

CURIS INC  
Form 10-Q  
May 10, 2006  
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**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, 2006

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
Commission File Number: 000-30347

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**CURIS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction)

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

of Incorporation or Organization)

**61 Moulton Street Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02138**  
(Zip Code)

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

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes  No

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

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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 May 3, 2006, there were 48,998,169 shares of the registrant's common stock outstanding.

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

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2006</b>	<b>2005</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 23,148,555	\$ 22,310,298
Marketable securities	19,866,847	21,899,024
Accounts receivable	1,333,226	1,002,511
Prepaid expenses and other current assets	570,479	680,320
<b>Total current assets</b>	<b>44,919,107</b>	<b>45,892,153</b>
Property and Equipment, net	5,048,771	5,347,639
Long-term investment restricted	195,998	195,998
Goodwill	8,982,000	8,982,000
Other intangible assets, net	8,282	27,050
Deposits and other assets, net	463,164	469,413
	<b>\$ 59,617,322</b>	<b>\$ 60,914,253</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Debt, current portion	\$ 1,252,335	\$ 1,260,045
Convertible notes payable, current portion		2,605,280
Accounts payable	1,675,336	1,361,752
Accrued liabilities	4,177,771	2,897,042
Deferred revenue, current portion	1,855,399	1,756,959
<b>Total current liabilities</b>	<b>8,960,841</b>	<b>9,881,078</b>
Debt obligations, net of current portion	1,658,333	1,966,667
Deferred revenue, net of current portion	11,021,840	10,236,725
Other long-term liabilities	642,659	830,204
<b>Total liabilities</b>	<b>22,283,673</b>	<b>22,914,674</b>
Commitments		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 50,045,876 and 48,998,169 shares issued and outstanding, respectively, at March 31, 2006 and 49,374,345 and 48,326,638 shares issued and outstanding, respectively, at December 31, 2005	500,459	493,743
Additional paid-in capital	721,968,336	718,732,982
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)

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Deferred compensation	(114,121)	(242,297)
Accumulated deficit	(684,103,167)	(680,054,173)
Accumulated other comprehensive expense	(26,584)	(39,402)
Total stockholders' equity	37,333,649	37,999,579
	\$ 59,617,322	\$ 60,914,253

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>REVENUES:</b>		
Research and development contracts	\$ 2,572,946	\$ 2,173,654
License fees	291,584	68,100
Substantive milestones		250,000
<b>Gross Revenues</b>	<b>2,864,530</b>	<b>2,491,754</b>
Contra-revenues from co-development with Genentech	(826,100)	(3,304,502)
<b>Net Revenues</b>	<b>2,038,430</b>	<b>(812,748)</b>
<b>COSTS AND EXPENSES:</b>		
Research and development	3,484,643	3,053,023
General and administrative	2,885,738	1,699,652
Amortization of intangible assets	18,768	18,768
<b>Total costs and expenses</b>	<b>6,389,149</b>	<b>4,771,443</b>
<b>Loss from operations</b>	<b>(4,350,719)</b>	<b>(5,584,191)</b>
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	373,846	259,460
Other income		24,958
Interest expense	(72,121)	(81,541)
<b>Total other income</b>	<b>301,725</b>	<b>202,877</b>
<b>Net loss</b>	<b>\$ (4,048,994)</b>	<b>\$ (5,381,314)</b>
<b>Net loss per common share (basic and diluted)</b>	<b>\$ (0.08)</b>	<b>\$ (0.11)</b>
<b>Weighted average common shares (basic and diluted)</b>	<b>48,854,964</b>	<b>47,846,903</b>
<b>Net loss</b>	<b>\$ (4,048,994)</b>	<b>\$ (5,381,314)</b>
Unrealized gain (loss) on marketable securities	12,818	(14,001)
<b>Comprehensive loss</b>	<b>\$ (4,036,176)</b>	<b>\$ (5,395,315)</b>

See accompanying notes to unaudited condensed consolidated financial statements.

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**CURIS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

	Three Months Ended	
	March 31,	
	2006	2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,048,994)	\$ (5,381,314)
Adjustments to reconcile net loss to net cash used in operating activities-		
Depreciation and amortization	326,075	196,817
Stock-based compensation expense	762,885	(49,733)
Non-cash interest expense on notes payable		55,844
Amortization of intangible assets	18,768	18,768
Changes in operating assets and liabilities:		
Accounts receivable	(330,715)	(863,444)
Prepaid expenses and other assets	116,090	49,074
Accounts payable and accrued liabilities	1,399,058	770,523
Deferred revenue	883,555	(193,433)
Total adjustments	3,175,716	(15,584)
Net cash used in operating activities	(873,278)	(5,396,898)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of marketable securities	(15,210,525)	(7,916,071)
Sale of marketable securities	17,255,520	6,370,642
Sale of long-term investments		1,558,333
Purchases of property and equipment	(27,207)	(945,916)
Net cash provided by (used in) investing activities	2,017,788	(933,012)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	2,081	69,872
Proceeds from line of credit		1,110,301
Repayments of obligations under notes payable	(308,334)	
Net cash provided by (used in) financing activities	(306,253)	1,180,173
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	838,257	(5,149,737)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	22,310,298	22,679,924
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 23,148,555	\$ 17,530,187
	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</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 (see Note 5)	\$ 2,638,445	\$

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Issuance of common stock in connection with conversion of note payable to Elan Pharma International, Limited	\$	\$ 3,305,523
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See accompanying notes to unaudited condensed consolidated financial statements.



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**CURIS, INC. AND SUBSIDIARY**

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

**1. Nature of Business**

Curis, Inc. (the Company or Curis) is a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. 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 or unregulated. The Company has successfully used its product development approach to produce multiple compounds with potential use for several different disease indications. The Company's lead development candidate is a topically applied Hedgehog agonist, currently in Phase I clinical trials, that the Company is co-developing with Genentech. The Company has also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders and hair growth regulation. 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, 2005, as filed with the Securities and Exchange Commission on March 31, 2006.

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, 2006 and the results of operations and cash flows for the three-month periods ended March 31, 2006 and 2005. 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 carrying value of property and equipment and intangible assets, assumptions used to calculate stock compensation expense under SFAS 123(R) and the value of certain 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. Financial Statement Reclassifications**

The Company has reclassified (\$50,000) for the three month period ended March 31, 2005 from Stock-based compensation expense to Research and development expenses and General and administrative expenses in the Company's Costs and Expenses section of its Consolidated Statements of Operations and Comprehensive Loss to conform with the current period presentation. Of these amounts, (\$52,000) was reclassified to Research and development expenses and \$2,000 was reclassified to General and administrative expenses for the three month period ended March 31, 2005.

**4. Revenue Recognition**

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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, payments based upon achievement of clinical development milestones and royalties on product sales. The Company follows the provisions of the Securities and Exchange 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

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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 our revenue recognition policy, see Note 4 (c) included within our annual report on Form 10-K, as previously filed with the Securities & Exchange Commission on March 31, 2006.

