CURIS INC
Form 10-Q
October 29, 2009
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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, 2009

OR

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

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	04-3505116
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

45 Moulton Street

Cambridge, Massachusetts	02138
(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). ¨ 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 x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes x No

As of October 26, 2009, there were 66,568,005 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, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,803,801	$ 10,158,795
Marketable securities	20,411,153	18,694,200
Accounts receivable	226,979	107,341
Prepaid expenses and other current assets	432,027	373,373
Total current assets	27,873,960	29,333,709
Property and equipment, net	889,597	1,448,176
Long-term investment restricted	216,002	210,007
Goodwill	8,982,000	8,982,000
Other assets	7,980	7,980
	$ 37,969,539	$ 39,981,872
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,287,653	$ 1,961,439
Accrued liabilities	751,082	624,462
Deferred revenue	1,458,334	
Total current liabilities	3,497,069	2,585,901
Other long-term liabilities	42,843	171,375
Total liabilities	3,539,912	2,757,276
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 66,514,255 shares outstanding at September 30, 2009 and 63,653,698 shares outstanding at December 31, 2008	675,620	647,014
Additional paid-in capital	749,736,303	745,360,736
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(16,843)	(12,550)
Accumulated deficit	(715,087,459)	(707,970,836)
Accumulated other comprehensive income	13,280	91,506
Total stockholders equity	34,429,627	37,224,596
	$ 37,969,539	$ 39,981,872

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,	
	2009	2008	2009	2008
REVENUES:				
License fees	$ 666,666	$	$ 6,666,666	$ 4,852,518
Research and development contracts	98,647	86,721	199,037	409,596
Total revenues	765,313	86,721	6,865,703	5,262,114
COSTS AND EXPENSES:				
Research and development	2,295,997	3,000,266	7,493,123	9,676,761
General and administrative	2,566,475	1,861,971	6,691,403	6,402,274
Total costs and expenses	4,862,472	4,862,237	14,184,526	16,079,035
Loss from operations	(4,097,159)	(4,775,516)	(7,318,823)	(10,816,921)
OTHER INCOME (EXPENSE):				
Interest income	36,863	203,210	202,200	844,319
Other income (expense)		855		9,782
Interest expense				(3,854)
Total other income, net	36,863	204,065	202,200	850,247
Net loss	$ (4,060,296)	$ (4,571,451)	$ (7,116,623)	$ (9,966,674)
Net loss per common share (basic and diluted)	$ (0.06)	$ (0.07)	$ (0.11)	$ (0.16)
Weighted average common shares (basic and diluted)	66,270,778	63,435,070	64,516,816	63,339,767
Net loss	$ (4,060,296)	$ (4,571,451)	$ (7,116,623)	$ (9,966,674)
Unrealized gain (loss) on marketable securities	(6,199)	18,447	(78,226)	(62,530)
Comprehensive loss	$ (4,066,495)	$ (4,553,004)	$ (7,194,849)	$ (10,029,204)

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,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,116,623)	$ (9,966,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	566,050	762,916
Stock-based compensation expense	1,484,748	1,774,031
Changes in current assets and liabilities:		
Accounts receivable	(119,638)	154,250
Prepaid expenses and other assets	(58,654)	(92,369)
Accounts payable and accrued liabilities	(675,698)	(1,965,992)
Deferred revenue	1,458,334	(1,852,518)
Total adjustments	2,655,142	(1,219,682)
Net cash used in operating activities	(4,461,481)	(11,186,356)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(28,843,925)	(27,328,912)
Sale of marketable securities	27,048,746	26,767,978
Increase in restricted cash	(5,995)	
Purchases of property and equipment	(7,471)	(60,547)
Net cash used in investing activities	(1,808,645)	(621,481)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	2,915,132	180,501
Repayments of notes payable		(401,213)
Net cash provided by (used in) financing activities	2,915,132	(220,712)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(3,354,994)	(12,028,549)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,158,795	17,396,599
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 6,803,801	$ 5,368,050

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Business

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

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

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by its competitors of new or better technological innovations, dependence on key personnel, its ability to protect proprietary technology, its ability to successfully advance discovery and preclinical stage drug candidates in its internally funded programs, unproven technologies and drug development approaches, reliance on its corporate collaborator Genentech and its licensee Debiopharm S.A., a Swiss corporation, (Debiopharm), to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA, or foreign equivalent, government regulations and approval requirements as well as its ability to execute on its business strategies and obtain adequate financing to fund its operations through corporate collaborations, sales of equity or otherwise.

The Company s future operating results will largely depend on the magnitude of payments from its current and potential future corporate collaborators and the progress of drug candidates currently in its research and development pipeline. The results of the Company s operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of its entry into new collaborations, if any, the timing of the receipt of payments from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being conducted. The Company anticipates that existing capital resources at September 30, 2009 should enable it to maintain current and planned operations through the fourth quarter of 2010. The Company s ability to continue funding its planned operations beyond 2010 is dependent upon, among other things, anticipated near-term payments from its licensee Debiopharm, which include a payment upon the acceptance by regulatory authorities of Debiopharm s application to begin a phase I clinical trial and upon Debiopharm s treatment of the fifth patient in the first phase I clinical trial; payments that it may receive from Genentech upon the achievement of development and regulatory approval objectives, if any; its ability to manage its expenses; and its ability to raise additional funds through equity, debt, entry into new collaborations or other sources of financing.

2. Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the United States of America for complete financial statements and should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission on February 26, 2009.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company s financial position at September 30, 2009 and the results of operations and cash flows for the three- and nine-month periods ended September 30, 2009 and 2008. The preparation of the Company s Consolidated Financial Statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities. 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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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of the agreements may provide for the Company s licensees and collaborators to agree to make non-refundable license fees, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives and royalties on product sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on February 26, 2009.

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the accompanying Consolidated Balance Sheets. Amounts not expected to be recognized during the twelve-month period ended September 30, 2010 would be classified as long-term deferred revenue. As of September 30, 2009, the Company had $1,458,000 in short-term deferred revenue primarily related to its license agreement with Debiopharm (see Note 5).

4. Genentech, Inc. Hedgehog Pathway Inhibitor Collaboration

In March 2009 and in May 2008, the Company received payments of $6,000,000 and $3,000,000, respectively, from Genentech under the parties June 2003 Hedgehog pathway inhibitor collaboration for the achievement of certain clinical development objectives related to GDC-0449, which is the lead drug candidate in development under this collaboration. The Company has recorded these amounts as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the nine months ended September 30, 2009 and 2008, respectively, because the Company has no ongoing material performance obligations under the collaboration.

5. Debiopharm License Agreement

(i) Agreement Summary

In August 2009, the Company entered into a license agreement with Debiopharm, pursuant to which Curis has granted to Debiopharm a worldwide, exclusive royalty-bearing license, with the right to grant sublicenses and to develop, manufacture, market and sell any product containing Curis Hsp90 inhibitor technology, including its lead Hsp90 compound under development, CUDC-305, which Debiopharm has since renamed Debio 0932. Debiopharm will assume all future development responsibility and incur all future costs related to the development, registration and commercialization of products under the agreement.

Pursuant to the terms of the agreement, the Company has agreed to use its reasonable commercial efforts to transfer to Debiopharm know how, information and materials necessary for Debiopharm to continue the development of products in accordance with the development plan outlined in the agreement for a specified period of time. Furthermore, at no cost to Debiopharm, the Company will provide a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement.

Pursuant to the terms of the agreement, Debiopharm has agreed to undertake reasonable commercial efforts to implement the development plan in the timeframes described in the agreement in order to develop, register and commercialize the product in specified markets and will be solely responsible for all the costs relating thereto. Debiopharm will retain final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to the product.

As consideration for the exclusive license rights provided in the agreement, and subject to the terms of the agreement, Debiopharm has agreed to pay the Company up to an aggregate of $90 million comprised of the following:

a $2,000,000 up-front license fee which the Company received in September 2009 upon the transfer to Debiopharm certain information specified in the agreement ;

a payment upon the first regulatory approval in a major market country of an open IND or CTA to initiate human clinical trials;

a payment upon the administration of Debio 0932 in the 5th patient in the first phase I clinical trial; and

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

additional contingent payments assuming the successful achievement of additional specified clinical development and regulatory approval objectives.

