

CURIS INC  
Form 10-Q  
May 02, 2007  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2007**

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**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**04-3505116**  
(I.R.S. Employer  
Identification No.)

**45 Moulton Street**

**Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02138**  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 503-6500

## Edgar Filing: CURIS INC - Form 10-Q

---

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.  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

As of April 30, 2007, there were 49,381,517 shares of the registrant's common stock outstanding.

---

---

**Table of Contents**

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

**INDEX**

	<b>Page Number</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Unaudited Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2007 and December 31, 2006</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three Months ended March 31, 2007 and 2006</u>	4
<u>Consolidated Statements of Cash Flows for the Three Months ended March 31, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
Item 4. <u>Controls and Procedures</u>	26
<b>PART II. OTHER INFORMATION</b>	
Item 1A. <u>Risk Factors</u>	27
Item 6. <u>Exhibits</u>	42
<u>SIGNATURE</u>	43

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS****CURIS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	<b>March 31,</b>	<b>December 31,</b>
	<b>2007</b>	<b>2006</b>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 16,498,533	\$ 18,829,332
Marketable securities	16,241,462	17,826,675
Accounts receivable	1,302,024	1,315,412
Prepaid expenses and other current assets	490,264	541,182
<b>Total current assets</b>	<b>34,532,283</b>	<b>38,512,601</b>
Property and equipment, net	3,810,508	4,393,604
Long-term investment restricted	201,844	201,844
Goodwill	8,982,000	8,982,000
Deposits and other assets, net	172,384	178,204
	<b>\$ 47,699,019</b>	<b>\$ 52,268,253</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities:</b>		
Debt, current portion	\$ 1,243,516	\$ 1,246,289
Accounts payable	1,792,951	1,461,195
Accrued liabilities	1,025,276	1,529,337
Deferred revenue, current portion	635,675	1,755,160
<b>Total current liabilities</b>	<b>4,697,418</b>	<b>5,991,981</b>
Debt obligations, net of current portion	223,371	733,333
Deferred revenue, net of current portion	8,993,586	9,131,673
Other long-term liabilities	471,283	514,127
<b>Total liabilities</b>	<b>14,385,658</b>	<b>16,371,114</b>
<b>Commitments</b>		
<b>Stockholders Equity:</b>		
Common stock, \$0.01 par value 125,000,000 shares authorized; 50,421,674 and 49,373,967 shares issued and outstanding, respectively, at March 31, 2007 and 50,381,561 and 49,333,854 shares issued and outstanding, respectively, at December 31, 2006	504,217	503,816
Additional paid-in capital	726,227,006	725,271,688
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(107,594)	(111,390)
Accumulated deficit	(692,424,268)	(688,883,495)
Accumulated other comprehensive income	5,274	7,794
<b>Total stockholders equity</b>	<b>33,313,361</b>	<b>35,897,139</b>

Edgar Filing: CURIS INC - Form 10-Q

\$ 47,699,019      \$ 52,268,253

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (unaudited)**

	Three Months Ended	
	2007	March 31, 2006
<b>REVENUES:</b>		
Research and development contracts	\$ 1,282,873	\$ 2,572,946
License fees	1,079,913	291,584
Gross Revenues	2,362,786	2,864,530
Contra-revenues from co-development with Genentech		(826,100)
Net Revenues	2,362,786	2,038,430
<b>COSTS AND EXPENSES:</b>		
Research and development	3,295,615	3,484,643
General and administrative	2,951,585	2,885,738
Amortization of intangible assets		18,768
Total costs and expenses	6,247,200	6,389,149
Loss from operations	(3,884,414)	(4,350,719)
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	365,352	373,846
Other income	11,264	
Interest expense	(32,975)	(72,121)
Total other income, net	343,641	301,725
Net loss	\$ (3,540,773)	\$ (4,048,994)
Net loss per common share (basic and diluted)	\$ (0.07)	\$ (0.08)
Weighted average common shares (basic and diluted)	49,354,125	48,854,964
Net loss	\$ (3,540,773)	\$ (4,048,994)
Unrealized (loss) gain on marketable securities	(2,520)	12,818
Comprehensive loss	\$ (3,543,293)	\$ (4,036,176)

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****CURIS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,540,773)	\$ (4,048,994)
Adjustments to reconcile net loss to net cash used in operating activities-		
Depreciation and amortization	475,506	326,075
Stock-based compensation expense	915,263	762,885
Gain on sale of assets	(68,329)	
Amortization of intangible assets		18,768
Unrealized foreign currency exchange gain	(11,264)	
Changes in operating assets and liabilities:		
Accounts receivable	24,652	(330,715)
Prepaid expenses and other assets	56,738	116,090
Accounts payable and accrued liabilities	(217,922)	1,399,058
Deferred revenue	(1,257,572)	883,555
Total adjustments	(82,928)	3,175,716
Net cash used in operating activities	(3,623,701)	(873,278)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of marketable securities	(5,459,103)	(15,210,525)
Sale of marketable securities	7,041,796	17,255,520
Purchases of property and equipment	(20,769)	(27,207)
Net proceeds from the sale of assets	196,688	
Net cash provided by investing activities	1,758,612	2,017,788
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	44,252	2,081
Repayments of obligations under notes payable	(509,962)	(308,334)
Net cash used in financing activities	(465,710)	(306,253)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,330,799)	838,257
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	18,829,332	22,310,298
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 16,498,533	\$ 23,148,555
	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:</b>		
Issuance of common stock in connection with conversion of note payable to Becton Dickinson	\$	\$ 2,638,445

See accompanying notes to unaudited condensed consolidated financial statements.





---

**Table of Contents**

**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 seeking to leverage its innovative biological signaling pathway drug technologies to create new medicines primarily to treat cancer, and also to treat several other medical indications for which there are substantial unmet therapeutic needs. Biological signaling pathways, also referred to as signaling pathways, are prominent regulators of specific tissue and organ formation during prenatal development and are used by the body throughout life to repair and regulate human tissue. The Company's product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive. In expanding its drug development efforts in the field of cancer, the Company is building upon its previous experiences in targeting signaling pathways in the areas of cancer, neurological disease, hair growth regulation and cardiovascular disease. The Company operates in a single reportable segment: developmental biology products. 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 technological innovations, dependence on key personnel, its ability to protect proprietary technology, 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 grow its business and obtain adequate financing to fund this growth.

**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, 2006, as filed with the Securities and Exchange Commission on March 2, 2007.

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 March 31, 2007 and the results of operations and cash flows for the three-month periods ended March 31, 2007 and 2006. The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities. Actual results may differ from such estimates.

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

**3. Revenue Recognition**

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, contingent cash payments based upon achievement of clinical development objectives and royalties on product sales. The Company follows the provisions of the Securities and Exchange

---

**Table of Contents**

Commission's Staff 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 2, 2007.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the twelve-month period ended March 31, 2008 are classified as long-term deferred revenue. As of March 31, 2007, the Company has short- and long-term deferred revenue of \$636,000 and \$8,994,000, respectively, related to its collaborations.

**4. Genentech April 2005 Drug Discovery Collaboration**

On April 1, 2005, the Company entered into a drug discovery collaboration agreement with Genentech for the discovery and development of small molecule compounds that modulate the Wnt signaling pathway. The Wnt signaling pathway plays an important role in cell proliferation and has been implicated in several cancers, including colon, breast and ovarian cancers. Under the terms of the agreement, the Company has granted Genentech an exclusive, royalty-bearing license to make, use and sell the small molecule compounds that are modulators of the Wnt signaling pathway. Curis has retained the rights for ex vivo cell therapy, except in the areas of oncology and hematopoiesis.

Under the terms of the agreement, the Company has primary responsibility for research and development activities and Genentech is primarily responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration. Genentech paid the Company an up-front license fee of \$3,000,000 and agreed to fund up to \$6,000,000 for research and development activities during the initial two-year research term, subject to its termination rights described below, with an option to extend the initial two-year research term for up to two additional years in one-year increments. In January 2007, Genentech informed the Company that it would not extend the research term beyond the initial two-year term ending on March 31, 2007.

