CURIS INC
Form 10-Q
November 06, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2012

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

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 30, 2012, there were 79,960,906 shares of the registrant s common stock outstanding.

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

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Item 1. FINANCIAL STATEMENTS

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,809,408	$ 15,119,730
Investments	33,325,782	22,597,845
Accounts receivable	548,392	42,067
Prepaid expenses and other current assets	498,067	743,799
Total current assets	42,181,649	38,503,441
Property and equipment, net	461,591	455,730
Long-term investments	751,960	
Long-term investment restricted	194,282	235,914
Goodwill	8,982,000	8,982,000
Other assets	2,980	2,980
Total assets	$ 52,574,462	$ 48,180,065
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,690,855	$ 2,364,437
Accrued liabilities	1,290,855	1,422,107
Total current liabilities	3,981,710	3,786,544
Warrants	2,690,930	4,361,168
Other long-term liabilities	186,312	156,396
Total liabilities	6,858,952	8,304,108
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 80,998,363 shares issued and 79,950,656 shares outstanding at September 30, 2012; and 78,165,360 shares issued and 77,117,653 shares outstanding at December 31, 2011	809,984	781,654
Additional paid-in capital	781,906,444	772,039,254
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Accumulated deficit	(736,133,361)	(732,087,642)
Accumulated other comprehensive income	23,717	33,965
Total stockholders equity	45,715,510	39,875,957
Total liabilities and stockholders equity	$ 52,574,462	$ 48,180,065

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
REVENUES:				
License fees	$	$	$ 14,000,000	$ 300,000
Royalties	446,402		969,774	
Research and development	131,357	147,122	315,811	373,527
Total revenues	577,759	147,122	15,285,585	673,527
COSTS AND EXPENSES:				
Cost of royalty revenues	22,320		148,489	
Research and development	3,042,498	3,042,251	12,784,902	9,244,800
General and administrative	2,473,853	1,921,206	7,539,516	6,196,337
Total costs and expenses	5,538,671	4,963,457	20,472,907	15,441,137
Loss from operations	(4,960,912)	(4,816,335)	(5,187,322)	(14,767,610)
OTHER INCOME/(EXPENSE):				
Interest income	34,129	22,596	87,224	81,506
Change in fair value of warrant liability	1,541,779	587,184	1,054,379	(1,234,666)
Total other income/(expense)	1,575,908	609,780	1,141,603	(1,153,160)
Net loss	$ (3,385,004)	$ (4,206,555)	$ (4,045,719)	$ (15,920,770)
Net loss per common share (basic and diluted)	$ (0.04)	$ (0.05)	$ (0.05)	$ (0.21)
Weighted average common shares (basic and diluted)	79,639,433	76,543,074	78,752,687	76,251,709
Total comprehensive loss	$ (3,401,010)	$ (4,217,532)	$ (4,055,967)	$ (15,943,405)

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,045,719)	$ (15,920,770)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	91,383	76,753
Stock-based compensation expense	2,838,311	1,351,500
Issuance of common stock to licensees	964,000	
Change in fair value of warrant liability	(1,054,379)	1,234,666
Non-cash interest (income)/expense	(225,468)	299,653
Net gain on sale of assets		(59,651)
Changes in current assets and liabilities:		
Accounts receivable	(506,325)	(44,942)
Prepaid expenses and other assets	288,922	(283,747)
Accounts payable and accrued liabilities	170,004	95,145
Total adjustments	2,566,448	2,669,377
Net cash used in operating activities	(1,479,271)	(13,251,393)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(43,206,032)	(32,236,817)
Sale of marketable securities	32,691,355	47,993,617
Decrease in restricted cash	41,632	261,090
Purchase of long-term investments	(750,000)	
Proceeds from sale of assets		59,651
Purchases of property and equipment	(42,166)	(249,501)
Net cash (used in)/provided by investing activities	(11,265,211)	15,828,040
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Company s share-based compensation plans and warrant exercises	4,590,132	1,341,984
Proceeds from issuance of common stock under the Company s ATM Agreement, net of issuance costs of $27,356 and $123,374, respectively	844,028	139,073
Net cash provided by financing activities	5,434,160	1,481,057
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(7,310,322)	4,057,704
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	15,119,730	7,826,549
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 7,809,408	$ 11,884,253

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Business

Curis, Inc. (the Company or Curis) is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies in seeking to develop next generation network-targeted cancer therapies. Curis is building upon its past experiences in targeting signaling pathways, including the Hedgehog signaling pathway, in its efforts to develop network-targeted cancer therapies. Curis conducts research and development programs both internally and through strategic collaborations.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States, or the U.S., by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies. In January 2012, the FDA approved the Erivedge capsule for the treatment of adults with basal cell carcinoma, or BCC, that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and commercialized by F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under a collaboration agreement between the Company and Genentech (see Note 4).

The Company is subject to risks common to companies in the biotechnology industry as well as risk factors that are specific to the Company s business, including, but not limited to: the Company s reliance on Genentech and Roche to successfully commercialize Erivedge in the U.S. market and to seek approval for Erivedge in territories outside of the U.S. in the lead indication of advanced BCC; the Company s ability to advance its research and development programs, including those programs developed directly by the Company and those that are being developed by its collaborators and licensees; the potential for the Company to expand its research and development programs, either through internal discovery or through the licensing or acquisition of third-party programs; the Company s ability to obtain adequate financing to fund its operations; its ability to obtain and maintain intellectual property protection for its proprietary technology; development by its competitors of new or better technological innovations; dependence on key personnel and the Company s ability to attract and retain such key personnel; ; its ability to comply with FDA regulations and approval requirements; and its ability to execute on its overall business strategies.

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, a number of factors, including, but not limited to: Genentech s ability to successfully scale-up the commercialization of Erivedge in advanced BCC in the U.S.; Genentech s and/or Roche s receipt of approval to commercialize Erivedge in advanced BCC in Europe and other territories as well as its ability to successfully launch and commercialize Erivedge in these markets; positive results in Genentech s ongoing phase II clinical trial in patients with operable BCC; the timing, outcome and cost of the Company s planned clinical trials for CUDC-101, CUDC-907 and other potential research and development programs; and the Company s ability to successfully enter into one or more material licenses or collaboration agreements for its proprietary drug candidates.

The Company anticipates that existing capital resources at September 30, 2012 should enable the Company to maintain its current and planned operations into the first half of 2014. The Company s ability to continue funding its planned operations into and beyond the first half of 2014 is dependent upon, among other things, the success of its collaborations with Genentech, including its receipt of meaningful royalty revenue for sales of Erivedge, and Debiopharm S.A., or Debiopharm, and receipt of additional cash payments under these collaborations, its ability to control expenses and its ability to raise additional funds through equity or debt financings, new collaborations or other sources of financing. The Company may not be able to successfully enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. As a result, the Company may not be able to attain any further revenue under any collaborations or licensing arrangements. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

2. Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are

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condensed and do not include all disclosures required by generally accepted accounting principles, or GAAP, in the U.S. for complete financial statements and should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission on February 29, 2012.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary for a fair statement of the Company s financial position at September 30, 2012 and the results of operations and cash flows for the nine-month periods ended September 30, 2012 and 2011. The preparation of the Company s Condensed Consolidated Financial Statements in conformity with GAAP 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 collectability of receivables, the carrying value of property and equipment and intangible assets, management assumptions used in its calculations of stock-based compensation expense, and the value of certain investments and liabilities, including the value of its warrant liability. Actual results may differ from such estimates.

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

3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of these agreements may provide for the Company s licensees and collaborators to agree to make non-refundable license fee payments, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on February 29, 2012.

4. Collaboration Agreements

(a) Genentech June 2003 Collaboration

In January 2012, the FDA approved Genentech s new drug application for the Erivedge capsule for the treatment of adults with BCC that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. Erivedge is being developed and commercialized by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between the Company and Genentech. As a result of the FDA s approval of Erivedge in this indication, the Company earned a $10,000,000 milestone payment from Genentech and is also entitled to receive royalties on future sales of the product. In May 2012, Roche announced that it has submitted an application for marketing registration for Erivedge to Australia s Therapeutic Goods Administration, or TGA, and as a result of the acceptance of the application by Australia s TGA, the Company earned an additional $4,000,000 milestone payment. The Company is eligible to receive up to an aggregate of $115,000,000 in contingent cash payments under the collaboration for the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. As of September 30, 2012, the Company has received $46,000,000 in the aggregate since the inception of the agreement.

Pursuant to the milestone payments above, the Company recognized $14,000,000 as license revenue in its Condensed Consolidated Statement of Operations for the nine months ended September 30, 2012, as the Company does not have any further substantive performance obligations under the collaboration. The Company did not recognize license revenue under this collaboration during the three and nine months ended September 30, 2011.

In connection with the receipt of milestone payments from Genentech, the Company recorded research and development expenses of $2,114,000 during the nine months ended September 30, 2012, which represents the Company s obligations to university licensors. Of this amount, the Company recognized expense of $964,000, which represents the fair value of a one-time issuance of an aggregate of 200,000 shares of the Company s common stock in March 2012 to two university licensors in connection with the FDA-approval of Erivedge in January 2012. In

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addition, the Company recorded research and development expenses of $550,000 for obligations the Company incurred in connection with Roche s application to the TGA for marketing registration of Erivedge in Australia and the related $4,000,000 milestone that the Company received, and an additional $100,000 in research and development expense that represents an immaterial out-of-period expense associated with Roche s filing in 2009 of an investigational new drug application in Australia. The remaining expense recognized of $500,000 relates to the Company s receipt of the $10,000,000 milestone payment associated with the FDA s U.S. approval of Erivedge in January 2012.