In addition, Debiopharm will pay the Company:

a specified percentage of all sublicensing payments received by Debiopharm and its affiliates from sublicensees;

a specified percentage of royalties Debiopharm and its affiliates receive from sublicensees; and

a specified percentage of royalties on net sales of products by Debiopharm or its affiliates.

The agreement is effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Company s patents and joint patents relating to the products, and (ii) the 10th anniversary of the first commercial sale of the product in such country. Pursuant to the agreement, either party can terminate the agreement upon notice under prescribed circumstances, and the agreement specifies the consequences to each party for such early termination.

Curis and Debiopharm have the right to terminate the agreement on short notice under specified circumstances.

(ii) Accounting Summary

The Company considered its arrangement with Debiopharm to be a revenue arrangement with multiple deliverables, or performance obligations. The Company s substantive performance obligations under this collaboration included an exclusive license to its Hsp90 inhibitor technologies, a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement and participation on a steering committee for which the Company received a $2,000,000 up-front, nonrefundable license fee. The Company applied the provisions of FASB Codification Topic 605-25, *Revenue Recognition, Multiple Element Arrangements* to determine whether the performance obligations under this collaboration could be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, since, initially, the license does not have stand-alone value to Debiopharm without its technical expertise and steering committee participation during the initial six-month period. In addition, objective and reliable evidence of the fair value of the Company s technical support and steering committee participation could not be determined.

The Company will also provide clinical materials to Debiopharm, if and when requested, for which the Company will receive additional consideration. The Company has determined that this deliverable is a separate unit of accounting from the license and related support, and consideration received would be recognized as revenue in accordance with our revenue policy.

The Company s ongoing substantive performance obligations for the single unit of accounting under this collaboration consist of support to Debiopharm during the initial six months of the agreement and participation on a joint steering committee. The joint steering committee is comprised of four members, two from each company. Debiopharm retains final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to any products. The joint steering committee s function is limited to facilitation of the collaboration, including providing a contractual mechanism of information exchange related to the products being developed. The joint steering committee has no authority to make changes to the development plan, which can only be revised by Debiopharm upon advance notice to the Company. The Company has determined that its joint steering committee obligation is participatory for the initial six-month period in which it is also required to provide technical support. The Company s main contribution during this time is to support Debiopharm s preparation of the clinical trial application filing with regulatory authorities, which is expected to be filed in the fourth quarter of 2009. After January 2010, substantially all activities around the implementation and management of the development plan become the sole responsibility of Debiopharm, at which time, the Company believes that its role on the joint steering committee becomes protective and inconsequential or perfunctory. The Company has therefore estimated that its participation on the joint steering committee should only factor

into the performance period as it relates to the six-month period in which the Company has a participatory role. Because the Company estimates that its level of effort would be consistent over the six-month term of the arrangement, the Company is accounting for the arrangement under the proportional performance method.

The $2,000,000 up-front fee is being recognized ratably as the research and joint steering committee services are being provided over the estimated six-month performance period, through January 2010, at a rate of $333,000 per month. During the three and nine months ended September 30, 2009, the Company recorded revenue of $667,000 related to the Company s efforts under the Debiopharm arrangement, all of which was recorded in License Fees in the Company s Revenues section of its Consolidated Statement of Operations.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

The Company believes that contingent payments tied to preclinical, clinical development and drug approval objectives under this collaboration would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company s revenue recognition policy related to substantive milestones. Accordingly, the Company would recognize such contingent payments as revenue at the time the contingent payment is earned in an amount equal to the percentage of the performance period completed when the contingent payment is earned, multiplied by the total amount of the contingent payment. The remaining portion of the contingent payment would be recognized over the remaining performance period using the proportional performance method. For any contingent payments received by the Company subsequent to the conclusion of the performance period, the Company would have no future deliverables under the agreement, and the Company expects that it would record any such contingent payments as revenue in License Fees in the Company s Revenues section of its Consolidated Statement of Operations when the milestones are met and payable.

6. Fair Value Measurements

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

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company s Level 1 assets include cash and cash equivalents, investments in marketable securities, and a long-term restricted investment. As of September 30, 2009, the Company held cash equivalents and marketable securities of $5,272,000 and $20,411,000, respectively. The Company s marketable securities are investments with original maturities of greater than three months from the date of purchase, but less than twelve months from the balance sheet date, and consist of commercial paper and government obligations. These amounts are invested directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings, U.S. Treasury securities and U.S. Treasury money market funds.

The long-term restricted investment of $216,000 as of September 30, 2009 was solely comprised of a certificate of deposit.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company has no Level 2 assets or liabilities at September 30, 2009.

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 has no Level 3 assets or liabilities at September 30, 2009.

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

7. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2009	December 31, 2008
Accrued compensation	$ 216,000	$ 111,000
Professional fees	143,000	137,000
Facility-related costs	244,000	262,000
Other	148,000	114,000
Total	$ 751,000	$ 624,000

8. Accounting for Stock-Based Compensation

As of September 30, 2009, the Company had three shareholder-approved, share-based compensation plans: the 2000 Stock Incentive Plan (the 2000 Plan), the 2000 Director Stock Option Plan (the 2000 Director Plan) and the 2000 Employee Stock Purchase Plan (the ESPP). For a complete discussion of the Company s share-based compensation plans, see Note 5 included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, as previously filed with the Securities and Exchange Commission on February 26, 2009.

During the nine months ended September 30, 2009, the Company s board of directors granted options to purchase 1,160,000 shares of the Company s common stock to officers and employees of the Company under the 2000 Plan. These options vest over a four-year period and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant date.

During the nine months ended September 30, 2009, the Company s board of directors also granted options to its non-employee directors to purchase 175,000 shares of common stock under the 2000 Plan and options to purchase 45,000 shares of common stock under the 2000 Director Plan. All of these options were fully vested on the grant date and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market for the grant date.

Employee and Director Grants

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. The Company calculated the value of employee options awarded during the nine months ended September 30, 2009 and 2008 using the Black-Scholes valuation model based on the assumptions noted in the following table:

	For the nine months ended September 30, 2009	2008
Expected term (years) - Employees	6	6
Expected term (years) - Directors	6	7
Risk-free interest rate	2.1-2.6%	3.0-3.4%
Volatility	67-82%	84-93%
Dividends	None	None

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, accordingly, the expense that is to be recognized over the life

of the option. In determining the expense recorded in the Company s Consolidated Statements of Operations, the Company has applied an estimated forfeiture rate to the remaining unvested awards based on historical experience, as adjusted. This estimate is evaluated quarterly and the forfeiture rate is adjusted as necessary. If the actual number of forfeitures differs from management s estimates, additional adjustments to compensation expense may be required in future periods.

The aggregate intrinsic value of options outstanding at September 30, 2009 was $7,294,000, of which $3,839,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2009 and 2008 were $1.18 and $1.08 per share, respectively. As of September 30, 2009, there was approximately $2,487,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee and director stock option awards outstanding under the 2000 Plan and 2000 Director

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

Plan that is expected to be recognized as expense over a weighted average period of 2.74 years. The intrinsic value of employee stock options exercised during the nine months ended September 30, 2009 and 2008 was $79,000 and $37,000, respectively. The total grant date fair values of stock options that vested in the nine months ended September 30, 2009 and 2008 were $1,270,000 and $1,678,000, respectively.

During the nine-month periods ended September 30, 2009 and 2008, the Company recorded compensation expense related to its ESPP and calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model based on the following assumptions:

	For the nine months ended September 30,	
	2009	2008
Compensation expense recognized under ESPP	$ 59,000	$ 41,000
Expected term	6 months	6 months
Risk-free interest rate	0 0.3%	1.9 3.3%
Volatility	70 86%	64 - 75%
Dividends	None	None

Stock-based compensation for employees, including expense related to the ESPP, for the three and nine months ended September 30, 2009 and 2008 was calculated using the above assumptions and has been included in the Company s results of operations. The Company recorded $438,000 and $1,412,000 in compensation expense for the three and nine months ended September 30, 2009, respectively, and $498,000 and $1,737,000 in compensation expense for the three and nine months ended September 30, 2008, respectively, related to employee stock-based compensation. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is not likely that the net deferred tax asset will be realized.