The Company applied the provisions of EITF 00-21 and determined that its deliverables represented 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 Genentech would elect twice to extend the research service period and related funding, each in one-year increments, although there was no assurance Genentech would make such an election. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term. In developing this estimate, the Company assumed that Genentech would maintain its initially elected number of twelve full-time equivalent researchers throughout the estimated four-year period. The steering committee effort was also expected to be consistent over the estimated four-year period. The \$3,000,000 up-front fee plus \$12,000,000, the total amount of research funding which the Company would be entitled to for providing twelve full-time equivalents over four years, was being attributed to the research services.

As a result of Genentech's decision not to extend the research term, the Company's estimated performance period was changed during the fourth quarter of 2006 to coincide with the March 31, 2007 research term end date, and the Company accelerated amortization of the unamortized up-front license fee and the remaining amount of research funding to which the Company was entitled. Revenue for the three-month period ended March 31, 2006 was recognized as the research services were provided assuming a four-year term through March

**Table of Contents**

2009 at a rate of \$312,500 per full-time equivalent. Revenue for the three-month period ended March 31, 2007 was recognized as the research services were provided at a rate of \$562,500 per full-time equivalent, which includes the effect of accelerating revenue recognition on the unamortized portion of the up-front license fee. In April 2007, the Company returned \$141,000 in excess research funding that it received from Genentech for the first quarter of 2007 research services, and the Company has no remaining performance obligations under this agreement. This amount is included within Accounts payable at the Company's Consolidated Balance Sheet as of March 31, 2007.

The Company recorded revenue under this collaboration of \$1,577,000 and \$982,000 during the three-month periods ended March 31, 2007 and 2006, respectively. Of this amount, approximately \$938,000 and \$187,000 was attributed to the amortization of the up-front license fee and is included in License fees within the Revenue section of the Company's Consolidated Statement of Operations for the three-month periods ended March 31, 2007 and 2006, respectively. In addition, the Company recorded \$639,000 and \$794,000 related to research services performed by the Company's full-time equivalent researchers for the three-month periods ended March 31, 2007 and 2006, respectively, and is included within Research and development contracts within the Revenues section of the Company's Consolidated Statement of Operations.

The Company believes that contingent cash payments tied to preclinical, clinical development and drug approval objectives under this collaboration may not constitute substantive milestones since the successful achievement of these objectives may 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, it expects to recognize any such contingent payments as revenue in License Fees in the Company's Revenues section of its Consolidated Statement of Operations when the milestones are met.

**5. Accrued Liabilities**

Accrued liabilities consist of the following:

	March 31,	December 31,
	2007	2006
Accrued compensation	\$ 346,000	\$ 578,000
Professional fees	124,000	200,000
Facility-related costs	352,000	484,000
Other	203,000	267,000
<b>Total</b>	<b>\$ 1,025,000</b>	<b>\$ 1,529,000</b>

**6. Long-Term Debt**

Long-term debt, including accrued interest, consists of the following at March 31, 2007 and December 31, 2006:

	March 31,	December 31,
	2007	2006
Notes payable to financing agencies for capital purchases	\$ 1,467,000	\$ 1,980,000
Less current portion	(1,244,000)	(1,246,000)
<b>Total long-term debt obligations</b>	<b>\$ 223,000</b>	<b>\$ 734,000</b>

On March 23, 2005, the Company converted \$2,250,000 borrowed under an amended loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of \$62,500 plus any accrued interest beginning on May 1, 2005, and extending through the 36-month term.



**Table of Contents**

On December 9, 2005, the Company converted \$1,450,000 borrowed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006, and extending through the 36-month term. During the quarter ended March 31, 2007, the Company sold certain of its assets with a net book value of \$129,000. Gross proceeds from the sale of these assets were \$202,000 and were directly remitted to Boston Private Bank & Trust and applied to the principal obligation outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement. The Company also recorded expenses of \$5,000 related to this sale resulting in a net gain on sale of assets of \$68,000, which was reflected as a reduction of Research and development expenses in the Company's consolidated statement of operations for the period ended March 31, 2007.

These loans are collateralized by all of the Company's property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of March 31, 2007, the Company is in compliance with the sole covenant under each of the agreements with the Boston Private Bank & Trust Company. The covenant requires the Company to maintain a minimum working capital ratio. Should the Company fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

**7. Accounting for Stock-Based Compensation**

As of March 31, 2007, 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 2(l) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 2, 2007.

During the quarter ended March 31, 2007, 330,000 shares were issued under the 2000 Plan, of which 280,000 were granted to employees and 50,000 were granted to non-employees. The employee awards issued during the quarter ended March 31, 2007 vest over a four-year period and were issued with exercise prices equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date. The table below summarizes options outstanding and exercisable under the 2000 Plan and the 2000 Director Plan at March 31, 2007:

Exercise Price Range	Options Outstanding			Options Exercisable	
	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 - \$ 1.34	860,594	7.12	\$ 1.16	480,094	\$ 1.04
1.50 - 1.95	2,691,519	7.82	1.56	857,394	1.55
2.11 - 3.95	2,699,924	5.38	2.97	2,544,789	2.99
3.96 - 5.89	2,091,922	7.13	4.41	1,368,184	4.52
6.91 - 17.94	551,997	3.30	12.87	551,997	12.87
20.00 - 31.15	48,563	1.06	27.02	48,563	27.02
	8,944,519	6.54	\$ 3.45	5,851,021	\$ 4.11

**Table of Contents****Employee Grants**

The Company adopted the provisions of Statement of Financial Accounting Standards 123(R), Share-Based Payment (SFAS 123(R)), beginning January 1, 2006, using the modified prospective transition method. In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee options awarded during the quarters ended March 31, 2007 and 2006 based on the assumptions noted in the following table:

	Three Months Ended	
	March 31,	
	2007	2006
Expected life (years)	6.25	6.25
Risk-free interest rate	4.49%	4.85%
Volatility	96.2%	102.0%
Dividends	None	None

The stock price volatility and expected terms utilized in the calculation involve management's best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. In determining the expense recorded in the Company's consolidated statement 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 those estimated by management, additional adjustments to compensation expense may be required in future periods.

The aggregate intrinsic value of options outstanding at March 31, 2007 was \$324,000, of which \$241,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the quarters ended March 31, 2007 and 2006 were \$1.07 and \$3.30, respectively. As of March 31, 2007, there was approximately \$4,237,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee 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 3.29 years. The intrinsic value of employee stock options exercised during the quarters ended March 31, 2007 and 2006 were \$10,000 and \$2,000, respectively. The total fair value of vested stock options for the quarters ended March 31, 2007 and 2006 were \$241,000 and \$1,397,000, respectively.

For employee stock options with a market performance condition, which was used for a limited number of stock options issued in June 2002 that remained unvested as of January 1, 2006, the Company uses a lattice-based option valuation model. These awards accounted for \$15,000 and \$18,000 of the employee stock-based compensation expense recorded by the Company for the quarters ended March 31, 2007 and 2006, respectively. All outstanding unvested performance condition awards will be fully vested in November 2007. The lattice model utilizes assumptions including a 7-year expected life, 2.10% risk-free rate, 116% volatility, and a 0% dividend rate.

As of March 31, 2007, the Company had 10,000 non-vested restricted stock awards outstanding that were granted to the Chief Executive Officer during 2006 and that will become fully vested on May 31, 2007. The restricted common stock is subject to a right of repurchase by the Company, which the Company does not intend to exercise. As of March 31, 2007, there was \$3,000 in unrecognized compensation expense related to this non-vested stock award.