The Company also recognized $446,402 and $969,774 in royalty revenue from Genentech s net sales of Erivedge during the three and nine months ended September 30, 2012, respectively. The Company recorded cost of royalty revenues within the costs and expenses section of its Condensed Consolidated Statements of Operations of $22,320 and $148,489 during these same periods, which represents 5% of the royalties earned by the Company with respect to Erivedge that the Company is obligated to pay to two university licensors plus a one-time cash payment of $100,000 paid to a university licensor upon the first commercial sale of Erivedge for the nine months ended September 30, 2012.

(b) The Leukemia & Lymphoma Society Agreement

In November 2011, the Company entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will support the Company s ongoing development of CUDC-907 for patients with relapsed or refractory lymphomas or multiple myeloma. Under the agreement, LLS will fund approximately 50% of the direct costs of the development of CUDC-907, up to $4,000,000, through milestone payments upon the Company s achievement of specified research and development objectives. Under certain conditions associated with the successful partnering and/or commercialization of CUDC-907 in these indications, the Company may be obligated to make payments to LLS up to a maximum of $10,000,000. As of September 30, 2012, the Company had not received any payments or recorded any revenue under this agreement. In October 2012, the Company achieved the first two milestones under the agreement upon its filing of an investigational new drug application, or IND, with the FDA for CUDC-907. As a result, the Company earned $750,000 in milestone payments. Additional milestone payments may be earned assuming the Company progresses CUDC-907 into Phase I clinical development.

5. Fair Value Measurements

The Company discloses fair value measurements based on a framework outlined by GAAP which requires expanded disclosures regarding fair value measurements. GAAP also defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

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

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company s warrant liability was valued using a probability-weighted Black-Scholes model, discussed further in Note 7, and is therefore classified as Level 3.

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In accordance with the fair value hierarchy, the following table shows the fair value as of September 30, 2012 and December 31, 2011 of those financial assets and liabilities that are measured at fair value on a recurring basis, according to the valuation techniques the Company used to determine their fair value. No financial assets or liabilities are measured at fair value on a nonrecurring basis at September 30, 2012 and December 31, 2011.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of September 30, 2012:				
Cash equivalents				
Money market funds	$ 2,694,487	$	$	$ 2,694,487
Municipal bonds		1,825,000		1,825,000
Short- and long-term investments				
Corporate commercial paper, bonds and notes	9,001,665	24,324,117		33,325,782
US government obligations		751,960		751,960
Total assets at fair value	$ 11,696,152	$ 26,901,077	$	$ 38,597,229
Warrants			2,690,930	2,690,930
Total liabilities at fair value	$	$	$ 2,690,930	$ 2,690,930
As of December 31, 2011:				
Cash equivalents				
Money market funds	$ 5,366,747	$	$	$ 5,366,747
Municipal bonds	2,375,000			2,375,000
Short-term investments				
US government obligations		3,808,704		3,808,704
Corporate commercial paper, stock, bonds and notes	7,365,841	11,423,300		18,789,141
Total assets at fair value	$ 15,107,588	$ 15,232,004	$	$ 30,339,592
Warrants			4,361,168	4,361,168
Total liabilities at fair value	$	$	$ 4,361,168	$ 4,361,168

The following table rolls forward the fair value of the Company s warrant liability, the fair value of which is determined by Level 3 inputs for the nine months ended September 30, 2011 and 2012:

Balance at December 31, 2010	$ 1,604,742
Change in fair value	1,234,666
Balance at September 30, 2011	$ 2,839,408
Balance at December 31, 2011	$ 4,361,168
Warrants exercised	(615,859)
Change in fair value	(1,054,379)
Balance at September 30, 2012	$ 2,690,930

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6. Investments

The amortized cost, unrealized losses and fair value of marketable securities available-for-sale as of September 30, 2012, with maturity dates ranging between one and twelve months and with a weighted average maturity of 4.4 months are as follows:

	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds and notes	$ 33,334,510	$ (8,728)	$ 33,325,782
Total marketable securities	$ 33,334,510	$ (8,728)	$ 33,325,782

As of September 30, 2012, the Company recorded a long-term investment of $751,960 on its Condensed Consolidated Balance Sheet. This amount is comprised of a U.S. government obligation with a maturity date of November 2013 and with amortized cost totaling $752,053, less unrealized losses of $93.

The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2011, with maturity dates ranging between one and twelve months and with a weighted average maturity of 3.7 months are as follows:

	Amortized Cost	Unrealized Gain	Fair Value
U.S. Government obligations	$ 3,808,641	$ 63	$ 3,808,704
Corporate bonds, notes and stock	18,787,778	1,363	18,789,141
Total marketable securities	$ 22,596,419	$ 1,426	$ 22,597,845

7. Common Stock and Warrant Liability

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. As of September 30, 2012, warrants to purchase 238,805 shares of the Company s common stock have been exercised. The warrants have an initial exercise price of $3.55 per share and a five-year term. The warrants contain antidilution adjustment provisions that will result in a decrease in the price and an increase in the number of shares of common stock issuable upon exercise of such warrants in the event of certain issuances of common stock by the Company at prices below $3.55 per share. The warrants also included a cash-settlement option in the event of a change of control that expired on January 27, 2012. Due to the terms, the warrants are classified as a liability and, therefore, the fair value of the warrants was recorded as a liability in the Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011.

The Company has estimated the fair value of the warrants using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature of the warrants, with updated assumptions at each reporting date. The Company estimated that the fair value of the warrants at September 30, 2012 was $2,690,930, using the following assumptions: expected volatility of 74%, risk free interest rate of 0.3%, expected life of 2.3 years, and no dividends. The Company estimated that the fair value of the warrants at September 30, 2011 was $2,839,408 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 warrants are revalued at each reporting period and the resulting change in fair value of the warrant liability is recognized in the Consolidated Statement of Operations.

The Company recorded other income of approximately $1,541,779 and $1,054,379 for the three and nine months ended September 30, 2012, respectively, due to changes in fair value of the warrant liability which was primarily due to a decrease in the Company s stock price during the current year periods. During the nine months ended September 30, 2012, as a result of the exercise of warrants to purchase 237,301 shares of the Company s

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common stock, the warrant liability decreased by $615,859 with an offsetting increase to additional paid-in-capital. The Company recorded other income of $587,184 and other expense of $1,234,666 for the three and nine months ended September 30, 2011, respectively, as a result of a change in the fair value of the warrant liability that was primarily due to changes in the Company s stock price during those periods.

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 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, or the Securities Act. With the Company s prior written approval, MLV may also sell the common stock by any other method permitted by law, including in privately negotiated transactions. The Company or MLV may suspend or terminate the offering of common stock upon notice and subject to other conditions. MLV will act as sales agent on a commercially reasonable best efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ. The Company will pay MLV a commission equal to 3.0% of the gross sales price per share sold. The Company has agreed to provide indemnification and contribution to MLV against certain civil liabilities, including liabilities under the Securities Act. During the nine months ended September 30, 2012 and 2011, the Company sold 210,879 and 65,527 shares of common stock, respectively, under the ATM Agreement resulting in gross proceeds of $906,436 and $262,447, respectively. Total offering expenses incurred, including MLV s commission, related to the ATM Agreement through September 30, 2012 and 2011 were approximately $27,356 and $123,374, respectively, which offset the gross proceeds.

8. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2012	December 31, 2011
Accrued compensation	$ 953,248	$ 1,065,570
Professional fees	187,750	190,500
Other	149,857	166,037
Total	$ 1,290,855	$ 1,422,107

9. Related Party Transaction

License Agreement

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

Pursuant to the License Agreement, the Company has granted to GBMT an exclusive royalty-free license, with the right to grant sublicenses subject to certain conditions, to develop, manufacture, market and sell any product containing CU-906 or CU-908 in China, Macau, Taiwan and Hong Kong, or the GBMT Territory. The Company does not currently intend to internally develop these compounds. In addition, the Company has granted to GBMT a non-exclusive, royalty-free manufacturing license, with the right to grant sublicenses subject to certain conditions, to manufacture CU-906 or CU-908 or any product containing CU-906 or CU-908 outside of the GBMT Territory solely to import the compounds or products into the GBMT Territory. Pursuant to the terms of the License Agreement, the Company has retained rights, including the right to grant sublicenses, to develop, manufacture, market and sell any product containing CU-906 or CU-908 worldwide excluding the GBMT Territory. The Company also has certain specified rights to any GBMT technology developed under the License Agreement as well as certain specified rights to GBMT s interest in joint technology developed under the License Agreement. Furthermore, the Company has a right of first negotiation to obtain a license to CU-906 or CU-908 for the GBMT Territory from GBMT.

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The Company has agreed to transfer to GBMT know how, information and materials necessary for GBMT to continue the development of products in accordance with the development plan outlined in the License Agreement and has agreed not to assert certain Company patents against GBMT, its affiliates or sublicensee so that such party may manufacture, market and sell any product containing CU-906 or CU-908 in the GBMT Territory. Furthermore, the Company will provide GBMT with up to $400,000 in financial support for specified CU-908 pre-clinical activities related to enabling the filing by the Company of an IND with the FDA, provided that GBMT completes such CU-908 IND-enabling activities in accordance with specified criteria and delivers a U.S. IND package for CU-908 to the Company within prescribed timeframes as specified in the License Agreement. All costs incurred under the License Agreement will be expensed as incurred. As of September 30, 2012, the Company had not incurred any expenses under the License Agreement.