*(i) Basal Cell Carcinoma Co-Development Accounting*

The Company has recorded cumulative revenues under all of its collaboration agreements with Genentech of \$8,621,000 through March 31, 2006. In addition, at March 31, 2006, the Company's unamortized deferred revenue under its collaborations with Genentech was \$9,859,000. During the first quarter of 2006, the Company incurred \$826,000 in costs related to the co-development of the basal cell carcinoma therapeutic product candidate, which represents amounts owed to Genentech for the reimbursement of the Company's equal share of costs incurred by Genentech under the agreement. The cumulative costs incurred to date on this program were \$7,825,000 as of March 31, 2006. Since the sum of cumulative revenues recorded to-date of \$8,621,000 and the unamortized deferred revenue of \$9,859,000 exceeded cumulative co-development costs incurred to-date of \$7,825,000, the Company has recorded a reduction to revenues, or contra-revenue, of \$826,000 in its consolidated statement of operations and comprehensive loss for the three-month period ended March 31, 2006.

On January 19, 2006, the Company received notification from Genentech that Genentech believed that it had improperly invoiced the Company for the Company's share of basal cell carcinoma co-development costs. As a result of the invoicing errors, Genentech notified the Company that it believes that the Company owes Genentech an incremental \$667,000 for the reimbursement of costs that should have been charged by Genentech to the Company. The Company has disputed that these additional amounts are owed to Genentech, but management believes that it is probable that the Company will be required to pay Genentech some portion of this amount and has estimated that its liability will range from \$325,000 to \$667,000. Accordingly, the Company recorded \$325,000 as Contra revenues from co-development with Genentech at its Consolidated Statement of Operations for the year ended December 31, 2005. The Company has recorded a corresponding \$325,000 within Accrued liabilities at its consolidated balance sheets as of March 31, 2006 and December 31, 2005. As of May 9, 2006, no amounts related to these disputed charges have been paid or adjusted.

*(ii) Preclinical payment received from Procter & Gamble.*

In March 2006, the Company reached the first preclinical development objective in its hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company. The program is focused on the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female pattern hair loss. As part of the initial agreement signed in September 2005, P&G agreed to pay Curis up to \$2,800,000 in cash payments that are contingent upon the achievement of certain preclinical development objectives. The first of two preclinical development objectives was successfully completed and resulted in a payment to Curis of \$1,000,000.

The Company has determined that this payment did not meet all of the conditions outlined in its revenue recognition policy to constitute a substantive milestone. Accordingly, the Company has considered this payment as part of the single unit of accounting for its Procter & Gamble collaboration and the Company is recognizing the \$1,000,000 cash payment on a straight-line basis as its performance obligations are satisfied. The Company currently estimates that its performance obligations will be satisfied in September 2011.

*(iii) Payments due from Micromet*

On October 21, 2004, the Company amended a note receivable with Micromet, a former collaborator. Under the amended note, Micromet is obligated to pay Curis a total amount of EUR 4,500,000, subject to certain conditions. This note had been fully written down by the Company in 2003.

As of March 31, 2006, the Company had received two equal payments of EUR 1,250,000 each in 2004 and 2005. The future amounts are due under the amended note payable upon either the achievement of certain financing objectives or upon an exit event, as defined in the agreement. The Company believes that it is due EUR 533,000 of the remaining EUR 2,500,000 under Micromet's achievement of a financing milestone. During the first quarter of 2006, Micromet entered into a merger agreement with CancerVax, Inc., a U.S. publicly traded biotechnology company. The Company believes that this merger obligates Micromet to pay the remaining EUR 1,467,000 within 30 days of the merger's May 5, 2006 closing date. Micromet has disputed this claim and the Company has filed suit in Germany. In the Company's judgment, neither the EUR 533,000 nor the EUR 1,467,000 are probable of collection as of May 9, 2006. The Company has not recorded any revenues or receivables related to these payments, but will continue to evaluate the probability of collection in future periods. Once payment is reasonably assured, the Company will then record license fee revenues and the related receivables.



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Long-term debt and capital lease obligations consisted of the following at March 31, 2006 and December 31, 2005:

	March 31, 2006	December 31, 2005
Notes payable to financing agencies for capital purchases, including \$19,000 and \$27,000 of accrued interest at March 31, 2006 and December 31, 2005, respectively	\$ 2,911,000	\$ 3,227,000
Convertible subordinated note payable to Becton Dickinson, net of \$27,000 discount and including \$632,000 of accrued interest at December 31, 2005		2,605,000
	2,911,000	5,832,000
Less current portion	(1,253,000)	(3,865,000)
<b>Total long-term debt obligations</b>	<b>\$ 1,658,000</b>	<b>\$ 1,967,000</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. This loan is 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.

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. This loan is collateralized by any equipment and leasehold improvements financed thereunder.

As of March 31, 2006, 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.

On June 26, 2001, the Company received \$2,000,000 from Becton Dickinson under a convertible subordinated note payable in connection with the exercise of an option to negotiate a collaboration agreement. The note payable was repayable at the option of the Company in either cash or issuance of the Company's common stock, also at the option of the Company, at any time up to its maturity date of June 26, 2006. On January 20, 2006, the Company elected to prepay the then-outstanding principal and interest due under the note in the amount of \$2,639,000 by issuing to Becton Dickinson 669,656 shares of the Company's common stock, based on a 10-day trailing average of the Company's closing stock prices resulting in a conversion price of \$3.94 per share. The Company has no further obligations under this convertible note payable.

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On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), or SFAS 123R, *Share-Based Payment* (SFAS 123(R)), which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS No. 123(R) requires that the fair value of such equity instruments be recognized as an expense in the financial statements as services are performed. Prior to January 1, 2006, the Company accounted for share-based payments under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations, as permitted by SFAS Statement No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). In accordance with APB 25, no compensation cost was required to be recognized for options granted to employees that had an exercise price equal to the market value of the underlying common stock on the date of grant and only certain pro forma disclosures were required.

The Company adopted SFAS 123(R) using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the quarter ended March 31, 2006 includes: a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). The results for the prior periods have not been restated.

Effective January 1, 2006, the Company adopted the straight-line attribution method for recognizing compensation expense. Previously, under the pro forma disclosure-only provisions of SFAS 123, the Company used the straight-line attribution method for expense recognition. For all unvested options outstanding as of January 1, 2006, the previously measured but unrecognized compensation expense, based on the fair value at the original grant date, will be recognized on a straight-line basis over the remaining vesting period. For share-based payments granted subsequent to January 1, 2006, compensation expense, based on the fair value on the date of grant, will be recognized on a straight-line basis over the vesting period.

In March 2000, the Board of Directors adopted and, in June 2000, the stockholders approved, the 2000 Stock Incentive Plan (the 2000 Plan), which permits the grant of incentive and non-qualified stock options as well as the issuance of restricted shares. Beginning on January 1, 2001 and continuing through January 1, 2010, the number of shares of common stock reserved for issuance under the 2000 Plan is automatically increased by the lesser of 1,000,000 shares or 4% of outstanding stock on January 1 of each year. As of March 31, 2006, the number of shares of common stock subject to issuance under the 2000 Plan is 16,000,000. At March 31, 2006, 3,984,827 shares are available for grant under the 2000 Plan.

