CURIS INC
Form 10-Q
November 12, 2013
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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, 2013

OR

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

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3505116**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**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 November 4, 2013, there were 85,798,031 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, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,778,686	$ 12,747,709
Investments	49,438,298	42,791,689
Short-term investment (restricted)	13,877	13,877
Accounts receivable	1,156,469	908,064
Prepaid expenses and other current assets	505,084	390,564
Total current assets	64,892,414	56,851,903
Property and equipment, net	467,489	434,168
Long-term investments	3,921,672	3,162,025
Long-term investment (restricted)	166,487	180,405
Goodwill	8,982,000	8,982,000
Other assets	116,914	157,848
Total assets	$ 78,546,976	$ 69,768,349
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,290,679	$ 2,504,270
Accrued liabilities	1,976,927	1,474,556
Current portion of long-term debt, net	1,449,931	
Total current liabilities	5,717,537	3,978,826
Long-term debt, net	29,131,724	29,838,925
Warrants	1,926,465	1,488,179
Other long-term liabilities	197,912	194,921
Total liabilities	36,973,638	35,500,851
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 225,000,000 and 125,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 85,353,092 shares issued and 84,130,246 shares outstanding at	853,531	810,655

September 30, 2013; 81,065,488 shares issued and 80,017,781 shares outstanding at December 31, 2012		
Additional paid-in capital	798,858,239	782,837,507
Treasury stock (at cost, 1,222,846 shares and 1,047,707 shares at September 30, 2013 and December 31, 2012, respectively)	(1,524,029)	(891,274)
Accumulated deficit	(756,628,529)	(748,504,549)
Accumulated other comprehensive income	14,126	15,159
Total stockholders equity	41,573,338	34,267,498
Total liabilities and stockholders equity	$ 78,546,976	$ 69,768,349

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,	
	2013	2012	2013	2012
REVENUES:				
License fees	$ 6,000,000	$	$ 10,000,000	$ 14,000,000
Royalties	1,080,233	446,402	2,549,945	969,774
Research and development	121,850	131,357	927,950	315,811
Total revenues	7,202,083	577,759	13,477,895	15,285,585
COSTS AND EXPENSES:				
Cost of royalty revenues	54,014	22,320	127,499	148,489
Research and development	4,170,751	3,042,498	9,965,847	12,784,902
General and administrative	2,846,950	2,473,853	8,317,741	7,539,516
Total costs and expenses	7,071,715	5,538,671	18,411,087	20,472,907
Income/(loss) from operations	130,368	(4,960,912)	(4,933,192)	(5,187,322)
OTHER INCOME/(EXPENSE):				
Interest income	39,024	34,129	117,585	87,224
Interest expense	(964,543)		(2,870,087)	
Change in fair value of warrant liability	(1,072,687)	1,541,779	(438,286)	1,054,379
Total other income/(expense)	(1,998,206)	1,575,908	(3,190,788)	1,141,603
Net loss	$ (1,867,838)	$ (3,385,004)	$ (8,123,980)	$ (4,045,719)
Net loss per common share (basic and diluted)	$ (0.02)	$ (0.04)	$ (0.10)	$ (0.05)
Weighted average common shares (basic and diluted)	82,456,708	79,639,433	81,235,922	78,752,687
Total comprehensive loss	$ (1,862,631)	$ (3,401,010)	$ (8,125,013)	$ (4,055,967)

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,	
	2013	**2012**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (8,123,980)	$ (4,045,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	104,359	91,383
Stock-based compensation expense	2,499,091	2,838,311
Issuance of common stock to licensees		964,000
Change in fair value of warrant liability	438,286	(1,054,379)
Non-cash interest (income)/expense	161,586	(225,468)
Amortization of debt issuance costs	78,605	
Payment in-kind interest on debt	753,639	
Changes in operating assets and liabilities:		
Accounts receivable	(248,405)	(881,986)
Prepaid expenses and other assets	(126,482)	288,922
Accounts payable and accrued liabilities	436,449	170,004
Total adjustments	4,097,128	2,190,787
Net cash used in operating activities	(4,026,852)	(1,854,932)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investments	(43,908,127)	(43,956,032)
Sale of investments	36,339,252	32,691,355
Decrease in restricted cash	13,918	41,632
Purchases of property and equipment	(134,457)	(42,166)
Net cash used in investing activities	(7,689,414)	(11,265,211)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Company s share-based compensation plans and warrant exercises	3,514,595	4,965,793
Payment of debt issuance costs	(261,475)	
Proceeds from issuance of common stock under the Company s ATM Agreements, net of issuance costs of $367,706 and $27,356, respectively (see Note 8)	9,494,123	844,028
Net cash provided by financing activities	12,747,243	5,809,821

NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	1,030,977	(7,310,322)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	12,747,709	15,119,730
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 13,778,686	$ 7,809,408

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. is an oncology-focused drug development company seeking to develop novel targeted drug candidates for the treatment of human cancers. As used throughout these unaudited, condensed consolidated financial statements, the term the Company refers to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term Curis refers to Curis, Inc.

The Company conducts research and development programs both internally and through strategic collaborations. Erivedge® is the first and only approved medicine for the treatment of advanced basal cell carcinoma, and is being 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(a)). Roche and Genentech are also seeking to develop Erivedge for additional indications. The Company is also leveraging its experience in targeting signaling pathways in seeking to develop targeted cancer drug candidates CUDC-427, a small molecule IAP inhibitor, and CUDC-907, a dual PI3K and HDAC inhibitor. The Company s licensee Debiopharm S.A., or Debiopharm, is progressing the clinical development of HSP90 inhibitor, Debio 0932.

The Company initiated a phase 1 study of CUDC-427 in July 2013. On November 5, 2013, the Company received written notification from the United States Food and Drug Administration (FDA) that its Phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until Curis provides the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. The Company expects to respond to the FDA s requests for additional information and also plans to submit an amendment to the current protocol in a timely manner.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any products that are successfully developed and commercialized would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory authorities.

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; the Company s ability to advance and expand its research and development programs; the Company s ability to obtain adequate financing to fund its operations; Curis Royalty s ability to satisfy the terms of its loan agreement with BioPharma Secured Debt Fund II Sub, S.à r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II; the Company s ability to obtain and maintain necessary intellectual property protection; development by the Company s competitors of new or better technological innovations; dependence on key personnel; the Company s ability to comply with regulatory requirements; and the Company s 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 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: Roche and Genentech s ability to successfully commercialize Erivedge; positive results in Genentech s ongoing clinical trials; the timing, outcome and cost of the Company s preclinical studies and clinical trials for its drug candidates; whether or not the FDA removes the partial clinical hold on CUDC-427; 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 cash, cash equivalents, marketable securities, investments and working capital at September 30, 2013 should enable it to maintain current and planned operations into 2016. The Company s ability to continue funding its planned operations beyond this period is dependent upon, among other things, the success of its collaborations with Genentech, Debiopharm and the Leukemia & Lymphoma Society, or LLS, including its receipt of additional contingent 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 raise additional funds or enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. 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.

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2. Basis of Presentation

These condensed consolidated financial statements include the accounts of Curis and its wholly owned subsidiaries, Curis Royalty LLC (Curis Royalty), Curis Securities Corporation, Inc. (Curis Securities Corporation) and Curis Pharmaceuticals (Shanghai) Co., Ltd. (Curis Shanghai). The Company has eliminated all significant intercompany accounts and transactions in consolidation. See Note 7.

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the United States of America, or GAAP, 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, 2012, or the Annual Report, as filed with the Securities and Exchange Commission on March 13, 2013.

In the opinion of the Company, the unaudited condensed consolidated 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, 2013, the results of operations for the three- and nine-month periods ended September 30, 2013 and 2012 and the cash flows for the nine-month periods ended September 30, 2013 and 2012.

In the fourth quarter of 2012, the Company determined that its previously filed 2012 Forms 10-Q contained an error within the statements of cash flows. More specifically, in its Form 10-Q filed with the quarter ended September 30, 2012, the proceeds from the settlement of stock option exercises totaling $375,661 were incorrectly presented as cash flows from operating activities when such amount should have been classified as cash flows from financing activities for the nine -month period ending September 30, 2012 in the statements of cash flows. The Company determined that the effect of the error was not material and therefore did not restate its Form 10-Q filed with the quarter ended September 30, 2012, or any of its other Forms 10-Q filed in 2012. The Company has properly reflected the adjustment in its statement of cash flows for the nine months ended September 30, 2012 in this Form 10-Q. The as previously reported and as adjusted numbers are presented as follows:

	As Previously Reported		As Adjusted	
	Cash flow provided by		Cash flow provided by	
	Operating Activities	Financing Activities	Operating Activities	Financing Activities
Nine months ending September 30, 2012	($ 1,479,271)	$ 5,434,160	($ 1,854,932)	$ 5,809,821

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 the performance obligations under the Company s collaboration agreements; the estimated repayment term of the Company s debt and related short- and long-term classification; the fair value of the Company s debt; the collectability of receivables; the carrying value of property and equipment and intangible assets; the assumptions used in the Company s valuation of stock-based compensation and the value of certain investments and liabilities, including our long-term warrant liability. Actual results may differ from such estimates.

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

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3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s drug candidates. Pursuant to the terms of these agreements, the Company and its licensees and collaborators may 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.

4. Collaboration Agreements

(a) Genentech June 2003 Collaboration

In January 2012, the FDA approved Genentech s new drug application for the Erivedge capsule. As a result of the FDA s approval of Erivedge in this indication, the Company earned a $10,000,000 milestone payment from Genentech. In May 2012, Roche submitted an application for marketing registration for Erivedge to Australia s Therapeutic Goods Administration, or TGA, and as a result, the Company earned a $4,000,000 milestone payment. In May 2013, the TGA approved the sale of Erivedge in Australia resulting in an additional milestone payment of $4,000,000. In July 2013, Roche announced that it had received conditional marketing approval for Erivedge from the European Commission for the treatment of advanced BCC, which will be applicable to all 28 European Union member states, and resulted in a milestone payment to the Company of $6,000,000. The Company is eligible to receive up to an aggregate of $115,000,000 in contingent cash payments, exclusive of royalty payments, under the collaboration for the development of Erivedge or another small molecule Hedgehog pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this aggregate amount, the Company has received $56,000,000 as of September 30, 2013. The Company recognized milestone payments of $6,000,000 in the three months ended September 30, 2013, and $10,000,000 and $14,000,000 in the nine months ended September 30, 2013 and 2012, respectively, as license revenue in its Condensed Consolidated Statement of Operations and Comprehensive Loss as the Company does not have any further substantive performance obligations under the collaboration.

Pursuant to agreements by and between the Company and two university licensors, the Company has made certain payments to such licensors in connection with its receipt of milestone payments from Genentech. During the three and nine months ended September 30, 2013, the Company recorded research and development expenses of $300,000 and $500,000, respectively, related to payments the Company made to its licensors upon the Company s receipt of milestone payments from Genentech upon European Commission and Australian TGA approvals of Erivedge. During the nine months ended September 30, 2012, the Company recorded research and development expenses of $2,114,000. Of this amount, the Company recorded research and development expenses of $650,000 related to payments the Company made to its licensors in connection with (i) Roche s filing in 2009 of an investigational new drug application in Australia and (ii) the Company s receipt of the $4,000,000 milestone from Roche upon its application to the Australian TGA for marketing registration of Erivedge in Australia. In addition, the Company recorded research and development expense of (i) $964,000 related to the fair value of a one-time issuance of an aggregate of 200,000 shares of the Company s common stock in connection with FDA approval of Erivedge and (ii) $500,000 related to the Company s receipt of the $10,000,000 milestone payment from Genentech in the first quarter of 2012.