**Table of Contents**

The Company recorded a total of \$20,000 and \$18,000 in compensation expense for the quarters ended March 31, 2007 and 2006, respectively, related to the ESPP. The Company 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 March 31,	
	2007	2006
Expected term	6 months	6 months
Risk-free interest rate	4.98%	4.6%
Volatility	70%	85%
Dividends	None	None

Stock-based compensation for employees for the quarters ended March 31, 2007 and 2006 of \$864,000 and \$832,000, respectively, was calculated using the above valuation models 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. Based on basic and diluted weighted average shares outstanding of 49,354,125 and 48,854,964 for the quarters ended March 31, 2007 and 2006, respectively, the effect on the Company's net loss per share of stock-based compensation expense recorded under SFAS 123(R) was approximately \$0.02 per share for each period.

**Non-Employee Grants**

During the quarters ended March 31, 2007 and 2006, the Company granted stock options to consultants for services. These options were issued at or above their fair market value on the date of grant and have various vesting dates from date of grant, ranging from 3.5 months to 4 years. In addition, certain non-employee options vest only upon the achievement of performance objectives. Should the Company terminate the consulting agreements, any unvested options will be cancelled. Options issued to non-employees are marked-to-market liabilities, which means that as the Company's stock price fluctuates, the liability and related expense either increases or decreases. The Company recognized expense of \$51,000 related to non-employee stock options for the quarter ended March 31, 2007, and it reversed expense of \$69,000 related to non-employee stock options for the quarter ended March 31, 2006 as a result of a decline in the Company's stock price. As of March 31, 2007, the Company had recorded \$108,000 in deferred compensation related to unvested non-employee options.

For the quarters ended March 31, 2007 and 2006, 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 quarter ended March 31,	
	2007	2006
Research and development expenses	\$ 242,000	\$ 255,000
General and administrative expenses	673,000	508,000
Total stock-based compensation expense	\$ 915,000	\$ 763,000

**8. Loss of Subtenant Income**

In August 2006, the Company's subtenant to its 61 Moulton Street facility defaulted on the sublease and vacated the property. The Company's lease obligations extend through April 30, 2007, for which it has been responsible for the lease payments upon default by the subtenant and for which it established a reserve. As of December 31, 2006, this reserve was \$245,000 and consisted of the Company's remaining lease obligations and an estimate of other related facility costs through April 2007. During the quarter ended March 31, 2007, the Company charged \$191,000 against the reserve, which represents the rent obligations and other related facility expenses incurred by the Company related to the leased space, which is no longer in use.

---

## **Table of Contents**

In the first quarter of 2007, the subtenant entered into a purchase agreement with a third party for the sale of the subtenant's assets, provided that the agreement is not otherwise previously terminated for conditions specified within the purchase agreement. The termination conditions generally apply to certain insolvency situations of the subtenant, including, among others, a petition in bankruptcy against the subtenant or the subtenant's assignment of its assets for the benefit of creditors.

The subtenant's total obligation to the Company through the April 30, 2007 sublease term was \$368,000. On April 16, 2007, the Company entered into a settlement agreement with the subtenant under which it received approximately \$75,000. The Company applied \$50,000 of this payment to increase the reserve for final estimated costs associated with its obligations through the lease term of April 30, 2007. The remaining \$25,000 was applied against General and administrative expenses in the Company's consolidated statement of operations for the period ended March 31, 2007. The total remaining reserve for remaining costs of \$104,000 is included under Accrued liabilities within Current liabilities in the Company's consolidated balance sheet as of March 31, 2007. Effective April 30, 2007, the Company vacated the 61 Moulton Street facility and it has no further obligations under the lease.

As part of the settlement with the subtenant, the Company will receive an additional \$187,000 from the subtenant upon the subtenant's receipt from the third party of the second payment expected in June 2007, assuming the third party does not terminate the agreement. In addition, the subtenant will receive additional contingent cash payments upon the achievement of certain contractually defined preclinical and clinical development objectives. If the first such objective is achieved and upon the subtenant's receipt of such contingent cash payment, the subtenant would pay the Company the remaining \$106,000. The collection of these two amounts due to the Company under the settlement is not considered reasonably assured as of March 31, 2007 and, therefore, have not been recorded as a receivable.

## **9. Income Taxes**

On January 1, 2007, the Company adopted FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement 109* which was issued in July 2006. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. There were no unrecognized tax benefits as of January 1, 2007, the date FIN 48 was adopted.

For the quarters ended March 31, 2007 and 2006, the Company did not record any federal or state tax expense given its continued net operating loss position. As required by Statement of Financial Accounting Standards No. 109, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses (NOL), capitalized research and development expenditures and research and development credits (R&D credit). Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was established at March 31, 2007 and December 31, 2006.

As of December 31, 2006, the Company had federal and state NOL carryforwards and federal and state R&D credit carryforwards, which may be available to offset future federal and state income tax liabilities which expire at various dates starting in 2007 and going through 2026. Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of



---

**Table of Contents**

certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions (both pre and post initial public offering) which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not currently completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and that there could be additional changes in control in the future. If we have experienced a change of control at any time since Company formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48. The Company does not expect to have any taxable income for the foreseeable future.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had \$0 accrued for interest and penalties at March 31, 2007.

**10. 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. Securities consisting of stock options, warrants, shares issuable under the Company's 2000 Employee Stock Purchase Plan were excluded from diluted net loss per common share as they were antidilutive under the "if converted" method. Antidilutive securities were 10,156,898 and 9,155,296 as of March 31, 2007 and 2006, respectively.

**11. Related Party Transactions**

Under its August 23, 2006 consulting agreement, as amended, with Joseph M. Davie, Ph.D., M.D., a member of the Company's Board of Directors, the Company incurred \$6,000 in related consulting expenses in its consolidated statement of operations for the three-month period ended March 31, 2007.

**12. New Accounting Pronouncements**

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS No. 159). SFAS No. 159, which amends SFAS No. 115, allows certain financial assets and liabilities to be recognized, at the Company's election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS No. 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, the Company records the gains or losses for the period in the statement of comprehensive income and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. While the Company is currently evaluating the provisions of SFAS No. 159, the adoption is not expected to have a material impact on its consolidated financial statements.

**Table of Contents**

**13. Subsequent Events**

*(i) Final Payment received from Micromet*

Under the terms of a September 2006 settlement agreement, Micromet, a former collaborator, was required to repay a note receivable to the Company in two installments of 1,000,000, on each of November 1, 2006 and May 31, 2007. Under the terms of the settlement agreement, if Micromet were to make the second payment on or before April 30, 2007, the second payment would decrease to 800,000. The first payment of 1,000,000, or \$1,252,000, was received on October 17, 2006. The remaining 800,000, or \$1,067,000 based on the Euro-to-U.S. dollar exchange rate as of March 31, 2007, is included under Accounts receivable within Current assets in the Company's Consolidated Balance Sheet as of March 31, 2007. The final payment of 800,000, or \$1,082,000, was received on April 20, 2007. There are no additional amounts due from Micromet under this note receivable.

---

**Table of Contents**

**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 seeking to leverage our innovative biological signaling pathway drug technologies to create new medicines primarily in the field of cancer, and also to treat several other medical indications for which there are substantial unmet therapeutic needs. Biological signaling pathways, also referred to as signaling pathways, are prominent regulators of specific tissue and organ formation during prenatal development and are used by the body throughout life to repair and regulate human tissue. Our product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive. In expanding our drug development efforts in the field of cancer, we are building upon our previous experiences in targeting signaling pathways in the areas of cancer, neurological disease, hair growth regulation and cardiovascular disease.

Since our inception, we have funded our operations primarily through license fees, research and development funding from our strategic collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable and have incurred an accumulated deficit of \$692,424,000 as of March 31, 2007. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to research and development of our product candidates. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. A key driver to our success will be our ability to successfully advance the preclinical development of our internally developed Targeted Cancer Drug Development Platform programs, to commence and complete clinical trials, both for our internally developed programs and our programs under development in collaboration with our strategic collaborators, and to successfully commercialize products on the basis of these programs.