Non-Employee Grants

The Company has historically granted stock options to consultants for services. These options were issued at or above their fair market value on the date of grant and have various vesting dates from date of grant, ranging from 3.5 months to 4 years. Should the Company or the consultant terminate the consulting agreement, any unvested options will be cancelled. Options issued to non-employees are marked-to-market until they vest, which means that as the Company s stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of $31,000 and $73,000 related to non-employee stock options for the three and nine months ended September 30, 2009, respectively. The Company reversed expense of $4,000 related to non-employee stock options for the three months ended September 30, 2008 as a result of a decline in the Company s stock price during the period. The Company recognized expense of $37,000 related to non-employee stock options for the nine months ended September 30, 2008. As of September 30, 2009, the Company had recorded $17,000 in deferred compensation related to unvested non-employee options.

Total Stock-Based Compensation Expense

For the three and nine months ended September 30, 2009 and 2008, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

	For the three months ended September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
Research and development expenses	$ 188,000	$ 185,000	$ 526,000	$ 582,000
General and administrative expenses	281,000	309,000	959,000	1,192,000

Total stock-based compensation expense	$ 469,000	$ 494,000	$ 1,485,000	$ 1,774,000

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

The table below summarizes options outstanding and exercisable under the 2000 Plan and the 2000 Director Plan at September 30, 2009:

	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
$ 0.56 - $ 1.09	2,028,125	8.33	$ 1.00	802,144	$ 0.96
1.20 - 1.39	2,203,721	7.57	1.38	1,101,060	1.38
1.43 - 1.57	2,826,095	6.41	1.50	1,976,344	1.52
1.67 - 3.75	2,042,671	4.24	2.57	1,866,483	2.61
3.85 - 5.26	1,925,002	4.19	4.25	1,910,564	4.26
5.37 - 29.26	475,321	1.37	11.86	475,321	11.86
	11,500,935	6.00	$ 2.47	8,131,916	$ 2.94

9. Basic and Diluted Loss Per Common Share

Basic and diluted net losses per share were determined by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company s net loss position for all periods presented. Antidilutive securities consist of stock options, warrants and shares issuable under the Company s 2000 Employee Stock Purchase Plan; all of which are weighted based on the number of days outstanding during the respective reporting period. Antidilutive securities as of September 30, 2009 and 2008, respectively, are as follows.

	For the nine months ended September 30,	
	2009	2008
Weighted average stock options outstanding	9,884,172	9,527,896
Weighted average warrants outstanding	4,502,540	6,210,615
Shares issuable under ESPP	4,567	26,430
Total antidilutive securities	14,391,279	15,764,941

On July 7, 2009, a warrant holder exercised two warrants to purchase an aggregate of 2,632,198 shares of the Company s common stock at a purchase price of $1.02 per share, providing approximately $2,700,000 in cash proceeds to the Company. These warrants were originally issued in connection with the Company s August 2007 private placement.

10. Related Party Transactions

Pursuant to a scientific advisory and consulting agreement dated September 14, 2006 with Joseph M. Davie, Ph.D., M.D., a member of the Company s Board of Directors, the Company incurred $6,000 and $19,000 in related consulting expenses in its Consolidated Statement of Operations for each of the three- and nine-month periods ended September 30, 2009 and 2008, respectively. The consulting agreement extends through September 2011, unless terminated earlier in accordance with its terms.

11. New Accounting Pronouncements

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements, (* ASU 2009-13). ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Codification Subtopic 605-25 (previously included within EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21). The consensus to EITF Issue No. 08-01, *Revenue Arrangements with Multiple Deliverables*, or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead

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CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (Continued)

provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company will have to evaluate the impact of this standard on future revenue arrangements that the Company may enter into.

12. Subsequent Events

The Company has evaluated all subsequent events through October 29, 2009, which represents the filing date of this Form 10-Q with the Securities and Exchange Commission, to ensure that this Form 10-Q includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2009, and events which occurred subsequent to September 30, 2009 but were not recognized in the financial statements. As of October 29, 2009, there were no subsequent events which required recognition or disclosure.

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

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

Overview

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to develop next generation targeted cancer therapies. In expanding our drug development efforts with respect to these targeted cancer programs, we are building upon our past experience in targeting signaling pathways, including the Hedgehog pathway. We seek to conduct research programs both internally and through strategic collaborations.

Our most advanced program is our Hedgehog pathway inhibitor program under collaboration with Genentech, Inc., a wholly-owned member of the Roche Group. The lead drug candidate being developed under this program is GDC-0449, a first-in-class orally-administered small molecule Hedgehog pathway inhibitor. Genentech and Roche are responsible for the clinical development and commercialization of GDC-0449. We are eligible to receive up to $115 million in contingent cash payments under the collaboration for the development of GDC-0449 or another small molecule, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives, of which we have received $18 million to date. In addition to these payments, we are also eligible for a royalty on sales of any Hedgehog pathway inhibitor products that are successfully commercialized by Genentech and Roche. For GDC-0449, we are entitled to a mid- to high-single digit royalty, which escalates within this range with increasing product sales. In certain specified circumstances, the royalty rate applicable to GDC-0449 may be decreased to a low- to mid-single digit royalty.

Genentech and Roche are currently conducting three clinical trials of GDC-0449, including a pivotal phase II trial in advanced basal cell carcinoma, or BCC, that was initiated in February 2009. In addition, phase II clinical trials in metastatic colorectal cancer and in advanced ovarian cancer were initiated in 2008.

In the pivotal Phase II clinical trial of GDC-0449, approximately 100 patients with locally advanced or metastatic BCC will be evaluated in a global trial. This trial represents a significant development milestone for GDC-0449 in locally advanced and metastatic BCC and builds upon the encouraging phase I safety and efficacy data demonstrated by the drug, which was highlighted in a September 2009 *New England Journal of Medicine* article published by the phase I study investigators. This article reported data on 33 advanced basal cell carcinoma patients that were treated in the phase I clinical trial. Of these patients, 18, or 55%, responded to GDC-0449 including 2 complete responses and 16 partial responses. Of the remaining 15 patients, 11 patients had stable disease as a best response and 4 patients had progressive disease. At the time of the data cut-off for the article, the median time on study and the median duration of response for these patients was 9.8 and 8.8 months, respectively, with 19 patients still on study.

GDC-0449 has also demonstrated good tolerability in the phase I patients, with no dose limiting toxicity and no Grade 5, or fatal, adverse events observed. There also were no Grade 4, or life threatening, adverse events observed related to the study drug. There were several Grade 3, or severe, and Grade 2, or moderate, adverse events observed. GDC-0449 demonstrated a favorable pharmacokinetic and pharmacodynamic profile with a median steady-state plasma concentration of 16.1 micromolar. The median time to reach this steady-state level was 14 days. Dose escalation from 150 mg to 270 mg did not result in higher total plasma concentrations of GDC-0449 and as a result, Genentech has selected a daily dose of 150 mg for the ongoing Phase II clinical trials.

In July 2009, Roche provided an update on the program in which it stated that GDC-0449 was one of 10 new molecular entities that are currently enrolling patients in registrational studies within Roche. Pending a successful outcome of the ongoing pivotal study, Roche projects that regulatory submissions for GDC-0449 in advanced basal cell carcinoma could occur in 2011. As such, we believe that advanced basal cell carcinoma represents a potential opportunity that could enable first market entry for a compound that inhibits the Hedgehog signaling pathway.

GDC-0449 also is undergoing phase II clinical testing in colorectal and advanced ovarian cancer indications. Genentech has indicated that if the proof-of-concept data from the colorectal or ovarian cancer trials are positive, Genentech and Roche could consider a rapid expansion of development for the compound in several additional potential cancer indications. Genentech previously indicated that these data are expected in 2010. In July 2009, Roche provided further updates on this program including that the GDC-0449 Phase II clinical trial in metastatic colorectal cancer completed enrollment during the second quarter of 2009.

