CURIS INC
Form 10-Q
October 28, 2008
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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, 2008

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 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.

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 24, 2008, there were 63,465,485 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, 2008	December 31, 2007
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,368,050	$ 17,396,599
Marketable securities	24,560,981	24,062,577
Accounts receivable	76,217	230,467
Prepaid expenses and other current assets	441,822	349,453
Total current assets	30,447,070	42,039,096
Property and equipment, net	1,875,233	2,577,602
Long-term investment restricted	210,007	210,007
Goodwill	8,982,000	8,982,000
Other assets, net	7,980	7,980
	$ 41,522,290	$ 53,816,685
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Debt, current portion	$	$ 403,832
Accounts payable	1,776,947	3,222,091
Accrued liabilities	761,233	1,150,931
Deferred revenue, current portion		1,852,518
Total current liabilities	2,538,180	6,629,372
Other long-term liabilities	214,219	342,750
Total liabilities	2,752,399	6,972,122
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 125,000,000 shares authorized; 64,485,692 and 63,437,985 shares issued and outstanding, respectively, at September 30, 2008 and 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007	644,857	642,888
Additional paid-in capital	744,836,589	742,903,399
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(26,913)	(46,286)
Accumulated deficit	(705,814,412)	(695,847,738)
Accumulated other comprehensive income	21,044	83,574
Total stockholders equity	38,769,891	46,844,563
	$ 41,522,290	$ 53,816,685

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
REVENUES:				
License fees	$	$ 546,443	$ 4,852,518	$ 2,710,513
Research and development contracts	86,721	765,759	409,596	2,193,199
Total Revenues	86,721	1,312,202	5,262,114	4,903,712
COSTS AND EXPENSES:				
Research and development	3,000,266	3,203,388	9,676,761	9,545,827
General and administrative	1,861,971	2,231,474	6,402,274	7,542,245
Total costs and expenses	4,862,237	5,434,862	16,079,035	17,088,072
Loss from operations	(4,775,516)	(4,122,660)	(10,816,921)	(12,184,360)
OTHER INCOME (EXPENSE):				
Interest income	203,210	423,174	844,319	1,117,483
Other income (expense)	855	(889)	9,782	(114,700)
Interest expense		(17,925)	(3,854)	(75,040)
Total other income, net	204,065	404,360	850,247	927,743
Net loss	$ (4,571,451)	$ (3,718,300)	$ (9,966,674)	$ (11,256,617)
Net loss per common share (basic and diluted)	$ (0.07)	$ (0.06)	$ (0.16)	$ (0.22)
Weighted average common shares (basic and diluted)	63,435,070	57,534,767	63,339,767	52,129,126
Net loss	$ (4,571,451)	$ (3,718,300)	$ (9,966,674)	$ (11,256,617)
Unrealized gain (loss) on marketable securities	18,447	42,686	(62,530)	48,156
Comprehensive loss	$ (4,553,004)	$ (3,675,614)	$ (10,029,204)	$ (11,208,461)

See accompanying notes to unaudited condensed consolidated financial statements.

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CURIS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2008	**2007**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,966,674)	$ (11,256,617)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	762,916	1,046,692
Stock-based compensation expense	1,774,031	2,434,101
Gain on sale of assets		(87,761)
Impairment of investment		145,000
Impairment of assets		347,084
Realized foreign currency exchange gain		(26,935)
Changes in current assets and liabilities:		
Accounts receivable	154,250	1,101,148
Prepaid expenses and other assets	(92,369)	68,356
Accounts payable and accrued liabilities	(1,965,992)	(211,358)
Deferred contract revenue	(1,852,518)	(2,735,670)
Total adjustments	(1,219,682)	2,080,657
Net cash used in operating activities	(11,186,356)	(9,175,960)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(27,328,912)	(29,785,765)
Sale of marketable securities	26,767,978	24,451,907
Increase in restricted cash		(8,163)
Purchases of property and equipment	(60,547)	(66,469)
Net proceeds from sale of assets		316,121
Net cash used in investing activities	(621,481)	(5,092,369)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	180,501	14,577,524
Repayments of notes payable	(401,213)	(1,257,121)
Net cash provided by (used in) financing activities	(220,712)	13,320,403
NET DECREASE IN CASH AND CASH EQUIVALENTS	(12,028,549)	(947,926)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,396,599	18,829,332
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 5,368,050	$ 17,881,406

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 create new medicines, primarily for cancer. In expanding drug development efforts for its targeted cancer programs, Curis is building upon its past experiences in targeting signaling pathways for the development of next generation targeted cancer therapies.

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 corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company s technologies, its ability to comply with FDA 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, 2008, should enable it to maintain current and planned operations into the first half of 2010. The Company s ability to continue funding its planned operations is dependent upon, among other things, the success of its collaborations with Genentech, its ability to control the cash burn rate 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, 2007, as filed with the Securities and Exchange Commission on March 14, 2008.

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, 2008 and the results of operations and cash flows for the three- and nine-month periods ended September 30, 2008 and 2007. 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 in the financial statements. 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.

3. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s drug candidates. The terms of the agreements typically

include non-refundable license fees, funding of research and development, contingent cash payments based upon achievement of clinical development and sales objectives and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission s Staff

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Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables,* EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent,* and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).* For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 14, 2008.

Amounts received prior to satisfying the above revenue recognition criteria would be recorded as deferred revenue in the consolidated balance sheets.

4. June 2003 Collaboration with Genentech

In the second quarter of 2008, the Company received a payment of $3,000,000 from Genentech under the parties June 2003 Hedehog pathway inhibitor collaboration upon Genentech s initiation of a phase II clinical trial of GDC-0449 in metastatic colorectal cancer. GDC-0449 is the lead drug candidate in development under this collaboration. The Company has recorded this amount as revenue within License Fees in the Revenues section of its Consolidated Statement of Operations for the nine months ended September 30, 2008 because the Company has no ongoing material performance obligations under the collaboration.

5. Stryker Corporation

On December 27, 2007, the Company completed a transaction with Stryker Corporation, in which Stryker paid the Company $1,750,000 in cash in exchange for the sale and assignment of all of the Company s remaining BMP assets. As a result of the transaction, Stryker has assumed all future BMP costs subsequent to the December 27, 2007 effective date, including those related to future development, maintenance and prosecution of the patent portfolio. As of December 31, 2007, the Company recorded the $1,750,000 received as short-term deferred revenue because the Company had not delivered all of the assets to Stryker as required by the agreement as of that date. The Company completed the transfer of all assets during the first quarter of 2008, at which time no material ongoing performance obligations remained under the agreement. Accordingly, the Company recorded $1,750,000 as license revenue within the Revenues section of the Consolidated Statement of Operations for the nine months ended September 30, 2008.