Our research programs are conducted both internally and through strategic collaborations. Our most advanced program is our Hedgehog antagonist program that is under collaboration with Genentech. Genentech is currently conducting a 50-patient phase I clinical trial to test a systemically administered Hedgehog antagonist in cancer. The primary objectives of the phase I clinical 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. Early in 2006, we launched our Targeted Cancer Drug Development Platform programs, which are focused upon designing multiple classes of multi-targeted drugs for cancer therapy. In addition to these proprietary cancer programs, we currently have strategic collaborations with Genentech, Procter & Gamble, and Wyeth to develop therapeutics that modulate the signaling of the Hedgehog pathway. We have a second collaboration with Genentech focusing on the discovery and development of small molecule modulators of the Wnt signaling pathway. We have licensed our BMP pathway patent portfolio to Ortho Biotech Products, a subsidiary of Johnson & Johnson, for systemic administration in all non-orthopedic and non-dental therapeutic applications.

We believe that our Hedgehog agonist collaboration with Procter & Gamble is reaching a preclinical development decision. Procter & Gamble is currently conducting extensive preclinical studies and pending the successful completion of these studies, we continue to remain hopeful that we will achieve the second preclinical development objective in 2007, triggering a \$1,800,000 cash payment. We believe that the main decision criteria to achieving the second preclinical development objective is that testing being completed at Procter & Gamble on the potential lead molecule results in an acceptable toxicity profile.

We also believe that we are facing important decisions in the future development of our BMP-7 protein technologies under license agreement with Ortho Biotech Products, a subsidiary of Johnson & Johnson, as well

---

**Table of Contents**

as our screening efforts to discover small molecule agonists of the BMP pathway. Our BMP screening efforts were being conducted under agreement with Centocor, another subsidiary of Johnson & Johnson. Centocor is primarily responsible for all BMP protein and screening development decisions. This screening agreement concluded on March 15, 2007. We are currently in discussions with Centocor concerning the prospects of entering into a new screening agreement. In addition, we are discussing with Centocor potential development plans for the BMP protein. If we are unsuccessful in our efforts to enter into a new screening collaboration or reach a development path for the BMP protein, we plan to approach Centocor/Ortho Biotech about the possibility of working with other possible collaborators that may have an interest in BMP technologies. If we are unable to extend our collaboration with Centocor/Ortho Biotech or enter into a new collaboration for our BMP technologies and decide to end our internal program, certain of our assets would be impaired that could have a material impact on our financial statements.

During the fourth quarter of 2006 and the first quarter of 2007, research funding concluded on our Hedgehog antagonist and Wnt programs under collaboration with Genentech as well as our SMA program under a sponsored research agreement with the SMA Foundation. As the research funding concluded on programs under collaboration, we reallocated certain of these resources to our internal Targeted Cancer Drug Development Platform programs. We expect that our revenues recognized under our research and development contracts will continue to decline during 2007 as research funding ends on all existing collaborations other than Wyeth.

Our current strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be wholly or majority funded by our collaborators and provide us with the opportunity to receive additional payments if specified development, regulatory approval and sales objectives, are achieved. We are also entitled to receive royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic collaboration and license agreements included \$18,500,000 in up-front payments, of which we received \$11,871,000 in non-refundable license payments and \$6,629,000 from the sale of shares of our common stock. In addition, we received \$17,766,000 from the funding of our research and development personnel. These collaborations also include approximately \$750,000,000 in contingent cash payments that are tied to the achievement of future preclinical and clinical development objectives, regulatory approval and sales objectives. As of March 31, 2007, we have received \$4,250,000 in contingent cash payments under these collaborations.

Going forward, we intend to hire clinical development and regulatory employees in 2007 and beyond and we will seek to advance one or more of our proprietary multi-target cancer programs into early stages of clinical testing. We also plan to continue to seek corporate collaborators for the further development and commercialization of at least one of our multi-target cancer programs from our Targeted Cancer Drug Development Platform. When evaluating potential collaborative opportunities, we plan to seek to retain significant rights and involvement and/or control in at least the early stages of clinical development. We are currently meeting with potential collaborators for CUDC-101, the first development candidate under our Targeted Cancer Drug Development Platform, but we are not in any advanced negotiations, with new or existing collaborators, relating to this or other programs.

In some cases, we have retained rights under our programs under collaboration, including co-development rights and development and commercialization rights in specific therapeutic areas where we believe we can attain additional value through the application of our own internal resources. Examples of retained rights within our programs under collaboration include co-development rights through the end of phase IIb clinical development relating to a hair growth product candidate in exchange for a higher royalty rate under our dermatological Hedgehog agonist collaboration with Procter & Gamble. In addition, we have retained rights to our Hedgehog agonist for topical applications that was subsequently licensed to Procter & Gamble, for local delivery in cardiovascular applications and for *ex vivo* use under our broad Hedgehog agonist collaboration with Wyeth.

---

**Table of Contents**

**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 other product 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, the timing of the receipt of payments from collaborators and the cost and outcome of any clinical trials then being conducted. We believe that our existing capital resources at March 31, 2007, together with the payment of all contractually-defined research funding payments but excluding any cash payments that are contingent upon the achievement of defined development objectives under our research programs under collaboration with Genentech, Wyeth, and Procter & Gamble, assuming these programs continue as planned, should enable us to maintain current and planned operations into the fourth quarter of 2008. Our ability to continue funding our planned operations into and beyond into the fourth quarter of 2008 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt or other sources of financing. A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under 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, including Genentech, Wyeth, Procter & Gamble, and Ortho Biotech Products/Centocor. Our share of the basal cell carcinoma co-development costs were recorded as a reduction to any revenue recognized under our collaborations with Genentech in accordance with EITF 01-9. On August 31, 2006, we ceased our participation in co-development and we do not expect to record any additional contra-revenues. Genentech will be solely responsible for all development decisions and costs subsequent to August 31, 2006, and we are entitled to cash payments upon the occurrence of certain development objectives and royalties on product sales, if any should occur.

Research funding remaining for our existing collaborations consists of payments by Wyeth for five researchers through February 9, 2008. Accordingly, for the majority of our programs under collaboration, our future revenues are limited to the amortization of previously received license payments and to potential future cash payments, if any, that are contingent upon the successful completion of contractually defined development, regulatory, and product sales objectives.

In the future, we will seek to generate revenues from a combination of license fees, research and development funding, milestone payments and royalties resulting from strategic collaborations relating to the development of products that incorporate our intellectual property, and from sales of any products that we successfully develop and commercialize, either alone or in collaboration. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments received under our existing and any future strategic collaborations and license arrangements, and the amount and timing of payments that we receive upon the sale of our products, to the extent that any are successfully commercialized.

*Research and Development.* Research and development expense consists of costs incurred to discover, research and develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense for employee share-based payments. 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. We believe that our research and development expenses will neither increase nor decrease significantly in 2007 as compared to 2006. We expect, however, that a majority of our research and development effort and expense will continue to shift from our work primarily in the Hedgehog pathway and our various discovery programs, to the development of programs under our Targeted Cancer Drug Development Platform. We also expect in future years we will maintain approximately the same number of researchers as we currently employ,

**Table of Contents**

but will increase our clinical development and regulatory capacities. In addition, in the near-term we expect to continue contracting between 20-35 medicinal chemists in an effort to rapidly advance our programs under the Targeted Cancer Drug Development Platform.

Except for our systemically administered Hedgehog antagonist program, our programs are in various stages of preclinical drug development. The table below summarizes our primary research and development programs, including the current development status of each program. The terms used in the chart below are as follows:

Phase I means that we or a collaborator are currently treating human patients in a phase I clinical trial, the principal purpose of which is to evaluate the safety of the compound being tested;

Development candidate means that from our preclinical testing in several 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 that we are seeking to complete the relevant safety, toxicology, and other data required to file an investigational new drug application with the FDA seeking to commence a phase I clinical trial;

Preclinical means we are seeking to obtain demonstrations of therapeutic efficacy in preclinical models of human disease of one or more compounds within a particular class of drug candidates (i.e., Target A-HSP90 inhibitors); and

Discovery means that we are searching for compounds that may be relevant for treating a particular disease area. Because of the early stages of development of these programs, our ability and that of our collaborators and licensors to successfully complete preclinical and clinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain.