The 2000 Plan permits the granting of incentive and non-qualified stock options and stock awards to employees, officers, directors, and consultants of the Company and its subsidiaries at prices determined by the Company's Board of Directors. Awards of stock may be made to consultants, directors, employees or officers of the Company and its subsidiaries, and direct purchases of stock may be made by such individuals also at prices determined by the Board of Directors. Options become exercisable as determined by the Board of Directors and expire up to 10 years from the date of grant. Awards issued under the 2000 Plan have generally consisted of stock options that vest over a four-year period and are issued with exercise prices that are equal to the quoted market price of the Company's common stock on grant date.

In March 2000, the 2000 Director Stock Option Plan (the 2000 Director Plan) was adopted by the Board of Directors and in June 2000, was approved by the stockholders. The 2000 Director Plan provides for the granting of non-qualified options to non-employee directors. Awards issued under the 2000 Director Plan are generally as follows: (i) new directors receive an option to purchase 25,000 shares of the Company's common stock that vest over a four-year period and that are issued with exercise prices that are equal to the quoted market price of the Company's common stock on grant date; and (ii) each director receives an annual grant from the 2000 Director Plan of a stock option to purchase 5,000 shares of the Company's common stock that vests upon grant date and that is issued with an exercise price that is equal to the quoted market price of the Company's common stock on grant date. As of March 31, 2006, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000. As of March 31, 2006, 140,000 shares are available for grant under the 2000 Director Plan.

In March 2000, the Board of Directors adopted and, in June 2000, the stockholders approved, the 2000 Employee Stock Purchase Plan (the ESPP). The Company has reserved 1,000,000 of its shares of common stock for issuance under the ESPP. Eligible employees may purchase shares at 85% of the lower closing market price at the beginning or ending date of the ESPP period, as defined. During the quarter ended March 31, 2006, no shares were issued under the ESPP. As of March 31, 2006, 732,057 shares are available for future purchase under the ESPP.



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A summary of stock option activity under the 2000 Plan and the 2000 Director Plan for the three months ended March 31, 2006 is presented below:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term
Balance, January 1, 2006	9,340,769	\$ 4.35	6.71
Granted	349,000	\$ 3.99	9.78
Exercised	(1,875)	\$ 1.11	
Forfeited	(15,062)	\$ 3.62	
Expired	(88,686)	\$ 13.98	
Outstanding, March 31, 2006	9,584,146	\$ 4.25	6.64
Exercisable, March 31, 2006	6,267,008	\$ 4.68	5.85

The aggregate intrinsic value of options outstanding at March 31, 2006 was \$1,884,000, of which \$1,397,000 related to exercisable options. The weighted average grant-date fair value of stock options granted during the quarters ended March 31, 2006 and 2005 was \$3.30 and \$3.41, respectively. As of March 31, 2006, there was approximately \$6,021,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to un-vested stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 2.3 years. The intrinsic value of employee stock options exercised during the quarters ended March 31, 2006 and 2005, was \$2,000 and \$80,000, respectively. The total intrinsic value of vested stock options for the quarters ended March 31, 2006 and 2005, was approximately \$1,397,000 and \$4,191,000, respectively.

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. As discussed below, for stock options with a market performance condition, the Company uses a lattice-based option valuation model for specified options. The Black-Scholes option pricing model employs the following key assumptions for option grants.

	Three Months Ended March 31,	
	2006	2005
Expected term (years)	6.25	5
Risk-free interest rate	4.85%	3.8%
Volatility	102%	95%
Dividends	None	None

For the period ended March 31, 2006, the expected term of the options granted was calculated using the simplified approach, as outlined in Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment*. Using this approach, the Company assigned an expected term of 6.25 years to the grants issued during the period ended March 31, 2006. For the period ended March 31, 2005, the expected term of the options granted was calculated using an estimate of the expected term as calculated under SFAS 123. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant.

For the period ended March 31, 2006, expected volatility is based on the annualized daily historical volatility of the Company's stock price since August 1, 2000, the day Curis common stock began trading publicly, through the end of the reporting period. Management believes that the historical volatility of the Company's stock price best represents the volatility of the stock price. For the period ended March 31, 2005, the expected volatility of the options granted was calculated using an estimate of historical volatility as calculated under FAS 123. The Company does not anticipate declaring dividends in the foreseeable future.

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. SFAS 123(R) also requires that the Company recognize compensation expense for only the portion of options that are expected to



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vest. Therefore, management calculated an estimated annual forfeiture rate that is derived from historical employee termination behavior since the inception of the Company, as adjusted. The estimated annual forfeiture rate calculated and estimated for the first quarter of 2006 is 9.1%. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods. The Company does not have a policy to repurchase shares of its common stock upon employee stock option exercises. Further, no such repurchases have been made.

The lattice-based model was used to value a limited number of stock options issued in June 2002 that remained unvested as of January 1, 2006, and that contain a market condition. Under SFAS 123(R), such options are valued using a lattice model. These awards accounted for \$18,000 of the \$832,000 in employee stock-based compensation

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expense recorded by the Company. The lattice model utilizes assumptions including a 7-year expected life, 2.10% risk-free rate, 116% volatility, and a 0% dividend rate.

The Company recorded a total of \$17,530 in compensation expense for the quarter ended March 31, 2006 related to the ESPP. The Company estimated that approximately \$76,500 of its common stock would be purchased on the June 14, 2006 purchase date. This estimate assumed that 25% of the initially enrolled contributions of \$102,000 would be cancelled, either through employee termination or through withdrawal from the ESPP during the purchase cycle ending June 14, 2006. The Company calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model with the following assumptions:

- Expected life: 6 months
- Risk-free interest rate: 4.55%
- Volatility: 85%
- Expected dividend yield: 0%

Stock-based compensation for employees for the quarter ended March 31, 2006 of \$832,000 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 48,854,964 as of March 31, 2006, 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.

The following table shows the pro forma effect on the Company's net income and net income per share for the quarter ended March 31, 2005, had compensation expense been determined based upon the fair value at the grant date for awards consistent with the methodology prescribed by SFAS 123. The pro forma effect may not be representative of expense in future periods since the estimated fair value of stock options on the date of grant is amortized to expense over the vesting period, and additional options may be granted or options may be cancelled in future years:

	<b>March 31,</b>
	<b>2005</b>
Net loss applicable to common stockholders, as reported	\$ (5,381,000)
Add back: employee stock-based compensation included in net loss applicable to common stockholders, as reported	2,000
Less: stock-based employee compensation expense determined under fair value based methods for all awards	(1,178,000)
Pro forma net loss	\$ (6,557,000)
Net loss per common share (basic and diluted)	
As reported	\$ (0.11)
Pro forma	\$ (0.14)

**7. Loss of Subtenant Income**

Effective August 15, 2002, the Company sublet 11,980 square feet, or 67%, of the rentable square footage of its facility at 61 Moulton Street, Cambridge, Massachusetts. The original sublease included a contracted rate of \$40.00 per square foot through the end of the Company's lease term of April 30, 2007. In addition to the sublease payments, the subtenant is required to pay its pro rata share of all building operating costs. The sublease income exceeded the Company's cost of the sublet space so the Company did not record a loss on the lease at the time the Company ceased using the space. The Company has continued to use a portion of the remaining 33% of the leased space.