Under the terms of the agreement, the Company is entitled to contingent cash payments related to certain clinical development and sales objectives, if such objectives are achieved by Stryker. The Company believes that these contingent payments 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. However, because the Company has no future deliverables under the agreement, the Company intends to recognize such contingent payments as revenue in License Fees within the Revenues section of the Consolidated Statement of Operations if and when any such objectives are achieved and the related contingent cash payment from Stryker is reasonably assured.

6. Termination of January 2004 Wyeth Collaboration

On January 12, 2004, the Company licensed its Hedgehog proteins and small molecule Hedgehog pathway agonists to Wyeth Pharmaceuticals, or Wyeth, for therapeutic applications in the treatment of neurological and other disorders. Pursuant to the collaboration agreement, Wyeth agreed to make specified cash payments, including up-front payments of $3,000,000, which consisted of a $1,362,000 non-refundable license fee payment and $1,638,000 in exchange for 315,524 shares of the Company s common stock.

The Company applied the provisions of EITF 00-21 and determined that its performance obligations under this collaboration should be accounted for as a single unit of accounting. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company s level of effort required to complete its performance obligations, the Company estimated that Wyeth would elect twice to extend the research and development service period and related funding, each in one-year increments, for a total of four years. The agreement also provided for a one-year evaluation period immediately following the end of the research term, during which time the Company could have been obligated to serve on a steering committee that oversees the program and could have been required, at Wyeth s expense, to perform additional research and development services. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term plus the one-year evaluation period. In developing this estimate, the Company assumed that Wyeth

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would maintain its initially elected number of eight full-time equivalents throughout the five-year period. The steering committee effort was also expected to be consistent over the five-year period. On November 3, 2006, Wyeth agreed to extend the research funding term by one year through February 9, 2008 but elected to fund only five researchers working on the program through the research term. Accordingly, the Company revised its estimated level of effort over the remaining performance period. In December 2007, Wyeth informed the Company that it would not extend the current contractual research funding term beyond February 2008. As a result, the Company changed its estimated performance period to coincide with the conclusion of the research term from its original estimate of February 2009.

On May 6, 2008 the agreement terminated. On the termination date, the licenses granted by the Company to Wyeth terminated and all terminated license rights reverted to the Company.

The $1,362,000 up-front license fee plus $7,250,000**,** which was the total amount of research funding the Company received for providing an average of 7.25 full-time equivalents over the four-year performance period at a rate of $250,000 each, was attributed to the research services. Revenue was recognized as the research services were provided over the performance period of February 2004 through February 2008.

The Company recorded revenue under this collaboration of $298,000 and $1,392,000 during the nine-month periods ended September 30, 2008 and 2007, respectively. Of this amount, approximately $102,000 and $203,000 was attributed to the amortization of the $1,362,000 up-front license fee and is included in License fees within the Revenues section of the Consolidated Statements of Operations for the nine-month periods ended September 30, 2008 and 2007, respectively. Of the remaining amounts, $134,000 and $1,020,000 were related to research services performed by the Company s full-time equivalents for the nine months ended September 30, 2008 and 2007, respectively, and $62,000 and $169,000 for the nine months ended September 30, 2008 and 2007, respectively, related to expenses incurred on behalf of Wyeth by the Company for which Wyeth is obligated to reimburse the Company and have met the revenue recognition provisions of EITF 99-19. These amounts are included within the Research and development contracts line item within the Revenues section of the Consolidated Statements of Operations.

7. Fair Value Measurements

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements,* (SFAS No. 157) for its financial assets and liabilities. The adoption of SFAS No. 157 has not had a material impact on the Company s financial position or results of operations. As permitted by FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, the Company elected to defer the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* (SFAS No. 159) became effective January 1, 2008 and permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. GAAP and requires expanded disclosures regarding fair value measurements. SFAS No. 157 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.

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SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities. The Company s Level 1 assets include cash and cash equivalents, investments in marketable securities, and a long-term restricted investment. As of September 30, 2008, the Company held cash and cash equivalents and marketable securities of $5,368,000 and $24,561,000, respectively. The Company s marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, 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, U.S. Treasury money market funds and interest bearing bank accounts. The long-term restricted investment of $210,000 as of September 30, 2008 was solely comprised of a one-year 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, 2008.

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 material Level 3 assets or liabilities at September 30, 2008.

The Company s financial instruments consist mainly of cash and cash equivalents, marketable securities and accounts payable. All of the Company s cash, cash equivalents and marketable securities are valued by the Company using Level 1 inputs as described above and the Company therefore believes that its valuations for such assets are appropriate. Accounts payable are reflected in the accompanying Consolidated Financial Statements at cost, which approximates fair value due to the short-term nature of these instruments. While the Company believes its valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

8. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2008	December 31, 2007
Accrued compensation	$ 290,000	$ 708,000
Professional fees	135,000	73,000
Facility-related costs	245,000	192,000
Other	91,000	178,000
Total	$ 761,000	$ 1,151,000

9. Debt

Short-term debt, including accrued interest, was $404,000 at December 31, 2007. This debt related to two 36-month term notes that the Company entered into separate loan agreements with the Boston Private Bank & Trust Company, one for $2,250,000 at a fixed rate of 7.36% and the other for $1,450,000 at a fixed rate of 7.95% for the repayment periods. On April 1, 2008, the Company made the final repayments related to these notes and the Company has no further obligations under these notes.

10. Accounting for Stock-Based Compensation

As of September 30, 2008, 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, 2007, as previously filed with the Securities and Exchange Commission on March 14, 2008.

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During the nine months ended September 30, 2008, options to purchase 1,211,000 shares of the Company s common stock were issued under the 2000 Plan, all of which were granted to officers and employees of the Company. These options become exercisable, or vest, over a four-year period and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the grant dates. During the nine months ended September 30, 2008, the Company s board of directors also granted options to its non-employee directors to purchase 115,000 shares of common stock under the 2000 Plan and options to purchase 35,000 shares of common stock under the 2000 Director Plan. All of these options were fully vested on the January 25, 2008 grant date and bear exercise prices that are equal to the closing market price of the Company s common stock on the NASDAQ Global Market on the date of grant.

Employee and Director Grants

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model when applying the provisions of Statement of Financial Accounting Standards 123(R), *Share-Based Payment* (SFAS 123(R)). The Company calculated the Black-Scholes value of employee options awarded during the three and nine months ended September 30, 2008 and 2007 based on the assumptions noted in the following table:

	For the three months ended September 30,		For the nine months ended September 30,	
	2008	2007	2008	2007
Expected term (years) - Employees	6	6.25	6	5.5-7
Expected term (years) - Directors	N/A	N/A	7	7
Risk-free interest rate	3.0%	4.3%	3.0-3.4%	4.3-4.9%
Volatility	84%	91%	84-93%	91-97%
Dividends	None	None	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, ultimately, the expense that will 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, 2008 was $37,000, of which $36,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2008 and 2007 were $1.08 and $1.10 per share, respectively. As of September 30, 2008, there was approximately $3,400,000, 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 Plan that is expected to be recognized as expense over a weighted average period of 2.83 years. The intrinsic value of employee stock options exercised during the nine months ended September 30, 2008 and 2007 was $37,000 and $13,000, respectively. The total grant date fair values of stock options that vested in the nine months ended September 30, 2008 and 2007 were $1,678,000 and $2,553,000, respectively.