Product Candidate	Primary Indication	Collaborator/Licensee	Status
Hedgehog systemic small molecule or antibody antagonist	Cancer	Genentech	Phase I
CUDC-101	Cancer	Internal Development	Development candidate
Multi-target inhibitors (1)	Cancer	Internal Development	Preclinical
Wnt signaling pathway	Cancer	Genentech	Discovery
Hedgehog small molecule agonist or protein	Nervous system disorders	Wyeth	Preclinical
Hedgehog small molecule agonist	Hair growth	Procter & Gamble	Preclinical
BMP-7 protein	Kidney disease and other disorders	Ortho Biotech Products/ Centocor	Preclinical
Hedgehog protein/agonist	Cardiovascular disease	Wyeth/ Internal development	Preclinical
BMP-7 small molecule agonists	Kidney disease and other disorders	Centocor	Discovery

(1) These drug candidates are generated from our Targeted Cancer Drug Development Platform.

Because of the early stages of these programs, the successful development of our product candidates is highly uncertain. There are numerous risks and uncertainties associated with developing drugs, 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 clinical trials;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

---

**Table of Contents**

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 product 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 product candidates. Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

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

*General and Administrative.* General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. These expenses include stock-based compensation expense for employee share-based payments. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services.

*Strategic Collaborations and License Agreements.* Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties. We currently have collaborations with Genentech, Procter & Gamble, Wyeth Pharmaceuticals as well as a license agreement with Ortho Biotech Products. For a detailed discussion of these arrangements, please see Management's Discussion and Analysis of Financial Condition and Results of Operations Strategic Alliances and License Agreements in our annual report on Form 10-K for the year ended December 31, 2006, which is on file with the Securities and Exchange Commission, or SEC.

**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 disclosure of certain assets and liabilities at our balance sheet date. 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, 2006, which is on file with the SEC. The following sets forth material changes in our critical accounting policies and estimates described therein.

*Stock-based compensation.* Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). We adopted the modified prospective transition method. The valuation of employee stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable employee stock options. Accordingly, an



---

**Table of Contents**

option-pricing model is utilized to derive an estimated fair value. In calculating the estimated fair value of our stock options, we use a Black-Scholes pricing model for a majority of our stock awards and, for a small subset of our awards that contained a market condition, a lattice model is used. Both of these models require the consideration of the following six variables for purposes of estimating fair value which will vary for each option granted:

the stock option exercise price;

the expected term of the option;

the grant date price of our common stock;

the expected volatility of our common stock;

the expected dividends on our common stock, which we do not anticipate paying for the foreseeable future; and

the risk free interest rate for the expected option term.

Of the variables above, we believe that the selection of an expected term and expected stock price volatility are the most subjective. Under SFAS 123(R), we are also required to estimate the level of award forfeitures expected to occur, and record compensation expense only for those awards that we ultimately expect will vest. This requirement applies to all awards that are not yet vested. To derive an estimated forfeiture rate, we performed a historical analysis of option awards that were forfeited prior to vesting, as adjusted. This analysis is re-evaluated quarterly and the forfeiture rate is adjusted as necessary to reflect the actual forfeitures for the reporting period. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

For the options outstanding as of March 31, 2007, we estimate that we will record approximately \$2,400,000 to \$2,900,000, in stock-based compensation expense under SFAS 123(R) during 2007. We expect that we will issue additional options in 2007 that will increase the amount of stock-based compensation ultimately recognized. The amount of the incremental employee stock-based compensation expense attributable to 2007 employee stock awards will depend primarily on the number of stock awards issued to employees in 2007, the fair market value of our common stock at the respective grant dates, and the specific terms of the stock awards.

*Long-lived assets:* Long-lived assets consist of goodwill, equity securities held in privately-held companies and property and equipment. In the ordinary course of our business, we incur substantial costs related to property and equipment. Property and equipment is stated at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Determining the economic lives of property and equipment requires us to make significant judgments that can materially impact our operating results.

We assess the impairment of identifiable long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it were determined that the carrying value of our other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure an impairment based on application of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. During 2006, we initiated a realignment of our research programs, focusing on later-stage preclinical drug development programs and de-emphasizing our earlier discovery research programs. As a result, in 2006 we recorded an impairment charge of \$148,000 related to certain of our equipment that was no longer used in our discovery or other programs. In addition, we revised our estimates of the depreciable lives on the remaining equipment currently being used in our discovery research programs as a result of two of our discovery programs ending in late 2006 and early 2007. We will continue to review our estimates of remaining useful lives related to assets currently being used on our remaining discovery programs, which had a net book value of \$693,000 as of March 31, 2007. Any future changes to the estimated useful lives of our assets could have a material impact on our financial statements.

**Table of Contents**

The above list is not intended to be a comprehensive list 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 February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 ( SFAS No. 159 ). SFAS No. 159, which amends SFAS No. 115, allows certain financial assets and liabilities to be recognized, at our election, at fair market value, with any gains or losses for the period recorded in the statement of income. SFAS No. 159 includes available-for-sales securities in the assets eligible for this treatment. Currently, we record the gains or losses for the period in the statement of comprehensive income and in the equity section of the balance sheet. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007, and interim periods in those fiscal years. While we are currently evaluating the provisions of SFAS No. 159, the adoption is not expected to have a material impact on our consolidated financial statements.

**Results of Operations****Quarters Ended March 31, 2007 and March 31, 2006**

*Revenues.* Total revenues are summarized as follows:

	For the Three Months Ended March 31,		Percentage Increase/ (Decrease)
	2007	2006	
<b>REVENUES:</b>			
<i>Research and development contracts</i>			
Genentech	\$ 718,000	\$ 1,358,000	(47%)
Wyeth	454,000	606,000	(25%)
Procter & Gamble	32,000	53,000	(40%)
Centocor	73,000	100,000	(27%)
Spinal Muscular Atrophy Foundation		444,000	(100%)
Other	6,000	12,000	(50%)
Subtotal	1,283,000	2,573,000	(50%)
<i>License fees</i>			
Genentech	938,000	187,000	402%
Wyeth	76,000	68,000	12%
Procter & Gamble	66,000	36,000	83%
Subtotal	1,080,000	291,000	271%
<b>Gross revenues</b>	<b>2,363,000</b>	<b>2,864,000</b>	<b>(17%)</b>
<b>Contra-revenues from co-development with Genentech</b>		<b>(826,000)</b>	<b>(100%)</b>
<b>Net revenues</b>	<b>\$ 2,363,000</b>	<b>\$ 2,038,000</b>	<b>16%</b>

Gross revenues decreased by \$501,000 to \$2,363,000 for the three months ended March 31, 2007 from \$2,864,000 for the same prior year period. This decrease was primarily the result of a decrease in research funding under our collaborations. Two of our research funding arrangements concluded during the fourth quarter of 2006, including the research funding for our Hedgehog antagonist program under collaboration with Genentech and our research funding with the Spinal Muscular Atrophy Foundation. The termination of research funding under these two arrangements accounted for \$1,084,000 of the decrease in research and development contract revenues. In addition, the number of our scientists for whom we received research funding from Wyeth under our Hedgehog agonist program decreased from eight to five during the first quarter of 2007. We expect



**Table of Contents**

that our revenues recognized under our research and development contracts will continue to decline during 2007 as research funding ends on all existing collaborations other than Wyeth.

Offsetting the decrease in research and development contract revenue, our license revenues increased by \$789,000 to \$1,080,000 in the first quarter of 2007 from \$291,000 for the same period in 2006. The increase was the result of the accelerated amortization of license fee revenue under our April 2005 collaboration with Genentech, which resulted in additional revenue of \$751,000 for the quarter ended March 31, 2007. In the fourth quarter of 2006, we changed our estimated performance period under this collaboration from March 2009 to coincide with the end of the research term of March 31, 2007.