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In July 2005, the subtenant notified the Company that it expected that it would no longer be able to meet its obligations under the sublease. Effective August 1, 2005, the Company amended its sublease agreement to lower the monthly sublease rent payments to an amount equal to the rate the Company must pay through the remainder of the lease term of April 30, 2007. No other terms of the sublease agreement were changed. Should the tenant fail to comply with the lease as amended, the Company will seek to sublet the 61 Moulton Street facility to a new subtenant but the Company is uncertain that its efforts will be successful. Further, the Company expects that, should it be successful in its subleasing efforts, the sublease rent may be lower than the Company's cost to lease the space.

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In July 2005, the Company estimated that it did not expect to utilize the space, if vacated by the current tenant due to default of the amended sublease terms, for its current or future operations. In addition, the Company believes that its costs under the lease will exceed the estimated future sublease income for the duration of the lease. Based on these factors and the expected decline in sublease income, the Company recorded a charge of \$500,000 in the General and administrative expense line item of its Consolidated Statement of Operations during the second quarter of 2005. The Company increased its estimate to \$550,000 in the first quarter of 2006, which amount is included under Accrued liabilities within Current liabilities in the Company's consolidated balance sheet as of March 31, 2006. As of May 9, 2006, the subtenant continues to meet its obligations under the sublease.

**8. New Accounting Pronouncements**

In February 2006, FASB issued FASB 155, *Accounting for Certain Hybrid Financial Instruments*, an amendment to FASB 133, *Accounting for Derivative Instruments and Hedging Activities*, and FASB 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. FASB 155 provides the framework for fair value remeasurement of any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation as well as establishes a requirement to evaluate interests in securitized financial assets to identify interests. FASB 155 further amends FASB 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The FASB 155 guidance also clarifies which interest-only strips and principal-only strips are not subject to the requirement of FASB 133 and concentrations of credit risk in the form of subordination are not embedded derivatives. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. FASB 155 is not expected to have a material impact on the Company's consolidated financial statements.

In March 2006, FASB issued FASB 156, *Accounting for Servicing of Financial Assets - an amendment of FASB Statement No. 140*. FASB 156 requires the recognition of a servicing asset or servicing liability under certain circumstances when an obligation to service a financial asset by entering into a servicing contract. FASB 156 also requires all separately recognized servicing assets and servicing liabilities to be initially measured at fair value utilizing the amortization method or fair market value method. FASB 156 is effective the beginning of the first fiscal year that begins after September 15, 2006. FASB 156 is not expected to have a material impact on the Company's consolidated financial statements.

**9. Subsequent Events***Extension of Research Funding with Genentech*

In May 2006, the Company entered into a separate amendment to our June 2003 agreement with Genentech. The Company considered the provisions of EITF 00-21 and determined that this agreement was a separate contract from the June 2003 Hedgehog antagonist agreement since this amendment was not contemplated at the time of the June 2003 arrangement, was separately negotiated in order to extend the number of full-time equivalents providing research and development services, both under the Hedgehog antagonist and other collaborative programs between Curis and Genentech, and to provide xenograft tumor samples to Genentech, and was not entered into at or near the time of the June 2003 agreement.

The May 2006 amendment, effective from June 12, 2006 to December 11, 2006, provides for up to seven of the Company's full-time equivalent researchers to provide research and development services for the period of June 12, 2006 until December 11, 2006, in exchange for up to an additional \$918,750, payable quarterly in advance. The agreement also provides Genentech with the option to request that the Company provides up to seven full-time equivalent researchers to perform research services during the period of December 12, 2006 until June 11, 2007, provided that Genentech supplies the Company with adequate notice and that the Company consents to provide research services for this extension period.

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**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 therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. 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 or unregulated. We have successfully used our product development approach to produce multiple compounds with potential use for several different disease indications. For example, we have developed a product candidate for the topical treatment of basal cell carcinoma, which is currently in a Phase I clinical trial and under co-development with Genentech, a collaborator. We have also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders and hair growth regulation. We operate in a single reportable segment: developmental biology products. We expect 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.

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 \$684,103,000 as of March 31, 2006. 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.

Our research programs are conducted both internally and through strategic collaborations. We currently have strategic collaborations with Genentech, Procter & Gamble, and Wyeth Pharmaceuticals, or Wyeth, to develop therapeutics, which 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 another signaling pathway. We have licensed our bone morphogenetic protein, or 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. This program is under development at Centocor, another subsidiary of Johnson & Johnson. In 2005, Centocor entered into a new agreement with us whereby Centocor will fund a portion of a new Curis BMP small molecule screening program. Lastly, a majority of our Spinal Muscular Atrophy, or SMA, research is funded through a sponsored research agreement with the SMA Foundation.

Our current strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be wholly or the majority funded by our collaborators and provide us with the opportunity to receive additional payments if specified milestones are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic license and collaboration agreements included \$18,500,000 in up-front payments, of which we received \$6,629,000 from the sale of shares of our common stock, and also include approximately \$750,000,000 in contingent cash payments that are tied to future preclinical and clinical development and regulatory approval objectives, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are developed, and all contingent cash payments are received upon the successful completion of specified research and/or development objectives and regulatory approvals. In January 2005, we exercised a co-development option with Genentech pursuant to which we are now sharing equally in the U.S. development costs and will share equally in any future U.S. net profits and/or losses in this program. Through March 31, 2006, we had incurred \$7,825,000 in co-development costs under this program. In the future, we plan to continue to seek corporate collaborators for the further development and commercialization of some of our other technologies.

In some cases, we have retained rights under such programs, 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 for the development of a basal cell carcinoma product candidate under our Hedgehog antagonist collaboration with Genentech, as well as retained rights to our Hedgehog agonist for topical applications, for local delivery in cardiovascular applications and for ex vivo use under our broad Hedgehog agonist collaboration with Wyeth.

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### **Recent Developments**

*Extension of Research Funding collaboration with Genentech.* In May 2006, we entered into a separate amendment to our June 2003 Hedgehog antagonist agreement with Genentech. We considered the provisions of EITF 00-21 and determined that this agreement was a separate contract from our June 2003 agreement since this amendment was not contemplated at the time of the June 2003 arrangement, was separately negotiated in order to extend the number of full-time equivalents providing research and development services, both under the Hedgehog antagonist and other collaborative programs between Curis and Genentech, and to provide xenograft tumor samples to Genentech, and was not entered into at or near the time of the June 2003 agreement.

The May 2006 amendment, effective from June 12, 2006 to December 11, 2006, provides for up to seven of our full-time equivalent researchers to provide research and development services for the period of June 12, 2006 until December 11, 2006, in exchange for up to an additional \$918,750, payable quarterly in advance. The agreement also provides Genentech with the option to request that we provide up to seven full-time equivalent researchers to perform research services during the period of December 12, 2006 until June 11, 2007, provided that Genentech supplies us with adequate notice and that we consent to provide research services for this extension period.

