CURIS INC
Form 10-Q
October 31, 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 SEPTEMBER 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 October 27, 2011, there were 76,580,368 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)

	September 30, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,884,253	$ 7,826,549
Marketable securities	16,474,181	32,553,269
Short-term investment restricted		219,458
Accounts receivable	137,313	92,371
Prepaid expenses and other current assets	675,996	392,249
Total current assets	29,171,743	41,083,896
Property and equipment, net	475,469	302,721
Long-term investment restricted	235,914	277,546
Goodwill	8,982,000	8,982,000
Other assets	2,980	2,980
Total assets	$ 38,868,106	$ 50,649,143
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,331,767	$ 2,620,968
Accrued liabilities	1,148,468	854,605
Total current liabilities	3,480,235	3,475,573
Warrants	2,839,408	1,604,742
Other long-term liabilities	141,654	51,171
Total liabilities	6,461,297	5,131,486
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 77,623,388 shares issued and 76,575,681 shares outstanding at September 30, 2011; and 76,803,868 shares issued and 75,756,161 shares outstanding at December 31, 2010	776,234	768,039
Additional paid-in capital	770,648,639	767,825,232
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation		(955)
Accumulated deficit	(738,149,517)	(722,228,747)
Accumulated other comprehensive income	22,727	45,362
Total stockholders equity	32,406,809	45,517,657
Total liabilities and stockholders equity	$ 38,868,106	$ 50,649,143

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES

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

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
REVENUES:				
License fees	$	$ 3,180,000	$ 300,000	$ 15,655,833
Research and development	147,122	62,310	373,527	243,445
Total revenues	147,122	3,242,310	673,527	15,899,278
COSTS AND EXPENSES:				
Research and development	3,042,251	3,008,594	9,244,800	7,721,140
General and administrative	1,921,206	1,998,701	6,196,337	8,205,523
Total costs and expenses	4,963,457	5,007,295	15,441,137	15,926,663
Loss from operations	(4,816,335)	(1,764,985)	(14,767,610)	(27,385)
OTHER INCOME:				
Interest income	22,596	42,686	81,506	100,729
Change in fair value of warrant liability	587,184	207,500	(1,234,666)	1,098,135
Total other income/(expense)	609,780	250,186	(1,153,160)	1,198,864
Net (loss)/income	$ (4,206,555)	$ (1,514,799)	$ (15,920,770)	$ 1,171,479
Basic net (loss)/income per common share	$ (0.05)	$ (0.02)	$ (0.21)	$ 0.02
Diluted net (loss)/income per common share	$ (0.05)	$ (0.02)	$ (0.21)	$ 0.02
Basic weighted average common shares	76,543,074	75,623,465	76,251,709	74,720,168
Diluted weighted average common shares	76,543,074	75,623,465	76,251,709	77,400,608
Net (loss)/income	$ (4,206,555)	$ (1,514,799)	$ (15,920,770)	$ 1,171,479
Unrealized (loss)/gain on marketable securities	(10,977)	10,172	(22,635)	32,958
Comprehensive (loss)/income	$ (4,217,532)	$ (1,504,627)	$ (15,943,405)	$ 1,204,437

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)/income	$ (15,920,770)	$ 1,171,479
Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities:		
Depreciation and amortization	76,753	521,821
Stock-based compensation expense	1,351,500	1,664,063
Change in fair value of warrant liability	1,234,666	(1,098,135)
Non-cash interest income	299,653	(19,843)
Gain on sale of assets	(59,651)	
Changes in current assets and liabilities:		
Accounts receivable	(44,942)	320,762
Prepaid expenses and other assets	(283,747)	81,642
Accounts payable and accrued liabilities	95,145	(76,435)
Deferred revenue		(475,833)
Total adjustments	2,669,377	918,042
Net cash (used in)/provided by operating activities	(13,251,393)	2,089,521
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(32,236,817)	(53,897,181)
Sale of marketable securities	47,993,617	39,625,916
Decrease/(increase) in restricted cash	261,090	(281,002)
Proceeds from sale of assets	59,651	
Purchases of property and equipment	(249,501)	(95,743)
Net cash provided by/(used in) investing activities	15,828,040	(14,648,010)
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 issuance of common stock and exercise of warrants, net of issuance costs of $123,000	1,481,057	1,954,724
Net cash provided by financing activities	1,481,057	16,897,041
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,057,704	4,338,552
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	7,826,549	7,275,433
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 11,884,253	$ 11,613,985

See accompanying notes to unaudited condensed consolidated financial statements.

5

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 September 30, 2011 should enable the Company to maintain its current and planned operations into the fourth quarter of 2012, excluding any potential near-term milestones from its collaborations (see Note 5). 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, which includes the Company s at-the-market sales agreement discussed in Note 8, new collaborations or other sources of financing. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company cannot assure that it will attain any further revenue under any collaborations or licensing arrangements. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

2. Basis of Presentation

The accompanying 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 September 30, 2011, the results of operations for the three- and nine-month periods ended September 30, 2011 and 2010 and cash flows for the nine-month periods ended September 30, 2011 and 2010. The preparation of the Company s Condensed Consolidated Financial Statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities, including the value of its warrant liability. Actual results may differ from such estimates.

Table of Contents

These interim results are not necessarily indicative of results to be expected for a full year or subsequent interim periods.

3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of these agreements may provide for the Company s licensees and collaborators to agree to make 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 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 for this agreement. The performance period concluded during the first quarter of 2010, resulting in the recognition by the Company of $333,000 in license fee revenue during the nine-month period ended September 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, and $3,000,000 in July 2010 upon Debiopharm s treatment of the fifth patient in its ongoing phase I clinical trial. The Company recorded $3,000,000 and $11,333,000, respectively, as revenue within License Fees in the Revenues section of its Condensed Consolidated Statement of Operations for the three and nine months ended September 30, 2010, respectively, because the Company has no ongoing material performance obligations under the agreement.

5. Genentech, Inc. June 2003 Collaboration

In September 2011, the Company s collaborator Genentech, a member of the Roche Group, submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking sales and marketing approval for vismodegib (GDC-0449, RG3616) to treat people with advanced basal cell carcinoma (BCC), for whom surgery is considered inappropriate. Vismodegib is a first-in-class, investigational, oral medicine designed to selectively inhibit signaling in the Hedgehog pathway and is being developed by Genentech under a collaboration agreement with the Company. The Company currently expects that the FDA will respond to Genentech s submission in early November 2011. Provided that the FDA accepts and files for review this NDA submission, the Company will earn an $8,000,000 milestone payment from Genentech. The Company intends to recognize this payment as license revenue during the fourth quarter of 2011 because the Company does not have any further substantive performance obligations under the collaboration. If vismodegib receives FDA approval, the Company will also be entitled to receive an additional milestone payment as well as royalties on any future sales.

6. 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 payment within the License fee revenue line item in the Consolidated Statement of Operations for the nine months ended September 30, 2010. During the first quarter of 2010, the Company incurred approximately $1,526,000 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 nine months ended September 30, 2010.

Table of Contents

7. 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.

Financial Accounting Standards Board (FASB) Codification Topic 820, *Fair Value Measurements and Disclosures,* requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. GAAP also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. 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 $10,844,000 and $16,474,000, respectively, as of September 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 $236,000 as of September 30, 2011 and $278,000 as of 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 the long-term investment was reduced by $42,000 during the third quarter of 2011 in accordance with the terms of the Company s lease. The restriction on a prior short-term restricted investment of $219,000 at December 31, 2010 was discharged 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 September 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 nine-month periods ending September 30, 2011 and 2010. In accordance with the fair value hierarchy, the following table shows the fair value as of September 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 September 30, 2011 and December 31, 2010.