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During the three- and nine-month periods ended September 30, 2008 and 2007, 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 with the following assumptions:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2008	2007	2008	2007
Expected term	6 months	6 months	6 months	6 months
Risk-free interest rate	1.9%	4.8%	1.9-3.3%	4.8-5.0%
Volatility	75%	64%	64-75%	64-71%
Dividends	None	None	None	None

Stock-based compensation for employees, including expense related to the ESPP, for the three and nine months ended September 30, 2008 and 2007 was calculated using the above assumptions and has been included in the Company s results of operations. 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 periodically granted stock options to consultants for services. These options have been 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 agreements, 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 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, and expense of $3,000 and $68,000 related to non-employee stock options for the three and nine months ended September 30, 2007, respectively. As of September 30, 2008, the Company had recorded $27,000 in deferred compensation related to unvested non-employee options.

Total Stock-Based Compensation Expense

For the three and nine months ended September 30, 2008 and 2007, the Company recorded 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,	
	2008	2007	2008	2007
Research and development expenses	$ 185,000	$ 200,000	$ 582,000	$ 528,000
General and administrative expenses	309,000	436,000	1,192,000	1,906,000
Total stock-based compensation expense	$ 494,000	$ 636,000	$ 1,774,000	$ 2,434,000

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The table below summarizes options outstanding and exercisable under the 2000 Plan and the 2000 Director Plan at September 30, 2008:

	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 - $ 1.35	829,094	6.24	$ 1.20	500,999	$ 1.13
1.39 - 1.39	1,893,500	8.57	1.39	693,280	1.39
1.43 - 1.50	1,823,907	7.22	1.46	808,907	1.49
1.57 - 2.43	2,468,126	6.25	1.96	2,066,434	2.03
2.48 - 4.03	1,806,204	4.54	3.74	1,663,416	3.72
4.05 - 29.26	1,421,921	4.02	7.26	1,420,983	7.26
	10,242,752	6.24	$ 2.75	7,154,019	$ 3.28

11. Basic and Diluted Loss Per Common Share

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net losses per share were determined by dividing net loss by the weighted average 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, 2008 and 2007, respectively, are as follows.

	For the nine months ended September 30,	
	2008	2007
Stock options outstanding	9,527,896	8,955,911
Warrants outstanding	6,210,615	6,401,835
Shares issuable under ESPP	26,430	5,033
Total antidilutive securities	15,764,941	15,362,779

12. Related Party Transactions

Under its August 23, 2006 consulting agreement, as amended, and its September 14, 2006 scientific advisory and consulting agreement 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, 2008, respectively, and expense of $6,000 and $20,000 for the three- and nine-month periods ended September 30, 2007, respectively. The August 2006 consulting agreement terminated in accordance with its term in June 2007, and the September 2006 consulting agreement continues through September 2011, unless terminated earlier in accordance with its terms.

13. New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed,

any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. SFAS No. 141(R) will have an impact on the Company s financial statements if it is involved in a business combination that occurs after January 1, 2009.

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all

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collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company s financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Company has historically entered into collaborative arrangements in which this Issue would be applicable; however, the Company had no remaining joint operating activities under current collaborations at September 30, 2008. The Company will have to evaluate the impact of this Issue on future collaborations that the Company may enter into.

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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 create new medicines for cancer. In expanding our drug development efforts with respect to our targeted cancer programs, we are building upon our past experiences in targeting signaling pathways as we pursue the development of next generation targeted cancer therapies. We seek to conduct research programs both internally and through strategic collaborations.

Our Hedgehog Pathway Inhibitor Program under Collaboration with Genentech

Our most advanced program is our Hedgehog pathway inhibitor program that is the subject of a June 2003 collaboration agreement with Genentech. Our collaborator Genentech recently began recruiting for enrollment in a phase II clinical trial of GDC-0449, an orally-administered small molecule Hedgehog pathway inhibitor, as a maintenance therapy for ovarian cancer patients in second or third complete remission. Under our June 2003 collaboration agreement, we will receive a $3,000,000 cash payment from Genentech upon treatment of the first patient in this clinical trial. GDC-0449 was discovered by Genentech and jointly validated through a series of pre-clinical studies performed under a collaboration agreement between Genentech and Curis. Genentech is responsible for the clinical development and commercialization of GDC-0449. We would be eligible to receive additional cash payments assuming successful achievement of certain clinical development and regulatory approval milestones and royalties upon commercialization, if ever, of GDC-0449.

GDC-0449 will be evaluated in approximately 100 patients with ovarian cancer in second or third complete remission in a randomized, placebo-controlled, double-blind, multi-center phase II trial. Patients will be randomized in a 1:1 ratio to receive either GDC-0449 or a placebo comparator and will be stratified based on whether their cancer is in a second or third complete remission. The primary endpoint of the trial is progression-free survival. Secondary outcome measures include overall survival, measurement of Hedgehog protein expression in archival tissue and number and attribution of adverse events.

In May 2008, Genentech initiated a separate phase II clinical trial of GDC-0449 in first-line metastatic colorectal cancer for which we received a $3,000,000 cash payment under the agreement. The study is designed to evaluate GDC-0449 in approximately 150 patients with metastatic colorectal cancer in combination with the current standard of care as first-line therapy in a randomized, placebo-controlled, double-blind phase II trial. Patients will receive either FOLFOX or FOLFIRI chemotherapy regimens in combination with bevacizumab and will be randomized to receive GDC-0449 or placebo. They will be stratified based on the chemotherapy regimen chosen and whether or not RECIST measurable disease is present at baseline. The primary objective of the phase II clinical trial is progression-free survival from randomization to disease progression or death. Secondary outcome measures include the measurement of Hedgehog protein expression in archival tissue and tracking of adverse events.

Genentech has also indicated that it plans to initiate an additional phase II clinical trial of GDC-0449 in advanced basal cell carcinoma during the first half of 2009. Genentech scientists recently presented data from the ongoing Phase I clinical trial at the 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, including promising safety and efficacy data in advanced basal cell carcinoma patients. The data presented included 10 patients with locally advanced or metastatic BCC receiving continuous once-daily dosing at 150 mgs per day. As confirmed by an Independent Review Facility, two patients from this BCC cohort have experienced partial responses per the Response Evaluation Criteria in Solid Tumors (RECIST). The responses are ongoing with durations of 9.2+ and 5.6+ months (data cutoff was June 1, 2008). In addition, four patients have experienced partial responses assessed by clinical examination, with observations of shrinkage or resolution of subcutaneous masses, re-epithelialization and/or cessation of bleeding or discharge of ulcerated tumors and/or flattening of nodular tumors. Of the remaining BCC patients enrolled, one patient experienced progressive disease as best response, four patients have stable disease, and two are too early to evaluate.

