.

Stock-based compensation also increased $72,000 from the prior year period as a result of an increase in the grant date fair values of stock options expensed in the three months ended June 30, 2011 as compared to the three months ended June 30, 2010.

21

Table of Contents

General and Administrative Expenses. General and administrative expenses are summarized as follows:

	For the Three Months Ended June 30,		Percentage Increase/ (Decrease)
	2011	2010	
Personnel	$ 536,000	$ 580,000	(8%)
Occupancy and depreciation	113,000	87,000	30%
Legal services	524,000	400,000	31%
Consulting and professional services	250,000	309,000	(19%)
Insurance costs	62,000	64,000	(3%)
Other general and administrative expenses	200,000	170,000	18%
Stock-based compensation	183,000	170,000	8%
Total general and administrative expenses	$ 1,868,000	$ 1,780,000	5%

General and administrative expenses increased by $88,000, or 5%, to $1,868,000 for the three months ended June 30, 2011 as compared to $1,780,000 for the prior year period. This increase was primarily due to increased legal costs of $124,000 over the prior year period, specifically related to patent costs, and includes fees related to foreign patent filings. Offsetting this increase, consulting and professional services decreased $59,000 over the prior year period. For the three months ended June 30, 2010, we incurred consulting and professional services specifically related to the adoption of our 2010 Stock Incentive Plan and our 2010 Employee Stock Purchase Plan that were not incurred in the current year period.

We have not recorded any expense during the first half of 2011 for bonuses that our executive officers are eligible to receive based on performance objectives included in a 2011 short-term incentive program that was approved by our compensation committee in January 2011. The objectives included in this plan are primarily related to capital-raising objectives and we have determined that as of June 30, 2011, it is not probable that such objectives would be met. Potential bonuses under this plan total $475,000, of which $325,000 would be recorded in general and administrative expense and $150,000 would be recorded in research and development.

Change in Fair Value of Warrant Liability. In connection with our January 2010 registered direct offering, we issued warrants to purchase an aggregate of 1,612,322 shares of common stock which became exercisable as of the closing of the transaction. The warrants have an initial exercise price of $3.55 per share and have a five year term. The fair value of the warrants at the January 27, 2010 issuance and at December 31, 2010 was estimated at $2,181,000 and $1,605,000, respectively, using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective features of the warrants that include a possible cash-settlement option available to the warrantholder 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 an NDA for vismodegib. The fair value of the warrants was recorded as a long-term liability. The warrants will be revalued each reporting period, with the resulting gains and losses recorded as the change in fair value of warrant liability in the income statement. We 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 volatilities of 80%, risk free interest rates ranging from 0.8% to 1.1%, expected lives of three to four years and no dividends. We recorded a charge of $320,000 for the quarter ended June 30, 2011 as a result of the increase in the fair value of the warrant liability from March 31, 2011, primarily related to the increase in our stock price during this period.

We estimated that the fair value of these warrants as of June 30, 2010 was $1,290,000. We recorded a gain of approximately $1,797,000 for the three months ended June 30, 2010 as a result of the decrease in the fair value of the warrant liability from March 31, 2010.

Table of Contents

Six-Month Periods Ended June 30, 2011 and June 30, 2010

Revenues. Total revenues are summarized as follows:

	For the Six Months Ended June 30,		Percentage Increase/ (Decrease)
	2011	2010	
REVENUES:			
Research and development			
Genentech	$ 182,000	$ 141,000	29%
Other	44,000	40,000	10%
Subtotal	226,000	181,000	25%
License fees			
Debiopharm		8,333,000	(100%)
Micromet		4,000,000	(100%)
Other	300,000	143,000	110%
Subtotal	300,000	12,476,000	(98%)
Total revenues	$ 526,000	$ 12,657,000	(96%)

Total revenues decreased by $12,131,000, or 96%, to $526,000 for the six months ended June 30, 2011 as compared to $12,657,000 for the same period in 2010, primarily related to a decrease in our license fee revenues of $12,176,000. During the six months ended June 30, 2010, we recorded license fee revenue of $8,333,000 related to our Debiopharm agreement, primarily comprised of an $8,000,000 contingent payment we received from Debiopharm upon acceptance by French regulatory authorities of Debiopharm s clinical trial application for Debio 0932. During the six months ended June 30, 2010, we also received settlement proceeds of $4,000,000 from Micromet pursuant to a settlement, mutual release and termination agreement that we entered into with Micromet in February 2010. Research and development revenues are limited to expenses that we incur under our collaborations for which our collaborators are obligated to reimburse us.

Future contingent payments under our Genentech and Debiopharm agreements are tied to clinical and regulatory objective milestones. Based on the positive outcome of the pivotal phase II study in advanced basal cell carcinoma patients, Roche has indicated that it anticipates filing an NDA with the 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 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 provided that the regulatory agencies approve the respective regulatory submission as well as royalties on any future sales of vismodegib.

Research and Development Expenses. Research and development expenses are summarized as follows:

	For the Six Months Ended June 30,		Percentage Increase/
Research and Development Program	**2011**	**2010**	**(Decrease)**
Hedgehog pathway inhibitor	$ 97,000	$ 97,000	%
CUDC-101	2,217,000	714,000	211%
CUDC-907	1,355,000		100%
Debio 0932	24,000	24,000	%
Other network-targeted cancer programs	2,187,000	3,587,000	(39%)
Sublicense fees	15,000		100%
Gain on sale of assets	(36,000)	(93,000)	(61%)

Stock-based compensation	344,000	384,000	(10%)
Total research and development expense	$ 6,203,000	$ 4,713,000	32%

Our research and development expenses increased by $1,490,000, or 32%, to $6,203,000 for the six months ended June 30, 2011 as compared to $4,713,000 for the same period in the prior year. This increase was related to offsetting variances within our programs. The increase in research and development expenses is the result of a $1,503,000 increase in spending related to