The Company s wholly-owned subsidiary Curis Royalty is entitled to a royalty on net sales of Erivedge that ranges from 5% to high single digits based upon global Erivedge sales by Roche and Genentech, subject to reduction under

specified circumstances. The Company recognized royalty revenues from Genentech s net sales of Erivedge of $1,080,233 and $446,402 during the three months ended September 30, 2013 and 2012, respectively, and $2,549,945 and $969,774 during the nine months ended September 30, 2013 and 2012, respectively. The Company recorded cost of royalty revenues within the costs and expenses section of its Condensed Consolidated Statements of Operations and Comprehensive Loss of $54,014 and $22,320 during the three months ended September 30, 2013 and 2012, respectively, and $127,499 and $148,489 during the nine months ended September 30, 2013 and 2012, respectively. For each of these periods, the cost of royalty revenue amounts are comprised of 5% of the Erivedge royalties earned by Curis Royalty that the Company is obligated to pay to university licensors. In addition, during the nine months ended September 30, 2012, the Company recorded an additional expense of $100,000 due to a one-time cash payment to a university licensor upon the first commercial sale of Erivedge. As further discussed in Note 7, the Company

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expects that all royalty revenues received by Curis Royalty from Genentech on net sales of Erivedge will be used by Curis Royalty to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to specified quarterly caps, until such time as the loan is fully repaid.

(b) The Leukemia & Lymphoma Society Agreement

In November 2011, the Company entered into an agreement under which LLS agreed to make up to $4,000,000 in milestone payments to support the Company s ongoing development of CUDC-907 for patients with relapsed or refractory lymphoma and multiple myeloma, contingent upon the Company s achievement of specified clinical development objectives with CUDC-907. The Company earned milestone payments under the LLS agreement totaling $650,000 during the nine month period ended September 30, 2013, related to the progress of the ongoing phase 1 clinical trial of CUDC-907. Additional milestone payments may be earned assuming CUDC-907 continues to progress through the phase 1 clinical trial. Through September 30, 2013, the Company has received payments in the aggregate of $1,650,000 under its agreement with LLS.

The Company continues to apply the provisions of Accounting Standards Codification, or ASC, 605-28, *Revenue Recognition, Milestone Method* to determine whether the revenue earned under this agreement should be accounted for as substantive milestones. In determining whether the milestones in this arrangement are substantive, the Company considered whether uncertainty exists as to: (i) the achievement of the milestone event at the inception of the arrangement; (ii) whether the achievement of the milestone involves substantive effort and can only be achieved based in whole or part on the performance or the occurrence of a specific outcome resulting from the Company s performance; (iii) whether the amount of the milestone payment appears reasonable either in relation to the effort expected to be expended or to the projected enhancement of the value of the delivered items; (iv) whether there is any future performance required to earn the milestone; and (v) whether the consideration is reasonable relative to all deliverables and payment terms in the arrangement. When a substantive milestone is achieved, the accounting guidance permits recognition of revenue related to the milestone payment in its entirety. The Company determined that the milestones achieved in 2013 under the LLS agreement were substantive and recorded the related revenue of $650,000 during the nine month period ended September 30, 2013.

Under certain conditions associated with the successful partnering and/or commercialization of CUDC-907 in the specified indications, the Company may be obligated to make payments, including royalties, to LLS up to a maximum of $10,000,000. This obligation is limited to 2.5 times the amount the Company receives from LLS, and, as of September 30, 2013, the maximum obligation, assuming that CUDC-907 successfully enters into a collaboration agreement and/or progresses through future clinical trials, would be $4,125,000. If CUDC-907 does not continue to meet its clinical safety endpoints in future clinical trials in the defined field or fails to obtain necessary regulatory approvals, all funding provided to the Company by LLS will be considered a non-refundable grant. As of September 30, 2013, the Company has not recorded an obligation to repay any of the funds received from LLS because the contingent repayment obligation depends solely on the successful results of the continued development of CUDC-907, which are not probable at September 30, 2013 as this program remains in the early stages of 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 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 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.

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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 Black-Scholes model, further discussed in Note 8, and is therefore classified as Level 3.

In accordance with the fair value hierarchy, the following table shows the fair value as of September 30, 2013 and December 31, 2012 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, 2013 and December 31, 2012.

	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of September 30, 2013:				
Cash equivalents				
Money market funds	$ 10,235,389	$	$	$ 10,235,389
Municipal bonds		1,110,000		1,110,000
Short- and long-term investments				
US government obligations		1,505,961		1,505,961
Corporate commercial paper, stock, bonds and notes	16,719,904	34,133,420		50,853,324
Total assets at fair value	$ 26,955,293	$ 36,749,381	$	$ 63,704,674
Warrant liability			1,926,465	1,926,465
Total liabilities at fair value	$	$	$ 1,926,465	$ 1,926,465

The above table excludes a certificate of deposit in the amount of $1,000,685 that the Company held as of September 30, 2013.

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	Quoted Prices in Active Markets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)	Fair Value
As of December 31, 2012:				
Cash equivalents				
Money market funds	$ 7,597,598	$	$	$ 7,597,598
Corporate commercial paper, bonds and notes	2,263,323			2,263,323
Municipal bonds		1,825,000		1,825,000
Short- and long-term investments				
Corporate commercial paper, bonds and notes	13,366,420	32,587,294		45,953,714
Total assets at fair value	$ 23,227,341	$ 34,412,294	$	$ 57,639,635
Warrant liability			1,448,179	1,448,179
Total liabilities at fair value	$	$	$ 1,448,179	$ 1,448,179

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, 2013 and 2012:

Balance at December 31, 2012	$ 1,488,179
Change in fair value	438,286
Balance at September 30, 2013	$ 1,926,465
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

6. Investments

The amortized cost, unrealized losses and fair value of marketable securities available-for-sale as of September 30, 2013 with maturity dates ranging between one and twelve months and with a weighted average maturity of 5.2 months are as follows:

	Amortized Cost	Unrealized Gain	Fair Value
Corporate bonds and notes	$ 47,169,463	$ 12,456	$ 47,181,919

US government and municipal obligations	1,255,922	87	$ 1,256,009
Total marketable securities	$ 48,425,385	$ 12,543	$ 48,437,928

In addition, a certificate of deposit in the amount of $1,000,370 that the Company held as of September 30, 2013 was included within short-term investments in the consolidated balance sheet but is excluded from the table above as it was not deemed to be a security.

As of September 30, 2013, the Company also recorded long-term investments of $3,921,672 on its Consolidated Balance Sheet. This amount is comprised of corporate and government-secured debt securities with maturities ranging from November 2014 to March 2015 with a weighted average maturity of 16 months and with amortized cost totaling $3,920,089, plus unrealized net gains of $1,583.

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The amortized cost, unrealized gains and fair value of marketable securities available-for-sale as of December 31, 2012, with maturity dates ranging between one and twelve months and with a weighted average maturity of 5.2 months are as follows:

	Amortized Cost	Unrealized Gain	Fair Value
Corporate bonds, notes and stock	$ 42,775,952	$ 15,737	$ 42,791,689
Total marketable securities	$ 42,775,952	$ 15,737	$ 42,791,689

As of December 31, 2012, the Company recorded long-term investments of $3,162,025 on its Condensed Consolidated Balance Sheet. This amount was comprised of corporate debt securities with maturities ranging from March 2014 to May 2014 and with amortized cost totaling $3,161,848, plus unrealized net gains of $177.

7. Debt

In December 2012, Curis wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II. In connection with the loan, Curis transferred to Curis Royalty its right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that it may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by Curis pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) Curis royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by Curis enforcing its right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of $1,000,000 per quarter in 2013, $2,000,000 per quarter in 2014 and $3,000,000 per quarter in 2015, will be applied first to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive the remaining royalty amounts above the caps, if any, and Curis remains entitled to receive any contingent payments upon achievement of clinical development objectives. Curis Royalty retains its right to royalty payments related to sales of Erivedge following repayment of the loan.

The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty s right to receive royalties under the collaboration agreement with Genentech. At any time after January 1, 2017, Curis Royalty may, subject to certain limitations, prepay the outstanding principal of the loan in whole or in part, at a price equal to 105% of the outstanding principal on the loan, plus accrued but unpaid interest. The obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated upon the occurrence of an event of default as defined in the credit agreement.

Curis Royalty made interest payments under the loan agreement of $531,877 on March 6, 2013, $631,191 on May 31, 2013 and $764,999 on August 30, 2013. Each of these payments represented only a portion of the interest accrued

through each payment date. As a result, the shortfall in the unpaid but accrued interest totaling $753,639 was added to the principal portion of the loan. As of September 30, 2013, the Company recorded short- and long-term debt of $1,449,931 and $29,131,724, respectively (net of issuance costs of $53,484 and $118,500, respectively), and at December 31, 2012 recorded long-term debt of $29,838,925 (net of issuance costs of $161,075), related to the loan, with such amounts recorded within the Company s Condensed Consolidated Balance Sheets. In addition, the Company recorded related accrued interest on the debt of $313,943 and $204,167 as of September 30, 2013 and December 31, 2012, respectively, with such amounts included in the Company s accrued liabilities section of its Condensed Consolidated Balance Sheets. Because the repayment of the term loan is contingent upon the level of Erivedge royalties received, the repayment term may be shortened or extended depending on the actual level of Erivedge royalties. In addition, if Erivedge royalties are insufficient to pay the accrued interest on the outstanding loan, as was the case during the three and nine months ended September 30, 2013, the unpaid interest outstanding will be added to the principal on a quarterly basis. Currently, Curis management estimates that the loan will be repaid in early 2017.

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At September 30, 2013, the fair value of the principal portion of the debt is estimated as $31,320,000. Due to the assumptions required in estimating future Erivedge royalties and the expected repayment period, determining the fair value of the debt required application of Level 3 inputs.

The Company incurred debt issuance costs totaling $421,715 in connection with this loan transaction, of which $215,000 related to expenses that the Company paid on behalf of BioPharma-II and the remaining $206,715 were incurred directly by the Company. The debt issuance costs incurred directly by the Company were capitalized as assets and those costs paid on behalf of BioPharma-II have been netted against the debt and accrued interest in the Company s Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012 as detailed in the following table:

	September 30, 2013	December 31, 2012
Other current assets	$ 51,423	$ 49,019
Other assets	113,934	154,868
Total debt issuance costs	165,357	203,887
Accrued liabilities, net against accrued interest		(50,984)
Debt, current	1,503,415	
Debt issue costs, current	(53,484)	
Debt, current portion net of issuance costs	$ 1,499,931	$
Debt, long-term	29,250,224	30,000,000
Debt issue costs, long-term	(118,500)	(161,075)
Debt, net of current portion and issuance costs	$ 29,131,724	$ 29,838,925

All issuance costs are being amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method. For the three and nine months ended September 30, 2013, the Company recognized interest expense related to the loan with BioPharma-II of $964,543 and $2,870,087, respectively, with such amounts recorded within the Company s Condensed Consolidated Statement of Operations. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs requires management to make estimates that could impact the short- and long-term classification of these costs, as well as the period over which these costs will be amortized.

8. Common Stock and Warrant Liability

(a) Warrant Liability

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

offering expenses, of approximately $14,942,000.

In connection with this offering, the Company issued warrants to purchase an aggregate of 1,612,322 shares of common stock. As of September 30, 2013, warrants to purchase 238,805 shares of the Company s common stock have been exercised and warrants to purchase 1,373,517 shares of common stock remain outstanding. The warrants have an initial exercise price of $3.55 per share and a five-year term. The warrants contain anti-dilution 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.