Our Internal Research and Development Programs

Our internal drug development efforts are focused on our proprietary targeted cancer programs, under which we are seeking to develop a number of proprietary, small molecule, single agent, multi-targeted inhibitor drug compounds as potential cancer therapeutics. Each proprietary compound is being designed to inhibit clinically or biologically validated cancer targets, including targets such as the epidermal growth factor receptor (EGFR), human epidermal growth factor

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receptor 2 (Her2), Bcr-Abl, CDK, vascular endothelial growth factor receptor 2 (VEGFR2), and heat shock protein 90 (Hsp90), among others, and in combination with inhibition of histone deacetylase, or HDAC, which is a validated non-kinase cancer target. We are also seeking to develop proprietary single agent, single target drug candidates for cancer indications, including CUDC-305, an orally available, synthetic small molecule inhibitor of Hsp90.

CUDC-101 is the first compound selected as a drug candidate from our targeted cancer programs. CUDC-101 is being designed as a first-in-class therapeutic to simultaneously inhibit HDAC, EGFR and Her2. In preclinical studies, CUDC-101 demonstrated the potential to inhibit all three molecular targets resulting in the potent killing of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents. In August 2008, we treated the first patient in a phase I trial of CUDC-101. The phase I trial is designed as an open-label study of CUDC-101 in patients with advanced, refractory solid tumors. The primary objectives of the phase I trial are to evaluate the safety and tolerability of escalating doses of the phase I molecule and to establish the maximum tolerated dose and dose limiting toxicities. Secondary objectives will assess the pharmacokinetics, efficacy and ability of CUDC-101 to inhibit EGFR, HER2 and HDAC in this patient population. The study will be conducted at two sites within the United States and is expected to enroll between 18 and 40 patients spread across several dose-escalating cohorts.

In July 2008, we selected CUDC-305 as a development candidate. In addition to demonstrating potent efficacy across a broad range of cancers in preclinical cancer models, CUDC-305 exhibited promising pharmacological features in preclinical testing, particularly its high oral bioavailability, high tumor penetration and extended tumor retention. Most notably, Curis scientists observed complete tumor regression following oral administration of CUDC-305 in a mouse xenograft model of acute myelogenous leukemia (AML). Tumor regression has also been observed after treatment of CUDC-305 in mouse xenograft models of breast, non-small cell lung, gastric and colon cancers and glioblastoma brain cancers. In this preclinical testing, the compound also demonstrated an ability to effectively cross the blood brain barrier, and demonstrated an ability to extend survival in a preclinical intracranial glioblastoma model. Early stage preclinical toxicity studies suggest that CUDC-305 appears to have a higher maximum tolerated dose than several leading Hsp90 inhibitors in clinical development. We initiated IND-enabling studies in October 2008 and anticipate that, assuming the outcome of those studies is favorable, we will file an IND application for CUDC-305 in mid-2009.

We plan to continue to seek corporate collaborators for the further development and commercialization of at least one class of small molecules from our proprietary pipeline of targeted cancer programs but have not reached advanced stages of negotiation with any party. When evaluating potential collaborative opportunities, we plan to seek to retain significant rights and involvement or control in at least the early stages of clinical development.

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our strategic collaborators, the private and public placement of our equity securities and debt financings. We have never been profitable and have incurred an accumulated deficit of $705,814,000 as of September 30, 2008. 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:

- our ability to successfully enter into a material license or collaboration agreement for CUDC-305 and/or CUDC-101;
- our ability to continue to successfully enroll and treat patients in our phase I clinical trial for CUDC-101 and achieve the primary and secondary endpoints of the trial;
- our ability to successfully advance CUDC-305 through preclinical IND-enabling studies and file an IND application for this compound in 2009;
- 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; and

Genentech s ability to commence and successfully complete clinical trials for GDC-0449.

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.

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Collaboration Agreements

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog signaling pathway inhibitor technologies and to an April 2005 collaboration with Genentech relating to the Wnt signaling pathway. 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 principally 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. We currently expect to incur only nominal research and development costs under these collaborations related to the maintenance of licenses.

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 at September 30, 2008, should enable us to maintain current and planned operations into the first half of 2010. Our ability to continue funding our planned operations is dependent upon the success of our collaborations with Genentech, our ability to control our cash burn rate and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing.

In October 2008, we implemented a plan to reduce our spending in various general and administrative and research and development expense areas, particularly costs associated with preclinical research. Spending reductions include decreases in contract medicinal chemistry and biology work that is being performed in China, and in personnel, legal and occupancy costs. As we seek to reduce administrative expenses and our preclinical and discovery research costs, we expect that our expenses associated with the clinical development of CUDC-101 and the IND-enabling studies underway for CUDC-305 will increase, resulting in an overall increase in our research and development expenses for the remainder of 2008 and future periods as compared to prior years. We expect that our reductions in general and administrative expenses will result in modest decreases in such expenses in future periods.

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 the 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, and other amounts that we have received from our strategic collaborators and licensees.

We currently have two collaborations, both of which are with Genentech. We currently receive no research funding for our programs under collaboration with Genentech 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 royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter.

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. Research and development expenses also include the costs of supplies and reagents, outside service costs including medicinal chemistry, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. Although we have historically incurred research and development expenses under our collaborations with Genentech, we are currently incurring only nominal research and development expenses for these programs which are limited to the maintenance of third-party licenses. For each contingent payment, if any, received under our collaborations with Genentech, we would be obligated to make payments to these third parties 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(s)	Collaborator/Licensee	Status
Hedgehog pathway inhibitor			
GDC-0449	Metastatic colorectal cancer	Genentech	Phase II
	Advanced basal cell carcinoma		Phase I expansion cohort (1)
	Advanced ovarian cancer		(1)
Targeted cancer programs			
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Phase I
CUDC-305 (Hsp90 inhibitor)	Cancer	Internal development	Development candidate
Other targeted cancer programs	Cancer	Internal development	Preclinical

(1) Genentech has publicly stated that it plans to initiate phase II clinical trials of GDC-0449 in advanced ovarian cancer during the fourth quarter of 2008 and in advanced basal cell carcinoma during the first half of 2009.