Table of Contents

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of September 30, 2011:				
Cash equivalents				
Money market funds	$ 8,154,000	$	$	$ 8,154,000
Municipal bonds	2,690,000			2,690,000
Marketable securities				
US government obligations	2,657,000			2,657,000
Corporate commercial paper, bonds and notes	13,817,000			13,817,000
Restricted investment (certificate of deposit)	236,000			236,000
Total assets at fair value	$ 27,554,000	$	$	$ 27,554,000
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

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 nine months ended September 30, 2010 and 2011:

Balance at December 31, 2009	$
Issuance of warrants	2,180,000
Change in fair value for the nine months ended September 30, 2010	(1,098,000)
Balance at September 30, 2010	$ 1,082,000
Balance at December 31, 2010	$ 1,605,000
Change in fair value for the nine months ended September 30, 2011	1,234,000
Balance at September 30, 2011	$ 2,839,000

8. 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 without limitation sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock 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

Table of Contents

to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. Since the inception of the ATM agreement, the Company has sold 65,527 shares of common stock under the ATM agreement resulting in gross proceeds of $262,000. Total offering expenses, including MLV s commission, incurred related to the ATM agreement through September 30, 2011 were approximately $123,000, which offset the gross proceeds.

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 September 30, 2011 and December 31, 2010. The Company estimated that the fair value of the warrants at issuance was $2,180,000 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 September 30, 2011 was $2,839,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatility of 80%, risk free interest rates ranging from 0.4% to 0.5%, expected lives of three years, and no dividends. The Company estimated that the fair value of the warrants at September 30, 2010 was $1,082,000 using the following assumptions assigned to the varying outcomes: expected volatilities of 77.7% and 95.2%, risk free interest rates ranging from 0.6% to 1.1%, expected lives of three to four 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 Condensed Consolidated Statement of Operations and Comprehensive (Loss)/Income.

The Company recorded other income of $587,000 and other expense of $1,234,000 for the three and nine months ended September 30, 2011, respectively, and other income of $208,000 and $1,098,000 for the three and nine months ended September 30, 2010, respectively, as a result of the change in the fair value of the warrant liability. These changes are primarily due to changes in the Company s stock price during the respective reporting periods.

9. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2011	December 31, 2010
Accrued compensation	$ 678,000	$ 539,000
Professional fees	160,000	143,000
Facility-related costs	146,000	34,000
Other	164,000	139,000
Total	$ 1,148,000	$ 855,000

10. Accounting for Stock-Based Compensation

As of September 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

Table of Contents

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 nine months ended September 30, 2011 and consistent with past practices, the Company s board of directors granted options to purchase 867,000 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 nine months ended September 30, 2011, the Company s board of directors also granted options to its non-employee directors to purchase 260,000 shares of common stock under the 2010 Stock Incentive Plan. Of this amount, options to purchase 235,000 shares of common stock were fully vested on the January 7, 2011 grant date and options to purchase 25,000 shares of common stock will vest over a four-year period. All of these options bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the respective grant dates.

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 nine months ended September 30, 2011 and 2010 using the Black-Scholes valuation model based on the assumptions noted in the following table:

	For the nine months ended September 30,	
	2011	2010
Expected term (years) - Employees	6	6
Expected term (years) - Directors	6	6
Risk-free interest rate	1.2-2.5%	2.6-2.8%
Volatility	73-75%	69%
Dividends	None	None

The expected volatility is based on the annualized daily historical volatility of the Company s stock price through the grant date for a time period consistent with the expected term of 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 interest 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 September 30, 2011 was $14,298,000, of which $11,805,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2011 and 2010 were $1.45 and $1.46, respectively. As of September 30, 2011, there was approximately $2,254,000, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee and director stock option awards outstanding under the 2000 and 2010 Stock Incentive Plans that is expected to be recognized as expense over a weighted average period of 2.23 years. The intrinsic values of employee stock options exercised during the nine months ended September 30, 2011 and 2010 were $835,000 and $124,000, respectively. The total fair values of vested stock options for the nine months ended September 30, 2011 and 2010 were $1,218,000 and $2,030,000, respectively.

The Company recorded $299,000 and $1,311,000 in compensation expense for the three and nine months ended September 30, 2011, respectively, and the Company recorded $317,000 and $1,680,000 in compensation expense for the three and nine months ended September 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

11

Table of Contents

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 $477,000 in additional stock compensation expense during the nine months ended September 30, 2010.

Non-Employee Grants

The Company has periodically granted stock options and unrestricted stock awards to consultants for services. During the nine months ended September 30, 2011, the Company issued options to purchase a total of 125,000 shares of common stock to the chairman of the Company s Clinical and Scientific Advisory Board. These options were issued pursuant to the 2010 Stock Incentive Plan at an exercise price equal to the fair market value of the common stock on the dates of grant and will vest over a four-year period from the respective date of grant. Should the Company terminate the consulting agreement, any unvested options will be cancelled. All 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 $41,000 related to non-employee stock options for the three and nine months ended September 30, 2011, respectively. The Company recorded no expense related to non-employee stock options for the three months ended September 30, 2010 and reversed expense of $16,000 for the nine months ended September 30, 2010, as a result of a decline in the Company s stock price during the period.

Total Stock-Based Compensation Expense

For the three and nine months ended September 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 Income (Loss):

	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
Research and development expenses	$ 135,000	$ 145,000	$ 479,000	$ 529,000
General and administrative expenses	177,000	172,000	873,000	1,135,000
Total stock-based compensation expense	$ 312,000	$ 317,000	$ 1,352,000	$ 1,664,000

The table below summarizes options outstanding and exercisable under the 2010 Stock Incentive Plan, the 2000 Stock Incentive Plan and the 2000 Director Stock Option Plan at September 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 - $ 1.39	3,617,996	6.03	$ 1.19	3,219,430	$ 1.21
1.43 - 1.57	2,492,805	4.54	1.50	2,372,178	1.50
1.67 - 2.27	2,495,125	8.20	2.17	961,561	2.12
2.43 - 4.56	2,618,188	2.87	3.42	2,431,875	3.43
4.75 - 5.60	261,000	2.18	5.04	261,000	5.04
	11,485,114	5.37	$ 2.07	9,246,044	$ 2.07

11. 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 (loss) 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.

Table of Contents

Diluted net loss per common share is the same as basic net loss per common share for the three and nine months ended September 30, 2011, as well as for the three months ended September 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 the respective reporting periods as follows:

	For the three and nine months ended September 30, 2011	For the three months ended September 30, 2010
Stock options outstanding	11,485,114	11,879,750
Warrants outstanding	1,610,818	1,612,322
Total antidilutive securities	13,095,932	13,492,072

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

	For the nine months ended September 30, 2010
Weighted average shares for basic EPS	74,720,168
Dilutive securities:	
Warrants	156,633
Stock options	2,523,807
Subtotal of dilutive securities	2,680,440
Weighted average shares for diluted EPS	77,400,608

The weighted-average diluted shares outstanding for the nine months ended September 30, 2010 excludes the dilutive effect of approximately 3,789,171 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.

12. Recent Accounting Pronouncements

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance was effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The adoption of this guidance on January 1, 2011 did not materially change the Company s previous method of recognizing milestone payments and the adoption did not have a material impact on the Company s financial statements.

In June 2011, the 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.

In September 2011, the FASB issued an Accounting Standards Update (ASU) which simplifies how companies test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in goodwill accounting standard. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. The Company does not expect the new ASU to have a material effect on its financial position, results of operations or cash flows.

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 certain cancers, including basal cell carcinoma (BCC). Abnormal signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

In September 2011, Genentech submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking sales and marketing approval for vismodegib to treat people with advanced BCC, which includes BCC patients for whom surgery is considered inappropriate. We currently expect that the FDA will respond to Genentech s submission in early November 2011. Provided that the FDA accepts and files for review this NDA submission, we will earn an $8,000,000 milestone payment from Genentech. We intend to recognize this $8,000,000 payment as license revenue during the fourth quarter of 2011 because we do not have any further substantive performance obligations under the collaboration. If vismodegib receives FDA approval, we will also be entitled to receive an additional milestone payment as well as royalties on any future sales.

Genentech s NDA application was based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of vismodegib in patients with advanced BCC. 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. 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. ERIVANCE BCC/SHH4476g 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.

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

Table of Contents

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 locally advanced BCC cohort and 30% of patients in the metastatic BCC cohort. 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, 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 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 for milestone payments upon EMA acceptance of such submission and EMA approval to commercialize vismodegib in Europe as well as royalties on any future sales of vismodegib.

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). We expect that data will be available from this trial later this year or early in 2012. We also anticipate that Genentech will provide us with its plans for future development in operable BCC within this timeframe and we look forward to providing further updates on this in the future.