*Basal cell carcinoma Phase I clinical trial update.* On May 9, 2006, we announced a status update on our Phase I basal cell carcinoma trial under co-development with Genentech. This clinical trial is a double-blind, randomized, placebo-controlled study that began enrolling patients in the second quarter of 2005. The primary objective of this study is to obtain data about the preliminary safety and tolerability profile of a four-week regimen of the drug candidate. In addition, the companies will evaluate the clinical activity of the drug candidate, defining clinical activity as the complete eradication of the treated basal cell carcinoma lesion, which is determined by clinical and microscopic examinations of the lesions.

This study is enrolling a total of approximately 60 patients over three segments:

Segment 1, a dose-escalation segment in which patients are randomized to receive treatment at one of four dose levels

Segment 2, a segment in which additional patients are treated at the highest dose from the dose-escalation segment (Segment 1)

Segment 3, a pharmacodynamic segment to evaluate biologic activity of the molecule

As previously announced, preliminary data from Segments 1 and 2 revealed no significant safety concerns and suggested some signs of activity, although there was less clinical activity observed than anticipated. Final data from all three segments is planned to be unblinded and analyzed in late 2006; we originally anticipated that data would be available in June 2006.

*Preclinical payment received from Procter & Gamble.* In March 2006, we achieved the first preclinical development objective in our hair growth program with Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company, resulting in a payment to Curis of \$1,000,000. The program is focused upon the potential development of a topical Hedgehog agonist for hair growth disorders, such as male pattern baldness and female hair loss. We have determined that the resulting payment did not meet all of the conditions outlined in our revenue recognition policy to constitute a substantive milestone. Accordingly, we have considered this payment as part of the single unit of accounting for our Procter & Gamble collaboration and we are recognizing the payment as our performance obligations are satisfied.

### **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 upon, 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 clinical trials. We believe that our existing capital resources at March 31, 2006, together with the payment of all contractually-defined payments under our collaborations and research programs with

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Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these programs continue as planned, should enable us to maintain current and planned operations into the at least the second half of 2007, including expected spending related to our co-development of our lead product candidate for the treatment of basal cell carcinoma. Our ability to continue funding our planned operations beyond at least the second half of 2007 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 below in Part II Item 1A Risk Factors.

*Revenue.* We do not expect to generate any revenue from the sale of products for several years, if ever. Substantially all of our gross revenues to date have been derived from license fees, research and development payments, milestone payments and other amounts that we have received from our strategic collaborators and licensees, including Genentech, Wyeth, Ortho Biotech Products/Centocor, Procter & Gamble and the SMA Foundation as well as royalty revenue and payments received upon monetization of certain royalty rights from Stryker Corporation, under the terms of which Stryker paid us \$14,000,000 in cash in 2002 in exchange for the termination of Stryker's future royalty obligations. Since our equal share of the basal cell carcinoma co-development costs will be recorded as a reduction to any revenue recognized under our collaborations with Genentech in accordance with EITF 01-9, we do not expect to generate any net revenue from our two collaborations with Genentech unless and until we obtain FDA approval to commercialize our basal cell carcinoma product candidate. In the future, we will seek to generate revenues from a combination of license fees, research and development funding and milestone payments, royalties resulting from the sale of products that incorporate our intellectual property in connection with strategic licenses and collaborations, and sales of any products we successfully develop and commercialize, either alone or in collaboration with third parties. 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 strategic collaborations, and the amount and timing of payments we receive upon the sale of our products, to the extent that any are successfully commercialized.

*Research and Development Expense.* 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 beginning on January 1, 2006, supplies and reagents, outside service costs including medicinal chemistry, consulting and sponsored research collaborations, and occupancy and depreciation charges. We expense research and development costs as incurred. We believe that our research and development expenses will neither increase or decrease significantly in the short-term. Longer term changes in these expenses are contingent upon our then-current operating plan.

Most of our programs are in various stages of preclinical drug development. The following table summarizes our primary research and development programs, including the current development status of each program. In the table, the term discovery means that we are searching for compounds that may be relevant for treating a particular disease area, early preclinical means we are seeking to obtain initial demonstrations of therapeutic efficacy in preclinical models of human disease, mid-preclinical means we are seeking to obtain multiple demonstrations of efficacy in preclinical models of human disease, late preclinical means we are seeking to obtain both multiple demonstrations of efficacy in preclinical models of human disease and relevant toxicology and safety data required for an investigational new drug, or IND, application filing with the FDA seeking to commence a Phase I clinical trial to assess safety and tolerability in humans, and Phase I means that we are currently treating human patients in a Phase I clinical trial, the principal purpose of which is to evaluate safety of the compound being tested.

All of our estimates below regarding the status of our product development programs are solely our judgments. These estimates may not reflect the beliefs or expectations of our corporate collaborators or licensors, if applicable. Moreover, because of the early stages of development of these programs, our ability and that of our collaborators and licensors to successfully complete preclinical or clinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain.

<b>Product Candidate</b>	<b>Primary Indication</b>	<b>Collaborator/Licensee</b>	<b>Status</b>
Hedgehog topical small molecule antagonist	Basal cell carcinoma	Genentech	Phase I
Hedgehog systemic small molecule or antibody antagonist	Cancer (1)	Genentech	Late preclinical
Discovery research	Undisclosed pathway	Genentech	Discovery
Hedgehog small molecule agonist	Nervous system disorders	Wyeth	Mid-preclinical/ Discovery (2)
Hedgehog small molecule agonist	Hair growth	Procter & Gamble	Late preclinical
BMP-7 protein	Kidney disease and other disorders	Ortho Biotech Products/ Centocor	Mid preclinical
Discovery research	Spinal muscular atrophy	Spinal Muscular Atrophy Foundation	Discovery
Hedgehog agonist/gene	Cardiovascular disease	Internal development (3)	Mid preclinical
BMP-7 small molecule agonists	Kidney disease and other disorders	Centocor	Discovery

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- (1) Genentech has selected a lead clinical candidate for this program, a small molecule antagonist of the Hedgehog pathway. We currently expect that Genentech will file an IND for this program in the second half of 2006.



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(2) Curis and Wyeth are currently evaluating drug candidates in a particular class of agonist small molecule compounds. This class of compounds is currently in a mid-preclinical development status. We are currently also screening for a backup class of Hedgehog agonist compounds. Our efforts to seek a backup class of compounds are in the discovery stage of development.

(3) We have incurred nominal expenses related to our cardiovascular disease program. Our preclinical data relating to this program has been primarily derived from studies conducted at Caritas St. Elizabeth's Medical Center in Boston, Massachusetts. Wyeth has a right of first negotiation to obtain an exclusive license to the cardiovascular applications. If Wyeth declines to exercise its option, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for this program. In the event that Wyeth declines to exercise its option, we will actively explore other licensing opportunities for this program. Should we be successful in our efforts to license this program, either to Wyeth or to another collaborator, any investigational new drug filing will likely be the responsibility of the collaborator.

There is a risk that any drug discovery and development program may not produce products or revenues. Due to uncertainties inherent in drug discovery and development, including those factors described under Part II Item 1A, Risk Factors, we and our collaborators may not be able to successfully develop and commercialize any of the product candidates included in the table above.