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In the chart above, Phase II means that our collaborator, 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 expansion cohort means that our collaborator is currently treating human patients in an expanded phase I clinical trial, the principal purpose of which is to evaluate the safety and biological activity of the compound being tested in a specific solid tumor type at a defined dose. 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 have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an IND application with the FDA seeking to commence a phase I clinical trial. Preclinical means we are seeking to obtain evidence of therapeutic efficacy 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 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 collaborations, a portion of which is reimbursed by collaborators and a portion of which is borne by Curis. In October 2008, we extended previously-initiated efforts to reduce our spending in various general and administrative expense areas, including personnel, occupancy and legal services, among others. As a result of these changes, we expect that our general and administration expenses will decline modestly in future periods.

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 collectibility 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, 2007, which is on file with the SEC. The following sets forth material changes in our critical accounting policies and estimates described therein.

Fair Value Measurements. Effective January 1, 2008, we adopted the provisions of SFAS (SFAS) No. 157, *Fair Value Measurements* for our financial assets and financial liabilities. The adoption of SFAS No. 157 has not had a material impact on our financial position or results of operations. In accordance with Financial Accounting Standards Board Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157*, we will delay application of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* (SFAS No. 159) became effective January 1, 2008 and permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. generally accepted accounting principles and requires expanded disclosures regarding fair value measurements. SFAS No. 157 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.

SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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

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

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Our cash, cash equivalents and marketable securities have been classified as Level 1 assets. We do not hold any asset-backed or auction rate securities. Short-term accounts receivable and accounts payable are reflected in the consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. In general, fair value is based upon quoted market prices, where available. If such quoted market prices are not available, fair value is based upon internally developed models that primarily use, as inputs, observable market-based parameters. Valuation adjustments may be made to ensure that financial instruments are recorded at fair value. These adjustments may include unobservable parameters. Any such valuation adjustments would then be applied consistently over time. As of September 30, 2008, we do not have any Level 2 assets and no material Level 3 assets. Our valuation methodologies may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. While we believe our valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Our discussion of our critical accounting policies is not intended to be a comprehensive discussion of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management s judgment in their application. There are also areas in which management s judgment in selecting any available alternative would not produce a materially different result.

Recently Issued Accounting Standards

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. SFAS No. 141(R) will have an impact on our financial statements if we are involved in a business combination that occurs after January 1, 2009.

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company s financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. We have historically entered into collaborative arrangements in which this Issue would be applicable; however, we had no remaining joint operating activities under current collaborations at September 30, 2008. Management will have to evaluate the impact of this Issue on future collaborations that we may enter into.

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Results of Operations

Three-Month Periods Ended September 30, 2008 and September 30, 2007

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2008 (unaudited)	2007 (unaudited)	
REVENUES:			
Research and development contracts			
Genentech	$ 46,000	$ 142,000	(68)%
Wyeth	33,000	362,000	(91)%
Procter & Gamble		242,000	(100)%
Other	8,000	20,000	(60)%
Subtotal	87,000	766,000	(89)%
License fees			
Wyeth		63,000	(100)%
Procter & Gamble		483,000	(100)%
Subtotal		546,000	(100)%
Total revenues	$ 87,000	$ 1,312,000	(93)%

Total revenues decreased by $1,225,000, or 93%, to $87,000 for the three months ended September 30, 2008 from $1,312,000 for the same period in the prior year. Research and development contracts decreased by $679,000 because all research funding for programs under collaboration concluded at various times beginning in March 2007. The conclusion of research funding under our Hedgehog agonist collaboration with Wyeth in February 2008 and under our collaboration with Procter & Gamble in November 2007 accounted for $571,000 of the decrease. We currently receive no research funding for our programs under past or current collaborations. As a result of the foregoing changes, we expect that our future research and development contract revenues will be limited to expenses that we incur on behalf of our collaborators for which the collaborator is obligated to reimburse us.

License revenues under our collaborations with Wyeth and Procter & Gamble were $546,000 for the three months ended September 30, 2007. We did not recognize any license revenues during the three months ended September 30, 2008 as a result of the conclusion of these collaborations in prior periods.

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

Research and Development Program	Primary Indication	Collaborator	For the Three Months Ended September 30, 2008	2007	Percentage Increase/ (Decrease)
Hh pathway inhibitor	Cancer	Genentech	$ 48,000	$ 19,000	153%
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal	645,000	1,433,000	(55)%
CUDC-305 (Hsp90 inhibitor)	Cancer	Internal	1,144,000		100%
Other targeted cancer programs	Cancer	Internal	847,000	1,170,000	(28)%
Other targeted programs	Nervous system disorders/cardiovascular disease	Internal	118,000		100%
Hh agonist	Nervous system disorders/cardiovascular disease	Wyeth (1)	13,000	360,000	(96)%
Discovery research	Various	Various/internal		12,000	(100)%
Impairment of assets, net	N/A			10,000	(100)%
Stock-based compensation	N/A		185,000	199,000	(7)%
Total research and development expense			$ 3,000,000	$ 3,203,000	(6)%

(1) Our collaboration with Wyeth terminated effective May 6, 2008.

Our research and development expenses decreased by $203,000, or 6%, to $3,000,000 for the three months ended September 30, 2008 as compared to $3,203,000 for the same period in the prior year primarily due to decreased spending of $347,000 on our program with Wyeth for the Hedgehog agonist as a result of the February 2008 conclusion of the research funding. Certain of these resources were reallocated to our internal targeted cancer programs.

Offsetting this decrease, spending on our targeted programs increased $151,000, or 6%, during the three months ended September 30, 2008 as compared to the same period in the prior year. Our lead targeted drug development candidate, CUDC-101, was selected for planned clinical development in March 2007 and we began treating patients in a phase I clinical trial in August 2008. We selected CUDC-305 as a development candidate in July 2008 and initiated IND-enabling toxicology studies during October 2008. In October 2008, we implemented a plan to reduce our spending in various research and development expense areas, particularly in our costs associated with preclinical research. Spending reductions include decreases in contract medicinal chemistry and biology work that is being performed in China, and in personnel, and occupancy costs. As we seek to reduce our preclinical and discovery research costs, we expect that our expenses associated with the clinical development of CUDC-101 and the IND-enabling studies underway for CUDC-305 will increase, resulting in an overall increase in our research and development expenses for the remainder of 2008 and future periods as compared to prior years.

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

	For the Three Months Ended September 30, 2008 (unaudited)	2007 (unaudited)	Percentage Increase/ (Decrease)
Personnel	$ 332,000	$ 571,000	(42)%
Occupancy and depreciation	98,000	67,000	46%
Legal services	552,000	573,000	(4)%
Consulting and professional services	297,000	241,000	23%
Insurance costs	85,000	107,000	(21)%
Other general and administrative expenses	190,000	236,000	(19)%

Stock-based compensation	308,000	436,000	(29)%
Total general and administrative expenses	$ 1,862,000	$ 2,231,000	(17)%

General and administrative expenses decreased by $369,000, or 17%, to $1,862,000 for the three months ended September 30, 2008 as compared to $2,231,000 for the same period in the prior year primarily due to a decrease in personnel costs. Personnel costs decreased $239,000 due to the reversal of accrued expenses for employee and officer bonuses as well

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as our 401(k) matching contribution for the 2008 fiscal year. We currently estimate that we will not incur such costs prior to our entry into a material licensing or collaboration agreement for one or more of our targeted cancer programs, if at all. In addition, stock-based compensation decreased $128,000 for the three months ended September 30, 2008 as a result of fewer stock options, and related expense, awarded during 2008 as compared to the prior year period.