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Due to the warrant terms, the warrants are deemed to be a liability and, therefore, the fair value of the warrants was recorded as a liability in the Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012. The Company has estimated the fair value of the warrants using a Black-Scholes option pricing model with updated assumptions at each reporting date as detailed in the following table:

	As of September 30,	
	2013	2012
Fair value of the warrants	$ 1,926,465	$ 2,690,930
Expected term	1.3 years	2.3 years
Risk-free interest rate	0.17%	0.3%
Volatility	48.0%	74.0%
Dividends	None	None

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 and Comprehensive Loss. The Company recorded other expense of $1,072,687 and $438,286 for the three and nine months ended September 30, 2013, respectively, as a result of a change in the fair value of the warrant liability that was primarily due to an increase in the Company s stock price during the respective reporting periods. 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 nine months ended September 30, 2012, as a result of the exercise of warrants to purchase 237,301 shares of the Company s common stock, the warrant liability decreased $615,859 with an offsetting increase to additional paid-in-capital.

(b) 2013 Sales Agreement

On July 3, 2013, the Company entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to sell from time to time up to $30,000,000 of the Company s common stock through an at-the-market equity offering program under which Cowen will act as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker other than on an exchange. In addition, with the Company s prior written approval, Cowen may also sell the common stock by any other method permitted by law, including in negotiated transactions. Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market to sell on the Company s behalf all of the shares requested to be sold by the Company. The Company has no obligation to sell any of the common stock under the sales agreement. Either the Company or Cowen may at any time suspend solicitations and offers under the sales agreement upon notice to the other party. The sales agreement may be terminated at any time by either the Company or Cowen upon written notice to the other party as specified in the sales agreement. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. In addition, the Company reimbursed $34,268 of Cowen s expenses of Cowen in connection with the offering. Each party has agreed in the sales agreement to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, subject to the terms of the sales agreement. Common stock will be issued pursuant to the Company s currently-effective shelf registration statement on Form S-3. During the three and nine months ended September 30, 2013, the Company sold 2,288,396 shares of common stock under the sales agreement resulting in gross proceeds of $9,861,830. Total offering expenses incurred, including Cowen s commission, related to the sales agreement through September 30, 2013 were $430,295 which offset the gross proceeds. Issuance costs of $62,589

were paid subsequent to September 30, 2013.

In addition, in October 2013, the Company sold 1,561,810 shares of common stock under the sales agreement resulting in gross proceeds of $7,025,206.

(c) Stock Option Exercises Paid with Company Common Stock

The Company s 2000 Stock Incentive Plan and the Amended and Restated 2010 Plan generally allows participants to purchase common stock upon the exercise of a stock option by delivery of shares of Company common

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stock held directly by the participant, with such shares of common stock valued at the closing price on NASDAQ on the date of exercise. During the nine months ended September 30, 2013, certain executive officers and a director exercised stock options by remitting shares of Curis common stock then held by the respective person. The Company accounted for the value of the common stock remitted to the Company in satisfaction of the exercise price as treasury stock under the cost method. These option holders remitted an aggregate of 175,139 shares during the nine months ended September 30, 2013 with an aggregate value equal to $632,755.

(d) 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 could 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. The ATM Agreement terminated in June 2013 in accordance with the terms of the agreement. Upon delivery of a placement notice and subject to the terms and conditions of the ATM Agreement, MLV could 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 could also sell the common stock by any other method permitted by law, including in privately negotiated transactions. MLV acted 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 paid MLV a commission equal to 3.0% of the gross sales price per share sold. The Company 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, the Company sold 210,879 shares of common stock under the ATM Agreement resulting in gross proceeds of $906,436. Total offering expenses incurred, including MLV s commission, related to the ATM Agreement through September 30, 2012 were approximately $27,356, which offset the gross proceeds.

9. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2013	December 31, 2012
Accrued compensation	$ 1,297,382	$ 999,038
Professional fees	231,075	127,500
Accrued interest on debt (see Note 7)	313,943	204,167
Other	134,527	143,851
Total	$ 1,976,927	$ 1,474,556

10. Related Party Transaction

On March 7, 2013, the Company s Board of Directors elected Kenneth J. Pienta, M.D., to serve as a class I director until the 2015 Annual Meeting of Stockholders and thereafter until his successor is duly elected and qualified. Dr. Pienta has served as a member of the Company s Scientific Advisory Board since September 2006 and as its Chairman since June 2007, pursuant to the terms of a Scientific Advisory Board Agreement, or the SAB agreement,

effective September 13, 2006, as amended from time to time, by and between Dr. Pienta and the Company. Pursuant to the SAB agreement, Dr. Pienta receives compensation in the amount of $50,000 per year, payable in equal quarterly installments. In addition, pursuant to the terms of a consulting agreement dated June 11, 2011, as amended from time to time, by and between the Company and Dr. Pienta, Dr. Pienta served as a consultant to the Company in the areas of corporate strategy and business development. The Company and Dr. Pienta terminated the consulting agreement in connection with his election as a member of the Board of Directors in March 2013. Pursuant to the terms of the SAB agreement and the consulting agreement, the Company recognized expenses of $12,500 and $59,758 during the three and nine months ended September 30, 2013, respectively, as it relates to services provided by Dr. Pienta.

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11. Accounting for Stock-Based Compensation

As of September 30, 2013, the Company had two shareholder-approved, share-based compensation plans: (i) the Amended and Restated 2010 Stock Incentive Plan, or the Amended and Restated 2010 Plan, adopted by the Board of Directors in March 2013 and approved by shareholders in May 2013 and (ii) the 2010 Employee Stock Purchase Plan adopted by the Board of Directors in April 2010 and approved by shareholders in June 2010. The Company can issue up to 9,000,000 shares of its common stock pursuant to awards granted under the Amended and Restated 2010 Plan. As of September 30, 2013, 3,554,627 shares remained available for grant under the Amended and Restated 2010 Plan.

The Amended and Restated 2010 Plan permits the granting of incentive and non-qualified stock options and stock awards to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Company s Board of Directors. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant. The Amended and Restated 2010 Plan uses a fungible share concept under which each share of stock subject to awards granted as options and stock appreciation rights (SARs), will cause one share per share under the award to be removed from the available share pool, while each share of stock subject to awards granted as restricted stock, restricted stock units, other stock-based awards or performance awards where the price charged for the award is less than 100% of the fair market value of the Company s common stock will cause 1.3 shares per share under the award to be removed from the available share pool.

In the first quarter of 2010, the Company s 2000 Stock Incentive Plan expired in accordance with its terms. The 2000 Director Stock Option Plan has 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, Stock Plans and Stock Based Compensation in the notes to the Company s consolidated financial statements included in Item 8 of Part II of the Company s Annual Report.

During the nine months ended September 30, 2013, the Company s board of directors granted options to purchase 2,001,000 shares of the Company s common stock to officers and employees of the Company under the Amended and Restated 2010 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 dates.

During the nine months ended September 30, 2013, the Company s board of directors also granted options to its non-employee directors to purchase 260,000 shares of common stock under the Amended and Restated 2010 Plan. Of these, options to purchase 235,000 shares of common stock will vest monthly over a one-year period and options to purchase 25,000 shares of common stock will vest over a four-year period. All options granted to non-employee directors during the nine months ended September 30, 2013 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 dates.

Employee and Director Grants

In determining the fair value of stock options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee and director options awarded during the nine months ended September 30, 2013 and 2012 based on the assumptions noted in the following table:

	For the nine months ended September 30,	
	2013	2012

Expected term (years)	Employees	6	6
Expected term (years)	Officers and Directors	7	6
Risk-free interest rate		1.0-2.1%	1.0-1.2%
Volatility		70-72%	74-76%
Dividends		None	None

The expected volatility is based on the annualized daily historical volatility of the Company s stock price through the end of the reporting period for a time period consistent with the expected term of each 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 for the expected term of the respective grant. The Company does not anticipate declaring dividends in the foreseeable future.

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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, 2013 was $16,212,000, of which $13,816,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2013 and 2012 were $2.29 and $2.99, respectively. As of September 30, 2013, there was approximately $5,620,000, net of the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee and director stock option awards outstanding under the 2000 Stock Incentive and the Amended and Restated 2010 Plans that is expected to be recognized as expense over a weighted average period of 2.92 years. The intrinsic values of employee stock options exercised during the nine months ended September 30, 2013 and 2012 were $1,955,000 and $6,370,000, respectively. The total fair values of vested stock options for the nine months ended September 30, 2013 and 2012 were $2,308,000 and $1,761,000, respectively.

The Company recorded $608,448 and $2,004,475 in compensation expense for the three and nine months ended September 30, 2013, respectively, and the Company recorded $822,575 and $2,472,299 in compensation expense for the three and nine months ended September 30, 2012, respectively, related to employee and director stock option grants.

Non-Employee Grants

Pursuant to the Company s stock plans, the Company has periodically granted stock options and unrestricted stock awards to consultants for services at the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date. During the nine month ended September 30, 2013, the Company issued options to purchase a total of 500,000 shares of common stock to consultants. These options were issued pursuant to the Amended and Restated 2010 Plan at exercise prices equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date. Should the Company terminate any of its consulting agreements, the unvested options underlying the agreements would also be cancelled. Unvested non-employee options are marked-to-market, which means that as the Company s stock price fluctuates, the related expense either increases or decreases. The Company recognized expense related to non-employee stock options of $314,106 and $494,616, for the three and nine months ended September 30, 2013, respectively. 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.

Total Stock-Based Compensation Expense

For the three and nine months ended September 30, 2013 and 2012, 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	For the Nine Months Ended

	September 30,		September 30,	
	2013	2012	2013	2012
Research and development expenses	$ 345,390	$ 158,638	$ 841,909	$ 923,648
General and administrative expenses	577,164	649,256	1,657,182	1,914,663
Total stock-based compensation expense	$ 922,554	$ 807,894	$ 2,499,091	$ 2,838,311

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The table below summarizes options outstanding and exercisable at September 30, 2013:

		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	$ 1.43	2,732,280	4.37	$ 1.25	2,732,280	$ 1.25
1.57	3.02	2,501,377	5.89	2.14	1,806,305	1.94
3.25	3.98	2,373,874	7.24	3.49	916,930	3.72
4.03	4.52	2,219,025	8.32	4.40	972,144	4.49
4.56	5.60	705,000	0.62	4.73	699,500	4.73
		10,531,556	5.96	$ 2.86	7,127,159	$ 2.53

12. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive loss as of September 30, 2013:

	Unrealized Losses on Securities Available-for-Sale
Balance, as of December 31, 2012	$ 15,159
Other comprehensive loss before reclassifications	(1,033)
Amounts reclassified from accumulated other comprehensive income (loss)	
Net current period other comprehensive loss	(1,033)
Balance, as of September 30, 2013	$ 14,126

The above amounts do not reflect a tax effect as the Company expects to retain a net loss position for 2013.

13. 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, 2013 and 2012, 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	For the three and nine months ended
	September 30, 2013	**September 30, 2012**
Stock options outstanding	10,531,556	10,495,636
Warrants outstanding	1,373,517	1,373,517
Total antidilutive securities	11,905,073	11,869,153

14. Recent Accounting Pronouncements

In July 2013, the FASB issued an accounting standards update clarifying the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The updated guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward when settlement of the liability for an unrecognized tax benefit in this manner is available. The update is effective prospectively for reporting periods beginning after December 15, 2013, and early adoption and retrospective adoption are permitted. The adoption of this guidance is not expected to have an impact on the Company s consolidated financial statements.

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15. Subsequent Events

CUDC-427 Partial Clinical Hold

The Company initiated a phase 1 study of CUDC-427 in July 2013. On November 5, 2013, the Company received written notification from the FDA that its phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until Curis provides the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. The Company expects to respond to the FDA s requests for additional information and also plans to submit an amendment to the current protocol in a timely manner.

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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. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled Risk Factors in Part II, Item 1A of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. As used throughout this report, the terms the Company, we, us, and our refer to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term Curis refers to Curis, Inc.