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In addition to the ongoing clinical trials that Genentech and Roche are conducting, Genentech and the National Cancer Institute, or NCI, entered into a collaborative relationship that allows the NCI to study GDC-0449 in additional potential cancer indications. Under this arrangement with NCI, third-party investigators began enrolling patients in a phase I clinical trial that is designed to evaluate dose and safety of GDC-0449 in young patients with medulloblastoma and a phase II trial to test the molecule in adult medulloblastoma patients. A phase I clinical trial in pancreatic cancer patients and a randomized phase II clinical trial in small cell lung cancer patients were also initiated and additional phase II studies are planned to begin, including trials in glioblastoma multiforme and advanced stomach or gastroesophageal junction cancer patients under this NCI arrangement. In addition, an investigator-sponsored study evaluating GDC-0449 in patients with basal cell nevus (Gorlin) syndrome has been initiated.

Our internal drug development efforts are focused on our proprietary targeted cancer programs that target multiple signaling pathways. We believe that this approach of targeting multiple nodes in various signaling pathway networks may provide a better therapeutic effect than many of the targeted cancer drugs currently marketed or in development.

Our lead candidate from these programs is CUDC-101, a small molecule that is currently in a dose escalating phase I clinical trial and is designed to target histone deacetylase, or HDAC, epidermal growth factor receptor, or EGFR and human epidermal growth factor receptor 2, or Her2. We have treated 20 patients to-date in this study and estimate that we will establish our maximum tolerated dose and complete this dose escalation study during the fourth quarter of 2009 or in early 2010.

In addition to our CUDC-101 development efforts, we have spent the last several months progressing CUDC-305, an Hsp90 inhibitor, towards an investigational new drug, or IND, filing while simultaneously seeking to enter into a corporate collaboration for the clinical development of this molecule. In August 2009, we granted a worldwide, exclusive royalty-bearing license to our Hsp90 inhibitor technology, including CUDC-305 to Debiopharm S.A., a Swiss corporation, or Debipharm. Debiopharm has since renamed this candidate Debio 0932 and will assume all future development responsibility and incur all future costs related to the development, registration and commercialization of products under the agreement. As part of the consideration under the agreement, Debiopharm paid us an up-front license fee of $2,000,000, and we are eligible to receive up to an additional $88,000,000 if specified clinical development and regulatory approval objectives are met. Included in these future payments are payments for near-term objectives including for acceptance by a regulatory authority of a clinical trial application, or CTA, or IND, filing by Debiopharm as well as payments for Debiopharm s treatment of the fifth patient in the corresponding phase I clinical trial. We expect that Debiopharm will file the CTA during the fourth quarter and that the phase I clinical trial will begin early in 2010. In addition, we are eligible to receive royalties if any products under the license agreement are successfully developed and commercialized. The license agreement also provides certain provisions for termination as it relates to both parties.

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our corporate collaborators, the private and public placement of our equity securities and debt financings and the monetization of certain royalty rights. We have never been profitable and have an accumulated deficit of $715,087,000 as of September 30, 2009. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our research and development programs. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We believe that near term key drivers to our success will include:

- Genentech s ability to continue to successfully advance its clinical trials for GDC-0449;
- Debiopharm s ability to file a CTA for Debio 0932, the subsequent acceptance by regulatory authorities of such CTA filing, Debiopharm s initiation of phase I clinical testing and ultimately its advancement of Debio 0932 into later stages of clinical development;
- our ability to continue to successfully enroll and treat patients in our phase I clinical trial for CUDC-101;
- our ability to successfully enter into a material license or collaboration agreement for CUDC-101 or other of our proprietary drug candidates; and

our ability to advance the preclinical development of other small molecule cancer drug candidates that we are developing under our proprietary pipeline of targeted cancer programs.

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

Our Research and Development Programs under Collaboration

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog pathway inhibitor technologies, an April 2005 collaboration with Genentech relating to the Wnt signaling pathway, and an August 2009 license agreement with Debiopharm relating to our Hsp90 inhibitor technology. Our past and current collaborations have generally provided for research, development and commercialization programs to be wholly or majority-funded by our collaborators and provide us with the opportunity to receive additional contingent cash payments if specified development and regulatory approval objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaborations. We are currently not receiving any research funding and we do not expect to receive such funding in the future from Genentech or Debiopharm under our current agreements with these parties. We currently expect to incur only nominal research and development costs under our collaborations with Genentech related to the maintenance of licenses. We also expect to incur general and administrative costs associated with our share of intellectual property costs under our collaboration of the Hedgehog pathway inhibitor program. We do not expect to incur any material costs related to our Hsp90 technologies subsequent to our entry into a license agreement with Debiopharm for these technologies.

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, 2009 should enable us to maintain our current and planned operations through the fourth quarter of 2010. Our ability to continue funding our planned operations beyond 2010 is dependent upon the anticipated near-term payments from our licensee Debiopharm, which include a payment upon the acceptance by regulatory authorities of Debiopharm s application to begin a phase I clinical trial and a payment upon Debiopharm s treatment of the fifth patient in the first phase I clinical trial. We expect that Debiopharm will file an application with regulatory authorities to begin phase I clinical testing for Debio 0932 in the fourth quarter of 2009 and, pending acceptance by regulatory authorities, that these payments may be received in early 2010. Our ability to fund our operations beyond 2010 is also dependent on payments that we may receive from Genentech upon the achievement of development and regulatory approval objectives, our ability to manage our expenses and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing. We expect that our expenses associated with the clinical development of CUDC-101 will increase, resulting in an overall increase in our research and development expenses for future periods as compared to prior years.

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

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

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

Research and Development. Research and development expense consists of costs incurred to discover, research and develop our drug candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense as well as outside service costs including clinical research organizations and medicinal chemistry. Research and development expenses also include the costs of supplies and reagents, consulting, and occupancy

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and depreciation charges. We expense research and development costs as incurred. We are currently incurring only nominal research and development expenses under our Hedgehog Pathway Inhibitor collaboration with Genentech related to the maintenance of third-party licenses. For each contingent payment, if any, received under the Hedgehog Pathway Inhibitor collaboration, we would be obligated to make payments to such third-party licensors and recognize the related expense. Our research and development programs, both internal and under collaboration, are summarized in the following table:

Product Candidate	Primary Indication	Collaborator/Licensee	Status
Hedgehog Pathway Inhibitor			
- GDC-0449	Advanced basal cell carcinoma	Genentech	Pivotal Phase II
- GDC-0449	Metastatic colorectal cancer	Genentech	Phase II
- GDC-0449	Advanced ovarian cancer	Genentech	Phase II
Targeted cancer programs			
- CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I
- Debio 0932 (formerly CUDC-305) (Hsp90 inhibitor)	Cancer	Debiopharm	Development candidate
- Other targeted cancer programs	Cancer	Internal development	Preclinical

In the chart above, Pivotal Phase II means that Genentech is currently treating human patients in a pivotal phase II clinical trial, the primary objective of which is a therapeutic response in human patients. The endpoints of this clinical trial, if positive, may serve as the basis for a future NDA submission by Genentech. Phase II means that Genentech is currently treating human patients in a phase II clinical trial, the primary objective of which is a therapeutic response (i.e., for the metastatic colorectal cancer trial, progression-free survival from randomization to disease progression or death). Phase I means that we are currently treating human patients in a phase I clinical trial, the principal purpose of which is to evaluate the safety and tolerability of the compound being tested. Development candidate means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we or our collaborator or licensee has selected a single lead candidate for potential future clinical development and are seeking to complete and summarize in writing the relevant safety, toxicology, and other studies required to submit an IND application with the FDA, or foreign equivalent, seeking to commence a phase I clinical trial. Preclinical means we are seeking to obtain evidence of therapeutic efficacy and safety in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

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

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

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

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

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

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

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosures in the financial statements. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the collectability of receivables and the value of certain investments and liabilities. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. 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, 2008, which is on file with the Securities and Exchange Commission, or SEC.

While there have been no material changes to these critical accounting policies at September 30, 2009, significant management judgment was required in determining the level of effort required under our Debiopharm arrangement and the period over which we are expected to complete our performance obligations. In addition, we are involved in a steering committee under this arrangement and we assessed that our involvement constitutes a performance obligation for the estimated performance period, after which our continued involvement then becomes a protective right and is no longer an obligation. The steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with the other performance obligations required under the arrangement in determining the level of effort required in the arrangement and the period over which we expect to complete our aggregate performance obligations.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the twelve-month period ended September 30, 2009 are classified as long-term deferred revenue. As of September 30, 2009, we had short-term deferred revenue of $1,458,000, primarily related to the Debiopharm license agreement.

Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, in connection with our existing collaboration agreements, we have recorded on our balance sheet short-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue by September 30, 2010. Amounts that we expect will not be recognized prior to September 30, 2010 would be classified as long-term deferred revenue. However, this estimate is based on our current estimated performance period under our Debiopharm agreement as of September 30, 2009. If this estimate should change in the future, we may recognize a different amount of deferred revenue over the twelve-month period from October 1, 2009 through September 30, 2010.

Recently Issued Accounting Standards

In October 2009, the FASB issued ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements, (* ASU 2009-13). ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB Codification Subtopic 605-25 (previously included within EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21). The consensus to EITF Issue No. 08-01, *Revenue Arrangements with Multiple Deliverables*, or EITF 08-01, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique

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features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We will have to evaluate the impact of this standard on future revenue arrangements that we may enter into.

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Results of Operations

Three-Month Periods Ended September 30, 2009 and September 30, 2008

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30, 2009 (unaudited)	2008 (unaudited)	Percentage Increase/ (Decrease)
REVENUES:			
Research and development contracts			
Genentech	$ 89,000	$ 46,000	93%
Wyeth		33,000	(100%)
Other	9,000	8,000	13%
Subtotal	98,000	87,000	13%
License fees			
Debiopharm	667,000		100%
Subtotal	667,000		100%
Total revenues	$ 765,000	$ 87,000	779%

Total revenues increased by $678,000, or 779%, to $765,000 for the three months ended September 30, 2009 as compared to $87,000 for the same period in the prior year as a result of the increase in license fee revenue recognized under our August 2009 license agreement with Debiopharm. We expect that we will recognize the up-front license fee of $2,000,000 over a six-moth period through January 2010.

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

Research and Development Program	For the Three Months Ended September 30, 2009	2008	Percentage Increase/ (Decrease)
Hedgehog pathway inhibitor	$ 48,000	$ 48,000	%
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	513,000	645,000	(20%)
CUDC-305 (Hsp90 inhibitor)	286,000	1,144,000	(75%)
Other targeted cancer programs	1,261,000	847,000	49%
Other targeted programs		131,000	(100%)
Stock-based compensation	188,000	185,000	2%
Total research and development expense	$ 2,296,000	$ 3,000,000	(23%)

Our research and development expenses decreased by $704,000, or 23%, to $2,296,000 for the three months ended September 30, 2009 as compared to $3,000,000 for the same period in the prior year. The decrease is primarily attributable to lower spending of $858,000 on our CUDC-305 program as a result of licensing the program to Debiopharm on August 5, 2009. All future costs associated with this program will be assumed by Debiopharm. In addition, our spending relating to CUDC-101 decreased by $132,000 when compared to the same prior year period as we continue to enroll patients in the phase I clinical trial. Offsetting these decreases, we increased spending on other targeted programs by $283,000 as we aim to select additional preclinical candidates for future development. We expect that will incur a majority of our ongoing research and development expenses to further develop CUDC-101 and our targeted cancer programs.

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

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2009 (unaudited)	2008 (unaudited)	
Personnel	$ 485,000	$ 332,000	46%
Occupancy and depreciation	90,000	98,000	(8%)
Legal services	728,000	552,000	32%
Consulting and professional services	739,000	297,000	149%
Insurance costs	70,000	85,000	(18%)
Other general and administrative expenses	173,000	190,000	(9%)
Stock-based compensation	281,000	308,000	(9%)
Total general and administrative expenses	$ 2,566,000	$ 1,862,000	38%

General and administrative expenses increased by $704,000, or 38%, to $2,566,000 for the three months ended September 30, 2009 as compared to $1,862,000 for the same period in the prior year. This increase was primarily due to increased spending for consulting and legal services as well as for personnel costs. Consulting services increased $442,000 as a result of business development efforts used to facilitate the licensing agreement with Debiopharm and legal services increased $176,000 during the three months ended September 30, 2009 as compared to the same period in the prior year, due to costs associated with various corporate matters. Personnel costs increased $153,000 for the three months ended September 30, 2009 as compared to the prior year period primarily due to amounts expensed for employee and officer bonuses during the first six months of 2008 that we determined would not be paid, resulting in a reversal of $200,000 in related expense in the third quarter of 2008. We have not accrued any amounts for bonuses during 2009.

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Nine-Month Periods Ended September 30, 2009 and September 30, 2008

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30		Percentage Increase/ (Decrease)
	2009 (unaudited)	2008 (unaudited)	
REVENUES:			
Research and development contracts			
Genentech	$ 186,000	$ 182,000	2%
Wyeth		196,000	(100%)
Other	13,000	32,000	(59%)
Subtotal	199,000	410,000	(51%)
License fees			
Genentech	6,000,000	3,000,000	100%
Debiopharm	667,000		100%
Wyeth		102,000	(100%)
Stryker		1,750,000	(100%)
Subtotal	6,667,000	4,852,000	37%
Total revenues	$ 6,866,000	$ 5,262,000	30%

Total revenues increased by $1,604,000, or 30%, to $6,866,000 for the nine months ended September 30, 2009 as compared to $5,262,000 for the same period in the prior year. Research and development contracts decreased $211,000 as research funding concluded under our Hedgehog agonist collaboration with Wyeth in February 2008. We currently receive no research funding for our programs under past or current collaborations. We expect that our future research and development contract revenues under our current collaborations with Genentech will be limited to expenses that we incur on behalf of Genentech for which Genentech is obligated to reimburse us.

Offsetting the decrease in research and development contract revenue, our license revenues increased by $1,815,000 to $6,667,000 for the nine months ended September 30, 2009 from $4,852,000 for the same period in 2008. The increase is primarily due to $6,000,000 in license revenue recognized upon the achievement of a certain development objective under our June 2003 collaboration with Genentech during the nine months ended September 30, 2009, compared to $3,000,000 recognized during the same prior year period. In addition, we recognized $667,000 under our August 2009 license agreement with Debiopharm related to our Hsp90 technology. These increases in license fee revenues were offset in part by a decrease of $1,750,000 in license revenue recognized from the sale and assignment of our remaining bone morphogenetic protein assets to Stryker Corporation during the first quarter of 2008.

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

Research and Development Program	For the Nine Months Ended September 30, 2009	2008	Percentage Increase/ (Decrease)
Hedgehog pathway inhibitor	$ 447,000	$ 259,000	73%
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	1,158,000	3,417,000	(66%)
CUDC-305 (Hsp90 inhibitor)	2,022,000	1,144,000	77%
Other targeted cancer programs	3,340,000	3,536,000	(6%)
Other targeted programs		416,000	(100%)
Hedgehog agonist		199,000	(100%)
Discovery research		124,000	(100%)
Stock-based compensation	526,000	582,000	(10%)
Total research and development expense	$ 7,493,000	$ 9,677,000	(23%)

Our research and development expenses decreased by $2,184,000, or 23%, to $7,493,000 for the nine months ended September 30, 2009 as compared to $9,677,000 for the same period in the prior year. The decrease in research and development expenses was primarily the result of a $2,259,000 decrease in spending related to CUDC-101 when compared to the same prior year period. We incurred significant consulting and outside costs during the nine months ended September 30, 2008 as we prepared and filed the IND application for CUDC-101. Costs incurred during the nine months ended September 30, 2009 were primarily comprised of costs associated with the enrollment and support of our ongoing Phase I trial.

This decrease is also due to our implementation of a plan to decrease spending in various research and development expense areas, particularly preclinical research in areas other than in our targeted cancer programs. Spending reductions included decreases in contract medicinal chemistry and biology work that was being performed in China, and in personnel and occupancy costs. In addition, our Hedgehog agonist program under collaboration with Wyeth concluded in February 2008. As a result of these decreases we incurred no expenses in our other targeted programs, Hedgehog agonist or discovery research programs during the nine months ended September 30, 2009 as compared to $739,000 during the same period in 2009.

Offsetting these decreases was an increase of $878,000 in spending relating to our CUDC-305 program from the prior year period. We selected CUDC-305 as a development candidate in July 2008 and licensed it to Debiopharm in August 2009. Debiopharm has assumed all future costs related to this program.