Nine-Month Periods Ended September 30, 2008 and September 30, 2007

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30		Percentage Increase/ (Decrease)
	2008 (unaudited)	2007 (unaudited)	
REVENUES:			
Research and development contracts			
Genentech	$ 182,000	$ 905,000	(80)%
Wyeth	196,000	1,189,000	(84)%
Procter & Gamble		516,000	(100)%
Other	32,000	121,000	(74)%
Subtotal	410,000	2,731,000	(85)%
License fees			
Genentech	3,000,000	938,000	220%
Wyeth	102,000	203,000	(50)%
Stryker	1,750,000		100%
Procter & Gamble		1,032,000	(100)%
Subtotal	4,852,000	2,173,000	123%
Total revenues	$ 5,262,000	$ 4,904,000	7%

Total revenues increased by $358,000, or 7%, to $5,262,000 for the nine months ended September 30, 2008 from $4,904,000 for the same period in the prior year. Research and development contracts decreased by $2,321,000 because all research funding for programs under collaboration concluded at various times beginning in March 2007, and we currently receive no research funding for our programs under past or current collaborations. We expect that our future research and development contract revenues will be limited to expenses that we incur on behalf of our collaborators for which the collaborator is obligated to reimburse us.

Offsetting the decrease in research and development contract revenue, our license revenues increased by $2,679,000, or 123%, to $4,852,000 for the nine months ended September 30, 2008 from $2,173,000 for the same period in 2007. The increase is due to our receipt of a $3,000,000 contingent cash payment from Genentech under our June 2003 Hedgehog pathway inhibitor collaboration and $1,750,000 in license revenue recognized for the sale and assignment of our remaining BMP assets to Stryker Corporation during the nine months ended September 30, 2008. These increases were offset by decreases of $938,000 and $1,032,000 in license revenue recognized under our Wnt collaboration with Genentech and our collaboration with Procter & Gamble, respectively, as a result of the conclusion of these collaborations in prior periods.

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

Research and Development Program	Primary Indication	Collaborator	For the Nine Months Ended September 30, 2008	2007	Percentage Increase/ (Decrease)
Hh pathway inhibitor	Cancer	Genentech	$ 259,000	$ 75,000	245%
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal	3,417,000	2,499,000	37%
CUDC-305 (Hsp90 inhibitor)	Cancer	Internal	1,144,000		100%
Other targeted cancer programs	Cancer	Internal	3,536,000	3,837,000	(8)%
Other targeted programs	Nervous system disorders/cardiovascular disease	Internal	416,000		100%
Hh agonist	Nervous system disorders/cardiovascular disease	Wyeth (1)	199,000	1,201,000	(83)%
Wnt signaling pathway	Cancer	Genentech		637,000	(100)%
Discovery research	Various	Various/internal	124,000	509,000	(76)%
Impairment of assets, net	N/A			260,000	(100)%
Stock-based compensation	N/A		582,000	528,000	10%
Total research and development expense			$ 9,677,000	$ 9,546,000	1%

(1) Our collaboration with Wyeth terminated effective May 6, 2008.

Our research and development expenses increased by $131,000, or 1%, to $9,677,000 for the nine months ended September 30, 2008 as compared to $9,546,000 for the same period in the prior year due to increased spending on our targeted programs offset by decreased spending on programs under collaborations. Our lead targeted drug development candidate, CUDC-101, which was selected for clinical development in March 2007 and for which we initiated a phase I clinical trial in August 2008, accounted for an increase in spending of $918,000; and CUDC-305, which was selected as a development candidate in July 2008, accounted for $1,144,000 when compared to the same prior year period. Our spending on other targeted programs also increased by $115,000 from the prior year period as we continued to progress drug candidates in preclinical testing in an effort to select additional development candidates. During the nine months ended September 30, 2008, we also incurred expenses of $259,000, an increase of $184,000 over the same prior year period, related to sublicense payments we were required to make under our Hedgehog systemic small molecule pathway inhibitor program as a result of the $3,000,000 payment received from Genentech for the achievement of a clinical development objective in the second quarter of 2008. We expect that future research and development expenses related to our Hedgehog systemic small molecule pathway inhibitor program will be nominal.

Offsetting these increases, spending on our collaborator-funded programs with (i) Genentech for the Wnt signaling pathway; (ii) Wyeth for the Hedgehog agonist; and (iii) Centocor for BMP-7 small molecule agonists decreased by an aggregate amount of $2,075,000 as a result of the conclusion of the research funding for each of these programs at various times between March 2007 and February 2008. Certain of these resources were reallocated to our internal targeted cancer programs. In addition, we recognized a net impairment on certain of our assets of $260,000 during the nine months ended September 30, 2007. No such impairment costs were recorded during 2008.

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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)
	2008 (unaudited)	2007 (unaudited)	
Personnel	$ 1,780,000	$ 1,999,000	(11)%
Occupancy and depreciation	287,000	48,000	498%
Legal services	1,247,000	1,624,000	(23)%
Consulting and professional services	893,000	924,000	(3)%
Insurance costs	279,000	352,000	(21)%
Other general and administrative expenses	724,000	689,000	5%
Stock-based compensation	1,192,000	1,906,000	(37)%
Total general and administrative expenses	$ 6,402,000	$ 7,542,000	(15)%

General and administrative expenses decreased by $1,140,000, or 15%, to $6,402,000 for the nine months ended September 30, 2008 as compared to $7,542,000 for the same period in the prior year due to decreased spending in several areas. Stock-based compensation decreased $714,000 for the nine months ended September 30, 2008 as a result of fewer stock options, and related expense, awarded during 2008 compared to the prior year period. In addition, legal services decreased $377,000, primarily due to costs associated with foreign patent applications in the prior year period, and employee costs decreased $219,000 due to our current estimate that we will not incur bonus or 401(k) matching contribution costs prior to our entry into a material licensing or collaboration agreement for one or more of our targeted cancer programs.

Offsetting these decreases, occupancy and depreciation costs increased $239,000 as a result of proceeds received under a settlement agreement entered into with a former subtenant that had defaulted on a sublease of our 61 Moulton Street facility during the nine months ended September 30, 2007.

Liquidity and Capital Resources

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

At September 30, 2008, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of $29,929,000, excluding restricted long-term investments of $210,000. 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. However, we do not anticipate any losses with respect to such cash balances because the balances are invested in highly rated securities. Our marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, and government obligations. We do not hold any asset-backed or auction rate securities.