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

Unless terminated earlier in accordance with its terms, the License Agreement will expire on the later of (i) the expiration of the last-to-expire valid claim of the Company patents and the Company non-assert patents relating to the products, and (ii) such time as none of GBMT, its affiliates or sublicensees is commercializing any compound or product in the GBMT Territory. Either party can terminate the License Agreement with notice under prescribed circumstances, and the License Agreement specifies the consequences to each party for such early termination.

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

Severance Agreement

On February 16, 2012, the Company and Dr. Qian entered into a severance agreement that became binding and effective on February 24, 2012. The severance agreement provides that, in exchange for execution and nonrevocation of a general release of claims in favor of the Company, Dr. Qian will be provided certain severance benefits, including a lump-sum payment equivalent to one-half times his base annual salary rate in effect as of his termination date. This payment was made in August 2012. As a result, the Company recognized expenses of $137,500 related to Dr. Qian s severance during the nine months ended September 30, 2012 in the research and development line item of the Company s Condensed Consolidated Statement of Operations. The severance agreement also provides for the engagement of Dr. Qian as a consultant pursuant to the terms of a consulting agreement.

10. Accounting for Stock-Based Compensation

As of September 30, 2012, the Company had two shareholder-approved, share-based compensation plans: the 2010 Stock Incentive Plan and the 2010 Employee Stock Purchase Plan. These plans were adopted by the board of directors in April 2010 and approved by shareholders in June 2010. In the first quarter of 2010, the Company s 2000 Stock Incentive Plan expired in accordance with its terms and its 2000 Director Stock Option Plan had no available shares remaining under the plan. No additional awards will be made under these plans, although all outstanding awards under these plans will remain in effect until they are exercised or they expire in accordance with their terms. For a complete discussion of the Company s share-based compensation plans, see Note 5 included in the Company s Annual Report on Form 10-K for the year ended December 31, 2011, as previously filed with the Securities and Exchange Commission on February 29, 2012.

During the nine months ended September 30, 2012, the Company s board of directors granted options to purchase 1,182,000 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.

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During the nine months ended September 30, 2012, the Company s board of directors also granted options to its non-employee directors to purchase 470,000 shares of common stock under the 2010 Stock Incentive Plan. These options will vest monthly over a one-year period and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date.

Employee and Director Grants

In determining the fair value of stock options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee and director options awarded during the nine months ended September 30, 2012 and 2011 based on the assumptions noted in the following table:

	For the nine months ended September 30,	
	2012	2011
Expected term (years) - Employees	6	6
Expected term (years) - Directors	6	6
Risk-free interest rate	1.0-1.2%	1.2-2.5%
Volatility	74-76%	73-75%
Dividends	None	None

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

The stock price volatility and expected terms utilized in the calculation involve management s best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. GAAP also requires that the Company recognize compensation expense for only the portion of options that are expected to vest. Therefore, management calculated an estimated annual pre-vesting forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

The aggregate intrinsic value of employee options outstanding at September 30, 2012 was $17,145,000, of which $15,184,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2012 and 2011 were $2.99 and $1.45, respectively. As of September 30, 2012, there was approximately $4,897,000, 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 2.53 years. The intrinsic values of employee stock options exercised during the nine months ended September 30, 2012 and 2011 were $6,370,000 and $835,000, respectively. The total fair values of vested stock options for the nine months ended September 30, 2012 and 2011 were $1,761,000 and $1,218,000, respectively.

The Company recorded $822,575 and $2,472,299 in compensation expense for the three and nine months ended September 30, 2012, respectively, and the Company recorded $299,202 and $1,310,940 in compensation expense for the three and nine months ended September 30, 2011, respectively, related to employee and director stock option grants.

Non-Employee Grants

The Company has periodically granted stock options and unrestricted stock awards to consultants for services, pursuant to the Company s stock plans at the fair market value on the respective dates of grant. Should the Company terminate any of its consulting agreements, the unvested options underlying the agreements would also be cancelled. The Company reversed expense of $14,681 and recognized expense of $366,013 related to non-employee stock options for the three and nine months ended September 30, 2012, respectively. The Company recognized expense of $12,739 and $40,560 for the three and nine months ended September 30, 2011, respectively.

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Total Stock-Based Compensation Expense

For the three and nine months ended September 30, 2012 and 2011, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations:

	For the three months ended September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
Research and development expenses	$ 158,638	$ 134,816	$ 923,648	$ 478,676
General and administrative expenses	649,256	177,125	1,914,663	872,824
Total stock-based compensation expense	$ 807,894	$ 311,941	$ 2,838,311	$ 1,351,500

The table below summarizes options outstanding and exercisable at September 30, 2012:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number of Shares	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
$ 0.79 - $ 1.39	2,571,622	4.96	$ 1.19	2,465,681	$ 1.19
1.43 - 2.15	2,605,168	5.32	1.73	2,106,038	1.63
2.27 - 3.76	2,414,232	4.75	2.75	1,631,041	2.53
3.98 - 4.52	2,184,614	7.59	4.38	875,945	4.18
4.56 - 5.60	720,000	1.62	4.74	712,000	4.74
	10,495,636	5.32	$ 2.59	7,790,705	$ 2.25

11. Loss Per Common Share

The Company applies ASC Topic 260 - *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted loss per common share is computed using the weighted-average number of shares outstanding during the period. 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, 2012 and 2011, as the effect of the potential common stock equivalents is antidilutive due to the Company s net loss position for these periods. Antidilutive securities consist of stock options and warrants outstanding as of the respective reporting period as follows:

	For the three and nine months ended September 30, 2012	For the three and nine months ended September 30, 2011
Stock options outstanding	10,495,636	11,485,114
Warrants outstanding	1,373,315	1,610,818
Total antidilutive securities	11,868,951	13,095,932

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

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

Overview

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

Our research and development programs include Erivedge , a first-in-class orally-administered small molecule Hedgehog pathway inhibitor that is being developed under collaboration with Genentech, Inc., or Genentech, a member of the Roche Group. In January 2012, the U.S. Food and Drug Administration, or FDA, approved Genentech s new drug application, or NDA, for the Erivedge capsule for the treatment of adults with basal cell carcinoma, or BCC, that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation. We refer to this indication as advanced BCC. In addition, Genentech is testing Erivedge in less severe forms of BCC and third-party investigators are conducting clinical trials with Erivedge in BCC as well as in several other cancers.

Our lead proprietary drug candidate is CUDC-101, a first-in-class small molecule compound designed to simultaneously target epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and histone deacetylase, or HDAC, all of which are validated cancer targets. The intravenous formulation of CUDC-101 is currently the subject of a phase I clinical trial in locally advanced head and neck cancer patients along with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. We also recently initiated a phase I clinical trial of an oral formulation of CUDC-101 in patients with advanced solid tumor cancers.

We are also developing CUDC-907, an orally bioavailable, small molecule that is designed to inhibit phosphatidylinositol-3-kinase, or PI3K, and HDAC. In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will provide a portion of the funding for the development of CUDC-907 in patients with relapsed or refractory lymphoma and multiple myeloma and we recently filed an investigational new drug application, or IND, with the FDA seeking approval to advance CUDC-907 into phase I clinical testing.

Pursuant to our August 2009 license agreement with Debiopharm S.A., or Debiopharm, a Swiss pharmaceutical development company, is developing heat shock protein 90, or Hsp90, molecule Debio 0932. Debio 0932 is currently being tested in a phase Ib clinical study in advanced solid cancers as well as in a phase I/II clinical trial in patients with advanced non-small cell lung cancer, or NSCLC.

Hedgehog Pathway Inhibitor Program (Erivedge)

Erivedge (vismodegib) capsule. Our most advanced program is our Hedgehog pathway inhibitor program under collaboration with Genentech. Pursuant to this collaboration, Genentech and F. Hoffmann-La Roche Ltd, or Roche, are responsible for clinical development, and Genentech (in the United States, or U.S.), Roche (outside the U.S., excluding Japan) and Chugai Pharmaceuticals Co., Ltd. (in Japan) are responsible for commercialization of Erivedge. The lead drug candidate being developed under this program under this collaboration is Erivedge. Erivedge is designed to selectively inhibit signaling in the Hedgehog pathway by targeting a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. However, mutations in the pathway that reactivate Hedgehog signaling are seen in certain cancers, including BCC. Abnormal signaling in the Hedgehog pathway is implicated in over 90% of BCC cases.

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As a result of the FDA s approval of Erivedge in advanced BCC, we earned a $10,000,000 payment from Genentech in March 2012. During the three months ended March 31, 2012, we recognized the $10,000,000 milestone payment as license revenue. In addition, we recorded research and development expenses related to the FDA s approval of Erivedge of $1,464,000 during the three months ended March 31, 2012 which represents our obligations to university licensors. Of this amount, $964,000 represents the fair value of a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors in connection with the FDA approval of Erivedge. The remaining $500,000 represents sublicense fees we paid to these same university licensors upon our receipt of the $10,000,000 milestone payment in the first quarter of 2012.