Genentech and we are co-developing a Hedgehog small molecule antagonist formulated for the topical treatment of basal cell carcinoma. Genentech and we will share equally in all U.S. development costs. As a result of our election to exercise our co-development option, we have incurred approximately \$7,825,000 through the first quarter of 2006. We expect to incur additional costs to complete Phase II and III clinical trials and the remainder of the regulatory approval process, assuming that Genentech and we successfully complete Phase I and II clinical trials. Due to the uncertainties that are inherent to the drug discovery process, as more fully described below, we are not currently able to estimate the cost and timing to complete the Phase II and III trials and receive regulatory approval of this product candidate, if ever.

Because of the early stages of all of our programs the successful development of our product candidates is highly uncertain. 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 due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

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;

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.

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

*General and Administrative Expense.* General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expense for employee share-based payments beginning on January 1, 2006, in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. We believe that our general and administrative expenses will neither increase or decrease significantly in the short-term. Longer term changes in these expenses are contingent upon our then-current operating plan.

*Strategic Alliances and License Agreements.* Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties.

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We currently have collaborations with Genentech, Procter & Gamble, Wyeth Pharmaceuticals, and Ortho Biotech Products, as well as a screening program with Centocor and a sponsored research program with the Spinal Muscular Atrophy Foundation. For a detailed discussion of these arrangements, please see Management's Discussion and Analysis of

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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, 2005, which is on file with the Securities and Exchange Commission, or SEC. For an update on certain of our programs with Genentech, see Recent Developments of this Quarterly Report on Form 10-Q.

### **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 and the value of certain 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, 2005, which is on file with the SEC. The following sets forth material changes in our critical accounting policies and estimated 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))*. Prior to the adoption of SFAS 123(R), we followed Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, (APB 25) and related interpretations in accounting for share-based payments and had elected the disclosure-only alternative under SFAS 123, *Accounting for Stock-Based Compensation*. Accordingly, when options granted to employees had an exercise price equal to the market value of the stock on the date of grant, no compensation expense was recognized in our financial statements. SFAS 123(R) eliminates the ability to account for share-based compensation transactions using APB 25, and generally requires, instead, that such transactions be accounted for using a fair-value-based method.

We have adopted the modified prospective transition method and determined fair value for a majority of our options using the Black-Scholes valuation model. In June 2002, we had granted options to our directors, officers and certain employees that contained a market condition. As of January 1, 2006, 397,500 shares related to these market-condition options remained unvested. SFAS 123(R) requires that awards with market conditions be valued using a lattice model. Accordingly, we measured the fair value of the market-condition options using a lattice model.

We have recorded employee stock-based compensation expense of \$832,000 for the three-month period ended 2006. Stock-based compensation expense of \$2,000 for the same period in 2005 was recorded applying APB 25. We are estimating that we will record approximately \$3,000,000 to \$4,000,000 in stock-based compensation expense under SFAS 123(R) in 2006.

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 option-pricing model is utilized to derive an estimated fair value. In calculating the estimated fair value of our stock options, we used 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 as discussed above. Both of these models require the consideration of the following six variables for purposes of estimating fair value:

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

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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. The majority of the employee stock option expense recorded in the three-month period ended March 31, 2006 relates to continued vesting of stock options that were granted prior to January 1, 2006. In accordance with the transition provisions of

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SFAS 123(R), the grant date estimates of fair value associated with prior awards have not been changed. The specific valuation assumptions that were utilized for purposes of deriving an estimate of fair value at the time that prior awards were issued are as disclosed in our prior annual reports on Form 10-K, as filed with the SEC.

Upon adoption of SFAS 123(R), we were also required to estimate the level of award forfeitures expected to occur, and record compensation expense only for those awards that are ultimately expected to vest. This requirement applies to all awards that are not yet vested, including awards granted prior to January 1, 2006. Accordingly, we performed a historical analysis of option awards that were forfeited prior to vesting, and ultimately recorded total stock option expense that reflected this estimated forfeiture rate. This analysis will be re-evaluated quarterly and the forfeiture rate will be adjusted as necessary. Ultimately, the actual expense recognized over the vesting period will only be for those shares that vest.

*Long-term receivables.* On October 21, 2004, the Company amended a note receivable with Micromet, a former collaborator. Under the amended note, Micromet is obligated to pay Curis a total amount of EUR 4,500,000, subject to certain conditions. This note had been fully written down by the Company in 2003.

As of March 31, 2006, the Company had received two equal payments of EUR 1,250,000 each in 2004 and 2005. The future amounts are due under the amended note payable upon either the achievement of certain financing objectives or upon an exit event, as defined in the agreement. The Company believes that it is due EUR 533,000 of the remaining EUR 2,500,000 under Micromet's achievement of a financing milestone. During the first quarter of 2006, Micromet entered into a merger agreement with CancerVax, Inc., a U.S. publicly traded biotechnology company. The Company believes that this merger obligates Micromet to pay the remaining EUR 1,467,000 within 30 days of the merger's May 5, 2006 closing date. Micromet has disputed this claim and the Company has filed suit in Germany. In the Company's judgment, neither the EUR 533,000 nor the EUR 1,467,000 are reasonably assured of collection as of May 9, 2006. The Company has not recorded any receivable related to these payments during the first quarter of 2006, but will continue to evaluate the probability of collection in future periods.

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 2006, FASB issued FASB 155, *Accounting for Certain Hybrid Financial Instruments* an amendment to FASB 133, *Accounting for Derivative Instruments and Hedging Activities*, and FASB 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. FASB 155, provides the framework for fair value remeasurement of any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation as well as establishes a requirement to evaluate interests in securitized financial assets to identify interests. FASB 155 further amends FASB 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The FASB 155 guidance also clarifies which interest-only strips and principal-only strips are not subject to the requirement of FASB 133 and concentrations of credit risk in the form of subordination are not embedded derivatives. This statement is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. FASB 155 is not expected to have a material impact on our consolidated financial statements.

In March 2006, FASB issued FASB 156, *Accounting for Servicing of Financial Assets* an amendment of FASB Statement No. 140. FASB 156 requires the recognition of a servicing asset or servicing liability under certain circumstances when an obligation to service a financial asset by entering into a servicing contract. FASB 156 also requires all separately recognized servicing assets and servicing liabilities to be initially measured at fair value utilizing the amortization method or fair market value method. FASB 156 is effective the beginning of the first fiscal year that begins after September 15, 2006. FASB 156 is not expected to have a material impact on our consolidated financial statements.