We expect that a majority of our research and development expenses for the foreseeable future will be incurred in support of our efforts to advance CUDC-101 and our other targeted cancer programs.

During the nine months ended September 30, 2009, we also incurred expenses of $447,000 related to our Hedgehog pathway inhibitor program as compared to $259,000 during the same period in the prior year, an increase of $188,000. We paid $300,000 in sublicense payments relating to the $6,000,000 we received from Genentech for the achievement of a clinical development objective during the nine months ended September 30, 2009, as compared to sublicense payments of $150,000 for the prior year period. We expect that future sublicense payment obligations related to our Hedgehog pathway inhibitor program will continue to fluctuate in relation to future payments under this collaboration.

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

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2009 (unaudited)	2008 (unaudited)	
Personnel	$ 1,495,000	$ 1,780,000	(16%)
Occupancy and depreciation	267,000	287,000	(7%)
Legal services	1,971,000	1,247,000	58%
Consulting and professional services	1,281,000	893,000	43%
Insurance costs	220,000	279,000	(21%)
Other general and administrative expenses	498,000	724,000	(31%)
Stock-based compensation	959,000	1,192,000	(20%)
Total general and administrative expenses	$ 6,691,000	$ 6,402,000	5%

General and administrative expenses increased by $289,000, or 5%, to $6,691,000 for the nine months ended September 30, 2009 as compared to $6,402,000 for the same period in the prior year. This increase was primarily due to increased spending for consulting and legal services. Fees for legal services increased $724,000 during the nine months ended September 30, 2009 as compared to the same period in the prior year primarily due to costs associated with various corporate matters and costs associated with foreign patent applications. Consulting services increased $388,000 primarily as the result of business development efforts used to facilitate the licensing agreement with Debiopharm.

Offsetting these increases, personnel costs decreased $285,000 due to pay decreases for executive officers implemented in the fourth quarter of 2008. In addition, other general and administrative costs decreased by $226,000 as a result of lower travel costs and stock-based compensation decreased by $233,000 as a result of a decline in the grant date fair values of stock options expensed, and related expense, awarded in the first nine months of 2009 compared to the prior year period.

Liquidity and Capital Resources

We have financed our operations primarily through receipt of 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.

At September 30, 2009, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of $27,215,000, excluding restricted long-term investments of $216,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and 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. 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, 2009, 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.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees and legal fees. During 2008, we began incurring clinical costs associated with our phase I clinical trial of CUDC-101. We expect that costs associated with clinical studies will increase in future periods assuming that CUDC-101 advances into further stages of clinical testing and other of our targeted cancer drug candidates reach clinical trials.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. As a result of the conclusion of all research funding commitments under our past and current collaborations, the majority of our research and development effort and expense has shifted from such programs to our targeted cancer programs, particularly CUDC-101 and CUDC-305 until it was licensed to Debiopharm in August 2009. We believe that our research and development expenses will increase in future periods in connection with our plans to continue phase I clinical testing of CUDC-101 and with our plans to select an additional development candidate from our targeted

cancer programs in 2010.

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In general, our only source of cash flows from operations for the foreseeable future is expected to be from:

- 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 development objectives, if any are met, under new collaborations or our existing collaborations with Genentech; and
- royalty payments that are contingent upon the successful commercialization of any products based upon such collaborations.

Our ability to enter into new collaborations and our receipt of additional payments under our existing collaborations with Genentech and Debiopharm can not be assured, nor can we predict the timing of any such arrangements or payments, as the case may be.

Net cash used in operating activities was $4,461,000 for the nine-month period ended September 30, 2009 as compared to $11,186,000 for the nine-month period ended September 30, 2008. Cash used in operating activities during the nine-month period ended September 30, 2009 was primarily the result of our net loss for the period of $7,117,000. In addition, changes in certain operating assets and liabilities decreased operating cash during the nine-month period ended September 30, 2009, including a decrease of $676,000 in our accounts payable and accrued liabilities and an increase of $120,000 in our accounts receivables. Offsetting these decreases were an increase in our deferred revenue of $1,458,000 as a result of our August 2009 license agreement with Debiopharm and noncash items, including stock-based compensation expense of $1,485,000 and depreciation expense of $566,000.

Cash used in operating activities during the nine-month period ended September 30, 2008 was primarily the result of our net loss of $9,967,000. In addition, changes in certain operating assets and liabilities affected operating cash during the nine-month period ended September 30, 2008, including a decrease in deferred revenue of $1,853,000 as a result of the recognition of the $1,750,000 license fee that we received in December 2007 under our BMP transaction with Stryker Corporation and a decrease of $1,967,000 in our accounts payable and accrued liabilities. Offsetting these decreases were noncash items stock-based compensation expense of $1,774,000 and depreciation of $763,000.

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

Investing activities used cash of $1,809,000 for the nine-month period ended September 30, 2009 as compared to $621,000 in the nine-month period ended September 30, 2008. Cash used by investing activities resulted principally from $1,795,000 in net investment purchases for the nine months ended September 30, 2009 and $561,000 in net investment purchases for the nine months ended September 30, 2008.

Financing activities provided cash of approximately $2,915,000 for the nine-month period ended September 30, 2009, resulting principally from the exercise of two warrants for an aggregate of 2,632,198 shares of common stock under our August 2007 private placement providing approximately $2,700,000 in proceeds. The remaining cash was provided by the exercise of stock options and purchases of common stock under our employee stock purchase plan. Financing activities used cash of approximately $221,000 for the nine-month period ended September 30, 2008, resulting from repayment of $401,000 on our notes with the Boston Private Bank & Trust Company. This decrease in cash was offset by cash received of $181,000 upon the exercise of stock options and purchases under our employee stock purchase plan.

We anticipate that existing capital resources at September 30, 2009 should fund our current and planned operations through the fourth quarter of 2010. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials, for the foreseeable future. Our ability to continue funding planned operations beyond 2010 is dependent upon, among other things, the anticipated near-term payments from our licensee Debiopharm, which include a payment upon the acceptance by regulatory authorities of Debiopharm s application to begin a phase I clinical trial and payment upon Debiopharm s treatment of the fifth patient in the first phase I clinical trial. We expect that Debiopharm will file an application with regulatory authorities to begin phase I clinical testing for Debio 0932 in the fourth quarter of 2009 and, pending acceptance by regulatory authorities, that these payments may be received in early 2010. Our ability to fund our operations beyond 2010 is also dependent on receipt of further payments under our collaborations with Genentech, our ability to manage our expenses and our ability to raise additional funds through corporate collaborations, equity or debt financings, or from other sources of financing. We are seeking additional collaborative arrangements and also anticipate that we will seek to raise funds through one or more financing transactions, if conditions permit. If the current equity and credit markets deteriorate further, or do not improve, it may make our ability to successfully

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raise debt or equity financing more difficult, more costly, and the terms of any such transaction could result in significant dilution for our existing shareholders. Failure to secure additional financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may experience a failure of its business, which could directly affect our ability to attain our operating goals. See Part II, Item 1A Risk Factors, for a further discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional capital.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2009.

Inflation

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

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to the information provided under Item 7A Quantitative and Qualitative Disclosures About Market Risk set forth in our Annual Report on form 10-K for the year ended December 31, 2008.

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, 2009. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2009, 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, 2009 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 on Form 10-K for the year ended December 31, 2008.

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

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

As of September 30, 2009, we had an accumulated deficit of approximately $715,087,000. We have not successfully commercialized any products to date, either alone or in collaboration with others. If we are not able to successfully commercialize any products, whether alone or with a collaborator, we will not achieve profitability. All of our drug candidates are in early stages of development. For the foreseeable future, we will need to spend significant capital in an effort to develop products that we can commercialize and we expect to incur substantial operating losses for the foreseeable future. Our failure to become and remain profitable would be likely to 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 may not be able to generate substantial revenue from existing or future collaborations.