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 the third quarter of 2008, we began incurring clinical costs associated with our phase I trial of CUDC-101, which began in August 2008. 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, the majority of our research and development effort and expense has shifted from our programs that were funded under collaborations relating to the Hedgehog pathway and various discovery and preclinical programs to the development of our targeted cancer programs, particularly for our lead targeted cancer drug candidate, CUDC-101, which is currently being tested in patients in a phase I clinical trial and CUDC-305, which we selected as a development candidate in July 2008 and is currently being tested in IND-enabling studies.

While we are seeking a corporate collaborator for one or more of our targeted cancer programs, we are currently progressing the research and development of these programs on our own. We believe that our research and development expenses will increase for the remainder of 2008 and in future years in connection with our plans to continue phase I clinical

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testing for CUDC-101 and to progress CUDC-305 in preclinical testing toward an anticipated IND filing in mid-2009. We are actively seeking collaborators for our targeted cancer drug candidates, particularly CUDC-305, but have not reached advanced stages of negotiation with any party. Our intention is to enter into a license or collaboration agreement with CUDC-305 prior to initiation of phase I clinical testing. If we are unable to consummate such a transaction, we would consider suspending further development of CUDC-305, at least temporarily. Our decision would be based on a number of factors including, phase I data generated by CUDC-101, our future cash position and the overall financial markets, among others.

In general, our only source of 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 royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was $11,186,000 for the nine-month period ended September 30, 2008 as compared to $9,176,000 for the nine-month period ended September 30, 2007. 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.

Cash used in operating activities during the nine-month period ended September 30, 2007 was primarily the result of our net loss of $11,257,000 offset by increases in operating cash resulting from non-cash charges, including stock-based compensation expense of $2,434,000, depreciation of $1,047,000 and impairment of assets of $492,000 during the nine-month period ended September 30, 2007. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during the nine months ended September 30, 2007. Specifically, our accounts payable and accrued liabilities decreased $211,000 and our deferred revenue decreased $2,736,000 as a result of accelerated license fee amortization under our Genentech and Procter & Gamble collaborations. We also collected $1,101,000 of our accounts receivable primarily related to our Micromet settlement.

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

Investing activities used cash of $621,000 for the nine-month period ended September 30, 2008 as compared to cash of $5,092,000 generated in the nine-month period ended September 30, 2007. Cash used by investing activities resulted principally from $561,000 in net investment purchases for the nine months ended September 30, 2008. Cash used by investing activities resulted principally from $5,334,000 in net investment purchases for the nine months ended September 30, 2007 primarily related to investment of funds received from our August 2007 private placement. In addition, for the nine months ended September 30, 2007, we received $316,000 in net proceeds from the sale of certain of our assets. We currently do not expect to undertake any significant capital projects during 2008.

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. Financing activities provided cash of $13,320,000 for the nine-month period ended September 30, 2007, resulting primarily from $14,578,000 received in issuances of common stock, including net proceeds of $14,422,000 from our August 2007 private placement of common stock and $156,000 received upon the exercise of stock options. Offsetting these increases in cash, we repaid $1,257,000 on our term debt with the Boston Private Bank & Trust Company.

We anticipate that existing capital resources at September 30, 2008, should enable us to maintain current and planned operations into the first half 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 the first half of 2010 is dependent upon, among other things, the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through additional corporate collaborations,

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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. Due to our significant long-term capital requirements, we intend to seek to raise funds through the sale of debt or equity securities when conditions are favorable, even if we do not have an immediate need for additional capital at such time. Additional financing may not be available or, if available, it may not be available on favorable terms. In addition, the sale of additional debt or equity securities could result in dilution to our stockholders. If substantial additional funding is not available, our ability to fund research and development and other operations will be significantly affected and, accordingly, our business will be materially and adversely affected. 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, 2008.

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, 2007.

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, 2008. 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, 2008, 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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q and in other documents we file with the SEC, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors include any material changes to and restate and supersede the risk factors previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2007.

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, 2008, we had an accumulated deficit of approximately $705,814,000. 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. As a result, for the foreseeable future, we will need to spend significant capital, particularly on our internally funded targeted cancer programs, in an effort to develop products that we can commercialize. As such, we expect to incur substantial operating losses for the foreseeable future. Our failure to become and remain profitable may 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 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 and we expect that our only source of cash flows from operations for the foreseeable future would 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, CUDC-305 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 and working capital at September 30, 2008, should enable us to maintain current and planned operations into the first half 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;

- 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, is 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

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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.

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS

We depend on our collaborative relationship with Genentech and if Genentech 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 a phase II clinical trial and has stated that it plans to initiate a phase II trial in advanced ovarian cancer in the fourth quarter of 2008 and a phase II trial in advanced basal cell carcinoma in the first half of 2009. Our collaborations with Genentech 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 has 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 efforts, allocation of resources and successful development and commercialization of our drug candidates.

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

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Genentech 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 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 could be limited if Genentech decreases or fails to increase spending related to such drug candidates.

Genentech 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, in July 2008, Roche Holdings Ltd made an offer to acquire the remaining approximately 44% of Genentech outstanding common stock not then owned by Roche. Any such third-party transaction, including a 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 development programs such that it ceases to diligently pursue the development of our programs; and/or cause the collaboration with us to terminate.

Genentech may, under specified circumstances, terminate its 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.

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

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

Our current strategy is to seek corporate collaborators or licensees for the further development and commercialization of one or more of drug candidates under our targeted cancer drug programs. For example, we are currently seeking corporate collaborations for CUDC-101 and CUDC-305, the first two drug candidates we have selected 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, CUDC-305 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, CUDC-305 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, CUDC-305 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 being designed to simultaneously inhibit HDAC, EGFR and Her2, and CUDC-305, an orally available, synthetic small molecule inhibitor of Hsp90. In August 2008, we treated the first patient in a phase I trial of CUDC-101. We initiated IND-enabling studies of CUDC-305 in October 2008.

CUDC-101 and CUDC-305 are novel compounds and their potential benefit as therapeutic cancer drugs is unproven. These drug candidates may not prove to be effective inhibitors of the validated cancer targets they are being designed to act against and may not demonstrate in patients any or all of the pharmacological benefits that we believe they may possess or that may have been demonstrated in preclinical 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

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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, CUDC-305, 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 phase II clinical trial and Genentech has stated that it plans to initiate two additional phase II clinical trials of GDC-0449, including a phase II trial in advanced ovarian cancer in the fourth quarter of 2008 and a phase II trial in advanced basal cell carcinoma in the first half of 2009. In addition, in August 2008 we treated our first patient in a phase I clinical trial of CUDC-101, the lead drug candidate from our pipeline of proprietary targeted cancer programs.

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 and any future collaborators could experience delays or failures in preclinical or clinical trials of any of our drug candidates for a number of reasons. 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 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. Employment of such a debarred person may result in delays in FDA 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, 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 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 our 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

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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 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.