Overview

We are an oncology-focused drug development company seeking to develop novel, targeted drug candidates for the treatment of human cancers. We conduct our research and development programs both internally and through strategic collaborations. Erivedge® is the first and only approved medicine for the treatment of advanced basal cell carcinoma, or BCC, and is being 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 Curis and Genentech. We are also leveraging our experience in targeting signaling pathways in seeking to develop targeted drug candidates including CUDC-427, a small molecule antagonist of the inhibitor of apoptosis, or IAP, proteins, and CUDC-907, a dual phosphoinostide-3 kinase, or PI3K, and histone deacetylase, or HDAC, inhibitor. Our licensee Debiopharm is advancing the clinical development of the heat shock protein 90, or HSP90, inhibitor, Debio 0932.

We initiated a phase 1 study of CUDC-427 in July 2013. On November 5, 2013, we received written notification from the United States Food and Drug Administration, or FDA that our Phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. We expect to respond to the FDA s requests for additional information and also plan to submit an amendment to the current protocol in a timely manner.

Erivedge®

Erivedge® (vismodegib) capsule. Erivedge is a first-in-class orally-administered small molecule Hedgehog pathway inhibitor developed under collaboration with Genentech. Erivedge was discovered by Genentech and jointly validated by Genentech and Curis through a series of preclinical studies. Pursuant to this collaboration, Genentech and Roche are responsible for clinical development, and Genentech (in the U.S.), Roche (outside the U.S., excluding Japan) and Chugai (in Japan) are responsible for commercialization of Erivedge. We are eligible to receive cash payments upon the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties related to commercial sales of Erivedge.

In January 2012, based on the results of the phase 2 pivotal ERIVANCE BCC clinical study, the U.S. Food and Drug Administration, or FDA, approved Erivedge for 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. We refer to this indication as advanced BCC. The ERIVANCE BCC study enrolled 104 advanced BCC patients (71 had locally advanced and 33 had metastatic disease) from 31 study centers in the US, Australia and

Europe. The study showed that Erivedge substantially shrank tumors or healed visible lesions, as defined by objective response rate, in 42.9 percent of patients with locally advanced and 30.3 percent of patients with metastatic BCC as assessed by independent review. The most common adverse events included muscle spasms, hair loss, altered taste sensation, fatigue and weight loss. Serious adverse events (SAEs) were observed in 26 patients (25 percent), however of these only four patients (4 percent) had SAEs that were considered to be related to treatment with Erivedge. Fatal events were reported in seven patients (7 percent) although none were considered by investigators to be related to treatment with Erivedge. In all seven cases, patients had other pre-existing diseases or symptoms that were related to their presumed cause of death.

In May 2013, Australia s Therapeutic Goods Administration, or TGA, approved Erivedge, resulting in a $4,000,000 milestone payment to us. In July 2013, the European Commission granted conditional approval for the marketing of Erivedge in all 28 European Union member states. This conditional approval makes Erivedge the first licensed treatment in

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Europe for advanced BCC and also resulted in a $6,000,000 milestone payment to us from Genentech. A conditional marketing authorization is granted to medicinal products with a positive benefit/risk assessment that satisfy an unmet medical need and whose availability results in a significant public health benefit. Under the provisions of the conditional approval, Roche is expected to provide additional data on Erivedge in advanced BCC from the ongoing global safety study, known as STEVIE, which is an international, single-arm, open-label multicenter trial in patients with advanced forms of BCC. An interim analysis from STEVIE presented at the American Society of Clinical Oncology s, or ASCO, 2013 Annual Conference confirmed a similar safety profile to that observed in the ERIVANCE BCC study.

In addition to the United States, Australia and European Union, Erivedge is approved in several other countries and Roche has also filed several new drug applications for marketing registration with health agencies in other territories. Erivedge s regulatory approvals and Roche s submissions in other territories are based on positive clinical data from the ERIVANCE BCC study.

In addition to the lead indication of advanced BCC, Genentech evaluated Erivedge in a single-arm, three cohort phase 2 clinical trial to treat less advanced forms of BCC. Roche expects to present data from this study at a medical meeting during the first quarter of 2014. Roche has also initiated a randomized, placebo controlled phase 2 study to investigate the efficacy of 12 weeks of Erivedge treatment (versus placebo) prior to surgery in previously untreated BCC. The primary endpoint of this study is the percentage change in BCC tumor area following 12 weeks of Erivedge or placebo therapy.

Outside of BCC, in October 2013 Roche also initiated a phase 1b/2 clinical trial to investigate the safety and efficacy of Erivedge in patients with relapsed/refractory acute myelogenous leukemia, or AML, and relapsed/refractory high-risk myelodysplastic syndrome, or MDS. In contrast to BCC, these two clinical conditions are driven by mechanisms that are not linked to mutations in the Hedgehog pathway. It is believed that selective targeting and blocking of the Hedgehog signaling pathway may have an effect on leukemic (stem) cell proliferation and survival.

According to Roche, the open-label, non-randomized study is expected to enroll approximately 60 patients into two cohorts. Patients in Cohort 1 will receive 150 milligrams of Erivedge alone once daily, and patients in Cohort 2 will receive the same dose of Erivedge once daily in combination with the standard dose of cytarabine administered for 10 days. The primary endpoint of the trial is the overall response rate after 8 weeks of treatment. The secondary endpoints include overall response rate at any time during treatment, duration of response, overall survival, and safety and pharmacokinetics of the study drug(s).

In addition to Genentech/ Roche sponsored studies, several third-party investigators are also conducting clinical trials with Erivedge in BCC as well as in various other cancers.

Pursuant to the terms of our collaboration agreement with Genentech, we are entitled to a royalty on net sales of Erivedge that ranges from 5% to high single digits of global Erivedge sales, and which escalates within this range with increasing product sales. The royalty rate applicable to Erivedge may be decreased to a low-to-mid single digit royalty in certain specified circumstances, 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 or when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement with BioPharma Secured Debt Fund II Sub, S.à r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II. In connection with the loan, we

transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to us. Under the terms of the loan, quarterly royalty payments received by Curis Royalty from Genentech will first be applied to pay (i) escrow fees payable by us pursuant to an escrow agreement between Curis, Curis Royalty, BioPharma-II and Boston Private Bank and Trust Company, (ii) our royalty obligations to academic institutions, (iii) certain expenses incurred by BioPharma-II in connection with the credit agreement and related transaction documents, including enforcement of its rights in the case of an event of default under the credit agreement and (iv) expenses incurred by us enforcing our right to indemnification under the collaboration agreement with Genentech. Remaining amounts, subject to caps of $1,000,000 per quarter in 2013, $2,000,000 per quarter in 2014 and $3,000,000 per quarter in 2015, will be applied first, to pay interest and second, principal on the loan. Curis Royalty will be entitled to receive the remaining amounts above the caps, if any, and we remain entitled to receive any contingent payments upon achievement of clinical development objectives. Curis Royalty retains the right to royalty payments related to sales of Erivedge following repayment of the loan.

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The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty s right to receive royalties under the collaboration agreement with Genentech. At any time after January 1, 2017, Curis Royalty may, subject to certain limitations, prepay the outstanding principal of the loan in whole or in part, at a price equal to 105% of the outstanding principal on the loan, plus accrued but unpaid interest. The obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated upon the occurrence of an event of default as defined in the credit agreement. During 2013, Curis Royalty began making payments to BioPharma-II upon receipt of the Erivedge royalties. The amounts paid through September 30, 2013 were less than the interest accrued through the repayment dates resulting in a total of $754,000 being added to the outstanding principal. As of September 30, 2013, Curis Royalty owed a total of $31,068,000, gross, to BioPharma-II comprised of principal and accrued interest.

We recognized $2,550,000 of royalty revenue from Genentech s net sales of Erivedge during the nine months ended September 30, 2013 and an aggregate of $4,080,000 in royalty revenues since Erivedge was approved. As indicated above, we expect that some or all of such royalty revenues will be used to pay interest under the loan that Curis Royalty received from BioPharma-II, subject to quarterly caps.

We are also obligated to make payments to university licensors on royalties that Curis Royalty earns in all territories other than Australia in an amount that is equal to 5% of the royalty payments that Curis Royalty receives from Genentech for a period of 10 years from the first commercial sale of Erivedge, which occurred in February 2012. For royalties that Curis Royalty earns 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 April 2019, after which the amount will decrease to 5% of the royalty payments that Curis Royalty receives from Genentech for the remainder of the period ending 10 years from the first commercial sale of Erivedge, or February 2022. We recorded cost of royalty revenues of $127,000 and $304,000, respectively, during the nine months ended September 30, 2013 and 2012, respectively.

Targeted Cancer Drug Candidates

CUDC-427. In November 2012, we licensed from Genentech the exclusive, worldwide rights for the manufacture, development and commercialization of a small molecule Smac mimetic drug candidate, CUDC-427, that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis, or IAP, proteins. Under the terms of the license agreement, we have the sole right and responsibility for all research, development, manufacturing and commercialization activities related to CUDC-427. Genentech will be entitled to milestone payments upon the first commercial sale of CUDC-427 in certain territories and a tiered low-to-mid single-digit royalty on net sales of CUDC-427, if any.

IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, a process also referred to as apoptosis. Using IAP proteins and other anti-apoptotic factors, cancer cells evade cell death in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of the tumor necrosis factor, or TNF family. Evasion from apoptosis is a fundamental mechanism whereby human cancers develop resistance to standard anti-cancer treatments. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

We initiated a phase 1 study of CUDC-427 in July 2013. On November 5, 2013, we received written notification from the United States Food and Drug Administration (FDA) that our Phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month

following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. We expect to respond to the FDA s requests for additional information and also plan to submit an amendment to the current protocol in a timely manner.

A clinical hold is an order issued by FDA to the sponsor of an IND to delay or to suspend a clinical investigation. A clinical hold, including a partial clinical hold, involves the FDA (1) requiring additional information and/or data, (2) reviewing the additional information and/or data, and (3) after the review, informing the sponsor that they can proceed. A partial clinical hold is defined as a delay or suspension of only part of the clinical work requested under the IND (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND).

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The study was designed to determine the maximum tolerated dose (MTD) and recommended single-agent Phase 2 dose of CUDC-427 using a continuous, twice-daily treatment schedule. One patient with breast cancer metastatic to the liver, lungs, bone and ovaries developed serious adverse events related to liver function, including increases in serum levels of AST and ALT enzymes and bilirubin. Unlike prior clinical experience with CUDC-427, this patient s liver enzyme levels did not recover in response to CUDC-427 discontinuation, and the patient died of liver failure approximately one month following the discontinuation of CUDC-427 dosing. While elevations in liver enzyme levels have previously occurred in patients receiving CUDC-427, no other patients in this or a prior Phase 1 CUDC-427 trial have experienced a serious adverse event of this nature. There are no patients currently being treated with CUDC-427 in this study as all other patients enrolled in this study have discontinued dosing due to disease progression or patient or physician discretion during the ordinary course of the study.