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.

Table of Contents

Network-Targeted Cancer Programs

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

CUDC-101. Our lead candidate from these programs is CUDC-101, a first-in-class small molecule compound designed to simultaneously target 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 CUDC-101 in 25 patients with advanced, refractory solid tumors and we have completed enrollment in a phase I expansion trial to test CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The phase I expansion trial 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 via one-hour intravenous infusion either on a five days per week schedule (one week on/one week off) or on a three days per week schedule (three weeks on/one week off).

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 remained on study for nearly one year of treatment, while two additional patients achieved stable disease for approximately four months prior to disease progression.

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, and in August 2011 we treated the first patient in this study. 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 has the potential to 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 begin a phase I study of an oral formulation of CUDC-101 during the first half of 2012.

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 during the first half of 2012.

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

Hsp90 Program

Debio 0932. Our heat shock protein 90, or Hsp90, program is being developed by Debiopharm, a Swiss pharmaceutical development company, under an August 2009 license agreement between Curis and Debiopharm. The lead molecule under this license collaboration was designated Debio 0932 by Debiopharm. In April 2010, Debiopharm treated the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients suffering from advanced solid tumors. Debiopharm is finalizing this phase I dose escalation study and has indicated that it intends to initiate a phase Ib expansion study in particular tumor types in early 2012.

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, debt financings and the monetization of certain royalty rights. We have never been profitable and have an accumulated deficit of $738,150,000 as of September 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 receipt of FDA approval to commercialize vismodegib in advanced BCC as well as its ability to successfully launch and commercialize vismodegib in the US market;
- Roche s ability to make regulatory submissions to the EMA seeking the approval to commercialize vismodegib in advanced BCC in Europe and to have such filing approved by the EMA;
- Debiopharm s ability to advance Debio 0932 into later stages of clinical development;
- our ability to successfully plan, finance and complete clinical trials for CUDC-101 and advance CUDC-101 into later stages of clinical development in indications other than head and neck cancers;
- our ability to successfully advance early-stage development candidates, such as CUDC-907;
- our ability to successfully enter into one or more material licenses or collaboration agreements for 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.

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 September 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. Assuming we receive the $8,000,000 milestone from Genentech upon FDA acceptance of the vismodegib NDA, we will be obligated to pay $400,000 to these licensors. 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 that existing capital resources as of September 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.

Table of Contents

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.

Revenues. We do not expect to generate any revenues 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.

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 submitted
- 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 submitted means that Genentech filed an NDA with the FDA in September 2011 and, pending planned discussions with the EMA, will 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

Table of Contents

tested. Phase I means that we (CUDC-101) and Debiopharm (Debio 0932) 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.

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 September 30, 2011.

Table of Contents

Recently Issued Accounting Standards

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance was effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The adoption of this guidance on January 1, 2011 did not materially change our previous method of recognizing milestone payments and the adoption did not have a material impact on our financial statements.

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.

In September 2011, the FASB issued an Accounting Standards Update (ASU) which simplifies how companies test goodwill for impairment. The amendments permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in goodwill accounting standard. The amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted. We do not expect the new ASU to have a material effect on our financial position, results of operations or cash flows.

Table of Contents

Results of Operations

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

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
REVENUES:			
Research and development			
Genentech	$ 135,000	$ 55,000	145%
Other	12,000	7,000	71%
Subtotal	147,000	62,000	137%
License fees			
Debiopharm		3,000,000	(100%)
Other		180,000	(100%)
Subtotal		3,180,000	(100%)
Total revenues	$ 147,000	$ 3,242,000	(95%)

Total revenues decreased by $3,095,000, or 95%, for the three months ended September 30, 2011 as compared to the same period in 2010, primarily related to a decrease in license fee revenues of $3,180,000. We recognized no license fee revenue under our collaborations for the three months ended September 30, 2011. During the three months ended September 30, 2010, we recorded license fee revenues of $3,000,000 which represented a contingent payment from Debiopharm upon treatment of the fifth patient in its phase I clinical trial in July 2010. 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:

Research and Development Program	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
Hedgehog pathway inhibitor	$ 48,000	$ 48,000	%
CUDC-101	901,000	1,070,000	(16%)
CUDC-907	735,000		100%
Debio 0932	5,000	10,000	(50%)
Other network-targeted cancer programs	1,241,000	1,738,000	(29%)
Gain on sale of assets	(23,000)	(2,000)	1,050%
Stock-based compensation	135,000	145,000	(7%)
Total research and development expense	$ 3,042,000	$ 3,009,000	1%

Our research and development expenses increased by $33,000, or 1%, for the three months ended September 30, 2011 as compared to the same period in the prior year. The increase in research and development expenses is the result of a $735,000 increase in spending related to our CUDC-907 program as a result of shifting resources from our other network-targeted cancer programs, which decreased $497,000 when

compared to the prior year period. CUDC-907 was selected as a development candidate in January 2011.

Further offsetting the increase in spending on our CDCU-907 program, spending on our CUDC-101 program decreased $169,000 when compared to the prior year period which is attributed to several ongoing programs. Spending related to our phase Ia and the expansion trials of CUDC-101 decreased by $929,000 for the three month period ending September 30, 2011 primarily related to decreased outside services and clinical costs consisting of formulation and manufacturing costs of clinical material, clinical research organizations and patient costs. The phase I expansion of CUDC-101 trial had only one

Table of Contents

remaining patient at September 30, 2011, as the trial was fully enrolled. In contrast, spending related to our phase I trial in advanced head and neck cancers initiated during the second quarter of 2011 and for an oral formulation of CUDC-101 increased by an aggregate of $761,000.

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

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
Personnel	$ 612,000	$ 625,000	(2%)
Occupancy and depreciation	121,000	84,000	44%
Legal services	540,000	493,000	10%
Consulting and professional services	247,000	410,000	(40%)
Insurance costs	65,000	67,000	(3%)
Other general and administrative expenses	159,000	148,000	7%
Stock-based compensation	177,000	172,000	3%
Total general and administrative expenses	$ 1,921,000	$ 1,999,000	(4%)

General and administrative expenses decreased by $78,000, or 4%, for the three months ended September 30, 2011 as compared to the prior year period. This decrease was primarily due to decreased consulting and professional services of $163,000. For the three months ended September 30, 2010, we incurred consulting and professional services specifically related to business development efforts used to facilitate the licensing agreement with Debiopharm due upon receipt of the $3,000,000 payment we received in July 2010 that were not incurred in the current year period. Offsetting this decrease, legal costs increased by $47,000 over the prior year period, specifically related to patent costs which includes fees related to foreign patent filings.

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 $2,180,000 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 September 30, 2011 was $2,839,000 using this same model with the following assumptions assigned to the varying outcomes: expected volatility of 80%, risk free interest rates ranging from 0.4% to 0.5%, expected lives of three years and no dividends. We recorded a gain of $587,000 for the quarter ended September 30, 2011 as a result of the decrease in the fair value of the warrant liability from June 30, 2011, primarily related to the decrease in our stock price during this period. We estimated that the fair value of these warrants as of September 30, 2010 was $1,082,000. We recorded a gain of approximately $208,000 for the three months ended September 30, 2010 as a result of the decrease in the fair value of the warrant liability from June 30, 2010.

Table of Contents

Nine-Month Periods Ended September 30, 2011 and September 30, 2010

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
REVENUES:			
Research and development			
Genentech	$ 317,000	$ 196,000	62%
Other	57,000	47,000	21%
Subtotal	374,000	243,000	54%
License fees			
Debiopharm		11,333,000	(100%)
Micromet		4,000,000	(100%)
Other	300,000	323,000	(7%)
Subtotal	300,000	15,656,000	(98%)
Total revenues	$ 674,000	$ 15,899,000	(96%)

Total revenues decreased by $15,225,000, or 96%, for the nine months ended September 30, 2011 as compared to the same period in 2010, primarily related to a decrease in our license fee revenues of $15,356,000. During the nine months ended September 30, 2010, we recorded license fee revenues under our license agreement with Debiopharm, primarily comprised of an $8,000,000 contingent payment from Debiopharm upon acceptance by French regulatory authorities of its clinical trial application for Debio 0932 in February 2010 and a $3,000,000 contingent payment upon treatment of the fifth patient in this phase I clinical trial in July 2010. During the nine months ended September 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.

