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	