We are entitled to a royalty on net sales of Erivedge that ranges from the mid-to-high single digits, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge. We are obligated to make payments to university licensors on royalties that we earn in all territories other than Australia in an amount that is equal to 5% of the royalty payments that we receive from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that we earn from Roche s potential future sales of Erivedge in Australia, we will be obligated to make payments to university licensors in an amount that is equal to 2% of Roche s direct net sales in Australia until expiration of the patent in April 2019, after which the amount will decrease to 5% of the royalty payments that we receive from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. We recognized $970,000 of royalty revenue from Genentech s net sales of Erivedge during the nine months ended September 30, 2012, including $446,000 during the third quarter, which amounts were calculated at 5% of net sales. We recorded cost of royalty revenues of $148,000 during this same period, including a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and $48,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the nine months ended September 30, 2012.

In May 2012, we earned a $4,000,000 milestone payment in connection with Roche s filing of an application for marketing registration for Erivedge with Australia s Therapeutic Goods Administration, or TGA, which we recognized as license revenue during the three months ended June 30, 2012. In addition, we recorded research and development expenses for this period of $650,000 which represents our obligations to university licensors. Of this amount, $450,000 represents cash milestones specific to the Australian territory and the remaining $200,000 represents sublicense fees totaling 5% of the $4,000,000 milestone payment that we received.

During the fourth quarter of 2011, Roche submitted a Marketing Authorization Application, or MAA, for Erivedge to the European Medicines Agency, or EMA, for which we earned a $6,000,000 milestone payment. Roche has indicated that it anticipates potential EMA approval for Erivedge during the fourth quarter of 2012 or the first half of 2013. Roche has also filed new drug applications in 2012 for marketing registration with Canadian, Israeli, Mexican and Swiss health agencies seeking approval for Erivedge in advanced BCC. Erivedge s FDA approval and Roche s regulatory submissions in regards to Erivedge in Europe, Australia, and other territories are based on positive clinical data from ERIVANCE BCC/SHH4476g, a pivotal phase II study of Erivedge in patients with advanced BCC. We will receive additional milestone payments if Erivedge receives EMA or TGA marketing authorization and will be obligated to make payments to university licensors that total 5% of each of these milestone payments that we receive.

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

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histological clearance of the target nodular BCC lesions at the time of tumor excision (which may occur up to 12 or 20 weeks, respectively, following initiation of treatment) while the primary outcome measure for the second cohort is the rate of durable complete clearance of target nodular BCC lesions at the time of excision (which may occur up to 36 weeks following initiation of treatment).

Data from the first cohort were published from an abstract in April 2012 in the *Journal of Investigative Dermatology* and were also presented at the annual meeting of the Society for Investigative Dermatology in May 2012. This first cohort evaluated the safety and efficacy of 12 weeks of daily 150 mg dosing of Erivedge in 24 patients with newly diagnosed nodular, operable BCC. Patients then underwent Mohs surgery with independent pathology review. Pathologically confirmed complete clearance was reported in 10 (42%) patients and clinical complete and partial responses were reported for 23 (96%) patients. The most frequent adverse events were similar to those observed in previous studies with Erivedge and included muscle spasms (79%), ageusia/dysgeusia (79%), alopecia (38%), fatigue (21%) and nausea (21%). Most adverse events were of Grade 1-2 severity; seven patients (29%) reported Grade 3 adverse events, including four patients with muscle spasm. No serious adverse events were reported. Eight (33%) patients discontinued the study, including two (8%) due to adverse events. Cohort two is fully enrolled and accrual to cohort three is ongoing with full study results expected during the first half of 2013.

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

Network-Targeted Cancer Programs

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

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

In 2011, we initiated a phase I clinical trial of CUDC-101 in patients with locally advanced head and neck cancer patients whose cancer is human papilloma virus, or HPV, negative. In April 2012, we amended the protocol for this trial to allow enrollment of patients with HPV positive head and neck cancer and a prior smoking history. We have treated six patients in this trial as of November 2, 2012. The primary objectives of this study are to evaluate the safety and tolerability of CUDC-101 when administered in combination with the current standard-of-care of cisplatin, a chemotherapeutic drug, and radiation. Upon determination of the MTD and assuming the otherwise successful completion of this phase I trial, we will evaluate the data and determine whether to advance CUDC-101 into 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.

In September 2012, we initiated a phase I clinical trial of an oral formulation of CUDC-101. This study is designed as a standard dose escalation study in which a tablet form of CUDC-101 is orally administered to patients with advanced or refractory solid tumors. The trial is being conducted at two study centers in the U.S. The primary objectives are to determine the MTD and recommended phase II dose, and to assess the bioavailability and pharmacokinetics of orally administered CUDC-101. The secondary objectives of this study are to assess safety and tolerability, to evaluate biomarkers of CUDC-101 activity and to assess preliminary anti-cancer activity. The bioavailability of oral CUDC-101 will also be assessed among patients enrolled in the first 3 dose level cohorts, who will initially receive single, matched intravenous and oral doses of CUDC-101 prior to initiating the twice-daily oral dose escalation portion of the study. In the absence of dose limiting toxicity, each patient will receive oral CUDC-101 twice daily for a minimum of 21 days (1 cycle), and may continue to receive additional cycles of study treatment until disease progression or other treatment discontinuation criteria are met.

CUDC-907. CUDC-907 is an orally bioavailable, small molecule that is designed to inhibit PI3K, and HDAC. We are

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developing CUDC-907 based on published and internally generated data demonstrating that HDAC and PI3K inhibitors have synergistic interaction in certain preclinical cancer models, and based on published observations of clinical activity of such agents in hematological cancers. CUDC-907, with its synergistic mechanism of cancer signaling network disruption, has demonstrated potent preclinical antitumor activity in a variety of hematological tumor models including non-Hodgkin s lymphoma and multiple myeloma. We believe that CUDC-907 has the potential to possess clinical advantages over single targeted agents. In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS will provide a portion of the funding for the development of CUDC-907 in patients with relapsed or refractory lymphoma and multiple myeloma.

In October 2012, we filed an IND with the FDA seeking approval to advance CUDC-907 into phase I clinical testing. As a result, we are due to receive $750,000 in milestone payments during the fourth quarter of 2012 under the terms of the agreement with LLS. The phase I clinical trial is designed as a standard dose escalation study in which CUDC-907 will be orally administered to patients with relapsed or refractory lymphoma or multiple myeloma. The trial will take place at up to four study centers in the U.S. The primary objectives of the trial are to determine the MTD and recommended phase II dose of oral CUDC-907. The secondary objectives of this study are to assess safety and tolerability, to assess pharmacokinetics, to evaluate biomarker activity and to assess preliminary anti-cancer activity of CUDC-907 in this patient population. In the absence of dose limiting toxicity, each patient will receive oral CUDC-907 once daily for a minimum of 21 days (1 cycle), and may continue to receive additional cycles of study treatment until disease progression or other treatment discontinuation criteria are met.

Hsp90 Program

Debio 0932. Our heat shock protein 90, or Hsp90, program is being developed by Debiopharm under an August 2009 license agreement with Debiopharm.

In April 2010, Debiopharm recruited the first patient in a phase I clinical trial to evaluate the safety of Debio 0932 in patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of this phase I study. Debiopharm presented data from this study at the annual meeting of the American Society of Clinical Oncology in June 2012. In this portion of the study, Debio 0932 was tested in 50 patients, including 22 patients who received Debio 0932 every other day and 28 patients who received daily dosing of Debio 0932. Debio 0932 was generally well tolerated in this study, with most adverse events classified as Grade 1 or 2, or mild to moderate severity, with no apparent dose or schedule relationship. In addition, no ocular or cardiac toxicities were observed and no consistent changes in hematology or biochemistry parameters were seen. The most common adverse events included asthenia, constipation, decreased appetite, diarrhea, nausea, and vomiting. Anti-tumor activity was assessed in 45 of the 50 patients enrolled in this study, including a partial response observed in a patient with Kras-mutated lung cancer. Stable disease was observed in 12 patients and disease progression was observed in the remaining 31 patients.

The recommended dose for further study was determined by Debiopharm to be 1000 mg daily and Debiopharm advanced Debio 0932 into the phase Ib expansion portion of the study in the beginning of 2012 at this dose level. The primary objectives of the phase Ib portion of the study are to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 and to make a preliminary assessment of anti-tumor activity. Debiopharm expects that approximately 30 patients with advanced solid tumors will be treated in this portion of the study, including patients with non-small cell lung cancer.

In August 2012, Debiopharm initiated the HSP90 inhibition and lung cancer outcomes study, or HALO, a phase I-II clinical trial of the safety and efficacy of Debio 0932 in combination with standard of care first- and second-line chemotherapy agents in patients with advanced, stage IIIb or IV non-small cell lung cancer, or NSCLC, that is characterized as wild-type EGFR. The phase I portion of this trial is designed to determine the recommended phase II dose of Debio 0932 when given in combination with cisplatin/pemetrexed or cisplatin/gemcitabine in treatment-naive patients, and with docetaxel in previously treated patients. Once the recommended phase II dose of Debio 0932 in combination with each of the three chemotherapy regimens has been identified, the randomized, double-blind, placebo-controlled phase II portion of this study will then begin where approximately 140 eligible patients will be randomized to receive chemotherapy with either placebo or Debio 0932. The primary objective of the phase II study is to determine the efficacy of Debio 0932 in combination with chemotherapy. The Kras mutation status will also be assessed and used as a stratification factor.