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

Research and Development Program	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
Hedgehog pathway inhibitor	$ 144,000	$ 145,000	(1%)
CUDC-101	3,119,000	1,782,000	75%
CUDC-907	2,090,000		100%
Debio 0932	30,000	35,000	(14%)
Other network-targeted cancer programs	3,428,000	5,326,000	(36%)
Sublicense fees	15,000		100%
Gain on sale of assets	(60,000)	(96,000)	(38%)
Stock-based compensation	479,000	529,000	(9%)

Total research and development expense	$ 9,245,000	$ 7,721,000	20%

Our research and development expenses increased by $1,524,000, or 20%, for the nine months ended September 30, 2011 as compared to the same period in the prior year. This increase was related to changes within our programs. The increase in research and development expenses is the result of a $1,337,000 increase in spending related to our CUDC-101 program, which 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 and toxicology costs related to an oral formulation of CUDC-101. In addition, CUDC-907 was selected as a development candidate in January 2011 and we incurred costs of $2,090,000 related to this program as a result of shifting resources from our other network-targeted cancer programs, which decreased $1,898,000 when compared to the prior year period. We expect that a majority of our research and development expenses for the foreseeable future will be incurred in support of our efforts to advance CUDC-101, CUDC-907 and our other targeted cancer programs.

Table of Contents

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

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2011 (unaudited)	2010 (unaudited)	
Personnel	$ 1,720,000	$ 2,033,000	(15%)
Occupancy and depreciation	363,000	254,000	43%
Legal services	1,642,000	3,011,000	(45%)
Consulting and professional services	831,000	1,029,000	(19%)
Insurance costs	189,000	194,000	(3%)
Other general and administrative expenses	578,000	550,000	5%
Stock-based compensation	873,000	1,135,000	(23%)
Total general and administrative expenses	$ 6,196,000	$ 8,206,000	(24%)

General and administrative expenses decreased by $2,010,000, or 24%, for the nine months ended September 30, 2011 as compared to the prior year period. This decrease was related to a reduction in spending in several areas, primarily for legal services and employee-related costs. During the nine months ended September 30, 2010, we incurred approximately $1,526,000 in expenses related to an arbitration proceeding that we filed against our former collaborator that we did not incur in the current period. In addition, legal costs associated with various matters decreased $175,000 from the prior year period. Offsetting these decreases in legal spending, our patent-related costs increased $370,000 in the nine months ended September 30, 2011 as compared to the prior year period primarily related to fees for foreign patent filings.

Personnel costs decreased $313,000 primarily due to the payment of discretionary bonuses to our executive officers upon receipt of the $8,000,000 payment from Debiopharm in March 2010. Stock-based compensation also decreased $262,000 from the prior year period primarily related to vesting of certain performance-based stock options in the first quarter of 2010 that did not occur during the current year period. Offsetting these decreases, our allocated occupancy costs increased $109,000 for the nine months ended September 30, 2011.

Change in fair value of warrant liability. The fair value of the warrants issued in connection with our January 2010 registered direct offering at the January 27, 2010 issuance and at December 31, 2010 was estimated at $2,180,000 and $1,605,000, respectively. We estimated that the fair value of the warrants at September 30, 2011 was $2,839,000 using a Black-Scholes option pricing model with the following assumptions assigned to the varying probability-weighted outcomes: expected volatility of 80%, risk free interest rates ranging from 0.4% to 0.5%, expected lives of three years and no dividends. We recorded a charge of $1,235,000 for the nine months ended September 30, 2011 as a result of the increase in the fair value of the warrant liability from December 31, 2010, primarily related to the increase in our stock price during this period.

We estimated that the fair value of these warrants as of September 30, 2010 was $1,082,000 and we recorded a gain of approximately $1,098,000 for the nine months ended September 30, 2010 as a result of the decrease of our stock price during this period from January 27, 2010.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations to date primarily through license fees, contingent cash payments and research and development funding from our collaborators and licensors, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights.

On June 13, 2011, we entered into an At Market Issuance Sales Agreement, or ATM agreement, with McNicoll, Lewis & Vlak LLC, or MLV, pursuant to which we may issue and sell shares of our common stock, $0.01 par value per share, with an aggregate offering price of up to $20,000,000 from time to time through MLV. 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 without limitation, sales made directly on The NASDAQ Global Market, on any other existing trading market for the common stock or to or through a

24

Table of Contents

market maker. With our prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. We 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. We will pay MLV a commission equal to 3.0% of the gross sales price per share sold, and we have agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. Since the inception of the ATM agreement, we have sold 65,527 shares of common stock under the ATM agreement raising approximately $262,000 in gross proceeds, which was offset by offering expenses of approximately $123,000.

At September 30, 2011, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of $28,358,000, excluding our restricted investment of $236,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We maintain cash balances with financial institutions in excess of insured limits.

Cash Flows

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees and legal fees. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-101 advances into further stages of clinical testing and other of our targeted cancer drug candidates, including CUDC-907, reach clinical trials.

Operating activities used cash of $13,251,000 for the nine-month period ended September 30, 2011 as compared to cash provided by operating activities was $2,090,000 for the nine-month period ended September 30, 2010. Net cash used in operating activities during the nine-month period ended September 30, 2011 was primarily the result of our net loss for the period of $15,921,000. In addition, changes in certain operating assets affected operating cash during the nine-month period ended September 30, 2011, including an increase of $284,000 in prepaid expenses primarily related to advance payments made to vendors related to toxicology studies and formulation costs for our programs under development. These decreases were offset by non-cash charges and credits totaling $2,903,000 consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, depreciation and a gain on the sale of assets.

Cash provided by operating activities during the nine-month period ended September 30, 2010 was primarily the result of our net income for the period of $1,171,000, as well as non-cash charges consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense and depreciation totaling $1,068,000. In addition, changes in certain operating assets and liabilities affected operating cash during the nine-month period ended September 30, 2010, including a decrease of $476,000 in deferred revenue primarily related to our August 2009 license agreement with Debiopharm, which was offset by a decrease of $321,000 in our accounts receivable.

We expect to continue to use cash in operations as we continue to seek to advance our targeted cancer drug programs through preclinical testing and into clinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and other specified objectives.

Investing activities provided cash of $15,828,000 for the nine-month period ended September 30, 2011 and used cash of $14,648,000 for the nine-month period ended September 30, 2010, resulting primarily from net investment activity for the respective periods. During the nine-month period ended September 30, 2011, the restriction on our short-term investment ended and we reduced our long-term restricted investment resulting in an increase in our available cash for the period of $261,000. This increase in cash was offset by purchases of research equipment totaling $250,000 during the nine-month period ended September 30, 2011.

Financing activities provided cash of $1,481,000 for the nine-month period ended September 30, 2011, principally from the exercise of stock options and warrants and purchases of common stock under our employee stock purchase plan. We also received $139,000 in net proceeds from sales of common stock under our ATM agreement with MLV. Financing activities provided cash of approximately $16,897,000 for the nine-month period ended September 30, 2010, resulting principally from the issuance of 6,449,288 shares of common stock and warrants under our January 2010 registered direct offering, which provided $14,942,000 in net proceeds. In addition, warrants for an aggregate of 1,742,671 shares of common stock were exercised under our August 2007 private placement providing approximately $1,778,000 in proceeds. The remaining cash of $177,000 was provided by the exercise of stock options.

Table of Contents

Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2011, we had an accumulated deficit of approximately $738,150,000. We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for working capital to support our research and development activities for CUDC-101, CUDC-907 and other small molecules that we are seeking to develop from our pipeline of network-targeted cancer programs, and to fund our general and administrative costs and expenses.

Our ability to finance our company and to generate revenues will depend heavily on the ability of vismodegib to be approved for commercial sale by the FDA and/or the EMA, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales. Moreover, we have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. However, we have no current source of research funding revenue. We expect that our only source of cash flows from operations for the foreseeable future will be:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements;
- contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech and Debiopharm; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations.