**Table of Contents****Results of Operations****Quarters Ended March 31, 2006 and March 31, 2005**

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended		Percentage
	March 31,		Increase/ (Decrease)
	2006	2005	(Decrease)
<b>REVENUES:</b>			
<i>Research and development contracts</i>			
Genentech	\$ 1,358,000	\$ 979,000	39%
Wyeth	606,000	607,000	%
Procter & Gamble	53,000		100%
Centocor	100,000		100%
Spinal Muscular Atrophy Foundation	444,000	588,000	(24%)
Other	12,000		100%
Subtotal	2,573,000	2,174,000	18%
<i>License fees</i>			
Genentech	187,000		100%
Wyeth	68,000	68,000	%
Procter & Gamble	36,000		100%
Subtotal	291,000	68,000	328%
<i>Substantive milestones</i>			
		250,000	(100%)
<b>Gross revenues</b>	2,864,000	2,492,000	15%
<b>Contra-revenues from co-development with Genentech</b>	(826,000)	(3,305,000)	(75%)
<b>Net revenue</b>	\$ 2,038,000	\$ (813,000)	351%

The increase in net revenues for the three months ended March 31, 2006 as compared to the same period in the prior year, was primarily due to a \$2,479,000 decrease in contra-revenues. Contra-revenues for the first quarter of 2005 were significantly higher than the same period in 2006 due to significant preclinical costs that had been incurred by Genentech prior to the election to exercise our co-development in January 2005. Upon the exercise of our co-development option, 50% of such costs were payable by us in the first quarter of 2005. Gross revenues also increased from \$2,492,000 for the three months ended March 31, 2005 to \$2,864,000 for the three months ended March 31, 2006, an increase of \$372,000. Research and development contract revenues for the three months ended March 31, 2006 increased \$399,000 from three new collaborations entered into during 2005 – a new collaboration with Genentech entered into April 2005, a collaboration with Procter & Gamble entered into September 2005, and a collaboration with Centocor entered into December 2005. Our license fee revenues increased by \$223,000, to \$291,000 for the three months ended March 31, 2006 as compared to \$68,000 for the same period in the prior year. Our substantive milestones declined to zero from \$250,000 for the quarters ended March 31, 2006 and 2005, respectively. During the first quarter of 2005, we achieved a milestone under our Wyeth collaboration. These increases to gross revenues were offset by \$826,000 in contra-revenue, or a reduction to gross revenues, related to our co-development payments to Genentech. This reduction to gross revenue represents 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 therapeutic product candidate.

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

Research and Development Program	Primary Indication	For the Three Months Ended		Percentage
		March 31, 2006	March 31, 2005	Increase/ (Decrease)
Hh small molecule and antibody antagonist	Cancer	\$ 543,000	\$ 955,000	(43%)
Hh small molecule agonist	Nervous system disorders	682,000	704,000	(3%)
Hh small molecule agonist	Hair loss	277,000	243,000	14%
Discovery research	Spinal muscular atrophy	636,000	661,000	(4%)
Discovery research	Various	1,092,000	542,000	101%
Stock-based compensation	N/A	255,000	(52,000)	590%
Total research and development expense		\$ 3,485,000	\$ 3,053,000	14%

The increase of \$432,000, or 14%, in research and development expenses in the three months ended March 31, 2006 was primarily due to increased spending on our discovery research programs of \$525,000 offset by decreased spending of \$412,000 on the Hedgehog, or Hh, small molecule and antibody antagonist program under collaboration with Genentech. In addition, stock-based compensation expense increased by \$307,000 in the three months ended March 31, 2006 as compared to the prior year. The increase in stock-based compensation is due to the adoption of SFAS 123(R) on January 1, 2006.

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

	For the Three Months Ended		Percentage
	March 31, 2006	March 31, 2005	Increase/ (Decrease)
Personnel	\$ 794,000	\$ 745,000	7%
Occupancy and depreciation	252,000	134,000	88%
Legal services	612,000	291,000	110%
Professional and consulting services	408,000	279,000	46%
Insurance costs	105,000	107,000	(2%)
Other general and administrative expenses	207,000	142,000	46%
Stock-based compensation	508,000	2,000	25,300%
Total general and administrative expenses	\$ 2,886,000	\$ 1,700,000	70%

The increase in total general and administrative expenses for the three months ended March 31, 2006, was primarily due to an increase in stock-based compensation expense of \$506,000 in the three months ended March 31, 2006 as compared to the prior year. The increase in stock-based compensation is due to the adoption of SFAS 123(R) on January 1, 2006. Also, increases in legal costs of \$321,000 related to increased patent costs and an increase in professional and consulting services of \$129,000 related to the restatement of our financial statements. In addition, occupancy and depreciation expenses increased \$118,000 due to an increase in utility costs and other general and administrative expenses increased \$65,000. Other general and administrative expenses are comprised of travel expenses, temporary help, computer and office supplies.

*Interest Income.* Interest income was \$374,000 for the three-month period ended March 31, 2006 as compared to \$259,000 for the three-month period ended March 31, 2005, an increase of \$115,000, or 44%. The increase in interest income resulted from higher interest rates for the period ended March 31, 2006.



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*Other Income.* Other income for the three-month period ended March 31, 2006 was zero as compared to \$25,000 for the prior year period.

*Interest Expense.* Interest expense for the three-month period ended March 31, 2006 was \$72,000 as compared to \$82,000 for the three-month period ended March 31, 2005, a decrease of \$10,000, or 12%. The decrease in interest expense is due to the conversion of the note payable to Becton Dickinson in January 2006 offset by an increase in interest expense that was attributable to an increase in outstanding borrowings under our loan agreements with the Boston Private Bank & Trust Company. At March 31, 2006, we had outstanding debt of \$2,892,000 under these loan agreements compared to \$2,250,000 at March 31, 2005.

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**Liquidity and Capital Resources**

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

At March 31, 2006, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$43,015,000, excluding restricted long-term investments of \$196,000. Our cash and cash equivalents are highly liquid investments with maturities of three months or less at date of purchase and may consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government and corporate 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, and legal fees. In addition, during 2005 we began incurring significant costs to fund the equal share of our co-development expenses of our basal cell carcinoma product candidate, which is under development with Genentech and is currently in a Phase I clinical trial. During the first quarter of 2006, we recorded \$826,000 in contra revenues at our consolidated statement of operations in connection with these co-development costs. To date, the 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 will be up-front license payments, if any, payments for the achievement of milestones, if any, and funded research and development that we may receive under collaboration agreements. The timing of any new collaboration agreements and any payments under collaboration agreements cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was \$873,000 for the three-month period ended March 31, 2006 as compared to \$5,397,000 for the three-month period ended March 31, 2005. Cash used in operating activities during the three-month periods ended March 31, 2006 and 2005 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, depreciation, amortization and non-cash interest expense.

We expect to continue to use cash in operations as we continue to develop our products in clinical trials and advance new products into preclinical development. In addition, in the future we may owe royalties and other contingent payments to our licensees 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 collaborations with Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these collaborations and research programs continue in accordance with their terms.

Investing activities provided cash of \$2,018,000 for the three-month period ended March 31, 2006 as compared to \$933,000 used in the three-month period ended March 31, 2005. Cash generated in investing activities resulted principally from \$2,045,000 in net investment sales for the three months ended March 31, 2006. Net cash used in investing activities resulted principally from \$946,000 in fixed asset purchases for the three months ended March 31, 2005. We expect that we will continue to use cash in our investing activities; however, we expect that our cash spend on fixed asset purchases will decline in 2006 since we currently do not expect to undertake any significant capital projects.

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Financing activities used cash of approximately \$306,000 for the three-month period ended March 31, 2006, resulting from repayment of \$308,000 in debt for the purchase of fixed assets. Financing activities provided cash of approximately \$1,180,000 for the three-month period ended March 31, 2005, resulting from proceeds of \$1,110,000 from the issuance of debt for the purchase of fixed assets and \$70,000 received upon stock option exercises.