Our net revenues increased \$325,000 to \$2,363,000 for the three months ended March 31, 2007 as compared to \$2,038,000 for the same prior year period. The increase in our net revenues was primarily the result of a decrease in contra-revenues recorded during the first quarter of 2007 when compared to the same period in 2006. We did not record any contra-revenues during the first quarter of 2007, as compared to \$826,000 recorded in the prior year period. Contra-revenues represent amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma drug candidate. On August 31, 2006, we ceased our participation in co-development and we do not expect to incur any additional costs related to this program as Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program.

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

Research and Development Program	Primary Indication	Collaborator	For the Three Months Ended March 31,		Percentage Increase/ (Decrease)
			2007	2006	
Multi-target inhibitors	Cancer	Internal	\$ 1,705,000	\$	100%
Wnt signaling pathway	Cancer	Genentech	626,000	732,000	(14%)
Hh small molecule agonist	Neurological disorders	Wyeth	443,000	682,000	(35%)
Hh small molecule agonist	Hair growth	Procter & Gamble	18,000	277,000	(94%)
BMP-7 small molecule agonists	Kidney disease and other	Centocor	262,000	179,000	46%
Hh small molecule and antibody antagonist	Cancer	Genentech	35,000	543,000	(94%)
Discovery research	Spinal muscular atrophy	SMA Foundation		636,000	(100%)
Discovery research	Various	Internal	33,000	181,000	(82%)
Gain on sale of assets	N/A		(68,000)		(100%)
Stock-based compensation	N/A		242,000	255,000	(5%)
<b>Total research and development expense</b>			<b>\$ 3,296,000</b>	<b>\$ 3,485,000</b>	<b>(5%)</b>

Our research and development expenses decreased by \$189,000, or 5%, to \$3,296,000 for the three months ended March 31, 2007 as compared to \$3,485,000 for the same period in the prior year. During the fourth quarter of 2006, research funding concluded on our Hedgehog antagonist program under collaboration with Genentech as well as our SMA program under a sponsored research agreement with the SMA Foundation. As a result, our spending on these programs decreased \$1,403,000 for the three-month period ended March 31, 2007 as compared to the same prior year period. As the research funding concluded on programs under collaboration, we reallocated certain of these resources to our internal Targeted Cancer Drug Development Platform programs, which were initiated in the second quarter of 2006 and accounted for \$1,705,000, or 52%, of our first quarter research and development expense. Spending on our collaborator-funded programs with Genentech for the Wnt signaling pathway, Wyeth for the Hedgehog agonist and Procter & Gamble for our Hedgehog topical agonist decreased \$604,000 as a result of fewer researchers supporting the respective programs.

**Table of Contents**

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

	For the Three Months Ended March 31,		Percentage Increase/ (Decrease)
	2007	2006	
Personnel	\$ 704,000	\$ 794,000	(11%)
Occupancy and depreciation	74,000	252,000	(71%)
Legal services	761,000	612,000	24%
Professional and consulting services	330,000	408,000	(19%)
Insurance costs	123,000	105,000	17%
Other general and administrative expenses	287,000	207,000	39%
Stock-based compensation	673,000	508,000	32%
Total general and administrative expenses	\$ 2,952,000	\$ 2,886,000	2%

Our overall spending in general and administrative expenses remained consistent from period to period due to offsetting variances. The increase in legal costs of \$149,000 was the result of increased spending related to our patent portfolio, including filings of foreign patent applications. Other general and administrative expenses, comprised of travel expenses, temporary help, computer and office supplies, increased \$80,000. In addition, stock-based compensation expense increased by \$165,000 in the three months ended March 31, 2007 as compared to the same period in the prior year.

Offsetting these increases, personnel costs decreased \$90,000, occupancy and depreciation costs decreased \$178,000 and professional and consulting services also decreased \$78,000. The decrease in occupancy and depreciation costs related to costs incurred at our 61 Moulton Street facility, which we vacated in June 2006 and for which we increased the reserve for the loss of subtenant income by \$50,000 for the three months ended March 31, 2006. We incurred costs on the 61 Moulton Street facility through August 1, 2006, the date the subtenant defaulted on the sublease. All subsequent costs related to this facility are being charged against the reserve. Our lease obligations for the 61 Moulton Street facility ended on April 30, 2007. The decrease in professional and consulting services was related to expenses incurred as a result of the restatement of our prior financial statements during the first quarter of 2006.

**Liquidity and Capital Resources**

We have financed our operations primarily through license fees 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 March 31, 2007, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$32,740,000, excluding restricted long-term investments of \$202,000. 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 also maintain cash balances with financial institutions in excess of insured limits. 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.

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, legal fees and our equal share of co-development expenses for a basal cell carcinoma product candidate through August 2006 when we opted out of co-development.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. In general, our only source of cash flows from operations for the foreseeable future

---

**Table of Contents**

will be up-front license payments from new collaborations, contingent cash payments for the achievement of development objectives if any are met and funded research and development that we may receive under collaboration agreements. Except for five researchers who are funded by Wyeth through February 9, 2008, substantially all of our research staff is working on developing drug candidates from our Targeted Cancer Drug Development Platform. For the majority of our programs under existing collaborations, our future revenues are limited to the amortization of license fees and to revenues recognized for cash payments that are contingent upon the successful completion of contractually defined development, regulatory and product sales objectives. The timing of or entrance into any new collaboration agreements and any contingent cash payments under existing collaboration agreements cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was \$3,629,000 for the three-month period ended March 31, 2007 as compared to \$873,000 for the three-month period ended March 31, 2006. Cash used in operating activities during the three-month period ended March 31, 2007 was primarily the result of our net loss for the quarter. Increases in operating cash resulting from non-cash charges, including stock-based compensation expense and depreciation, of \$1,391,000 during the three-month period ended March 31, 2007 were offset by a decrease of \$1,258,000 in deferred revenue as a result of license fee amortization under our various collaborations. Cash used in operating activities during the three-month periods ended March 31, 2006 was primarily the result of our net loss for the period partially offset by an increase in working capital and by non-cash charges including stock-based compensation expense and depreciation.

We expect to continue to use cash in operations as we continue to research and develop certain of our existing product candidates and advance our Targeted Cancer Drug Development Platform programs through preclinical development and, we expect, 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 specified other objectives. We also expect that the increase in cash used will be partially offset by anticipated payments made under our collaboration with Wyeth through February 9, 2008, assuming this collaboration continues in accordance with its terms.

Investing activities provided cash of \$1,759,000 for the three-month period ended March 31, 2007 as compared to \$2,018,000 for the three-month period ended March 31, 2006. Cash generated in investing activities resulted principally from \$1,583,000 and \$2,045,000 in net investment sales for the three months ended March 31, 2007 and 2006, respectively. In addition, for the quarter ended March 31, 2007, we received \$202,000 in proceeds from the sale of certain of our assets. We currently do not expect to undertake any significant capital projects during 2007.

Financing activities used cash of approximately \$466,000 for the three-month period ended March 31, 2007, resulting from repayment of \$510,000 on our notes with the Boston Private Bank & Trust Company, \$202,000 of which resulted from the sale of certain of our assets during the quarter. Financing activities used cash of approximately \$306,000 for the three-month period ended March 31, 2006, resulting from repayment of \$308,000 on these same notes.

On March 23, 2005, we converted \$2,250,000 financed under an amended loan agreement with the Boston Private Bank & Trust Company, into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, we are required to make equal monthly payments of \$62,500 plus any accrued interest beginning on May 1, 2005 extending through the 36-month term.

On December 9, 2005, we converted \$1,450,000 financed under a separate loan agreement with the Boston Private Bank & Trust Company, into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. Under the terms of the note payable, we are required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006 extending through the 36-month term. During the quarter ended March 31, 2007, we sold certain of our assets for which we received \$202,000 in proceeds. The total proceeds were remitted to Boston Private Bank & Trust and were applied to the principal obligation

---

**Table of Contents**

outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement.