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. As a result, we cannot assure you that we will attain any further revenue under any collaborations or licensing arrangements.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at September 30, 2011, should enable us to maintain current and planned operations into the fourth quarter of 2012. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and

unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

We may seek additional funding through public or private financings of debt or equity, including, but not limited to, sales under our ATM agreement with MLV. For example, in June 2011 we entered into an agreement with MLV pursuant to which, from time to time, we may offer and sell up to $20 million of common stock through MLV pursuant to one or more at the market offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and the market for our common stock in particular, are highly volatile. Due to this and various other factors, including currently adverse general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

Table of Contents

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2011.

Inflation

We believe that inflation has not had a significant impact on our revenue and results of operations since inception.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to the information provided under Item 7A Quantitative and Qualitative Disclosures About Market Risk set forth in our Annual Report on Form 10-K for the year ended December 31, 2010.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls & Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2011. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q and in other documents we file with the SEC, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors include material changes to, and restate and supersede, the risk factors previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2010.

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

The successful development of our most advanced product candidate, vismodegib, is important to our success as a company. If Genentech does not successfully continue or complete the clinical development and regulatory approval process for vismodegib, our future prospects and our ability to finance our operations may be substantially harmed.

Our near-term prospects substantially depend upon Genentech s ability to successfully continue and complete clinical trials and regulatory submissions of our lead product candidate, vismodegib (GDC-0449, RG3616) and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. Genentech, a member of the Roche Group, filed a new drug application, or NDA, with the United States Food and Drug Administration, or FDA, in September 2011 to seek approval to commercialize vismodegib in the United States for the treatment of advanced basal cell carcinoma, or BCC. We expect that the FDA will notify Genentech whether its NDA submission has been accepted for filing within 60 days of submission. Assuming the FDA accepts the NDA submission, the FDA will communicate its expected timeframe for review of the submission to Genentech. 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. Roche is also testing vismodegib in a phase II clinical trial in operable BCC. 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.

Our ability to finance our company and to generate revenues will depend heavily on the ability of Genentech and Roche to: (i) successfully file regulatory submissions for, and obtain approval to sell, vismodegib in the U.S. and Europe for advanced BCC, (ii) obtain favorable results in the ongoing and planned clinical trials of vismodegib, including the ongoing clinical trial in operable BCC, and (iii) successfully develop and commercialize vismodegib in one or more indications. The development and commercialization of vismodegib could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in clinical trials, or otherwise does not meet applicable regulatory standards for approval;
- does not offer sufficient, clinically meaningful therapeutic or other improvements over existing or future drugs used to treat the cancer indications for which it is being tested, as occurred in Genentech s phase II clinical trials of vismodegib in colorectal cancer and ovarian cancer that were completed in 2010;
- is not capable of being produced in commercial quantities at acceptable costs; or
- is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payors.

If Genentech is not successful in developing and commercializing vismodegib or is significantly delayed in doing so, our financial condition and future prospects may be adversely affected, we may experience difficulties in raising the substantial additional capital required to fund our business and our stock price may decline.

The therapeutic efficacy of drug candidates being developed in our network-targeted cancer programs is unproven in humans, and we may not be able to successfully develop and commercialize CUDC-101 or any other future drug candidates that we may select from these programs.

Our internal drug development efforts are focused on our proprietary network-targeted cancer programs. These programs focus on the development of single-agent drug candidates targeting one or more molecular components within signaling pathways associated with certain cancers. We are also seeking to develop single-agent, single-target drug candidates for cancer indications. We have currently selected three drug candidates from these proprietary network-targeted

Table of Contents

cancer programs for further development: CUDC-101, which is designed to simultaneously inhibit HDAC, EGFR and Her2 and CUDC-907, an orally available synthetic small molecule inhibitor of HDAC and PI3K both of which we are developing internally, as well as Debio 0932, an orally available, synthetic small molecule inhibitor of Hsp90 which has been licensed to Debiopharm.

Our drug candidates in our network-targeted cancer program, including CUDC-101, Debio 0932 and CUDC-907, are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. These drug candidates may not prove to be effective inhibitors of the validated cancer targets they are being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits that we believe they may possess or that may have been demonstrated in preclinical studies. Moreover, there is a risk that these drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize CUDC-101, CUDC-907 or Debio 0932, or any other drug candidates from our network-targeted cancer programs, in which case we will not achieve profitability and the value of our stock will decline.

We depend on third parties for the development of certain of our programs. If one or more of our collaborators fails or delays in developing or commercializing drug candidates based upon our technologies, our business prospects and operating results would suffer and our stock price would likely decline.

We currently have a collaboration with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our Hedgehog pathway technologies. Vismodegib, which is the subject of an NDA submission in advanced BCC, is the lead compound under this collaboration. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm has tested Debio 0932 in a phase I clinical trial in advanced solid tumors and plans to initiate a phase I expansion study of Debio 0932 in particular tumor types. Our collaboration with Genentech and our license agreement with Debiopharm are our only current material collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

Genentech and Debiopharm each have significant discretion in determining the efforts and resources that they will apply to their respective collaboration with us. The timing and amount of any cash payments related to future royalties and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, our collaboration partners efforts, allocation of resources and successful development and commercialization of our drug candidates under the respective agreement.

Our strategic collaboration agreement with Genentech and our license agreement with Debiopharm permit such parties wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech or Debiopharm to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the collaboration or license agreement, as applicable. In the event of any such decision, our business and prospects may be adversely affected and we may not have the commercial rights or the resources necessary to advance such programs on our own.

Genentech and Debiopharm may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of its collaborations with us. For example, Genentech and Debiopharm each are developing several other programs in cancer.

Genentech or Debiopharm may change the focus of their development and commercialization efforts or pursue higher-priority programs. Our ability to successfully commercialize drug candidates under collaboration with Genentech or Debiopharm could be limited if Genentech or Debiopharm decreases or fails to increase spending related to such drug candidates.

Genentech or Debiopharm may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. For example, during the first quarter of 2009, Roche Holdings Ltd. completed its acquisition of Genentech. Any such transaction could divert the attention of our collaborative partner s management and adversely affect its ability to retain and motivate key personnel who are important to the continued development of the programs under our collaboration. In addition, an acquirer could determine to reprioritize Genentech s or

Debiopharm s development programs such that Genentech or Debiopharm ceases to diligently pursue the development of our programs, and/or cause the respective collaborations with us to terminate.

Genentech or Debiopharm may, under specified circumstances, terminate their collaboration with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific and financial communities.

Table of Contents

Genentech and Debiopharm have the first right to maintain or defend our intellectual property rights under the respective collaboration agreement and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic partners do not, our ability to do so may be compromised by our strategic partners acts or omissions.

Genentech and Debiopharm may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.

Genentech and Debiopharm may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If either Genentech or Debiopharm were to breach or terminate their arrangements with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own.

Genentech and Debiopharm may not have sufficient resources necessary to carry the product candidate through clinical development or may not obtain the necessary regulatory approvals.

If Genentech or Debiopharm fails to successfully develop and commercialize our drug candidates under collaboration, we may not be able to develop and commercialize these candidates independently or successfully enter into one or more alternative collaborations, in which event our financial condition, results of operations and stock price may be adversely affected.

We may not be successful in establishing additional strategic collaborations, which could adversely affect our ability to develop and commercialize products.

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more drug candidates under our network-targeted cancer drug programs. For example, we are seeking to enter into a corporate collaboration for CUDC-101, our lead product candidate being developed pursuant to these programs, and CUDC-907, our recently-selected development candidate, and we may seek to partner other drug candidates from these programs in the future. We do not currently have the experience, resources or capacity to advance these programs into later stages of clinical development or commercialization. As such, our success will depend, in part, on our ability to enter into one or more such collaborations. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for CUDC-101, CUDC-907 or any future programs because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy or sufficient differentiability compared to existing or emerging treatments. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. If we are not able to successfully enter into one or more collaborations or licensing arrangements for CUDC-101, CUDC-907 or any future programs, the clinical development of these programs could be significantly delayed and, as a result, our future prospects may be adversely affected and our stock price could decline.

Moreover, if we fail to establish and maintain additional strategic partnerships related to our product candidates:

the development of certain of our current or future product candidates may be terminated or delayed;

our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;

we may be required to hire additional employees or otherwise develop expertise, such as additional clinical, regulatory, sales and marketing expertise, for which we have not budgeted; and

we will bear all of the risk related to the development of any such product candidates.