We are eligible to receive our next milestone payment under our license agreement with Debiopharm if and when Debiopharm treats its fifth patient in a phase II clinical trial, assuming that Debiopharm advances Debio 0932 into phase II clinical testing. We currently anticipate that phase II testing could commence in 2013.

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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 on an annual basis and have an accumulated deficit of $736,133,000 as of September 30, 2012. We expect that we will incur significant operating losses for the next several years as we continue to incur significant costs and expenses as we seek to advance our research and development programs. Although Genentech recently received FDA approval to market Erivedge in the U.S., the level of future sales and the amount of resulting royalty revenue payable to us are both highly uncertain. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. As a result of uncertainty in the amounts of future Erivedge royalty revenue, the timing of potential milestone payments under our agreements with Genentech, Debiopharm and LLS and the variability in our operating expenses, we expect that our financial results in the future will be variable. We anticipate that existing capital resources as of September 30, 2012 should enable us to maintain current and planned operations into the first half of 2014. We believe that near term key drivers to our success will include:

Genentech s ability to successfully scale up the commercialization of Erivedge in advanced BCC in the U.S.;

Genentech s and/or Roche s receipt of approval to commercialize Erivedge in advanced BCC in Europe and other territories including in Australia, as well as its ability to successfully launch and commercialize Erivedge in these markets;

positive results in Genentech s ongoing phase II clinical trial in patients with operable BCC;

our ability to successfully plan, finance and complete current and planned clinical trials for CUDC-101 and advance CUDC-101 into phase II clinical testing in head and neck cancers;

our ability to successfully complete the ongoing phase I clinical trial of an oral formulation of CUDC-101 as well as to successfully advance CUDC-907 into phase I clinical testing;

Debiopharm s ability to advance Debio 0932 into later stages of clinical development; and

our ability to successfully enter into one or more material licenses or collaboration agreements for our proprietary drug candidates.

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

Collaboration Agreements

We are currently a party to a collaboration with Genentech relating to our Hedgehog pathway inhibitor technologies, a license agreement with Debiopharm relating to our Hsp90 inhibitor technology and an agreement with LLS related to CUDC-907. 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 milestone 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. Under our agreement with LLS, LLS will fund approximately 50% of the direct costs of the development of CUDC-907 up to $4,000,000, through milestone payments upon our achievement of specified research and development objectives. In October 2012, we earned $750,000 under our agreement with LLS related to the IND filing for CUDC-907. 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. Under our collaboration with Genentech, we currently expect to incur only costs related to the maintenance of licenses, including sublicense payments due upon milestone payments and any royalties we receive, as well as patent-related expenses. As a result of our licensing agreements with various

universities, we are also obligated to make payments to these university licensors when we receive certain payments from Genentech. As of September 30, 2012, we have incurred expenses in an aggregate amount of approximately $2,938,000 related to ongoing agreements, of which $2,898,000 relates to payments that we have or will receive from Genentech. As we receive additional milestone payments from Genentech upon European or Australian approval of Erivedge, if achieved, we would be obligated to pay additional sublicense fees to these licensors, as well as fees related to any royalties received from the sale of Erivedge. In addition, we were obligated to issue 200,000 shares of our common stock to certain licensees upon FDA approval of Erivedge that represented $964,000 in expense during the first quarter of 2012. We do not expect to incur any material costs in the foreseeable future related to our Hsp90 technologies under development by Debiopharm.

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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, 2012 should enable us to maintain current and planned operations into the first half of 2014. Our ability to continue funding our planned operations into and beyond the first half of 2014 is dependent on future contingent payments that we may receive from Debiopharm or Genentech upon the achievement of development and regulatory approval objectives, our ability to manage our expenses and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

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

Revenue. We do not expect to generate any 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. Since the first quarter of 2012, we have recognized royalty revenues related to Genentech s sales of Erivedge in the U.S. We expect to recognize royalty revenue in future quarters from Genentech s sales of Erivedge in the U.S. and in other markets where Genentech and Roche successfully obtain marketing approval, if any.

We could receive additional milestone payments from Genentech, Debiopharm, and LLS, provided the respective programs meet contractually-specified development and regulatory objectives. For example, we earned a $10,000,000 milestone payment from Genentech in January 2012 upon FDA approval of Erivedge and a $4,000,000 milestone payment upon Roche s submission with Australian health authorities seeking to commercialize Erivedge in advanced BCC in Australia. Erivedge is currently being reviewed for potential marketing approval by the EMA in European territories as well as by Australian, Canadian, Israeli, Mexican and Swiss health authorities. We are eligible to receive additional milestone revenue should Erivedge receive approval by the EMA and/or Australian health authorities, and we are also eligible to receive royalties on net sales of Erivedge in all territories where Erivedge is sold.

We currently receive no research funding for our programs under our collaborations with Genentech, Debiopharm, and LLS 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, Debiopharm, and LLS 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, Debiopharm, and LLS cannot be assured, nor can we predict the timing of any such arrangements or payments, as the case may be.

Cost of Royalty Revenues. Cost of royalty revenues consists of all expenses incurred that are associated with royalty revenues that we record in the Revenues section of our Consolidated Statements of Operations.

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; (3) sublicense payments; and (4) the costs of supplies and reagents, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We are currently incurring research and development expenses under our Hedgehog pathway inhibitor collaboration with Genentech related to the maintenance of third-party licenses to certain background technologies. In addition, we record research and development expense for payments that we are obligated to make to certain third-party university licensors upon our earning payments from Genentech related to the achievement of clinical development and regulatory objectives under our Hedgehog pathway inhibitor collaboration

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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			
- Erivedge (vismodegib)	Advanced BCC	Genentech	FDA approved; Regulatory submissions pending in EU, Australia, and other territories
Erivedge (vismodegib)	Operable Nodular BCC	Genentech	Phase II
Network-targeted Cancer Programs			
- CUDC-101 intravenous formulation (EGFR, HER2, HDAC inhibitor)	Cancer	Internal development	Phase I expansion (study completed)
- CUDC-101 intravenous formulation (EGFR, HER2, HDAC inhibitor)	Locally advanced head and neck cancer	Internal development	Phase I in combination with cisplatin and radiotherapy
- CUDC-101 oral formulation (EGFR, HER2, HDAC inhibitor)	Cancer	Internal development	Phase I dose escalation
- CUDC-907 (PI3K, HDAC inhibitor)	Cancer	Internal development/LLS	IND submitted
- Debio 0932 (Hsp90 inhibitor)	Non-small cell lung cancer	Debiopharm	Phase I/II
- Debio 0932 (Hsp90 inhibitor)	Cancer	Debiopharm	Phase Ib

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 under 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

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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 U.S. 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, 2011, and there have been no material changes to such policies.

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Results of Operations

Three-Month Periods Ended September 30, 2012 and September 30, 2011

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2012 (unaudited)	2011 (unaudited)	
REVENUES:			
Research and development			
Genentech	$ 92,000	$ 135,000	(32%)
Other	39,000	12,000	225%
Subtotal	131,000	147,000	(11%)
Royalty revenues from Genentech	446,000		100%
Total revenues	$ 577,000	$ 147,000	293%

Total revenues increased by $430,000 to $577,000 for the three months ended September 30, 2012 as compared to $147,000 for the same period in the prior year, primarily related to $446,000 of royalty revenues from the net sales of Erivedge by Genentech during the third quarter of 2012. Erivedge was approved by the FDA for commercial sale in January 2012.

All potential future contingent payments under our collaboration agreements are tied to clinical and regulatory objective milestones as well as royalties on future net sales. 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.

Cost of Royalty Revenues. Cost of royalty revenues of $22,000 for the three months ended September 30, 2012 represents the amount we are obligated to pay to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the three months ended September 30, 2012. We did not have cost of royalty revenues for the three months ended September 30, 2011 as Erivedge was approved in January 2012.

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

Research and Development Program	For the Three Months Ended September 30, 2012 (unaudited)	2011 (unaudited)	Percentage Increase/ (Decrease)
Hedgehog pathway inhibitor	$ 39,000	$ 48,000	(19%)
CUDC-101	1,110,000	901,000	23%
CUDC-907	936,000	735,000	27%
Debio 0932	11,000	5,000	120%
Other network-targeted cancer programs	787,000	1,241,000	(37%)
Gain on sale of assets		(23,000)	(100%)
Stock-based compensation	159,000	135,000	18%
Total research and development expense	$ 3,042,000	$ 3,042,000	%

Our research and development expenses remained consistent at $3,042,000 for the three months ended September 30, 2012 and 2011, respectively, due to offsetting variances within our various programs. Spending on our CUDC-907 program increased $201,000 over the prior year period primarily related to expenses for outside services related to formulation studies. In addition, spending related to our CUDC-101 programs increased $209,000 over the prior year period due to employee-related expenses, as more resources have been allocated to the CUDC-101 programs, including the initiation of a phase I clinical trial with an oral formulation of CUDC-101, the ongoing phase I clinical trial in head and neck cancer patients and a

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biomarker study of CUDC-101 in patients with invasive breast cancer. Offsetting these increases, spending on our other network-targeted cancer programs decreased $454,000 when compared to the prior year period as resources were allocated to our other development programs, as discussed above.

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. In addition, we will be obligated to pay additional sublicense fees when we receive milestone payments upon the achievement of certain regulatory objectives as well as for royalty payments that we receive on Genentech or Roche s net sales of Erivedge.