We have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. However, we have no current source of research funding revenue. We expect that our only source of cash flows from operations for the foreseeable future will be:

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

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

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

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

We anticipate that existing cash, cash equivalents, marketable securities and working capital at September 30, 2009 should enable us to maintain current and planned operations through the fourth quarter of 2010. Our future capital requirements, however, may vary from what we currently expect. There are a number of factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing, many of which are outside our control, including the following:

unanticipated costs in our research and development programs;

the timing and cost of obtaining regulatory approvals for our drug candidates;

the timing, receipt and amount of payments, if any, from current and potential future collaborators;

the timing and amount of payments due to licensors of patent rights and technology used in our drug candidates;

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- the costs of preparing, filing, prosecuting, maintaining and enforcing 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. 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 the currently adverse general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of such a financing may be dilutive or otherwise adversely affect other rights of our stockholders. We also expect to seek additional funds through arrangements with collaborators, licensees or other third parties. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, whether through sales of debt or equity or through third party collaboration or license arrangements, we may be required to curtail or terminate some or all of our development programs, including some or all of our drug candidates.

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

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

- the cost of research and development that we engage in;

- a failure to successfully complete preclinical studies and clinical trials in a timely manner or at all, resulting in a delay in receiving, or a failure to receive, the required regulatory approvals to commercialize our drug candidates;

- the timing, receipt and amount of payments, if any, from current and potential future collaborators;

- the entry into, or termination of, collaboration agreements;

- the scope, duration and effectiveness of our collaborative arrangements;

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

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

- costs to comply with changes in government regulations;

- changes in management and reductions or additions of personnel;

- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators operations and financial results;

revenue recognition policies;

changes in accounting estimates, policies or principles; and

the introduction of competitive products and technologies by third parties.

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

Unstable market and economic conditions may have serious adverse consequences on our business.

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

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At September 30, 2009, we had $27,215,000 of cash, cash equivalents and marketable securities consisting of cash, money market, commercial paper, corporate debt securities, and government obligations. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since September 30, 2009, 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.

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

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We depend on our Hedgehog pathway inhibitor collaborative relationship with Genentech and our Hsp90 license agreement with Debiopharm. If Genentech and/or Debiopharm 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 two collaborations with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our technologies in defined fields of use, including GDC-0449, an orally-administered small molecule pathway inhibitor of the hedgehog signaling pathway. Genentech is currently testing GDC-0449 in two phase II clinical trials and a pivotal phase II trial in advanced basal cell carcinoma. In addition, we entered into a license agreement with Debiopharm in August 2009 related to our Hsp90 technologies. Our collaborations with Genentech and our license agreement with Debiopharm are our only current 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 it will apply to each collaboration. The timing and amount of any cash payments related to future royalties and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, Genentech s and Debiopharm s efforts, allocation of resources and successful development and commercialization of our drug candidates under the respective agreement.

Our strategic collaboration agreements with Genentech and our license agreement with Debiopharm permit Genentech and Debiopharm wide discretion in deciding which drug candidates to advance through the clinical trial process. It is possible for Genentech or Debiopharm to reject drug candidates at any point in the research, development and clinical trial process, without triggering a termination of the collaboration or license agreement, as applicable. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress drug candidates ourselves.

Genentech and Debiopharm may develop and commercialize, either alone or with others, products that are similar to or competitive with the drug candidates that are the subject of its collaborations with us.

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.

Genentech or Debiopharm may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or change of control. For example, during the first quarter of 2009, Roche Holdings Ltd. completed its acquisition of Genentech. This merger with Roche could divert the attention of Genentech s management and adversely affect Genentech s ability to retain and motivate key personnel who are important to the continued development of the programs under our collaboration. In addition, the third-party could determine to reprioritize Genentech s or Debiopharm s development programs such that Genentech or Debiopharm ceases to diligently pursue the development of our programs; and/or cause the respective collaborations with us to terminate.

Genentech or Debiopharm may, under specified circumstances, terminate the respective collaborations 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.

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

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

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more drug candidates under our targeted cancer drug programs. For example, in August 2009 we entered into a license agreement with Debiopharm for our Hsp90 technologies and expect that in the future we will seek to enter into corporate collaborations for CUDC-101 or another drug candidate from these programs. We do not currently have the experience, resources or capacity to advance these programs into later stages of clinical development or commercialization. As such, our success will depend, in part, on our ability to enter into one or more such collaborations. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for CUDC-101 or any future programs because our research and development pipeline may be insufficient, our programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our drug candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. If we are not able to successfully enter into one or more collaborations or licensing arrangements for CUDC-101 or any future programs, the clinical development of these programs could be significantly delayed and our future prospects may be adversely affected and our stock price could decline.

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

Our internal drug development efforts are focused on our proprietary targeted cancer programs. These programs focus on the development of single agent drug candidates targeting one or more molecular components within signaling pathways associated with certain cancers. We are also seeking to develop proprietary single agent, single target drug candidates for cancer indications. We have currently selected two drug candidates from this program for further development: CUDC-101, which is designed to simultaneously inhibit HDAC, EGFR and Her2, and CUDC-305 (renamed Debio 0932), an orally available, synthetic small molecule inhibitor of Hsp90 that was licensed to Debiopharm in August 2009. In August 2008, we treated the first patient in a phase I trial of CUDC-101.

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

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

In order to obtain regulatory approval for the commercial sale of our drug candidates, we and any current or potential future collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our drug candidates are safe and effective. For example, our lead product candidate, GDC-0449, is currently being tested by our collaborator, Genentech, in a pivotal phase II clinical trial in advanced basal cell carcinoma and two phase II clinical trials in other cancer indications. In addition, we are currently treating patients in a phase I clinical trial of CUDC-101, the lead drug candidate from our pipeline of proprietary targeted cancer programs.

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Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials of our drug candidates under development may not be successful. We, Genentech, Debiopharm and any future 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, and 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 product 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 product candidate used in any preclinical study or clinical trial;
- the timing and completion of clinical trials of our drug candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;
- our products under development may not be effective in treating any of our targeted cancer indications or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;
- institutional review boards or regulators, including the FDA, or foreign equivalent, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our drug candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and
- we, along with any of our current or potential future collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such a debarred person may result in delays in FDA s or foreign equivalent s review or approval of our products, or the rejection of data developed with the involvement of such person(s).

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

We expect to rely primarily on third parties for the performance and management of later-stage clinical trials and if such third parties fail to perform then we will not be able to successfully develop and commercialize drug candidates and grow our business.

We have very limited experience in conducting later-stage clinical trials. We expect to rely primarily on third parties to conduct at least our later-stage clinical trials and provide services in connection with such clinical trials. For example, we have granted development and commercialization rights to Genentech under our existing collaboration agreements with Genentech and we expect that any future collaboration partners may similarly be fully responsible for conducting at least the later-stage clinical trials of drug candidates. In the near term, we expect to rely primarily on third parties such as consultants, contract research organizations and other similar entities to complete IND-enabling preclinical studies, create and submit IND applications, enroll qualified subjects, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with the trial design. In addition, the FDA,

or foreign equivalent, requires us to comply with certain standards, referred to as good clinical practices, 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 may in the future rely do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the trial. Any failure by a third party to conduct our clinical trials as planned or in accordance with regulatory requirements could delay or otherwise adversely affect our efforts to obtain regulatory approvals for and commercialize our drug candidates.

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

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

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

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

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

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

Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our drug candidates and to produce, market and distribute products after approval.

On September 27, 2007, the President of the United States signed the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

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

Even if we or any current or potential future collaborators obtain regulatory approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product is marketed or require costly post-marketing follow-up studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA, or foreign equivalent, and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If there is a failure to comply with applicable regulatory requirements, we or any collaborator may be subject to fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products and criminal prosecution.

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We, Genentech and Debiopharm are, and any potential future collaborators will be, subject to governmental regulations in connection with the research, development and commercialization of our drug candidates in addition to those imposed by the FDA, or foreign equivalent. We and any such collaborators may not be able to comply with these regulations, which could subject us, or such collaborators, to penalties and otherwise result in the limitation of our or such collaborators operations.

In addition to regulations imposed by the FDA, or foreign equivalent, we, our current collaborators, Genentech and Debipharm, and any potential future collaborators are 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 applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

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

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

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

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

We, our current collaborators, Genentech and Debiopharm, and any potential future 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 and Debiopharm have also made public statements regarding their expectations for the clinical development and potential commercial launch of GDC-0449 and Debio 0932, respectively, and may in the future make additional statements about their goals and expectations for these collaborations with us. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our and our current and potential future collaborators preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and potential future collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that our or our current and potential future collaborators preclinical studies and clinical trials will advance or be completed in the time frames we or they announce or expect, that we or our current and potential future collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or any collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

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

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

In addition, our small molecule targeted cancer drug development candidates, which are focused primarily on clinically validated cancer targets, face significant competition from marketed drugs and drugs under development that seek to inhibit the same targets as our drug candidates.