If preclinical studies and clinical trials of our drug candidates are not successful then our future profitability and success could be adversely affected.

In order to obtain regulatory approval for the commercial sale of our drug candidates, we and any current or potential future collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our drug candidates are safe and effective. For example, our lead drug candidate, vismodegib, is currently being tested by our collaborator, Genentech, in a phase II clinical trial in operable BCC; and Debiopharm plans to initiate a phase Ib expansion study of Debio 0932 in particular tumor types. In addition, we have completed enrollment in a phase I expansion trial in CUDC-101 in specific tumor types and we have also initiated a phase I trial in head and neck cancer of CUDC-101.

Table of Contents

Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Preclinical testing and clinical trials of our drug candidates may not be successful. We and our collaborators could experience delays or failures in preclinical testing or clinical trials of any of our drug candidates for a number of reasons including, for example:

- preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, as occurred in Genentech s recently-completed phase II clinical trials of vismodegib in colorectal cancer and ovarian cancer;
- we or any collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular drug candidate;
- the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- we may encounter difficulties or delays in manufacturing sufficient quantities of the drug candidate used in any preclinical study or clinical trial;
- the timing and completion of clinical trials of our drug candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;
- our products under development may not be effective in treating any of our network-targeted cancer indications or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;
- institutional review boards, regulators, including the FDA or its foreign equivalents, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and
- we, along with any of our current or potential future collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such a debarred person may result in delays in FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s).

If the preclinical studies and/or clinical trials for any of our drug candidates that we and any collaborators pursue are not successful, then our ability to successfully develop and commercialize products on the basis of the respective technologies will be materially adversely affected, our reputation and our ability to raise additional capital will be materially impaired and the value of an investment in our stock price is likely to decline.

For a further discussion of risks relating to the successful clinical development of vismodegib, see: The successful development of our most advanced product candidate, vismodegib, is important to our success as a company. If Genentech does not successfully continue or complete the clinical development and regulatory approval process for vismodegib, our future prospects and our ability to finance our operations will be substantially harmed.

We expect to rely primarily on third parties for the conduct of clinical trials, and if such third parties perform inadequately then we will not be able to successfully develop and commercialize drug candidates and grow our business.

We have very limited experience in conducting clinical trials. We expect to rely primarily on third parties to conduct our clinical trials and provide services in connection with such clinical trials. For example, we have granted development and commercialization rights to Genentech and Debiopharm under our existing collaboration agreements with each of them and we expect that any future collaboration partners may similarly be fully responsible for conducting at least the later-stage clinical trials of drug candidates. In the near term, we expect to rely primarily on third parties such as consultants, contract research organizations and other similar entities to complete IND-enabling preclinical studies, assist us in creating and submitting IND applications, enroll qualified subjects, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with the clinical trial protocol or design. In addition, the FDA and its foreign equivalents require us to comply with certain standards, referred to as good clinical practices, and applicable regulatory requirements, for conducting,

Table of Contents

recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of the third party contractors on whom we may in the future rely do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the trial. Any failure by a third party to conduct our clinical trials as planned or in accordance with regulatory requirements could delay or otherwise adversely affect our efforts to obtain regulatory approvals for and commercialize our drug candidates.

If we and our collaborative partners do not obtain necessary regulatory approvals, then our business will be unsuccessful and the market price of our common stock could substantially decline.

We and our collaborators will be required to obtain regulatory approval in order to successfully advance our drug candidates through the clinic and prior to marketing and selling such products. The process of obtaining required regulatory approvals is expensive and the time required for these approvals is uncertain and typically takes a number of years, depending on the type, complexity and novelty of the product. With respect to our internal programs, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the approved indicated uses for which we or our collaborative partners may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We and our collaborators are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA or a foreign equivalent does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition, regulatory agencies may change existing requirements or adopt new requirements or policies. We and any collaborative partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

As a result of these factors, we and any collaborators may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell our drug candidates in the time periods estimated, if at all. Moreover, if we or any collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

Even if marketing approval is obtained, any products we or any collaborators develop will be subject to ongoing regulatory oversight, which may affect the successful commercialization of such products.

Even if we or any collaborators obtain regulatory approval of a drug candidate, the approval may be subject to limitations on the approved indicated uses for which the product is marketed or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA, or foreign equivalent, and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, or a failure to comply with regulatory requirements, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market, fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products and criminal prosecution.

The FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Table of Contents

We and our current collaborators are, and any potential future collaborators will be, subject to governmental regulations in connection with the research, development and commercialization of our drug candidates. We and our collaborators may not be able to comply with these regulations, which could subject us or such collaborators to penalties and result in the imposition of limitations on our or such collaborators operations.

In addition to regulations imposed by the FDA or foreign equivalents, we and our current collaborators are, and any potential future collaborators will be, subject to regulation under, among other laws, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of pharmaceutical and biotechnology companies. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury caused by these materials.

If we or any of our collaborators fail to achieve market acceptance for our products under development, our future revenue and ability to achieve profitability may be adversely affected.

Our future products, if any are successfully developed, may not gain commercial acceptance among physicians, patients and third-party payors, even if necessary marketing approvals have been obtained. We believe that recommendations and endorsements by physicians will be essential for market acceptance of any products we successfully develop. If we are not able to obtain market acceptance for such products, our expected revenues from sales of these products would be adversely affected and our business may not be successful.

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have incurred substantial losses, expect to continue to incur substantial losses for the foreseeable future and may never generate significant revenue or achieve profitability.

As of September 30, 2011, we had an accumulated deficit of approximately $738,150,000. We have not successfully commercialized any products to date, either alone or in collaboration with others. If we are not able to successfully commercialize any products, we will not achieve profitability. All of our drug candidates are in early stages of development. For the foreseeable future, we will need to spend significant capital in an effort to develop and commercialize products and we expect to incur substantial operating losses. Our failure to become and remain profitable would, among other things, depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

We will require substantial additional capital, which is likely to be difficult to obtain.

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements include the need for substantial working capital to support our research and development activities for CUDC-101, CUDC-907 and other small molecules that we are seeking to develop from our pipeline of network-targeted cancer programs, and to fund our general and administrative costs and expenses.

We have historically derived a substantial portion of our operating cash flow from the research funding portion of collaboration agreements with third parties. However, we have no current research funding revenue under collaboration agreements. Our only potential source of cash flows from operations for the foreseeable future is contingent payments that we could receive under existing or new collaborations as follows:

- up-front license payments and research and development funding that we may receive if we are able to successfully enter into new collaboration agreements for our technologies under development;

contingent cash payments that we may receive for the achievement of development objectives under any new collaborations or our existing collaborations with Genentech and Debiopharm; and

royalty payments that are contingent upon the successful commercialization of products based upon these collaborations.

Table of Contents

We may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of us receiving payments under such collaborations is highly uncertain. As a result, we cannot assure you that we will attain adequate future operating capital, if any, from collaborations or licensing arrangements.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at September 30, 2011 should enable us to maintain current and planned operations into the fourth quarter of 2012. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and accelerate our need for additional working capital, many of which are outside our control, including the following:

- unanticipated costs in our research and development programs;
- the timing and cost of obtaining regulatory approvals for our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;
- unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and
- unexpected losses in our cash investments or an inability to otherwise liquidate our cash investments due to unfavorable conditions in the capital markets.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates; or
- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through public or private financings of debt or equity. For example, in June 2011 we entered into an agreement with McNicoll, Lewis & Vlak, LLC, or MLV, pursuant to which, from time to time, we may offer and sell up to $20 million of common stock through MLV pursuant to one or more at the market offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. The market for emerging life science stocks in general, and the market for our common stock in particular, are highly volatile. Due to this and various other factors, including adverse general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell additional shares under the arrangement with MLV at favorable prices, if at all. In addition, the terms of any financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates. Moreover, we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party

collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs.

We may face fluctuations in our operating results from period to period, which may result in a decline in our stock price.