We licensed CUDC-427 from Genentech, which completed enrollment in a phase 1 clinical trial of CUDC-427 (previously GDC-0917), in which 42 patients with refractory solid tumors or lymphoma received daily oral doses of CUDC-427 for two weeks, followed by a one week rest period until disease progression or study discontinuation for any other reason. Results of this phase 1 study were presented during an oral session at the ASCO 2013 Annual Conference in June 2013. In this study, patients were enrolled across 11 cohorts and received CUDC-427 monotherapy at doses ranging from 5 mg to 600 mg daily. Unconfirmed complete responses were reported in 2 patients, including one patient with ovarian cancer and another with mucosa-associated lymphoid tissue (MALT) lymphoma. Additionally, one patient experienced a mixed response and four patients (one patient each with breast cancer, sarcoma, small cell lung cancer and Kaposi s sarcoma) had stable disease for greater than or equal to three months, including a patient on study for greater than 10 months. The maximum tolerated dose, or MTD, of CUDC-427 was not determined in this study, although plasma concentrations in the order of preclinically predicted ED90 were reached. ED90 refers to the dose that leads to 90% of the maximal response. There were three deaths reported during the study, none of which was considered related to the study drug: two died due to progression of breast cancer and one patient died due to pneumonia. Adverse events (AEs) that resulted in treatment discontinuation were Grade 3 fatigue (one patient), Grade 2 QTc prolongation (one patient), Grade 2 drug hypersensitivity (one patient), Grade 2 pneumonitis (one patient), and Grade 3 pruritus/Grade 2 rash (one patient). Other treatment related AEs that were equal to or greater than Grade 3 in severity in more than one patient were elevated levels of liver enzymes (two patients at 450 and 600 mg dose). Biomarker analyses of tumor samples (obtained from two patients) and peripheral blood cells (obtained from all patients) showed changes that were consistent with CUDC-427 s mechanism of action.

CUDC-907. CUDC-907 is an orally bioavailable drug candidate designed to predominantly inhibit certain isoforms of phosphoinositide-3-kinase, or PI3K (mainly PI3K- alpha, delta and beta) and select classes of histone deacetylase, or HDAC enzymes (primarily Classes I and IIB). In January 2013, we initiated a phase 1 clinical trial in patients with advanced lymphoma or multiple myeloma. This first-in-human study is designed to assess the safety (including the MTD), pharmacokinetics, and anti-cancer activity of CUDC-907. In July 2013, we amended the protocol of the ongoing phase 1 study to include two additional dosing regimens, wherein oral CUDC-907 will be administered either two times per week or three times per week. Additionally, exploratory biomarkers will be assessed for the activity of CUDC-907.

In November 2011, we entered into an agreement with The Leukemia & Lymphoma Society, or LLS, under which LLS agreed to make up to $4,000,000 in milestone payments to support our ongoing development of CUDC-907 for patients with relapsed or refractory lymphoma, contingent upon the Company s achievement of specified clinical objectives. As of September 30, 2013, we have earned $1,650,000 in milestone payments under our agreement with LLS. Under certain conditions associated with the successful partnering and/or commercialization of CUDC-907 in the specified indications, we may be obligated to make payments, including royalties, to LLS up to a maximum of $10,000,000. This obligation is limited to 2.5 times the amount we receive from LLS, and, as of September 30, 2013,

the maximum obligation, assuming that CUDC-907 successfully progresses through future clinical trials, would be $4,125,000. Our scientists are also conducting ongoing preclinical studies of CUDC-907 in solid tumor cancers and we are currently planning a phase 1 study in patients with solid tumors.

Debio 0932. In August 2009, we granted a worldwide, exclusive royalty-bearing license to develop, manufacture, market and sell our HSP90 inhibitor technology, including Debio 0932, to Debiopharm. Debiopharm has assumed all future development responsibility for Debio 0932 and Debiopharm or a Debiopharm licensee will incur all future costs related to the development, registration and commercialization of products under the agreement.

In April 2010, Debiopharm initiated a phase 1 clinical trial to evaluate the safety of Debio 0932 given orally to patients with advanced solid tumors. In 2011, Debiopharm successfully advanced Debio 0932 through the dose escalation portion of this phase 1 study and determined 1000 mg daily to be the recommended dose for further development. In the beginning of 2012, Debiopharm advanced Debio 0932 into the phase 1b expansion portion of the study at this 1000 mg daily dose level. The primary objectives of this study were to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the oral 1000 mg daily dose and to make a preliminary assessment of its anti-tumor activity. Debiopharm completed the phase 1b expansion portion of the study, enrolling approximately 30 patients with advanced solid tumors, including patients with non-small cell lung cancer, or NSCLC.

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In August 2012, Debiopharm initiated the HALO (HSP90 inhibition And Lung cancer Outcomes) phase 1/2 clinical trial of Debio 0932 in combination with various chemotherapy regimens in patients with stage IIIb or IV NSCLC without known EGFR mutations. In the phase 1 portion of this study, various doses of Debio 0932 are being investigated in combination with either cisplatin/pemetrexed or cisplatin/gemcitabine in treatment-naïve patients, and with docetaxel in previously treated patients. Once a recommended phase 2 dose of Debio 0932 in combination with the chemotherapy regimen(s) has been identified, Debiopharm expects to initiate the randomized, double-blind, placebo-controlled phase 2 portion of the study. The phase 2 portion of the HALO trial is expected to enroll approximately 140 eligible patients with NSCLC, who will be randomized to receive standard of care chemotherapy treatment in combination with either Debio 0932 or placebo. The primary objective of this study is to compare the effect of adding Debio 0932 to combination chemotherapy with cisplatin/pemetrexed and cisplatin/ gemcitabine on the rate of progression-free survival at 6 months in first-line therapy of patients in this study population. Under our agreement with Debiopharm, we are eligible for our next milestone payment when Debiopharm treats its fifth patient in a phase 2 clinical trial, which we expect could occur in 2014. We have received $13,000,000 in milestone payments to-date from Debiopharm under this collaboration.

In October 2013, Debiopharm initiated an open-label, multicenter phase 1 dose-finding study of Debio 0932, in combination with everolimus, an inhibitor of mammalian target of rapamycin (mTOR), in patients with advanced or metastatic renal cell carcinoma, or RCC, who have been previously treated with a VEGF-directed tyrosine kinase inhibitor. This dose escalation study is designed to determine the safety and maximum tolerated dose of Debio 0932.

The pharmacokinetic profiles and any potential drug-drug interactions between the two agents will also be assessed. The trial also includes an expansion cohort of 25 patients with metastatic clear cell RCC. While approved monotherapy treatments for RCC, including mTOR inhibitors, have been shown to be effective in RCC, improved therapies are needed to enhance the depth and duration of response. Several mTOR signaling pathway components such as mTOR, AKT and LKB1 are HSP90 client proteins. Mechanistic data suggest the potential for improved efficacy through dual mTOR and HSP90 inhibition, which may also prevent the development of acquired resistance to this cancer therapy.

CUDC-101/EGFR Preclinical Program. CUDC-101 is a drug candidate that is designed to target epidermal growth factor receptor, or EGFR, human epidermal growth factor receptor 2, or HER2, and certain HDAC enzymes. In October 2012, we initiated a phase 1 clinical trial of an oral formulation of CUDC-101 in cancer patients. We subsequently terminated this study as the bioavailability observed in the first cohort of patients was too low to achieve effective drug levels with this formulation. We are currently pursuing the development of alternative formulations that may provide improved oral bioavailability and allow us to progress CUDC-101 towards clinical testing and expect that we will have sufficient data to determine whether to advance CUDC-101 into clinical development in the coming months.

We initially developed CUDC-101 as an intravenous formulation and we completed two clinical trials with this formulation, including a phase 1 dose escalation clinical trial of CUDC-101 in 25 patients with advanced, refractory solid tumors and a phase 1 expansion trial that tested CUDC-101 in 46 patients with specific tumor types, including breast, gastric, head and neck, NSCLC or liver cancers. In 2011, we began testing an intravenous formulation of CUDC-101 in a phase 1 clinical trial in patients with locally advanced squamous cell carcinoma of the head and neck in combination with the current standard-of-care of cisplatin and radiation. In April 2013, we determined that we would discontinue enrolling patients in this study and that the future development of CUDC-101 would be dependent on our ability to successfully develop an oral formulation of CUDC-101. Our decision was based largely on the difficulty in enrolling patients in this trial as well as our desire to direct our available financial resources to the development of CUDC-427 and CUDC-907.

In addition to CUDC-101, we are exploring additional preclinical compounds that are designed to target specific aspects of the EGFR receptor.

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 $756,629,000 as of September 30, 2013. We expect that we will incur significant operating losses for the next several years as we seek to advance our research and development programs.

We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We anticipate that existing capital resources as of September 30, 2013 should enable us to maintain current and planned operations into 2016. Our ability to continue funding our planned operations into and beyond

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this point is dependent on future contingent payments that we may receive from Genentech, Debiopharm, or LLS 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.

Key Drivers

We believe that near term key drivers to our success will include:

- Genentech s ability to successfully commercialize Erivedge in advanced BCC;
- positive results in Genentech s ongoing phase 2 clinical trial in patients with operable BCC;
- our ability to successfully plan, finance and complete current and planned clinical trials for CUDC-427, subject to the FDA removing the partial clinical hold, and CUDC-907;
- Debiopharm s ability to advance Debio 0932 into later stages of clinical development; and
- our ability to advance preclinical efforts to develop an oral formulation of CUDC-101 and to advance this candidate into clinical development.

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 develop and commercialize additional product candidates.

Collaboration Agreements

We are currently a party to a collaboration with Genentech related to our Hedgehog pathway inhibitor technologies, a license agreement with Debiopharm related 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. We are currently not receiving any funding for our research activities and we do not expect to receive such funding in the future from Genentech, Debiopharm or LLS 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, 2013, we have incurred aggregate expenses over the term of this collaboration of $3,554,000 in connection with royalties and other cash payments received from Genentech. In addition, during 2012 we incurred $964,000 in expense related to the issuance of 200,000 shares of our common stock to such university licensors upon FDA approval of Erivedge. We do not expect to incur any material costs in the foreseeable future related to our Hsp90 technologies under development by Debiopharm.

Financial Operations Overview

General. Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of drug candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments, if any, from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. We anticipate that existing capital resources as of September 30, 2013 should enable us to maintain current and planned operations into 2016.

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.

Debt. In December 2012, our wholly-owned subsidiary, Curis Royalty, entered into a $30,000,000 debt transaction with BioPharma-II at an annual interest rate of 12.25% collateralized with certain future Erivedge royalty and royalty-related payment streams. For a further discussion of this loan, see Overview Erivedge.

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, including royalty payments. Since the first

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quarter of 2012, we have recognized royalty revenues related to Genentech s sales of Erivedge in the U.S. We expect to continue 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. However, we expect that all of such royalty revenues will be used by our wholly-owned subsidiary, Curis Royalty, to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to quarterly caps, until such time as the loan is fully repaid. We currently estimate that the debt will be repaid in early 2017.

We could receive additional milestone payments from Genentech, Debiopharm, and LLS, provided the respective programs meet contractually-specified development and regulatory objectives. In May 2013, Erivedge was approved for marketing registration by Australia s TGA for the treatment of adult patients with metastatic or locally advanced BCC. The Australian approval resulted in a $4,000,000 milestone payment to us in the second quarter of 2013. Additionally, in July 2013, Erivedge received conditional approval from the European Commission for the marketing of Erivedge in all 28 European Union member states. As a result of this conditional approval, we earned a $6,000,000 milestone payment from Genentech, which was received in the third quarter of 2013. Erivedge is also currently being reviewed for potential marketing approval by health authorities in several additional territories.

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 and Comprehensive Loss. These costs currently consist of payments we are obligated to make to university licensors on royalties that we earn from Genentech on net sales of Erivedge. In all territories other than Australia, our obligation 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 would earn from Roche s 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 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.