These loans are collateralized by all of our property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of March 31, 2007, we were in compliance with the sole covenant under each of these financing agreements. The covenant requires us to maintain a minimum working capital ratio. Should we fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

Under the terms of a September 2006 settlement agreement, Micromet was required to repay a note receivable to us in two installments of 1,000,000, the first of which was received on October 17, 2006. Under the terms of the settlement agreement, should Micromet make the second payment on or before April 30, 2007, the second payment would decrease to 800,000. The remaining 800,000, or \$1,067,000 based on the Euro-to-U.S. dollar exchange rate as of March 31, 2007, is included under Accounts receivable within Current assets in our consolidated balance sheet as of March 31, 2007. The final payment of 800,000, or \$1,082,000, was received on April 20, 2007.

We anticipate that existing capital resources at March 31, 2007, together with the payment of all contractually-defined research funding payments but excluding any cash payments that are contingent upon the achievement of defined development objectives under our collaborations and research programs with Wyeth, assuming this contract is not earlier terminated, should enable us to maintain current and planned operations into the fourth quarter of 2008. 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 into the fourth quarter of 2008 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through entering into additional corporate collaborations, equity or debt financings, or from other sources of financing. Our ability to generate sufficient cash flows depends on a number of factors, including the ability of either us, or our collaborators, to obtain regulatory approval to market and commercialize products to treat indications in major commercial markets. 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.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of March 31, 2007.

**Inflation**

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

**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, 2006.

**Table of Contents**

**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 March 31, 2007. 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 March 31, 2007, 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 March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents**

**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, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede the risk factors previously disclosed in Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2006 and we have denoted with an asterisk (\*) in the following discussion those risk factors that are new or materially revised.

**Factors That May Affect Results**

**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.**

We expect to incur substantial operating losses for the foreseeable future, and we have no current sources of material ongoing revenue. As of March 31, 2007, we had an accumulated deficit of approximately \$692,424,000. If we are not able to commercialize any products, whether alone or with a collaborator, we will not achieve profitability. Other than OP-1, a bone-inducing protein developed for use in orthopedic and other therapeutic applications, which we and Stryker Corporation discovered under a former collaboration and which Stryker has subsequently commercialized, we have not commercialized any products to date, either alone or with a third-party collaborator. All of our product 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 proprietary research and development programs in an effort to produce products that we can commercialize. Even if our collaboration agreements provide funding for a portion of our research and development expenses, we will need to generate significant revenues in order to fund our operations and achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business, including the various risks described in this section titled "Risk Factors". 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 product offerings or continue our operations.

**\*We will require additional financing, which may be difficult to obtain and may result in stockholder dilution.**

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 primarily include the need for working capital to:

support our research and development activities for our internal programs, particularly on CUDC-101 and other small molecule multi-targeting inhibitors that we are seeking to develop under our Targeted Cancer Drug Development Platform;

fund our general and administrative costs and expenses; and

expand our infrastructure.

We believe that our existing cash and working capital should be sufficient to fund our operations into the fourth quarter of 2008; however, our future capital requirements may vary from what we currently expect. There are factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing. These factors, many of which are outside our control, include the following:

unanticipated costs in our research and development programs, as well as the magnitude of these programs;



**Table of Contents**

the cost of additional facility requirements;

the unplanned or early termination of any of our collaborative arrangements or decreases in funding of our portion of the research and development programs despite continuation of the collaboration agreement;

the timing, receipt and amount of research funding and contingent cash payments, license, royalty and other payments, if any, from collaborators;

the timing, payment and amount of research funding and contingent cash payments, license, royalty and other payments due to licensors of patent rights and technology used to make, use and sell our product candidates;

the timing, receipt and amount of sales revenues and associated royalties, if any, that we may receive in the future if any of our product candidates are successfully developed and commercialized;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and technology license fees; and

potential difficulties in effectively accessing monies that we have transferred to our Chinese subsidiary to satisfy Chinese capital investment requirements due to currency restrictions and current status of operations.

We expect to seek additional funding in the near term through public or private financings of debt or equity and may seek funding from additional strategic collaborators. The market for biotechnology stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including 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. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research and development activities will be adversely affected.

If we raise additional funds by issuing equity securities, dilution to our stockholders will result. In addition, the terms of such a financing may adversely affect other rights of our stockholders. We also could elect to seek funds through arrangements with collaborators or others that may require us to relinquish rights to certain technologies, product candidates or products.

**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;

the number of product candidates we have and their progress in achieving pre-clinical and clinical development objectives;

the scope, duration and effectiveness of our collaborative arrangements;

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

## Edgar Filing: CURIS INC - Form 10-Q

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting policies or principles; and

the introduction of competitive products and technologies by third parties.

Except for our systemically administered Hedgehog antagonist program, which is in a Phase I clinical trial, all of our programs are in various stages of preclinical drug development. Accordingly, our revenues from the

---

**Table of Contents**

sales of any products resulting from our research and development efforts may not occur for several years, if at all. A significant amount of our expenses are fixed costs such as lease obligations. As a result, we may experience fluctuations in our operating results from quarter to quarter and continue to generate losses. 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.

**We determined that certain accounting errors in our financial statements had a material impact on our previously reported financial information. As a result of this determination, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. The restatement could subject us to securities litigation.**

As discussed in Note 2 of the notes to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2005, in March 2006, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005, and September 30, 2005. The restatement relates primarily to accounting errors in prior periods with respect to our revenue recognition accounting for \$7,509,000 in license and maintenance fee payments paid by Genentech as part of our June 2003 Hedgehog antagonist collaboration with Genentech. We had been recognizing revenue in connection with the \$7,509,000 in payments over an eight-year period based on our estimate that our participation on the steering committees for the collaboration would become inconsequential after the first product was approved in each of the two programs covered under this collaboration, and would therefore no longer represent a performance obligation. Accordingly, from fiscal year 2003 through the third quarter of 2005, we had recognized \$2,239,000 in license fee revenue related to these payments. Following discussions with the SEC, we determined we should not have recognized any of this revenue in 2003, 2004 or 2005. Instead, we have deferred the \$7,509,000 in payments and will recognize this amount as revenue only when we can reasonably estimate when our contractual steering committee obligations will cease or after we no longer have contractual steering committee obligations under this agreement with Genentech. The contractual term of our steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of our steering committee obligations is indefinite and we expect that we will not record any revenue related to these payments for at least several years.

Securities class action litigation has often been brought in connection with restatements of financial statements. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our business, results of operations and financial condition.

**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. For example, as discussed above in March 2006 we determined that certain accounting errors in our financial statements had a material impact on our previously reported financial information. As a result of this

---

**Table of Contents**

determination, we restated our financial results for 2003, 2004 and for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. The restatement could cause our stock price to decline and could subject us to securities litigation. For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates elsewhere in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2006, which was filed with the SEC on March 2, 2007.

**RISKS RELATING TO OUR COLLABORATIONS**

**We are dependent on collaborators for the development and commercialization of many of our key product candidates and for substantially all of our revenue. If we lose any of these collaborators, or if they fail or delay in developing or commercializing our product candidates, our anticipated product pipeline and operating results would suffer.**

The success of our strategy for development and commercialization of certain licensed product candidates depends upon our ability to form and maintain productive and successful strategic collaborations. During the three-month period ended March 31, 2007 and the year ended December 31, 2006, \$2.4 million and \$13.2 million, or 100% and 79%, respectively, of our gross revenue was derived from licensing, research and development and substantive milestone payments we received from collaborators. We currently have collaborations with Genentech, Proctor & Gamble, Wyeth Pharmaceuticals and Ortho Biotech Products, and we are seeking to enter into additional collaborations in the future, including a potential collaboration related to the development of CUDC-101, the first development candidate from our Targeted Cancer Drug Development Platform. Of our existing collaborations, our license agreement with Ortho Biotech and our collaboration with Proctor & Gamble have involved limited development effort and corresponding funding by us. To date, our collaborations with Genentech and Wyeth have involved substantial development effort by us, a significant amount of which has been funded by our respective collaborative partner. Our research effort concluded for both of our Genentech programs and the number of researchers being funded by Wyeth declined from eight to five. Accordingly, the third-party funding of our development effort will be significantly reduced or eliminated. As a result of the decreased need for our internal development efforts and the related reduction in third-party funding, we have been required to terminate the employment of or reassign personnel working on such programs to other programs. We may not be successful in reassigning personnel and we do not have adequate funding on other programs to support such personnel. Moreover, our existing and any future collaborations may not be scientifically or commercially successful.