Our operating results have fluctuated significantly from period to period in the past and may rise or fall significantly from period to period in the future as a result of many factors, including:

- the cost of research and development that we engage in;
- a failure to successfully complete preclinical studies and clinical trials in a timely manner or at all, resulting in a delay in receiving, or a failure to receive, the required regulatory approvals to commercialize our drug candidates;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaborative arrangements;

Table of Contents

- the costs involved in prosecuting, maintaining and enforcing patent claims;
- our ability to operate without infringing upon the proprietary rights of others;
- costs to comply with changes in government regulations;
- changes in management and reductions or additions of personnel;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators operations and financial results;
- changes in accounting estimates, policies or principles, including changes in revenue recognition policies; and
- the introduction of competitive products and technologies by third parties.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of our future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a drop of our stock price.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Our general business strategy may be adversely affected by unfavorable economic conditions, a volatile business environment and continued unpredictable and unstable market conditions. If equity and credit markets are unfavorable, it may make future debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2011, we had $28,358,000 of cash, cash equivalents and marketable securities consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since September 30, 2011, no assurance can be given that further deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or marketable securities or our ability to meet our financing objectives. Further dislocations in the credit market may adversely impact the value and liquidity of marketable securities owned by us.

There is a possibility that our stock price may decline due to the volatility of the stock market and the general economic downturn.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

We and our collaborators may not achieve projected research and development goals in the time frames that we or they announce, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. Genentech has also made public statements regarding its expectations for the clinical development and potential filing of regulatory submissions for approval of vismodegib, and may in the future make additional statements about their goals and expectations for this collaboration with us. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our and our current and potential future collaborators preclinical studies or clinical trials, the

amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that our or our current and potential future collaborators preclinical studies and clinical trials will advance or be completed in the time frames we or they announce or expect, that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or any collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

Table of Contents

We face substantial competition, which may result in our competitors discovering, developing or commercializing products before or more successfully than we do.

Our drug candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the Hedgehog signaling pathway is highly competitive. We are developing Hedgehog-based therapies under our collaborations with Genentech in the field of cancer. Competitors may discover, characterize and develop Hedgehog pathway inhibitor drug candidates before we do or may compete with us in the same market sector.

In addition, our small molecule network-targeted cancer drug development candidates, which are focused primarily on validated cancer targets, face significant competition from marketed drugs and drugs under development that seek to inhibit the same targets as our drug candidates. We expect competition to intensify in cancer generally and, specifically, in targeted approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities, and more extensive experience than we have. As a result, efforts by other life science, medical device and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop alone or with a collaborator.

For those programs that we have selected for internal development, we face competition from companies that are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, any of these companies may be more successful in obtaining collaboration agreements or other monetary support, approval and commercialization of their products and/or may develop competing products more rapidly and/or at a lower cost. For those programs that are subject to a collaboration agreement, competitors may have greater expertise in discovery, research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than our collaborators and, consequently, may discover, develop and commercialize products that render our products non-competitive or obsolete.

If we are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our drug candidates, which would adversely affect our ability to grow our business and become profitable.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend may also result in fewer potential collaborators or licensees for our therapeutic drug candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or collaborators as a result of such consolidation. This trend may adversely affect our ability to enter into agreements for the development and commercialization of our drug candidates, and as a result may harm our business.

We could be exposed to significant monetary damages and business harm if we are unable to obtain or maintain adequate product liability insurance at acceptable costs or otherwise protect ourselves against potential product liability claims.

Product liability claims are inherent in the process of researching, developing and commercializing human health care products could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our future products or result in reputational harm and could result in the payment of a significant damage award.

Although we currently have product liability insurance for our clinical trials of CUDC-101, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. If any of our drug candidates advance in clinical trials and/or are approved for marketing, we may seek additional insurance coverage. Product liability insurance is expensive and may be difficult to procure. As such, it is possible that we will not be able to obtain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims, which may harm our business.

Table of Contents

If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

We depend upon our senior management and scientific staff, including Daniel R. Passeri, our President and Chief Executive Officer, Michael P. Gray, our Chief Operating Officer and Chief Financial Officer and Changgeng Qian, Ph.D., M.D., our Senior Vice President, Discovery and Preclinical Development. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers can terminate their employment with us at any time. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency. We do not maintain key man life insurance on any of these executive officers.

Our ability to operate successfully will depend on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

We may seek to acquire complementary businesses and technologies in the future or otherwise seek to expand our operations to grow our business, which may divert management resources and adversely affect our financial condition and operating results.

We may seek to expand our operations in the future, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

- a diversion of management from our existing operations;
- increased operating complexity of our business, requiring greater personnel and resources;
- significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;
- incurrence of debt, other liabilities and contingent liabilities; and
- dilutive stock issuances.

Any business that we conduct in China will expose us to the risk of adverse changes in political, legal and economic policies of the Chinese government, which changes could impede our preclinical efforts in China and materially and adversely affect the development of our network-targeted cancer programs.

We currently engage approximately 16 medicinal chemists in China pursuant to a contract research agreement with a medicinal chemistry provider in China. In addition, we have a subsidiary in China, Curis Shanghai, which is currently licensed but is not operational.

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development efforts in China. If

our research and development efforts in China are delayed due to such interruptions, we may not realize the reductions in costs anticipated from engaging chemists in China. We would also have to consider moving our chemistry and/or biology research that is currently conducted in China to U.S. or European providers, thereby potentially either increasing our overall costs for such services or reducing the total number of chemists and or/biologists that we could engage.

In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a

Table of Contents

comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or the inability to enforce applicable Chinese laws and regulations.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition, the value of certain liabilities, including the fair value of our warrant liability, and stock-based compensation expense. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates elsewhere in this Quarterly Report on Form 10-Q.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. Despite our adoption of an Insider Trading Policy, we may not be able to prevent a director, executive or employee from trading in our common stock on the basis of, or while having access to, material, nonpublic information. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

If we or any of our licensees or assignees breach any of the agreements under which we or they license or transfer our intellectual property to others, we could be deprived of important intellectual property rights and future revenue.

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business, including our collaboration agreement with Genentech and our license agreement with Debiopharm, and we expect to enter into similar agreements with third parties in the future. Under these agreements, we generally license or transfer intellectual property to third parties and impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations on them. If a third party breaches its responsibilities under these agreements, we generally retain the right to terminate the agreement, and to bring a legal action in court or in arbitration. In the event of breach, we may need to enforce our rights under these agreements by resorting to arbitration or litigation. During the period of arbitration or litigation, we may be unable to effectively use, assign or license the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.

39

Table of Contents

We may not be able to obtain patent protection for our technologies and the patent protection we do obtain may not be sufficient to stop our competitors from using similar technology.

The patent positions of pharmaceutical and life science companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The laws, procedures and standards that the United States Patent and Trademark Office and various foreign intellectual property offices use to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and has changed in significant ways and are expected to continue to change. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our business depends in significant part on our ability to:

- obtain patents to protect our technologies and discoveries;
- protect trade secrets from disclosure to third-party competitors;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficient to protect our technology from exploitation by our competitors. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and abroad are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge.

We may not have rights under patents that may cover one or more of our drug candidates. In some cases, these patents may be owned or controlled by third-party competitors and may prevent or impair our ability to exploit our technology. As a result, we or our current or potential future collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our drug candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners may not be able to develop and commercialize the affected drug candidate or candidates.

We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings, which could result in liability for damages or require us to cease our development and commercialization efforts.

There are substantial litigation and other adversarial opposition proceedings regarding patent and other intellectual property rights in the pharmaceutical and life science industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Situations that may give rise to patent litigation or other disputes over the use of our intellectual property include:

- initiation of litigation or other proceedings against third parties to enforce our patent rights, to seek to invalidate the patents held by these third parties or to obtain a judgment that our drug candidates do not infringe the third parties patents;
- participation in interference and/or derivation proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;
- initiation of opposition proceedings by third parties that seek to limit or eliminate the scope of our patent protection;

initiation of litigation by third parties claiming that our processes or drug candidates or the intended use of our drug candidates infringe their patent or other intellectual property rights; and

initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or any collaborative partners may be enjoined from manufacturing or selling our future products without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or any collaborative partner may not prevail in any

Table of Contents

patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace.

We face risks relating to the enforcement of our intellectual property rights in China that could adversely affect our business.