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 and 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 commercial and clinical-stage development programs, both internal and under collaboration, are summarized in the following table:

Drug candidate	Primary Disease	Collaborator/Licensee	Status
Hedgehog Pathway Inhibitor			
- Erivedge	Advanced BCC	Genentech (Roche)	Approved in US, EU, Australia and others; Regulatory submissions/ approvals pending in certain other territories
- Erivedge	Operable Nodular BCC	Genentech (Roche)	Completed Phase 2
- Erivedge	Operable BCC	Genentech (Roche)	Phase 2
- Erivedge	Relapsed/Refractory AML and High Risk MDS	Roche	Phase 1b/2
Antagonist of IAP Proteins			
- CUDC-427	Advanced solid tumors and lymphomas	Internal development*	Completed Phase 1*
- CUDC-427	Advanced solid tumor & lymphomas including expansion cohort of ovarian and fallopian tube derived cancers	Internal development	Phase 1 partial clinical hold as of November 5, 2013
Dual PI3K and HDAC Inhibitor			
- CUDC-907	Advanced lymphomas and multiple myeloma	Internal development/LLS	Phase 1
HSP90 Inhibitor			
- Debio 0932	Advanced NSCLC	Debiopharm	Phase 1 2
- Debio 0932	Advanced renal cell carcinoma	Debiopharm	Phase 1
EGFR/HER2 and HDAC Inhibitor			
- CUDC-101 oral formulation	Solid tumors	Internal development	Preclinical

* The first Phase I clinical trial was conducted by Genentech prior to Curis acquisition of CUDC-427

Because of the early stages of development of most of our programs other than Erivedge in advanced BCC, 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 other 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 and maintaining compliance with regulatory requirements;

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- 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 otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by us.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosures in the financial statements. Such estimates and judgments of the performance obligations under our collaboration agreements; the estimated repayment term of our debt and related short- and long-term classification; the collectability of receivables; the carrying value of property and equipment and intangible assets; the assumptions used in our valuation of stock-based compensation and the value of certain investments and liabilities, including our long-term warrant liability. 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, 2012, or the Annual Report, which was filed with the SEC on March 13, 2013.

Recent Accounting Pronouncements

In July 2013, the FASB issued an accounting standards update clarifying the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The updated

guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward when settlement of the liability for an unrecognized tax benefit in this manner is available. The update is effective prospectively for reporting periods beginning after December 15, 2013, and early adoption and retrospective adoption are permitted. The adoption of this guidance is not expected to have an impact on our consolidated financial statements.

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Results of Operations

Three-Month Periods Ended September 30, 2013 and September 30, 2012

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2013	2012	
REVENUES:			
Research and development			
Genentech	$ 88,000	$ 92,000	(4%)
Other	34,000	39,000	(13%)
Subtotal	122,000	131,000	(7%)
License fees from Genentech	6,000,000		100%
Royalty revenues from Genentech	1,080,000	446,000	142%
Total revenues	$ 7,202,000	$ 577,000	1,148%

Total revenues increased in the quarter ended September 30, 2013, as compared to the prior period, primarily due to an increase of $6,000,000 in our license fee revenues related to a payment we received from Genentech in connection with Erivedge s conditional approval by European health authorities in July 2013. In addition, royalty revenues earned on net sales of Erivedge increased to $1,080,000 during the third quarter of 2013 as compared to $446,000 during the same period in 2012. We expect that all Erivedge royalty revenues will be used by Curis Royalty to pay principal and interest under the loan received from BioPharma II, subject to quarterly caps, until such time as the loan is fully repaid.

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 increased in the quarter ended September 30, 2013, as compared to the prior period, as a result of an increase in Erivedge royalties during the three months ended September 30, 2013, which requires us to make payments to two university licensors.

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

Research and Development Program	For the Three Months Ended September 30, 2013	2012	Percentage Increase/ (Decrease)
Erivedge	$ 56,000	$ 39,000	44%

CUDC-907	1,123,000	936,000	20%
CUDC-427	1,922,000		100%
Debio 0932	3,000	11,000	(73%)
CUDC-101	306,000	1,110,000	(72%)
Other network-targeted cancer programs	116,000	787,000	(85%)
Sublicense fees incurred on development and regulatory milestones under our Genentech collaboration	300,000		100%
Stock-based compensation	345,000	159,000	117%
Total research and development expense	$ 4,171,000	$ 3,042,000	37%

Our research and development expenses increased in the quarter ended September 30, 2013, as compared to the prior period, primarily due to increases in spending on CUDC-427, which was exclusively licensed from Genentech in November 2012. We initiated a phase 1 clinical trial for CUDC-427 in July 2013. We expect that a majority of our research and

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development expenses for the foreseeable future will be incurred in support of our efforts to continue to advance the Phase 1 study for CUDC-907 and to respond to the FDA s requests for additional information including the submission of a protocol amendment for CUDC-427 in connection with the partial clinical hold. Spending in the third quarter of 2013 for CUDC-907 and CUDC-427 increased $187,000 over the prior year period. In addition, during the quarter ended September 30, 2013, we incurred sublicense fees of $300,000 related to the $6,000,000 milestone payment we received upon Erivedge s conditional approval by European health authorities. Finally, stock-based compensation increased $186,000 in the third quarter of 2013 as compared to the prior year period 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.

Offsetting these increases, spending related to our CUDC-101 programs decreased $804,000 during the three months ended September 30, 2013, primarily due to our decision to discontinue clinical development of this drug candidate while continuing to research oral formulations of this molecule. Spending on our other preclinical network-targeted cancer programs also decreased $671,000 when compared to the prior year period as our internal resources were primarily allocated to CUDC-907 and CUDC-427.

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

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2013 (unaudited)	2012 (unaudited)	
Personnel	$ 847,000	$ 581,000	46%
Occupancy and depreciation	90,000	126,000	(29%)
Legal services	699,000	614,000	14%
Consulting and professional services	343,000	260,000	32%
Insurance costs	89,000	74,000	20%
Other general and administrative expenses	202,000	170,000	19%
Stock-based compensation	577,000	649,000	(11%)
Total general and administrative expenses	$ 2,847,000	$ 2,474,000	15%

General and administrative expenses increased in the quarter ended September 30, 2013, as compared to the prior period, primarily due to increased personnel costs and related accrual of cash incentive payments under our 2013 short-term incentive program, legal fees related to foreign patent filings and professional services, including audit fees. Offsetting these increases, stock-based compensation expense decreased $72,000 as a result of a decrease in the grant-date fair value of, options granted during 2013 compared to the prior year period.

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. The warrants are 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 income statement. 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, 2013 was $1,926,000 using this model with the following assumptions: expected volatility of 48%, risk free interest rate of 0.2%, expected life of 1.3 years and no dividends. 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 recorded a charge of $1,073,000 and income of $1,542,000 for the quarters ended September 30, 2013 and 2012, respectively, related to changes in the assumptions used in the valuation of the warrants, including changes 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.

Other Expense (Income)

For the three months ended September 30, 2013, interest expense was $965,000 related to interest accrued on our outstanding debt with the BioPharma-II. We had no interest expense during the prior year period because we did not have debt at that time. Interest income was $39,000 and $34,000 for the three month periods ended September 30, 2013 and 2012, respectively.

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Nine-Month Periods Ended September 30, 2013 and September 30, 2012

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2013	2012	
REVENUES:			
Research and development			
Genentech	$ 182,000	$ 250,000	(27%)
LLS	650,000		100%
Other	96,000	66,000	45%
Subtotal	928,000	316,000	194%
License fees from Genentech	10,000,000	14,000,000	(29%)
Royalty revenues from Genentech	2,550,000	970,000	163%
Total revenues	$ 13,478,000	$ 15,286,000	(12%)

Total revenues decreased in the nine month period ended September 30, 2013, as compared to the prior period, primarily due to a decrease in license fee revenues from Genentech, as milestone payments received from Genentech during the nine months ended September 30, 2012 were larger than milestone payments received during the same current year period.

Offsetting the decrease in license fee revenue, we recognized $2,550,000 and $970,000 of royalty revenues from the net sales of Erivedge during the nine months ended September 30, 2013 and 2012, respectively, a 163% increase over the prior year period. We expect that all Erivedge royalty revenues will be used by Curis Royalty to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to quarterly caps, until such time as the loan is fully repaid. We also recognized revenues totaling $650,000 during the nine months ended September 30, 2013 under our agreement with LLS for achievement of clinical development objectives related to our phase 1 clinical trial of CUDC-907. We are eligible for additional milestone payments of up to $2,350,000 over the term of our agreement with LLS, if our CUDC-907 program continues to successfully meet clinical development objectives.

Cost of Royalty Revenues. Cost of royalty revenues decreased in the nine month period ended September 30, 2013, as compared to the prior period, largely due to a $100,000 one-time cash payment paid to a university licensor upon the first commercial sale of Erivedge during the nine months ended September 30, 2012.

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

Research and Development Program	For the Nine Months Ended September 30, 2013	2012	Percentage Increase/ (Decrease)

Erivedge	$ 119,000	$ 112,000	6%
CUDC-907	3,283,000	3,100,000	6%
CUDC-427	3,750,000		100%
Debio 0932	32,000	48,000	(33%)
CUDC-101	1,046,000	3,640,000	(71%)
Other network-targeted cancer programs	394,000	2,847,000	(86%)
Sublicense fees incurred on development and regulatory milestones under our Genentech collaboration	500,000	2,114,000	(76%)
Stock-based compensation	842,000	924,000	(9%)
Total research and development expense	$ 9,966,000	$ 12,785,000	(22%)

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Our research and development expenses decreased primarily due to decreases in spending on CUDC-101, our research stage network targeted cancer programs and Erivedge-related payments to sublicensors, offset in part by spending on CUDC-427 that was exclusively licensed from Genentech in November 2012.

Spending related to our CUDC-101 and research stage network-targeted cancer programs decreased by $5,047,000 during the nine months ended September 30, 2013, primarily due to our decisions to discontinue clinical development of CUDC-101 while continuing to research oral formulations of this molecule and to focus our internal resources on our clinical development programs, CUDC-907 and CUDC-427. Future development related-expenses associated with CUDC-427 will be dependent on the FDA lifting the partial clinical hold.

In addition, sublicense fees decreased by $1,614,000 during the nine months ended September 30, 2013 as compared to the prior year period, primarily resulting from one-time sublicense fees and the one-time issuance of an aggregate of 200,000 shares of our common stock in connection with Erivedge s FDA approval, Roche s NDA filing in Australia and our receipt of related milestone payments during the nine months ended September 30, 2012.

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

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2013 (unaudited)	2012 (unaudited)	
Personnel	$ 2,522,000	$ 1,889,000	34%
Occupancy and depreciation	263,000	389,000	(32%)
Legal services	1,771,000	1,706,000	4%
Consulting and professional services	1,171,000	873,000	34%
Insurance costs	241,000	193,000	25%
Other general and administrative expenses	693,000	575,000	21%
Stock-based compensation	1,657,000	1,915,000	(13%)
Total general and administrative expenses	$ 8,318,000	$ 7,540,000	10%

General and administrative expenses increased in the nine month period ended September 30, 2013, as compared to the prior period, primarily due to an increase in personnel costs and related accrual of cash incentive payments under our 2013 short-term incentive program, legal fees related to foreign patent filings and other various corporate matters and an increase in professional services, including audit fees, and business development expenses. In addition, other general and administrative spending increased $118,000 over the prior year period, which is comprised of travel, banking and listing fees and other operating expenses.

Offsetting these increases, stock-based compensation expense decreased $258,000 from the prior year period as a result of a decrease in the grant-date fair value of options issued during the nine months ended September 30, 2013 compared to the prior year period.

Change in fair value of warrant liability. As a result of revaluing the warrants issued in January 2010, we recorded a charge of $438,000 and other income of $1,054,000 for the nine months ended September 30, 2013 and 2012, respectively. During the nine months ended September 30, 2012, warrants to purchase 237,301 shares of our common stock were exercised.

Other Expense (Income)

For the nine months ended September 30, 2013, interest expense was $2,870,000 related to interest accrued on our outstanding debt with the BioPharma-II. We had no interest expense during the prior year period because we did not have debt at that time. Interest income was $118,000 and $87,000 for the nine months ended September 30, 2013 and 2012, respectively.