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

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2012 (unaudited)	2011 (unaudited)	
Personnel	$ 581,000	$ 612,000	(5%)
Occupancy and depreciation	126,000	121,000	4%
Legal services	614,000	540,000	14%
Consulting and professional services	260,000	247,000	5%
Insurance costs	74,000	65,000	14%
Other general and administrative expenses	170,000	159,000	7%
Stock-based compensation	649,000	177,000	267%
Total general and administrative expenses	$ 2,474,000	$ 1,921,000	29%

General and administrative expenses increased by $553,000, or 29%, to $2,474,000 for the three months ended September 30, 2012 as compared to $1,921,000 for the prior year period. This increase was primarily due to an increase in stock-based compensation of $472,000 from the prior year period as a result of an increase in the number of, and grant-date fair value of, options granted during 2012 compared to the prior year period.

In addition, legal fees increased $74,000 from the prior year period due to increased spending on patent costs, which includes fees related to foreign patent filings, and costs associated with various corporate matters.

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, and the fair value of the warrants is recorded as a long-term liability. The fair value of the warrants was estimated using a Black-Scholes option pricing model under various probability-weighted outcomes which take into consideration the protective, but limited, cash-settlement feature for the benefit of the warrant holder that expired on January 27, 2012. The warrants will be revalued each reporting period, with updated assumptions and the resulting gains and losses recorded as the change in fair value of warrant liability in the statement of operations. Expected volatilities used in the models were based on our historical volatility commensurate with the term of the warrants.

We estimated that the fair value of the warrants at September 30, 2012 was $2,691,000 using this model with the following assumptions: expected volatility of 74%, risk free interest rate of 0.3%, expected life of 2.3 years and no dividends. 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 volatilities of 80%, risk free interest rates ranging from 0.4% to 0.5%, expected lives of three years and no dividends.

We recorded other income of $1,542,000 and $587,000 for the quarters ended September 30, 2012 and 2011, respectively, due to the change in the fair value of the warrant liability which was primarily related to the change in our stock price during the respective periods. During the quarter ended September 30, 2012, warrants to purchase 24,801 shares of our common stock were exercised.

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Nine-Month Periods Ended September 30, 2012 and September 30, 2011

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30		Percentage Increase/ (Decrease)
	2012 (unaudited)	2011 (unaudited)	
REVENUES:			
Research and development			
Genentech	$ 250,000	$ 317,000	(21%)
Other	66,000	57,000	16%
Subtotal	316,000	374,000	(16%)
License fees			
Genentech	14,000,000		100%
Other		300,000	(100%)
Subtotal	14,000,000	300,000	4,567%
Royalty revenues from Genentech	970,000		100%
Total revenues	$ 15,286,000	$ 674,000	2,168%

Total revenues increased by $14,612,000 to $15,286,000 for the nine months ended September 30, 2012 as compared to $674,000 for the same period in 2011, primarily related to an increase in our license fee revenues of $14,000,000 due to payments we received from Genentech upon FDA approval of Erivedge in January 2012 and Roche s filing for marketing registration in Australia in May 2012. We recognized license fee revenues of $300,000 under a separate collaboration for the nine months ended September 30, 2011. In addition, we recognized $970,000 of royalty revenues from the net sales of Erivedge during nine-month period ended September 30, 2012.

Cost of Royalty Revenues. Cost of royalty revenues of $148,000 for the nine months ended September 30, 2012 includes a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge and $48,000 paid to two university licensors, which represents 5% of the royalties that we earned with respect to Erivedge during the nine months ended September 30, 2012. We did not have cost of royalty revenues for the nine months ended September 30, 2011 as Erivedge was approved in January 2012.

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

Research and Development Program	For the Nine Months Ended September 30, 2012 (unaudited)	2011 (unaudited)	Percentage Increase/ (Decrease)
Hedgehog pathway inhibitor	$ 112,000	$ 144,000	(22%)
CUDC-101	3,640,000	3,119,000	17%
CUDC-907	3,100,000	2,090,000	48%
Debio 0932	48,000	30,000	60%
Other network-targeted cancer programs	2,847,000	3,428,000	(17%)
Sublicense fees incurred on development and regulatory milestones under our Genentech collaboration	2,114,000		100%
Other sublicense fees		15,000	(100%)
Gain on sale of assets		(60,000)	(100%)

Stock-based compensation	924,000	479,000	93%
Total research and development expense	$ 12,785,000	$ 9,245,000	38%

Our research and development expenses increased by $3,540,000, or 38%, to $12,785,000 for the nine months ended September 30, 2012 as compared to $9,245,000 for the same period in the prior year. We incurred sublicense fees of $2,114,000 to various university licensors in connection with Erivedge s FDA approval and our receipt of milestone payments during the first half of 2012. Of this amount, $964,000 represents the fair value of a one-time issuance of an aggregate of 200,000 shares of our common stock to two university licensors in connection with the FDA-approval of

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Erivedge. The remaining $1,150,000 represents sublicense fees we paid to these same licensors upon receipt of $14,000,000 in milestone payments, of which payments of $450,000 are specific to milestones achieved pursuant to Roche s NDA filing in Australia.

In addition, spending on our CUDC-907 program also increased $1,010,000 over the prior year period primarily related to costs for additional IND-enabling toxicology studies that were completed during 2012 as well as formulation development. Spending related to our CUDC-101 programs increased $521,000 over the prior year period as a result of an increase in employee-related expenses as more resources have been allocated to the various development programs, including the initiation of a phase I clinical trial with an oral formulation of CUDC-101, the ongoing phase I clinical trial in head and neck cancer patients and a window study of CUDC-101 in breast cancer patients. These increases were offset by decreased spending on our CUDC-101 Phase Ib trial, as the last patient on trial was treated in October 2011. Further offsetting these increases, spending on our other network-targeted cancer programs decreased $581,000 when compared to the prior year period as resources have been allocated to our development programs.

Stock-based compensation also increased $445,000 from the prior year period primarily related to the expense recognized on unvested non-employee stock options that are marked-to-market at each reporting period, and which increased as our stock price increased over the prior year period.

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

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2012 (unaudited)	2011 (unaudited)	
Personnel	$ 1,889,000	$ 1,720,000	10%
Occupancy and depreciation	389,000	363,000	7%
Legal services	1,706,000	1,642,000	4%
Consulting and professional services	873,000	831,000	5%
Insurance costs	193,000	189,000	2%
Other general and administrative expenses	575,000	578,000	(1%)
Stock-based compensation	1,915,000	873,000	119%
Total general and administrative expenses	$ 7,540,000	$ 6,196,000	22%

General and administrative expenses increased by $1,344,000, or 22%, to $7,540,000 for the nine months ended September 30, 2012 as compared to $6,196,000 for the prior year period. This increase was primarily due to an increase in stock-based compensation of $1,042,000 from the prior year period as a result of an increase in the number of and grant-date fair value of options granted during 2012 compared to the prior year period. In addition, personnel costs increased $169,000 primarily due to an increase in the accrual of cash incentive payments for executive officers under short-term incentive programs when compared to the same prior year period. Finally, legal fees increased $64,000 from the prior year period due to increased costs associated with various corporate matters.

Change in fair value of warrant liability. As a result of revaluing the warrants issued in January 2010, we recorded other income of $1,054,000 and other expense of $1,235,000 for the nine months ended September 30, 2012 and 2011, respectively, as a result of the change in the fair value of the warrants, primarily related to the change in our stock price during the respective periods. During the nine months ended September 30, 2012, warrants to purchase 237,301 shares of our common stock were exercised.

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Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations 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. In the first quarter of 2012, we received a milestone payment of $10,000,000 based upon the FDA approval of Erivedge and, in May 2012, we earned a $4,000,000 milestone payment in connection with Roche s filing of an application for marketing registration in Australia. We also earned royalty revenues of $970,000 in connection with Genentech s net sales of Erivedge during the nine-month period ended September 30, 2012. In addition, during the fourth quarter of 2011, Roche submitted a MAA for Erivedge to the EMA for which we earned a $6,000,000 milestone payment. Roche has indicated that it anticipates potential EMA approval for Erivedge during the fourth quarter of 2012 or the first half of 2013.

At September 30, 2012, our principal sources of liquidity consisted of cash, cash equivalents and investments of $41,887,000, excluding our restricted investment of $194,000. 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. During 2008, we began incurring clinical costs associated with our phase I clinical trial of CUDC-101. 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 network-targeted cancer drug candidates, such as CUDC-907, reach clinical trials.

Operating activities used cash of $1,479,000 for the nine-month period ended September 30, 2012, which was primarily the result of the receipt of $14,970,000 in milestone and royalty payments from Genentech during the period. Offsetting the cash receipts, we incurred operating and other expenses of $21,615,000 for the nine months ended September 30, 2012, of which $2,614,000 related to non-cash charges consisting of stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense, the issuance of common stock to licensees and depreciation. This resulted in a net loss of $4,046,000 for the nine-month period. Changes in certain operating assets and liabilities had offsetting impacts on operating cash during the nine-month period ended September 30, 2012. A decrease of $289,000 in prepaid expenses and other current assets and an increase of $170,000 in our accounts payable and accrued liabilities were offset by an increase of $506,000 in our accounts receivable, primarily related to quarterly royalties earned on the sale of Erivedge.

Operating activities used cash of $13,251,000 for the nine-month period ended September 30, 2011. 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.