The risks that we face in connection with these collaborations include the following:

Each of our collaborators has significant discretion in determining the efforts and resources that it will apply to the collaboration. The timing and amount of any cash payments related to future royalties, research support and the achievement of development objectives that we may receive under such collaborative arrangements will depend on, among other things, each collaborator's efforts and allocation of resources.

All of our strategic collaboration agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If any collaborator were to terminate an agreement, we may not have the funds or capability to independently undertake product development, manufacturing and commercialization, which could result in a discontinuation of such program.

Our strategic collaboration agreements permit our collaborators wide discretion in terms of deciding which product candidates to advance to development candidate selection and through the clinical trial process. It is possible for product candidates to be rejected by a collaborator, at any point in the clinical trial process, without triggering a termination of the collaboration agreement with us. In the event of

---

**Table of Contents**

such decisions, we may be adversely affected due to our inability to progress product candidates ourselves.

Our collaborators may develop and commercialize, either alone or with others, products and services that are similar to or competitive with the products and services that are the subject of the collaboration with us.

Our collaborators may change the focus of their development and commercialization efforts or pursue higher-priority programs. The ability of certain of our product candidates to be successfully commercialized could be limited if our collaborators decrease or fail to increase spending related to such product candidates.

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

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new strategic collaborations for the development and commercialization of products in our development pipeline. For example, we are currently seeking a corporate collaboration for CUDC-101 which is the first development candidate selected from our propriety Targeted Cancer Drug Development Platform. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a collaboration for CUDC-101 or any additional strategic collaborations or other alternative arrangements. Our research and development pipeline may be insufficient or our programs' stages of development may be deemed to be too early for collaborative effort. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. Finally, any such strategic alliances or other arrangements may not result in the successful development and commercialization of products and associated revenue.

**RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS**

**We and our collaborators may not achieve our projected research and development goals in the time frames we announce and expect, 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 and clinical trials, anticipated regulatory approval dates and other developments and milestones under our collaboration agreements. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or our collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us or our collaborators and the uncertainties inherent in the regulatory approval process. There can be no assurance that our or our collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we announce or expect, that we or our collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our 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 our 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 product 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 fields of regulatory signaling pathways and functional genomics, which includes our work with Genentech in the field of cancer, with Wyeth in the field of neurology and with Procter &

---

**Table of Contents**

Gamble in the field of hair growth regulation, is highly competitive. Our competitors may discover, characterize and develop important inducing molecules or genes before we do. We also face competition from these and other entities in gaining access to human tissue samples used in our research and development projects.

Many of our competitors have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other biotechnology, 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 commercialization 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, which render our products non-competitive or obsolete.

We expect competition to intensify in cancer generally and, specifically, in regulatory signaling pathway approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known.

**If we or any of our 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.

**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 product candidates. Although we do not currently commercialize any products, claims could be made against us based upon the use of our drug candidates in clinical trials. Product liability claims would require us to spend significant time, money and other resources to defend such claims and could ultimately lead to our having to pay a significant damage award. Product liability insurance is expensive to procure for biopharmaceutical companies such as ours. Although we would maintain product liability insurance coverage for any future clinical trials of our products under proprietary development, it is possible that we will not be able to obtain this product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage would not prove to be adequate to protect us from all potential claims. We currently do not carry any product liability insurance since we are not currently running any proprietary clinical trials. Our only ongoing clinical trial is being run by Genentech, a collaborator.



---

## **Table of Contents**

### **If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our product 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. 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.

### **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 expect 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 and other contingent liabilities; and

dilutive stock issuances.

## **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 and 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 fails to comply with these requirements, 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



---

## **Table of Contents**

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 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 biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office uses to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be 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 sufficiently broad 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 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 product candidates. In some cases, these patents may be owned or controlled by third-party competitors and may impair our ability to exploit our technology. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our product candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners will not be able to develop and commercialize the affected product candidate or candidates.

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

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology 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;

initiation of litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our product candidates do not infringe the third parties' patents;

## Edgar Filing: CURIS INC - Form 10-Q

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;

---

**Table of Contents**

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 product candidates or the intended use of our product 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 our 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 our 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. Patent litigation and other proceedings may also absorb significant management time and expense.

**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 CLINICAL AND REGULATORY MATTERS**

**If preclinical studies and clinical trials of our product candidates are not successful, and we or our collaborators are not able to obtain the necessary regulatory approvals, then we and our collaborators will not be able to commercialize those product candidates on a timely basis, if at all, which would adversely affect our future profitability and success.**

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our 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 product candidates are safe and effective. Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials of our product candidates under development may not be successful. We and our collaborators could experience delays or failures in preclinical or clinical trials of any of our product candidates for a number of reasons. For example:

preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or terminate testing for a particular product candidate;

---

**Table of Contents**

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 product candidates depend on, among other factors, the number of patients we will be required to enroll 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 disorders 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 our collaborators may hold, suspend or terminate our clinical research or the clinical trials of our product 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 our 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 product candidates that we and our 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 have very limited experience in conducting clinical trials. We are currently recruiting clinical/regulatory management but we expect to rely primarily on collaborative partners for our programs under collaboration and, to a lesser extent, contract research organizations for our internal programs for the performance and management of clinical trials of our product candidates. If such third parties fail to perform then we will not be able to successfully develop and commercialize product candidates and grow our business.**

We have limited experience in conducting clinical trials. We expect to rely to varying degrees 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, Proctor & Gamble, Wyeth and Johnson & Johnson. In most instances, such collaboration partners are fully responsible for conducting clinical trials of product candidates, even in the event that we elect to participate in co-development during the clinical trial process. We have also reserved limited rights to further develop and commercialize products that are subject to current collaborations. In these instances and for product candidates associated with new programs, we will be responsible for clinical trials. While we expect that we will add clinical/regulatory employees, we are likely to rely on third parties such as contract research organizations and other similar entities to enroll qualified patients, 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 regulatory requirements or the trial design. If any such events were to occur, efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

In addition, for those product candidates where we are responsible for clinical trials, we must ensure that each such clinical trial is conducted in accordance with the general investigational plan and protocols for the trial.

---

## **Table of Contents**

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, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approvals for and commercialize our product candidates may be delayed.

**The development process necessary to obtain regulatory approval is lengthy, complex and expensive. If we and our collaborative partners do not obtain necessary regulatory approvals, then our business will be unsuccessful and the market price of our common stock could substantially decline.**

We and our collaborative partners will be required to obtain regulatory approval in order to successfully advance our product 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. The process of obtaining FDA and other required regulatory approvals for many of our products under development is further complicated because some of these products use non-traditional or novel materials in non-traditional or novel ways, and the regulatory officials have little precedent to follow. With respect to internal programs to date, 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, or our collaborative partners, also are 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, or our 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 or our collaborators may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell our product candidates in the time periods estimated, if at all. Moreover, if we or our collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

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

Even if we or our 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

---

**Table of Contents**

regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If there is a failure to comply with applicable regulatory requirements, we or our 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 our collaborators are subject to governmental regulations other than those imposed by the FDA. We and our 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 and our 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.

**RISKS RELATING TO MANUFACTURING AND SALES**

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

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop product candidates, apply for regulatory approvals, and commercialize our products under development, we or our 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 product candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product 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 our 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 our 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.



---

**Table of Contents**

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, our 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 product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product 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 our collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;

we and our collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and

we and our 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, Wyeth, Procter & Gamble and Ortho Biotech Products, we have granted our collaborators 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.

---

**Table of Contents**

**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 our 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 or device 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 our 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 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.

**RISKS RELATED TO OUR COMMON STOCK**

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as \$6.59 and as low as \$0.91 per share for the period January 1, 2004 through March 31, 2007. 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;