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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 December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to us. The final maturity date of the loan will be the earlier of the date when the principal is paid in full and the termination of Curis Royalty s right to receive royalties under the collaboration agreement with Genentech. Payments to BioPharma-II through September 30, 2013 totaled $1,928,000 and covered only a portion of the interest accrued on the loan. As a result, $754,000 of the unpaid and accrued interest through September 30, 2013 has been capitalized and added to the principal portion of the loan. As of September 30, 2013, Curis Royalty owed a total of $31,068,000, gross of issuance costs, to BioPharma-II comprised of principal and accrued interest.

For the year ended December 31, 2012 and the nine months ended September 30, 2013, we received aggregate milestone payments totaling $24,000,000 under our collaboration with Genentech. In addition, we received royalty revenues during 2012 in connection with Genentech s net sales of Erivedge. Royalty revenues earned subsequent to December 2012 are being used to repay our outstanding principal and interest under the loan due to BioPharma-II, subject to specified quarterly caps. We will be entitled to receive the remaining amounts above the caps, if any, and we remain entitled to receive any contingent payments upon achievement of clinical development objectives and royalty payments related to sales of Erivedge following repayment of the loan. Upon earning any such payments, as well as on royalties that are earned in any territory other than Australia, we are required to make payments to certain university licensors totaling 5% of these amounts. For royalties that we would earn from Roche s 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 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.

In July 2013, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to sell from time to time up to $30,000,000 of the Company s common stock through an at-the-market equity offering program under which Cowen will act as sales agent. Subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an at-the-market offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on the NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker other than on an exchange. The aggregate compensation payable to Cowen shall be 3% of the gross sales price of the common stock sold by Cowen pursuant to the sales agreement. Through November 4, 2013, we have sold 3,850,206 shares of common stock pursuant to this sales agreement for net proceeds of $16,380,000.

At September 30, 2013, our principal sources of liquidity consisted of cash, cash equivalents, and investments of $67,139,000, excluding our restricted investments of $180,000. 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 and clinical studies, laboratory supplies, consulting fees and legal fees. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-427 and CUDC-907 advance into further stages of clinical testing.

Net cash used in operating activities was $4,027,000 during the nine-month period ended September 30, 2013, primarily the result of $21,602,000 in operating and other expenses incurred during the period, of which $4,036,000 related to non-cash charges including stock-based compensation, changes in the fair value of our warrant liability, non-cash interest expense and depreciation and amortization. For the nine months ended September 30, 2013, we had earned $13,200,000 in milestone and royalty payments under our collaborations with Genentech and LLS.

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Operating activities used cash of $1,855,000 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 $882,000 in our accounts receivable, primarily related to quarterly royalties earned on the sale of Erivedge.

We expect to continue to use cash in operations as we seek to advance our targeted cancer drug candidates. 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 $7,689,000 and $11,265,000 for the nine-month periods ended September 30, 2013 and 2012, respectively, resulting primarily from net investment activity for the respective periods. The increase in investments during the nine-month period ended September 30, 2013 was the result of an increase in investable cash as compared to the prior year period, while the decrease in the nine-month period ended September 30, 2012 was a result of the need for cash to fund our operations. During the nine-month periods ended September 30, 2013 and 2012, we reduced our long-term restricted investment resulting in an increase in our available cash for the periods of $14,000 and $42,000, respectively. We also purchased $134,000 and $42,000 in fixed assets during the six months ended June 30, 2013 and 2012, respectively.

Financing activities provided cash of $12,747,000 for the nine-month period ended September 30, 2013. We received $9,494,000 in net proceeds from sales of common stock under our sales agreement with Cowen for the nine-month period ended September 30, 2013. We received an additional $6,814,000 in net proceeds for sales of common stock that were initiated in September but were settled in early October 2013. We also received proceeds of $3,515,000 from the exercise of stock options to purchase 1,999,208 shares of our common stock during the nine-month period ended September 30, 2013. These proceeds were offset by the payment of debt issuance costs of $261,000 related to Curis Royalty s financing transaction with BioPharma-II. Financing activities provided cash of $5,810,000 for the nine-month period ended September 30, 2012, principally from the exercise of stock options and warrants that resulted in the issuance of 2,422,124 shares of our common stock.

Funding Requirements

We have incurred significant losses since our inception. As of September 30, 2013, we had an accumulated deficit of approximately $756,629,000. 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-427 and CUDC-907, 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 these 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 (subject to our obligation to transfer certain royalties to BioPharma-II pursuant to the terms of our credit

agreement). 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 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, subject to our obligation to transfer certain royalties to BioPharma-II pursuant to the terms of our credit agreement.

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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. 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. Our wholly-owned subsidiary Curis Royalty, received a $30,000,000 loan pursuant to a credit agreement entered into by and among Curis, Curis Royalty and BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to certain future royalty and royalty-related payments on commercial sales of Erivedge by Genentech. The loan and accrued interest will be repaid by Curis Royalty from the proceeds of the royalty and royalty-related payments that it receives from time to time from Genentech. Curis Royalty will be entitled to receive and distribute to Curis only those royalty amounts, if any, in excess of the amounts it is required to remit each quarter to BioPharma-II. As a result, for the foreseeable future, we will only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty s obligation to remit such royalties to BioPharma-II in repayment of the loan.

To become and remain profitable, we must develop and eventually commercialize one or more drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling those drugs for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We are currently only in early clinical testing for our most advanced drug candidates.

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 anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at September 30, 2013, should enable us to maintain current and planned operations into 2016. 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 and maintaining compliance with regulatory requirements;
- the timing, receipt and amount of payments, if any, from current and potential future collaborators;
- the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;

unplanned costs to prepare, file, prosecute, maintain and enforce patent claims and other patent-related costs, including litigation costs and technology license fees; and

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

We may seek additional funding through public or private financings of debt or equity. For example, in July 2013 we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, pursuant to which, from time to time, we may offer and sell up to $30,000,000 of common stock registered pursuant to our universal shelf registration statement through Cowen in one or more at the market or other specified offerings, of which we have sold approximately $16,900,000 representing the gross proceeds of common stock sold under our agreement with Cowen to date. 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.

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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 drug candidates; or

- delay, limit, reduce or prevent us from establishing sales and marketing capabilities, either internally or through third parties, or other activities that may be necessary to commercialize our drug candidates.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2013.

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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, 2013, 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, 2013. 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, 2013, 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, 2013 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 restate and supersede the risk factors previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report.

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, 2013, we had an accumulated deficit of approximately $756,629,000. We have incurred net losses of $8,124,000 for the nine months ended September 30, 2013, and $16,417,000, $9,859,000, and $4,435,000 for the years ended December 31, 2012, 2011 and 2010, respectively. 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 have historically derived a substantial portion of our operating cash flow from the research funding, milestone payments and royalty revenues under collaboration agreements with third parties. 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.

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. Our wholly-owned subsidiary Curis Royalty, received a $30,000,000 loan pursuant to a credit agreement entered into by and among Curis, Curis Royalty and BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to certain future royalty and royalty-related payments on commercial sales of Erivedge by Genentech. The loan and accrued interest will be repaid by Curis Royalty from the proceeds of the royalty and royalty-related payments that it receives from time to time from Genentech. Curis Royalty will be entitled to receive and distribute to Curis only those royalty amounts, if any, in excess of the amounts it is required to remit each quarter to BioPharma-II. As a result, for the foreseeable future, we will only receive royalties under our collaboration agreement with Genentech to the extent net sales are generated at a level sufficient to derive royalties in excess of Curis Royalty s obligation to remit such royalties to BioPharma-II in

repayment of the loan.

To become and remain profitable, we must develop and eventually commercialize one or more drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling those drugs for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We are currently only in early clinical testing for our most advanced drug candidates. 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

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working capital to support our research and development activities for CUDC-427, if the FDA s partial clinical hold is lifted, CUDC-907, and other drug candidates that we may seek to develop in the future and to fund our general and administrative costs and expenses.

We anticipate that existing cash, cash equivalents, marketable securities, investments and working capital at September 30, 2013 should enable us to maintain current and planned operations into 2016. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may affect our planned future capital requirements and accelerate our need for additional working capital, many of which are outside our control, including the following:

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

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

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drug candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may seek additional funding through public or private financings of debt or equity. For example, in July 2013 we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, pursuant to which, from time to time, we may offer and sell up to $30,000,000 of common stock registered pursuant to our universal shelf registration statement through Cowen in one or more at the market or other specified offerings, of which we have sold approximately $16,900,000 representing the gross proceeds of common stock sold under our agreement with Cowen to date. 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 of our internal development pipeline, additional funding may not be available to us on acceptable terms, if at all, and we may not be able to sell shares under the arrangement with Cowen at favorable prices, 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.

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 drug candidates; or

- delay, limit, reduce or terminate our establishment of sales and marketing capabilities, either internally or through third parties, or other activities that may be necessary to commercialize our drug candidates.

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We transferred and encumbered certain royalty and royalty-related payments relating to commercial sales of Erivedge in and, as a result, we could lose all rights to future royalty and royalty-related payments.

In December 2012, our wholly-owned subsidiary, Curis Royalty, received a $30,000,000 loan pursuant to a credit agreement with BioPharma-II. In connection with the loan, we transferred to Curis Royalty our right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that we receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis.

Per the terms of the credit agreement, neither Curis nor Curis Royalty guaranteed any level of future royalty or royalty-related payments or the value of such payments as collateral to the loan. However, in certain circumstances, the obligations of Curis Royalty under the credit agreement to repay the loan may be accelerated, including:

- if any payment of principal is not made within three days of when such payment is due and payable or otherwise made in accordance with the terms of the credit agreement;
- if any representations or warranties made in the credit agreement or any other transaction document proves to be incorrect or misleading in any material respect when made;
- if there occurs a default in the performance of affirmative and negative covenants set forth in the credit agreement or under certain ancillary transaction documents;
- the failure by Genentech to pay material amounts owed under the collaboration agreement with Genentech because of an actual breach or default by Curis under the collaboration agreement;
- a material breach or default by Curis Royalty under certain ancillary transaction documents, in each case, which breach or default is not cured within 30 days after written demand thereof by BioPharma-II;
- the voluntary or involuntary commencement of bankruptcy proceedings by either Curis or Curis Royalty and other insolvency related defaults;
- any materially adverse effect on the binding nature of any of the transaction documents or the Genentech collaboration agreement;

if any person shall be designated as an independent director of Curis Royalty other than in accordance with its limited liability company operating agreement; or

if Curis shall at any time cease to own, of record and beneficially, 100% of the equity interests in Curis Royalty.

If any of the above were to occur, Curis Royalty may not have sufficient funds to pay the accelerated obligation and BioPharma-II could foreclose on the secured royalty and royalty-related payment stream. In such an event, we could lose our right to royalty and royalty-related payments not transferred to BioPharma-II, including those we would otherwise be entitled to receive if, or when, Curis Royalty satisfied its obligations to BioPharma-II under the credit agreement.

Fluctuations in our quarterly operating results could adversely affect the price of our common stock.

Our quarterly operating results may fluctuate significantly. Some of the factors that may cause our operating results to fluctuate on a period-to-period basis include:

the status of our preclinical and clinical development programs, including whether the FDA lifts the partial clinical hold and allows us to pursue further development of CUDC-427;

the level of expenses incurred in connection with our preclinical and clinical development programs, including development costs relating to CUDC-427, if the FDA s partial clinical hold is lifted, and CUDC-907;

any intellectual property infringement lawsuit or other litigation in which we may become involved;

the implementation of restructuring and cost-savings strategies;

the occurrence of an event of default under the credit agreement by and among Curis, Curis Royalty and BioPharma II;

the implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, and non-recurring revenue or expenses under any such agreement; and

compliance with regulatory requirements.

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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 uncertain economic conditions, volatile business environment and continued unpredictable and unstable market conditions that are ongoing, 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.