Pursuant to our contract research agreement with a medicinal chemistry provider in China, we currently engage approximately 16 medicinal chemists in China to perform drug discovery research and we seek to protect our intellectual property rights under this arrangement through, among other things, non-disclosure and assignment of invention covenants. Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed may fail to reflect the true value of the infringed technology and its market. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through confidentiality and intellectual property license or assignment provisions in agreements with our employees, consultants and other third-party contractors, including our contract research agreement with a medicinal chemistry provider in China, as well as through other security measures. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

RISKS RELATING TO MANUFACTURING AND SALES

We will depend on collaborators and third-party manufacturers to produce most, if not all, of our products under development, and if these third parties do not successfully formulate or manufacture these products, our business will be harmed.

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our drug candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our product candidates may make them prohibitively expensive.

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by our contract manufacturers, any collaborators or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

41

Table of Contents

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

- we and any collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;
- we and any collaborators may be delayed in submitting applications for regulatory approvals for our drug candidates; and
- we and any collaborators may not be able to meet commercial demands for any approved products.

Because we rely on a limited number of suppliers for the raw materials used in our product candidates, any delay or interruption in the supply of such raw materials could lead to delays in the manufacture and supply of our product candidates.

We rely on third parties to supply certain raw materials necessary to produce our drug candidates, including CUDC-101, for preclinical studies and clinical trials. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Such suppliers may not sell these raw materials to us at the times we need them or on commercially reasonable terms, or delivery of these raw materials may be delayed or interrupted. Although we generally do not begin a preclinical study or clinical trial unless we believe we have a sufficient supply of a drug candidate to complete such study or trial, any significant delay in the supply of raw materials for our drug candidates for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we were unable to purchase raw materials after regulatory approval had been obtained for our drug candidates, the commercial launch of our drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our drug candidates.

We have no sales or marketing experience and, as such, plan to depend significantly on third parties who may not successfully market and sell any products we develop.

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech and Debiopharm, we have granted Genentech and Debiopharm the exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

We may seek to independently market products that are not already subject to marketing agreements with other parties. If we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

Even if we successfully commercialize any products under development, either alone or in collaboration, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could adversely affect the commercial success of our product candidates.

Our ability to collect significant revenues from sales of our products, if commercialized successfully, may depend on our ability, and the ability of any current or potential future collaboration partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance organizations;

Table of Contents

pharmacy benefit management companies; and

other healthcare-related organizations.

Third party payers are increasingly challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices could also be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any collaborators may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA. This legislation may have far reaching consequences for life science companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for our approved product candidates, if any, is substantially less that we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted. In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MPDIMA, reformed the way Medicare will cover and reimburse for pharmaceutical products. This legislation could also decrease the coverage and price that we may receive for our approved product candidates, if any.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA and the MPDIMA may prevent us from maintaining prices for our approved product candidates that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our approved product candidates, if any, are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

RISKS RELATED TO OUR COMMON STOCK

If we fail to meet the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the NASDAQ Global Market. We are required to meet specified financial requirements in order to maintain our listing on the NASDAQ Global Market. One such requirement is that we maintain a minimum closing bid price of at least $1.00 per share for our common stock. If our stock price falls below $1.00 per share for 30 consecutive business days, we will receive a deficiency notice from NASDAQ advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least $1.00 for a minimum of ten consecutive business days. Under certain circumstances, NASDAQ could require that the minimum bid price exceed $1.00 for more than ten consecutive days before determining that a company complies with its continued listing standards. If in the future we fail to satisfy the NASDAQ Global Market s continued listing requirements, our common stock could be delisted from the NASDAQ Global Market, in which case we may transfer to the NASDAQ Capital Market, which generally has lower financial requirements for initial listing or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the NASDAQ Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

Table of Contents

Our stock price may fluctuate significantly and the market price of our common stock could drop below the price paid.

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock traded within a range of a high price of $4.42 and a low price of $0.68 per share for the period January 1, 2008 through October 27, 2011. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical and biotechnology company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

- announcements regarding new technologies by us or our competitors;
- market conditions in the biotechnology and pharmaceutical sectors;
- rumors relating to us or our competitors;
- litigation or public concern about the safety of our potential products;
- actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;
- actual or anticipated changes to our research and development plans;
- deviations in our operating results from the estimates of securities analysts;
- entering into new collaboration agreements or termination of existing collaboration agreements;
- adverse results or delays in clinical trials being conducted by us or any collaborators, as was seen with our [2010] announcement of Genentech s unfavorable results in its phase II clinical trials for vismodegib (GDC-0449) in colorectal cancer and ovarian cancer;
- any intellectual property or other lawsuits involving us;
- third-party sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors or significant stockholders;
- equity sales by us of our common stock to fund our operations;
- the loss of any of our key scientific or management personnel;

FDA or international regulatory actions; and

general economic and market conditions, including recent adverse changes in the domestic and international financial markets.

While we cannot predict the individual effect that these factors may have on the price of our common stock, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time. Moreover, in the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management s attention and resources.

The limited liquidity for our common stock could affect an investor s ability to sell our shares at a satisfactory price and makes the trading price of our common stock more volatile.

Our common stock is relatively illiquid. As of September 30, 2011, we had approximately 76.6 million shares of common stock outstanding. The average daily trading volume in our common stock during the prior 90 trading days ending on September 30, 2011 was approximately 453,000 shares. A more active public market for our common stock may not develop, which would continue to adversely affect the trading price and liquidity of our common stock. Moreover, common stock with a thin trading market may experience greater price fluctuation than the stock market as a whole. Without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile.

Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants or pursuant to our universal shelf registration statement could result in dilution to our stockholders and negatively affect our stock price.

Most of our outstanding common stock can be traded without restriction at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants and in the

Table of Contents

future we may issue additional options, warrants or other derivative securities convertible into our common stock. The exercise of any such options, warrants or other derivative securities, and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Furthermore, as of September 30, 2011, we have outstanding warrants to purchase 1,610,818 shares of our common stock that contain antidilution adjustment provisions that will result in a decrease in the price and an increase in the number of shares of common stock issuable upon exercise of such warrants in the event of certain issuances of common stock by us at prices below $3.55 per share. For example, assuming that we issued and sold shares of common stock in a public offering at $3.00 per share, these warrants would become exercisable for an aggregate of 1,631,055 shares of our common stock, at an exercise price of $3.51 per share, which is equal to an aggregate of additional 20,237 shares as a result of the adjustment. To the extent that we are required to adjust the price and number of shares underlying these warrants as a result of this antidilution clause, and thereafter such warrants are exercised, additional shares of our common stock will be issued that will be eligible for resale in the public market, which could result in added dilution to our security holders and could also have an adverse effect on the market price of our common stock.

We currently have on file with the SEC a universal shelf registration statement which allows us to offer and sell registered common stock, preferred stock and warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. For example, in June 2011 we entered into an agreement with MLV pursuant to which, from time to time, we may offer and sell up to $20 million of the common stock that was registered on this shelf registration statement through MLV pursuant to one or more at the market offerings. In addition, with our prior written approval, MLV may also sell these shares of common stock by any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities under this registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

We do not intend to pay dividends on our common stock, and any return to investors will come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no common stock dividends have been declared or paid by us and we have no intention of paying any common stock dividends in the foreseeable future.

Insiders have substantial influence over us and could delay or prevent a change in corporate control.

As of September 30, 2011, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 25% of our outstanding common stock. As a result, these stockholders, if acting together, will be able to exert influence over the management and affairs of our company and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

We have anti-takeover defenses that could delay or prevent an acquisition that our stockholders may consider favorable and the market price of our common stock may be lower as a result.

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized blank check preferred stock and our stockholders are limited in their ability to call special stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control transaction.

Table of Contents

Item 6. EXHIBITS

The exhibits filed herewith or incorporated by reference are set forth on the exhibit index attached hereto.

Table of Contents

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CURIS, INC.

Dated: October 31, 2011

By: /s/ MICHAEL P. GRAY

Michael P. Gray

Chief Operating Officer and Chief Financial Officer

(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
+101.INS	XBRL Instance Document
+101.SCH	XBRL Taxonomy Extension Schema Document
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
+101.LAB	XBRL Taxonomy Extension Label Linkbase Document
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Furnished, not filed, herewith.