We expect to continue to use cash in operations as we 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 used cash of $11,265,000 for the nine-month period ended September 30, 2012 and provided cash of $15,828,000 for the same period in 2011, resulting primarily from net investment activity for the respective periods. During the nine-month period ended September 30, 2012, we reduced our long-term restricted investment resulting in an increase in our available cash for the period of $42,000. 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 $42,000 and $250,000 during the nine-month periods ended September 30, 2012 and 2011, respectively.

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Financing activities provided cash of $5,434,000 and $1,481,000 for the nine-month period ended September 30, 2012 and 2011, respectively, primarily from the exercise of stock options and warrants and purchases of common stock under our employee stock purchase plan. We issued 2,422,124 shares of our common stock related to these exercises and purchases during the nine-month period ended September 30, 2012 compared to 753,993 shares for the prior year period. We also received $844,000 and $139,000 in net proceeds from sales of common stock under our At Market Issuance Sales Agreement, or ATM Agreement, with McNicoll, Lewis & Vlak, LLC, or MLV, for the nine-month period ended September 30, 2012 and 2011, respectively.

Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2012, we had an accumulated deficit of approximately $736,133,000. 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.

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 ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge and the ability of Erivedge to be approved for commercial sale in other countries, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales. 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, Debiopharm and the LLS; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations, including royalties on sales of Erivedge in advanced BCC by Genentech, which is approved in the U.S. and is under review for approval in Europe, Australia and other territories by the respective health authorities in those countries.

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. For example, the amount of future royalty payments that we will receive as a result of Genentech s U.S. net sales of Erivedge, as well as potential future royalty payments that we may receive on net sales of Erivedge in territories outside of the U.S., to the extent that Genentech successfully obtains marketing approval in such territories, is highly uncertain.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at September 30, 2012, should enable us to maintain current and planned operations into the first half of 2014. 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, including the level of any royalty payments from sales of Erivedge;

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.

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We may seek additional funding through public or private financings of debt or equity. 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 potentially adverse general market conditions and the early-stage status of our internal development pipeline and the early stage of the commercial U.S. launch of Erivedge, additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any potential 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.

While we anticipate receiving royalty payments in future periods from sales of Erivedge by Genentech, we anticipate that we will require additional funding. If we are unable to obtain such additional funding on a timely basis, whether through payments under existing or future collaborations or license agreement or sales of debt or equity, 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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2012.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our current cash balances in excess of operating requirements are invested in cash equivalents and short-term marketable securities, which consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations with an average maturity of less than one year. All marketable securities are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. This objective may be adversely affected by the ongoing economic downturn and volatile business environment and continued unpredictable and unstable market conditions. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. 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, 2012, but 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/or liquidity of marketable securities owned by us. Our investments are investment grade securities, and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as we currently have the ability to hold our investments for a sufficient period of time to recover the fair value of the investment and there is sufficient evidence to indicate that the fair value of the investment is recoverable. We do not use derivative financial instruments in our investment portfolio. We do not believe that a 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

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, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or 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, 2012, 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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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, 2011.

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We are reliant on Genentech for the successful development and commercialization of Erivedge. If Genentech does not successfully commercialize Erivedge for advanced BCC, or develop Erivedge for other indications, our future prospects and our ability to finance our operations may be substantially harmed.

In January 2012, Erivedge was approved by the FDA as the first and only FDA-approved medicine for people with advanced forms of BCC. Genentech and/or Roche have also filed an MAA with the EMA as well as regulatory submissions with Australian regulatory authorities and in other territories seeking regulatory approvals of Erivedge in these territories for this same indication. Genentech and Roche are also conducting a phase II clinical trial of Erivedge in operable nodular BCC and Erivedge is currently being tested in other cancers under collaborative agreements between Genentech and either third-party investigators or the NCI. Our near-term prospects substantially depend upon Genentech s ability to successfully develop and commercialize Erivedge in one or more indications and to demonstrate its safety and efficacy, as well as its superiority over existing therapies and standards of care. Moreover, our ability to finance our company and to generate revenues will depend heavily on the ability of Genentech and Roche to: (i) successfully commercialize Erivedge in the advanced BCC indication such that net sales are generated at a level for which we will derive meaningful royalties from Genentech, (ii) successfully file regulatory submissions for, and obtain approval to sell, Erivedge in Europe and/or other territories for advanced BCC, and (iii) obtain favorable results in ongoing and planned clinical trials of Erivedge in other indications, including the ongoing clinical trial in operable BCC. The development and commercialization of Erivedge could be unsuccessful if:

- Erivedge for the treatment of advanced BCC is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payors;
- Genentech and/or Roche fails to apply the necessary financial resources and expertise to manufacturing, marketing and selling Erivedge for advanced BCC and to regulatory approvals for this indication outside of the U.S.;
- Genentech and/or Roche does not develop and implement effective marketing, sales and distribution strategies and operations, for development and commercialization of Erivedge for advanced BCC;
- Genentech and/or Roche does not develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;
- Genentech and/or Roche does not successfully obtain third party reimbursement and generate commercial demand that results in sales of Erivedge for advanced BCC in any geographic areas where requisite approvals have been, or may be, obtained;
- we or Genentech and/or Roche encounter any third party patent interference or patent infringement claims with respect to Erivedge;

Genentech and/or Roche does not comply with any and all regulatory and legal requirements applicable to the sale of Erivedge for advanced BCC;

new safety risks are identified after Erivedge is commercially marketed; and/or

Erivedge does not demonstrate acceptable safety and efficacy in current or future clinical trials, or otherwise does not meet applicable regulatory standards for approval in indications other than advanced BCC.

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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 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 cancer targets they are being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits 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 may 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. Genentech recently obtained FDA approval to commercialize Erivedge, the sole compound being developed under this collaboration, in advanced BCC. Genentech and Roche are also seeking to obtain regulatory approval for this same indication in the EU, Australia, Canada, Israel, Mexico and Switzerland and are also conducting, both alone and in collaboration, further studies of Erivedge for other indications. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is testing Debio 0932 in a phase Ib clinical trial in advanced solid tumors. Our collaboration agreement with Genentech and our license agreement with Debiopharm are our most significant 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 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 their respective agreements with us. For example, our ability to obtain meaningful amounts of royalty income from sales of Erivedge for advanced BCC will depend in large part upon the degree to which Genentech applies suitable financial and other resources to the manufacture, commercialization and sale of Erivedge for advanced BCC and to obtaining regulatory approvals outside of the U.S.

Our agreements with Genentech and Debiopharm each permits the other party 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 applicable agreement. 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.

We have granted clinical development rights to Genentech and Debiopharm, respectively, under our agreements with each of them. If they fail to allocate sufficient time, attention and resources to clinical trials of product candidates under these collaborations, or fail to comply with good clinical practices or other applicable regulatory requirements for such clinical trials, the successful clinical development and commercialization of such product candidates is likely to be adversely affected, as will our ability to generate revenue from such collaborations.

Genentech or 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 collaboration with us. For example, Genentech and Debiopharm each are developing several other programs in cancer.

Genentech or Debiopharm may change the focus of its 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.

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Either 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 such collaboration. In addition, an acquirer could determine to reprioritize our collaborator s development programs such that our collaborator ceases to diligently pursue the development of our programs, and/or terminates its collaboration with us.

Genentech or Debiopharm may, under specified circumstances, terminate its 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.

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

Genentech or 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 or 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 its arrangement 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.

Either Genentech or Debiopharm may not have sufficient resources necessary to advance clinical development of product candidates under our collaborations with each of them 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.

For a further discussion of risks relating specifically to our dependence on Genentech for the successful development and commercialization of Erivedge, see our separate risk factor: We are reliant on Genentech for the successful development and commercialization of Erivedge. If Genentech does not successfully commercialize Erivedge for advanced BCC, or develop Erivedge for other indications, our future prospects and our ability to finance our operations will be substantially harmed.

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, generally following our completion of at least phase I clinical testing. For example, while we are not presently seeking to enter into corporate collaborations for CUDC-101, we are likely to seek to partner CUDC-101, CUDC-907 as well as other drug candidates from these programs in the future. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., phase III) 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.

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;

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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;

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

our future prospects may be adversely affected and our stock price could decline.

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 each indication for which approval is sought.

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 phase II clinical trials of Erivedge in colorectal cancer and ovarian cancer, both of which were completed in 2010;

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, nor may we or any of our current or potential future collaborators or subcontractors use disqualified clinical investigators or institutions to perform clinical trials of our drug candidates. Employment or use of such a debarred or disqualified person or institution 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) or institution(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 our stock price is likely to decline.

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We expect to rely in part on third parties to conduct clinical trials of our internally-developed product candidates, 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 a limited internal group for overseeing our clinical trials. For the foreseeable future, we expect to rely in part 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, 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 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 applicable 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 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 or to distribution and use restrictions or other requirements under a Risk Evaluation and Mitigation Strategy, or REMS. 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 potential future products outside of the U.S. 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 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 can be marketed, impose restrictions on how the product can be distributed and used pursuant to a REMS, 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 its 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 or those of our collaborators, and criminal prosecution.

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The FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our or our collaborators 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 U.S. or abroad. If we or our collaborators 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 or they may lose any marketing approvals that have been obtained, which would adversely affect the amount of revenue generated from such products and adversely affect our ability to achieve or sustain profitability.

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 any collaborators would be able to comply with any applicable regulations.