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

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

We expect competition to intensify in cancer generally and, specifically, in targeted approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known. If we are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our drug candidates, which would adversely affect our ability to grow our business and become profitable.

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

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

This trend may adversely affect our ability to enter into agreements for the development and commercialization of our product candidates, and as a result may harm our business.

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

Product liability claims inherent in the process of researching, developing and commercializing human health care products could expose us to significant liabilities and prevent or interfere with the development or commercialization of our drug candidates. Regardless of their merit or eventual outcome, product liability claims would require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our future products or result in reputational harm and could result in the payment of a significant damage award. We currently have product liability insurance for our phase I clinical trial of CUDC-101. However, this insurance is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. If any of our drug candidates advance in clinical trials and/or are approved for marketing, we may seek additional insurance coverage. Product liability insurance is expensive and may be difficult to procure. As such, it is possible that we will not be able to obtain product liability insurance on acceptable terms, if at all, or that our product liability insurance coverage will prove to be inadequate to protect us from all potential claims, which may harm our business.

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

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

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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.

While we have no current plans, in the future, we may seek to acquire complementary businesses and technologies in the future or otherwise seek to expand our operations to grow our business, which may divert management resources and adversely affect our financial condition and operating results.

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

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

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

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

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development efforts in China. If our research and development efforts in China are delayed due to such interruptions, we may not realize the reductions in costs anticipated from engaging chemists in China. We would also have to consider moving our chemistry and/or biology research that is currently conducted in China to U.S. or European providers, thereby either increasing our overall costs for such services or reducing the total number of chemists and or/biologists that we could engage.

In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or the inability to

enforce applicable Chinese laws and regulations.

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such

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estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates elsewhere in this quarterly report on Form 10-Q and as included in our annual report on Form 10-K, as previously filed with the SEC on February 26, 2009.

Compliance with changing regulation of corporate governance and public disclosure as well as potential new accounting pronouncements is likely to impact our future financial position or results of operations.

Changing laws, regulations and standards relating to corporate governance and public disclosure, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New accounting pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies.

Our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. We expect these efforts to require the continued commitment of significant resources. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Failure to maintain effective internal controls in accordance with section 404 of the Sarbanes-Oxley act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires management s annual review and evaluation of our internal controls, and attestations of the effectiveness of our internal controls by our independent auditors. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of section 404 of the Sarbanes-Oxley Act, as such standards are modified, supplemented or amended from time to time, could have a material adverse effect on our business, operating results and stock price.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

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

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business, including our June 2003 and April 2005 collaboration agreements with Genentech, our December 2007 assignment agreement with Stryker Corporation and our August 2009 license agreement with Debiopharm, and we expect to enter into similar agreements with third parties in the future. Under these agreements, we generally license or transfer intellectual property to third parties and impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations on them. If a third party breaches its responsibilities under these agreements, we generally retain the right to terminate the agreement, and to bring a legal action in court or in arbitration. In the event of breach, we may need to enforce our rights under these agreements by resorting to arbitration or litigation. During the period of arbitration or litigation, we may be unable to effectively use, assign or license the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.

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

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

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

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

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

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

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management, and could result in significant monetary or equitable judgments against us. For example, lawsuits by employees, licensors, licensees, suppliers, distributors, stockholders, or competitors could be very costly and substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure that we will always be able to resolve such disputes out of court or on terms favorable to us. Any claims, with or without merit, and regardless of whether we prevail in the dispute, would be time-consuming, could result in costly litigation and the diversion of technical and management personnel.

In recent years, there have been substantial litigation and other 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 proceedings to determine the priority of invention if our competitors file U.S. patent applications that claim technology also claimed by us;

initiation of foreign opposition proceedings by third parties that seek to limit or eliminate the scope of our patent protection in a foreign jurisdiction;

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

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

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The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or any collaborative partners may be enjoined from manufacturing or selling our products and services 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 partners may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace.

Our commercial success will depend in part on our ability to obtain and maintain protection of our intellectual property, which covers inventions which may have been subject to chemistry or biology related work performed by contract research organizations in China.

We rely on trade secrets, proprietary know-how and other non-patentable technology, which we seek to protect through agreements containing non-disclosure and intellectual property assignment provisions with the chemists and biologists we have engaged in China. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets, proprietary know-how and other non-patentable technology will not otherwise become known to, or be independently developed by, our competitors.

Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed fail to reflect the true value of the infringed technology and its market. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

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

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

RISKS RELATING TO MANUFACTURING AND SALES

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

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop drug candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our drug candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our drug candidates or related materials become unavailable or are not delivered on a timely basis or at all, or are contaminated or otherwise lost, certain preclinical studies and/or clinical trials by us and any collaborators could be seriously delayed. This is due to the fact that such materials are time-consuming to manufacture and cannot be readily obtained from third-party sources.

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

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

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.

We have no sales or marketing experience and, as such, will depend significantly on third parties who may not successfully sell our products.

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

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

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

Even if we successfully commercialize any products under development, either alone or in collaboration, we face uncertainty with respect to coverage, pricing, third-party reimbursements and healthcare reform, all of which could affect our future profitability.

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

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

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pharmacy benefit management companies; and

other healthcare-related organizations.

Third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any collaborators may not be able to market our products effectively. We also face the risk that we will have to offer our products at prices lower than anticipated as a result of the current trend in the United States towards managed healthcare through health maintenance organizations. Currently, third-party payers are increasingly challenging the prices charged for medical products and services. Prices could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. Existing U.S. laws, such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or future legislation to reform healthcare or reduce government insurance programs could also adversely affect prices of our approved products, if any. The cost-containment measures that healthcare providers are instituting and the results of potential healthcare reforms may prevent us from maintaining prices for our products 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 products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell our products, if approved, and impair our ability to derive revenue from these products.

Legislation has been introduced in the U.S. Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenue. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

RISKS RELATED TO OUR COMMON STOCK

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

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

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock traded within a range of a high price of $2.61 and a low price of $0.68 per share for the period January 1, 2008 through October 26, 2009. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical- and biotechnology-based 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;

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market conditions in the biotechnology and pharmaceutical sectors;

rumors relating to us or our competitors;

litigation or public concern about the safety of our potential products;

actual or anticipated variations in our quarterly operating results and any subsequent restatement of such results;

actual or anticipated changes to our research and development plans;

deviations in our operating results from the estimates of securities analysts;

entering into new collaboration agreements or termination of existing collaboration agreements;

adverse results or delays in clinical trials being conducted by us or any collaborators;

any intellectual property or other lawsuits involving us;

third-party sales of large blocks of our common stock;

sales of our common stock by our executive officers, directors or significant stockholders;

equity sales by us of our common stock to fund our operations;

the loss of any of our key scientific or management personnel;

FDA or international regulatory actions; and

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

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

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

Our common stock is relatively illiquid. As of September 30, 2009, we had approximately 66.5 million shares of common stock outstanding. The average daily trading volume in the common stock during the prior 50 trading days ending on September 30, 2009 was 664,000 shares. A more active public market for our common stock, may not develop, which would continue to adversely affect the trading price and liquidity of the common stock. Moreover, a thin trading market for the common stock causes the market price for the common stock to fluctuate significantly more than the stock market as a whole. Without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile.

Future sales of shares of our common stock, including upon the exercise of currently outstanding options and warrants or pursuant to our universal shelf registration statement could 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. The exercise of these options and warrants 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.

We currently have the ability to offer and sell common stock, preferred stock and warrants under a currently effective universal shelf registration statement. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities. In the future, we may issue additional options, warrants or other derivative securities convertible into our common stock.

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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 control over us and could delay or prevent a change in corporate control.

As of September 30, 2009, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 32% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, if acting together, will have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

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

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

Item 6. EXHIBITS

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

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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: October 29, 2009

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

Chief Operating Officer and Chief Financial Officer

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1	License Agreement, dated August 5, 2009, by and between Curis, Inc. and Debipharm S.A.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350

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