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 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 and other required regulatory approvals is expensive. The time required for FDA and other 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 approvals. Moreover, approval by the FDA 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 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.

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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.

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. Genentech has also made public statements regarding its expectations for the clinical development of GDC-0449 and may in the future make additional statements about its goals and expectations for this collaboration with us. The actual timing of these events can vary dramatically due to a number of factors 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.

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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.

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.

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 adequate 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.

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.

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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 an agreement with a medicinal chemistry provider in Shanghai. We also currently engage biologists at another third-party provider in Beijing, China. In addition, we have a subsidiary in China, Curis Shanghai, which is currently licensed but is not operational.

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

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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.

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, for example the 2006 requirement under Statement of Financial Accounting Standards No. 123 (revised 2004), or SFAS 123(R), to expense stock options.

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 and our December 2007 assignment agreement with Stryker Corporation, 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.

We in-license certain of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, or fail to secure any required new licenses, we could lose license rights that are necessary to commercializing our drug candidates.

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. Our most significant in-license agreements are with Harvard University, Columbia University, the Johns Hopkins University both alone and with the University of Washington, and Leland Stanford Junior University. Some of these license agreements impose various development, commercialization, funding, royalty, diligence, and other obligations on us, which provide that our failure to

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meet any agreed upon requirements may allow the licensor to terminate the agreement. Some of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our drug candidates. In addition, continued development and commercialization of our drug candidates may require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

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;

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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.

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 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 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

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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.

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

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

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.

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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;
- 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 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

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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 has traded as high as $2.35 and as low as $0.75 per share for the period January 1, 2007 through October 24, 2008. 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;
- 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.

Substantially all of our outstanding common stock may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

As of September 30, 2008, we had outstanding approximately 63.4 million shares of common stock, most of which can be traded without restriction at any time. 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.

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

As of September 30, 2008, we believe that our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 33% 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;

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

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

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

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

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

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PART II OTHER INFORMATION

Item 5. OTHER INFORMATION

Reduction in Base Salaries of Executive Officers

On October 24, 2008, the compensation committee of our board of directors approved reductions to the annual base salaries paid to our executive officers, effective October 27, 2008, as follows:

Name	Old Annual Base Salary	New Annual Base Salary
Daniel R. Passeri	$400,000	$300,000
Michael P. Gray	$300,000	$250,000
Changgeng Qian	$250,000	$225,000
Mark W. Noel	$210,000	$189,000

Equity Grants to Executive Officers

On October 24, 2008, in consideration for the reduction of annual base salaries described herein, the compensation committee of our board of directors authorized the grant to each executive officer listed below, pursuant to our 2000 Stock Incentive Plan, as amended, of an incentive stock option or, to the extent that the applicable provisions of the Internal Revenue Code do not permit such grants to be treated as incentive stock options, then non-qualified stock options, to purchase the number of shares of our common stock set forth next to such executive officer s name below, at an exercise price equal to the closing price of our common stock on the NASDAQ Global Stock Market on October 24, 2008. Each option shall be evidenced by our standard form of stock option agreement and shall vest as to one twelfth of the shares underlying such option on November 24, 2008 and at the end of each month thereafter until all the shares underlying such option shall become vested on October 24, 2009, subject to the executive officer s continued employment with us.

Name	Number of Shares Underlying Option
Daniel R. Passeri	202,000
Changgeng Qian, Ph.D., M.D.	51,000
Mark W. Noel	43,000

On October 24, 2008, in consideration for the reduction of Mr. Gray s annual base salary described herein, the compensation committee of our board of directors authorized the grant to Mr. Gray, pursuant to our 2000 Stock Incentive Plan, as amended, of 79,113 shares of our restricted common stock, at a purchase price of $0.01 per share, which shares shall be evidenced by our standard form of restricted stock agreement and shall become vested as to one twelfth of the shares on November 24, 2008 and at the end of each month thereafter until all such shares shall become vested on October 24, 2009, subject to Mr. Gray s continued employment with us.

Letter Agreements with Executive Officers

On October 27, 2008, we entered into a letter agreement with each of our executive officers (each, a Letter Agreement and collectively, the Letter Agreements) to, among other things:

reflect the reductions in annual base salaries paid to the executive officers as described herein; and

reflect the grants of equity to the executive officers as described herein.

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In addition, the Letter Agreements amend the offer letters, as amended, by and between us and Changgeng Qian, Michael P. Gray and Mark W. Noel and the employment agreement by and between us and Daniel R. Passeri to provide that:

certain severance amounts to be paid to the executive officer as a result of his termination for Good Reason (as defined in the applicable employment agreement or offer letter) or without Cause (as defined in the applicable employment agreement or offer letter) be changed from twelve (for Mr. Passeri) or six (for the other executive officers) monthly payments each equal in amount to one twelfth of his then base salary to twelve (for Mr. Passeri) or six (for the other executive officers) monthly payments each equal in amount to one twelfth of the greater of (x) his salary in effect on September 30, 2008 and (y) his then base salary;

certain severance amounts to be paid to the executive officer as a result of his termination for Good Reason or without Cause within twelve months following a Change in Control Event (as defined in the applicable employment agreement or offer letter) be changed from twelve (for Mr. Passeri) or six (for the other Executive Officers) monthly payments each equal in amount to one twelfth of his then base salary to twelve (for Mr. Passeri) or six (for the other executive officers) monthly payments each equal in amount to one twelfth of the greater of (x) his salary in effect on September 30, 2008 and (y) his then base salary;

the definition of base salary used to calculate certain severance amounts to be paid to the executive officer in connection with a Change in Control Event be changed from the greater of the amount in effect either immediately prior to the Change in Control Event or his employment termination date to the greater of the amount in effect (x) on September 30, 2008, (y) immediately prior to the Change in Control Event or (z) on his employment termination date; and

for Mr. Passeri, we pay fees for the preparation of such executive officer s tax return by a tax professional.

The foregoing summary of the Letter Agreements does not purport to be complete and is qualified in its entirety by reference to the full text of such Letter Agreements, copies of which are attached hereto as Exhibits 10.1, 10.2, 10.3 and 10.4 and are incorporated into this Item 5 by reference.

Item 6. EXHIBITS

See exhibit index.

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SIGNATURE

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

CURIS, INC.

Dated: October 28, 2008

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	Amendment to Employment Agreement, dated as of October 27, 2008, to the employment agreement dated September 18, 2007, by and between Curis and Daniel R. Passeri
10.2	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated December 10, 2003, by and between Curis and Michael P. Gray
10.3	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated May 2, 2001, by and between Curis and Changgeng Qian
10.4	Amendment to Offer Letter, dated as of October 27, 2008, to the offer letter dated January 11, 2001, by and between Curis and Mark W. Noel
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