At September 30, 2013, we had $67,139,000 of cash, cash equivalents and 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, 2013. 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 RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We are reliant on Genentech and/or Roche 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 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 BCC. Erivedge has also been approved in a number of foreign countries. Genentech and/or Roche have filed regulatory submissions in additional territories seeking approval to commercialize Erivedge for this same indication. Genentech and Roche are also conducting a phase 2 clinical trial of Erivedge in operable nodular BCC, a phase 1b/2 trial in relapsed/ refractory AML and MDS, 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. 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, 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 do 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 do not develop, validate and maintain a commercially viable manufacturing process for Erivedge that is compliant with current good manufacturing practices;

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

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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.

In addition, pursuant to the terms of our credit agreement with BioPharma-II, for the foreseeable future we will only realize royalty revenue under our collaboration agreement with Genentech to the extent that Genentech and Roche successfully commercialize Erivedge in the advanced BCC indication such that net sales are generated at a level sufficient to derive royalties in excess of the obligation of our wholly-owned subsidiary, Curis Royalty, to remit such royalties to BioPharma-II.

The therapeutic efficacy of targeted drug candidates being developed by us and our collaborators is unproven in humans, and we may not be able to successfully develop and commercialize drug candidates pursuant to these programs.

Our targeted drug candidates are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. Our ability to generate revenues from these drug candidates, which we do not expect will occur in the short term, if ever, will depend heavily on their successful development and commercialization, which is subject to many potential risks. For example, our 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. These drug candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. If the FDA determines that it will not lift the partial clinical hold on CUDC-427, or if any of our other drug candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound. 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 drug candidates, in which case we will not achieve profitability and the value of our stock may decline.

The FDA has placed a partial clinical hold on CUDC-427, one of our lead compounds under development. Our business may be adversely affected if the partial clinical hold cannot be resolved or if such regulatory concerns lead to more burdensome preclinical or clinical studies that cause significant delays in developing our drug candidates.

In November 2012, we licensed from Genentech the exclusive, worldwide rights for the manufacture, development and commercialization of CUDC-427, a compound designed to promote cancer cell death by antagonizing IAP proteins. On November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until we provide the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. We expect to respond to the FDA s requests for additional information and also plan to submit an amendment to the current protocol in a timely manner.

We cannot assure you that the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427. If the FDA fails to lift the partial clinical hold, our development timelines and our business would be adversely affected and our stock price may decline. Further, even if the FDA lifts the partial clinical hold, or if the FDA or other regulatory agencies continue to express safety concerns after the hold is lifted, future preclinical or clinical studies involving CUDC-427 may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instances, our progress in the development of CUDC-427 may be significantly slowed and the associated costs may be significantly increased, adversely affecting our business.

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We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future proprietary research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

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. In addition, we entered into a license agreement with Debiopharm pursuant to which Debiopharm is developing Debio 0932, our Hsp90 inhibitor. 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 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.

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 drug 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 drug 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 seeking to develop several other cancer drug therapies.

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.

Our collaborators 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. 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.

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Genentech is a wholly-owned member of the Roche Group and as such is subject to the risk that Roche could determine to reprioritize Genentech s development programs which could reduce Genentech s efforts on the development or commercialization of Erivedge or cause Genentech to terminate our collaboration.

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, may select clinical investigators who are not qualified or who fail to comply with protocols or applicable regulatory requirements, or may 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 drug candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the drug candidate on our own.

Either Genentech or Debiopharm may not have sufficient resources necessary to advance clinical development of drug 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.

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 of our targeted drug candidates, generally following our completion of at least phase 1 or phase 2 clinical testing. We do not currently have the resources or capacity to advance these programs into later stage clinical development (i.e., phase 3) or commercialization on our own. 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 a number of recent business combinations among large pharmaceutical companies have resulted in a reduced number

of potential future collaborators. In addition, collaborations are complex and time-consuming to negotiate and document. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements 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 and such collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all.

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

- the development of certain of our current or future drug candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future drug 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 drug candidates; and
- our future prospects may be adversely affected and our stock price could decline.

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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;
- 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;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- 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 cancer or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

we, our clinical investigators, or our current or potential future collaborators and subcontractors, may fail to comply with applicable regulatory requirements, including good clinical practices and requirements regarding the disclosure of clinical trial information;

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. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing; 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 we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, including with respect to CUDC-427 if the FDA lifts its partial clinical hold, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

be delayed in obtaining marketing approval for our drug candidates;

not obtain marketing approval at all;

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obtain approval for indications that are not as broad as intended or with labeling that highlights undesirable safety risks;

have the product removed from the market after obtaining marketing approval;

be subject to additional post-marketing testing requirements;

be subject to restrictions on how the product is distributed or used; or

be unable to obtain reimbursement for use of the product.

If any of the above were to occur, our reputation and our ability to raise additional capital will be materially impaired and our stock price is likely to decline.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. In addition, many of our competitors have ongoing clinical trials for drug candidates that could be competitive with our drug candidates. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors drug candidates or rely upon treatment with existing therapies that may preclude them from eligibility for our clinical trials.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our stock price to decline, which could limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials, and/or the reporting of adverse events by companies with competing drug candidates, could result in significant delays or may require us to abandon one or more clinical trials altogether.

We expect to rely in part on third parties to conduct clinical trials of our internally-developed drug candidates, and if such third parties perform inadequately, including failing to meet deadlines for the completion of such trials, research or testing, then we will not be able to successfully develop and commercialize drug candidates and grow our business.

For the foreseeable future, we expect to rely substantially on third parties such as consultants, clinical investigators, contract research organizations and other similar entities to complete certain aspects of our preclinical testing and 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. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. 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, or if there are delays in obtaining, necessary regulatory approvals, then we will not be able to commercialize our drug candidates and our business will be materially impaired 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. We have limited experience in filing and prosecuting applications to obtain marketing approval. 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. During the course of this process, the FDA or a foreign equivalent may determine that a drug candidate is not effective, or is only moderately effective, or has undesirable or unintended side effects, toxicities, safety profile or other characteristics that preclude our obtaining marketing approval. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the

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discontinuation of CUDC-427 dosing. We cannot guarantee when or if the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427. 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, to labeling that highlights undesirable safety risks, 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, our ability to generate revenues will be materially impaired 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, require labeling that highlights undesirable safety risks, 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.

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 drug 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.

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. Failure to comply with regulatory requirements may result in actions such as:

restrictions on such products, manufacturers or manufacturing processes;

restrictions on the marketing of a product;

restrictions on product distribution;

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requirements to conduct post-marketing clinical trials;

withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications that we submit;

recall of products;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

Our potential future relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our potential future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid;

the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or

conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations would involve substantial costs. It is possible that governmental authorities will conclude that such business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties,

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damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business in the future are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- efficacy and potential advantages compared to alternative treatments;
- the price we charge for our drugs;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to successfully develop companion diagnostics that effectively identify patient populations likely to benefit from treatment with our therapeutic products;
- the strength of marketing and distribution support; and
- sufficient third party coverage or reimbursement.

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 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. For example, on November 5, 2013, we received written notification from the FDA that our phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. We cannot guarantee when or if the FDA will lift the partial clinical hold and allow us to pursue further development of CUDC-427;

- we or our current and potential future collaborators may not make regulatory submissions or receive regulatory approvals as planned; and

- 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 the above research and development goals 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, we are aware of several biotechnology and pharmaceutical companies that have drug development programs relating to compounds that modulate the Hedgehog pathway. We believe that there are currently at least five other companies that have progressed Hedgehog pathway inhibitors into clinical development: Eli Lilly and Company, Exelixis, Inc. (in co-development with the Bristol-Myers Squibb Company); Pfizer Inc.; Novartis International AG; and Millennium: The Takeda Oncology Company.

In addition, there are several companies developing drug candidates that target the same cancer pathways that we are targeting or that are testing drug candidates in the same cancer indications that we are testing. For example, Debiopharm SA, Novartis AG and Tetralogic Pharmaceuticals are all developing IAP inhibitors and several companies are investigating HSP90 inhibitors in clinical testing, including, among others Astex Therapeutics Ltd., Daiichi Sankyo, Esanex, Inc., Infinity Pharmaceuticals, Kyowa Hakko Kirin Co, Ltd., Novartis International AG, Samus Therapeutics, Inc. and Synta Pharmaceuticals Corp. Although we are not aware of other molecules in clinical testing that are designed to simultaneously target HDAC, EGFR and Her2 or HDAC and PI3K simultaneously, there are commercially-available drugs that individually target either HDAC or EGFR as well as a drug that targets EGFR/Her2. There are also several drug candidates in clinical testing that are designed to inhibit one or more of these targets.

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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. 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.

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.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

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.

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. Product liability insurance is expensive and may be difficult to retain. As such, it is possible that we will not be able to retain 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.

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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 team. 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 efforts in China and materially and adversely affect the development of our targeted cancer drug candidates.

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 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

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is a system in which decided legal cases have little precedential value. 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, the repayment term of our loan with BioPharma-II 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 set forth in our Annual Report.

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 drug candidates may be delayed.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We may not be able to obtain and maintain patent protection for our technologies and products, our licensors may not be able to obtain and maintain patent protection for the technology or products that we license from them and the patent protection we or they 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 recently passed the Leahy-Smith America Invents Act, or the America Invents Act, which

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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 instituting 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 certain 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.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties and are reliant on our licensors. For example, we do not control the prosecution of certain patent rights licensed to us under our IAP agreement with Genentech. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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.

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. In addition, our collaborators and licensors may have rights to file and prosecute claims of infringement of certain of our intellectual property and we are reliant on them. 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

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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.

We have historically conducted synthetic chemistry work through a contract research agreement with a medicinal chemistry provider in China. 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 on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. 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 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.

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RISKS RELATING TO MANUFACTURING AND SALES

We depend on third parties to produce our products under development, and if these third parties do not successfully formulate or manufacture these drug candidates, 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 drug 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 or Quality System Regulation 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, imposition of clinical holds, 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 drug candidates, any delay or interruption in the supply of such raw materials could lead to delays in the manufacture and supply of our drug candidates.

We rely on third parties to supply certain raw materials necessary to produce our drug candidates 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. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. 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 to commercialize any of our drug candidates, 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 commercializing Erivedge. 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 drug 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third party payers are increasingly challenging the prices charged for medical products and services. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or a foreign equivalent. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the US. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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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. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MPDIMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MPDIMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MPDIMA may result in a similar reduction in payments from private payors.

More recently, 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, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the PPACA revises the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. Although it is too early to determine the full effect of the PPACA, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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 drug 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 drug 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 4, 2013. 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;

the amount and timing of any royalty revenue we receive from Genentech related to Erivedge;

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;

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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, including the recent partial clinical hold placed on CUDC-427 by the FDA;

the limited trading volume in our common stock; 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.

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, 2013, 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 1,388,933 shares of our common stock, at an exercise price of $3.51 per share, which is equal to an aggregate of additional 15,416 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 July 2013 we entered into a sales agreement with Cowen pursuant to which, from time to time, we may offer and sell up to $30,000,000 of the common stock that was registered on this shelf registration statement through Cowen pursuant to one or more at the market offerings. In addition, with our prior written approval, Cowen 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.

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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.

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.

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, 2013, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 22% 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 or prevent attempts by our stockholders to replace or remove our current management 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

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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 12, 2013

By: /s/ MICHAEL P. GRAY
Michael P. Gray
Chief Business and Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1(1)	Sales Agreement, dated as of July 3, 2013, between Curis, Inc. and Cowen and Company, LLC.
10.2	Employment Agreement, dated as of August 28, 2013 between Curis, Inc. and Jaye Viner, M.D.
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

(1) Incorporated by reference to the Exhibit 1.2 to the Registrant s Registration Statement on Form S-3 filed July 3, 2013.