Our business involves the use of hazardous materials and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

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. Violation of these laws and regulations could lead to substantial fines and penalties. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

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

Our future products, including those developed under collaborations with third parties, 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 or our collaborators successfully develop. If we or our collaborators 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, 2012, we had an accumulated deficit of approximately $736,133,000. We have incurred net losses of $9,859,000, $4,435,000 and $9,823,000 for the years ended December 31, 2011, 2010, and 2009, respectively, and a net

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loss of $4,046,000 for the nine months ended September 30, 2012. Other than Erivedge, which was approved by the FDA in January 2012 for the treatment of advanced forms of BCC, we have not successfully commercialized any products to date, either alone or in collaboration with others. We are entitled to royalties on net sales of Erivedge by Genentech. If these royalties are not meaningful or we are not able to successfully commercialize any other products, we will not achieve sustainable profitability. All of our drug candidates other than Erivedge 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 may 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 ability to generate cash flow to operate our business will depend, in part, on royalty payments from the commercial sale of Erivedge and the ability of Erivedge to be approved for commercial sale in other countries, which would result in us becoming eligible to receive additional milestone payments as well as royalties on any future sales. 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 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, Debiopharm and LLS; and
- royalty payments that are contingent upon the successful commercialization of products based upon these collaborations, including royalties on sales of Erivedge in advanced BCC by Genentech, which is approved in the U.S. and is under review for approval in Europe, Australia and other territories by the respective health authorities.

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. For example, the amount of future royalty payments that we will receive as a result of Genentech s U.S. net sales of Erivedge, as well as potential future royalty payments that we may receive on net sales of Erivedge in territories outside of the U.S., to the extent that Genentech successfully obtains marketing approval in such territories, is highly uncertain.

We anticipate that existing cash, cash equivalents, marketable securities and working capital at September 30, 2012 should enable us to maintain current and planned operations into the first half of 2014. 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, including the level of any royalty payments from sales of Erivedge;

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates, including the level of any royalty payments from sales of Erivedge;

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.

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We may seek additional funding through public or private financings of debt or equity. 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 potentially adverse general market conditions and the early-stage status of our internal development pipeline and the early stage of the commercial U.S. launch of Erivedge, additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any potential 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.

While we anticipate receiving royalty payments in future periods from sales of Erivedge by Genentech, we anticipate that we will require additional funding. If we are unable to obtain such additional funding on a timely basis, whether through payments under existing or future collaborations or license agreement or sales of debt or equity, 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 the ATM Agreement with MLV pursuant to which, from time to time, we may offer and sell up to $20 million of common stock that was registered pursuant to our universal 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. The market for emerging life science stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including adverse general market conditions, the early-stage status of our development pipeline and the early stage of the commercial U.S. launch of Erivedge, 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, including the level of any royalty payments from sales of Erivedge;

the entry into, or termination of, collaboration agreements;

the scope, duration and effectiveness of our collaborative arrangements;

the costs involved in prosecuting, maintaining and enforcing patent claims;

our ability to operate without infringing upon the proprietary rights of others;

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costs to comply with changes in government regulations;

costs related to changes in management and reductions or additions of personnel;

litigation costs;

costs and accounting charges associated with financing or borrowing arrangements we may enter into from time to time;

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 decline in 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 and prospects may be adversely affected by the unfavorable economic conditions, volatile business environment and continued unpredictable and unstable market conditions, both domestically and abroad. 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 research and 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, 2012, we had $41,887,000 of cash, cash equivalents, marketable securities and long-term investments 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, 2012, 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 is a wholly-owned member of the Roche Group and Roche has also made public statements regarding its expectations for the clinical development and potential regulatory approval of Erivedge in territories other than the U.S., and may in the future make additional statements about its 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, our or our current and potential future collaborators preclinical studies and clinical trials may not advance or be completed in the time frames we or they announce or expect, we or our current and potential future collaborators may not make regulatory submissions or receive regulatory approvals as planned that we or our current and potential future collaborators may not 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.

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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, there are several Hedgehog pathway inhibitors presently in clinical development by companies including Bristol-Myers Squibb Company, Infinity Pharmaceuticals, Inc., Millennium Pharmaceuticals, Inc., Novartis International AG and Pfizer Inc. that may compete with Erivedge. Genentech and Roche are currently commercializing Erivedge in advanced BCC and also conducting a phase II trial in less severe forms of BCC. In addition, Erivedge is also currently being tested in other cancers in trials under collaborative agreements between Genentech and either third-party investigators or the NCI. We currently believe that the nearest competitive molecule to Erivedge in clinical development is in phase II clinical testing in locally advanced and metastatic BCC. Competitors may discover, characterize and develop their Hedgehog pathway inhibitor drug candidates and compete with us in the same cancer indications in which Erivedge is currently being studied.

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 and 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.

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Although we currently have product liability insurance for our clinical trials, 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.

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, including Daniel R. Passeri, our President and Chief Executive Officer, Maurizio Voi, our Chief Medical and Chief Development Officer, and Michael P. Gray, our Chief Operating Officer and Chief Financial Officer. 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 all serve pursuant to at will employment arrangements and can terminate their employment with us at any time. We do not maintain key man life insurance on any of these officers. 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.

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 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, 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;
- unanticipated expenses and potential delays related to integration of the operations, technology and other resources of any acquired companies;
- uncertainty related to the value, benefits or legitimacy of intellectual property or technologies acquired;
- retaining and assimilating key personnel and the potential impairment of relationships with our employees;
- incurrence of debt, other liabilities and contingent liabilities, including potentially unknown contingent liabilities; and

dilutive stock issuances.

Any business that we conduct in China will expose us to risks resulting from adverse changes in political, legal and economic policies of the Chinese government, which 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 to conduct business 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

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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. Recent evidence of a slowdown in 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 doing business 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 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 generally accepted accounting principles, or GAAP . 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.

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RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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 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.

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 U.S. 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 have 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.

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 U.S. and in many countries 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. The U.S. Congress passed the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011. The America Invents Act reforms U.S. patent law in part by changing the standard for patent approval from a first to invent standard to a first to file standard and developing a post-grant review system. This new legislation changes U.S. patent law in a way that may weaken our ability to obtain or maintain patent protection for future inventions in the U.S.

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, reexamination, post grant review or inter partes review 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.

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The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial and a distraction to management. 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 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. 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 U.S. 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.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, we could lose license rights that are important to our business.

We are party to agreements that provide for licenses to us of intellectual property or sharing of rights to intellectual property that is important to our business, and we may enter into additional agreements in the future that provide licenses to us of valuable technology. These licenses impose, and future licenses may impose, various commercialization, milestone and other obligations on us, including the obligation to terminate our use of patented subject matter under certain contingencies. If a licensor becomes entitled to, and exercises, termination rights under a license, we would lose valuable rights and could lose our ability to develop our products. We may need to license other intellectual property to commercialize future products. Our business may suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or if we are unable to enter into necessary licenses on acceptable terms.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although

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no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATING TO MANUFACTURING AND SALES

We will depend on our 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 and our collaborators 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 and our collaborators.

Any contract manufacturers with whom we or our collaborators 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 or our collaborators 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 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 or a collaborator 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.

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.

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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, and Genentech is currently distributing Erivedge as part of its U.S. commercialization rights following FDA approval of Erivedge in February 2012. 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;
- 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 U.S., 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

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source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. 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. Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. In addition, some details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on our business remains unclear. 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 U.S., 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

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 is likely to continue to be volatile in the future. For example, our stock traded within a range of a high price of $5.65 and a low price of $1.97 per share for the period January 1, 2011 through November 2, 2012. 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 collaborators or 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;

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.

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.

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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, 2012, we had approximately 80.0 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, 2012 was approximately 484,000 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 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, 2012, we have outstanding warrants to purchase 1,373,517 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 1,389,769 shares of our common stock, at an exercise price of $3.51 per share, which is equal to an aggregate of additional 16,252 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 the ATM 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.

Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to devote substantial time to compliance initiatives, and if our independent registered public accounting firm is required to provide an attestation report on our internal controls but is unable to provide an unqualified attestation report, our stock price could be adversely affected.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. The internal control report must contain (i) a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting and (iii) management s assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective.

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To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional employees for our finance and audit functions, potentially engage outside consultants and adopt a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) continue steps to improve control processes where appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. In addition, in connection with the attestation process by our independent registered public accounting firm, if required, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. There are currently nine research analysts that publish research coverage related to Curis. These securities and industry analysts may not maintain such coverage or we may fail to obtain research coverage by additional securities and industry analysts. If we do not maintain such existing coverage, and additional securities or industry analysts do not commence coverage of our company, the trading price for our stock may be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

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, 2012, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 35% 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.

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Item 6. EXHIBITS

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

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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: November 6, 2012

By: /s/ MICHAEL P. GRAY
Michael P. Gray

Chief Operating Officer and Chief Financial Officer

(Duly Authorized Officer and

Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1	Collaborative Research, Development and License Agreement, dated June 11, 2003, between Curis and Genentech, Inc.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
+101.INS	XBRL Instance Document
+101.SCH	XBRL Taxonomy Extension Schema Document
+101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
+101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
+101.LAB	XBRL Taxonomy Extension Label Linkbase Document
+101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Confidential treatment has been requested as to certain portions, which portions have been separately filed with the Securities and Exchange Commission.

+ Furnished, not filed, herewith.