On March 23, 2005, we 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, 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. This loan is 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. On December 9, 2005, we 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, 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. This loan is collateralized by any equipment and leasehold improvements financed thereunder. As of December 31, 2005, we were in compliance with the sole covenant under each of the 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.

Since August 2002, we have sublet 11,980 of the 17,800 square feet of our facility at 61 Moulton Street in Cambridge, Massachusetts. Under the terms of our sublease, as amended, we receive sublease payments that total approximately \$320,000 per year. In addition, we receive approximately \$50,000 for facilities-related services and also receive a pro-rata portion of the 61 Moulton Street facility overhead, including real estate taxes and utilities. In July 2005, our subtenant informed us that it was terminating approximately 50% of its workforce and that it may encounter difficulties meeting its sublease obligations beyond December 2005. Our lease obligation on our 61 Moulton Street facility extends to April 2007 and our lease obligation from May 2006 to April 2007 is approximately \$472,000, excluding real estate taxes and other operating costs. Should our current subtenant vacate the 61 Moulton facility, as expected, we will seek to sublet all or part of the facility. There is no guarantee that we will be able to sublease the premises or that any sublease would be on terms that are similar to our current sublease. Accordingly, we have increased our estimated loss to \$550,000 reflected under accrued liability at our consolidated balance sheet as of March 31, 2006. We recorded expense of \$500,000 to our General and Administrative expenses in the second quarter of 2005 and we recorded \$50,000 in the first quarter of 2006. As of May 9, 2006, the subtenant continues to meet its obligations under the sublease.

Pursuant to our co-development arrangement with Genentech, under which we share equally in U.S. development costs and any future net profits and/or losses derived from sales in the U.S. of a therapeutic product candidate for the topical treatment of basal cell carcinoma, we incurred \$7,825,000 in development expenses through the first quarter of 2006. We expect to incur additional costs to complete phase II and III clinical trials and complete the regulatory approval process, assuming that Genentech and we successfully complete phase I and II clinical trials.

On January 19, 2006, we received notification from Genentech that Genentech believed that it had improperly invoiced us for our share of basal cell carcinoma co-development costs. As a result of the invoicing errors, Genentech notified us that it believes that we owe Genentech an incremental \$667,000 for the reimbursement of costs that should have been charged by Genentech to us. We have disputed that these additional amounts are owed to Genentech, but management believes that it is probable that we will be required to pay Genentech some portion of this amount and have estimated that our liability will range from \$325,000 to \$667,000. Accordingly, we recorded \$325,000 as Contra revenues from co-development with Genentech at our Consolidated Statement of Operations for the year ended December 31, 2005. We have recorded a corresponding \$325,000 within Accrued liabilities at our Consolidated Balance Sheet as of December 31, 2005. As of May 9, 2006, no amounts related to these disputed charges have been paid or adjusted.

We anticipate that existing capital resources at March 31, 2006, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, Procter & Gamble and the SMA Foundation, assuming these contracts are not earlier terminated, should enable us to maintain current and planned operations at least into the second half of 2007, including spending related to the co-development of our basal cell carcinoma product candidate under development with Genentech. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials for the foreseeable future. Our ability to continue funding planned operations beyond the second half of 2007 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 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.

**Table of Contents****Contractual Obligations**

In addition to our loan agreement with Boston Private Bank & Trust Company, we also have contractual obligations related to our facility lease, research services agreements, consulting agreements, and license agreements. The following table summarizes our contractual obligations due by the period indicated at March 31, 2006:

	(amounts in 000 s)(1)						Total
	Remainder						
	of 2006	2007	2008	2009	2010	Thereafter	
Debt obligations under note payable	\$ 1,068	1,342	758				3,168
Operating lease obligations	\$ 1,067	1,105	948	948	948		5,016
Outside service obligations(2)	\$ 878						878
Licensing obligations	\$ 438	82					520
<b>Total future obligations (3)</b>	<b>\$ 3,451</b>	<b>\$ 2,529</b>	<b>\$ 1,706</b>	<b>\$ 948</b>	<b>\$ 948</b>	<b>\$</b>	<b>\$ 9,582</b>

(1) Obligations do not include amounts we will owe Genentech under our co-development arrangement.

On January 19, 2006, we received notification from Genentech that Genentech believed that it had improperly invoiced Curis for our share of basal cell carcinoma co-development costs. As a result of the invoicing errors, Genentech notified Curis that it believes that we owe Genentech an incremental \$667,000 for the reimbursement of costs that should have been charged by Genentech to Curis. We have disputed that these additional amounts are owed to Genentech, but management believes that it is probable that we will be required to pay Genentech some portion of this amount and has estimated that our liability will range from \$325,000 to \$667,000. Accordingly, we have recorded \$325,000 within accrued liabilities at our consolidated balance sheet as of March 31, 2006. As of May 9, 2006, no amounts related to these disputed charges have been paid or adjusted.

(2) Outside service obligations consist of agreements we have with outside labs, consultants and various other service organizations.

(3) In the future, we may owe royalties and other contingent payments to our licensees based on the achievement of developmental milestones, product sales and specified other objectives. These potential future obligations are not included in the above table.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of March 31, 2006.

**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**

We invest our cash balances in excess of operating requirements in cash equivalents and short-term marketable securities, generally money market funds, corporate debt and government securities with an average maturity of less than one year. All marketable securities are considered available for sale. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, because of the short-term nature of the marketable securities, we do not believe that interest rate fluctuations would materially impair the principal amount of our investments. Our investments are investment grade securities, and deposits are with investment grade financial institutions. We believe that the realization of losses due to changes in credit spreads is unlikely as

we expect to hold our investments to maturity. We do not use derivative financial instruments in our investment portfolio. We have operated primarily in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations.

**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, 2006. 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, 2006, 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, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, 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 2005 Annual Report on Form 10-K for the year ended December 31, 2005 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 recently 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 have 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.**

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 primarily relating 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 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 2005, 2004 or 2003. 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.

We have also restated previously reported research and development expenses associated with \$410,000 in license fee payments that were payable to university licensors in connection with the June 2003 Hedgehog antagonist collaboration with Genentech. We had previously capitalized this amount as Prepaid expenses and other current assets and Deposits and other assets in our consolidated balance sheets and amortized this amount to research and development expense as the related license fee was recognized. We have determined that we should have instead recognized the entire \$410,000 immediately as research and development expense in June 2003.

In connection with the restatement, we have also corrected other previously identified immaterial errors which had previously been corrected through a cumulative adjustment to the consolidated financial statements in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. The restatement allocates the adjustment among the correct periods.

The restatement could result in a decline in our stock price and securities class action litigation. In the past, 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 will be expensive and will 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.

**We have incurred substantial losses, we expect to continue to incur substantial losses and we may never achieve profitability.**

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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, 2006, we had an accumulated deficit of approximately \$684,103,000. If we are not able to commercialize any products, whether alone or with a collaborator, we will not achieve profitability. Other than OP-1, which



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we and Stryker discovered under a former collaboration and 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 on our research and development programs in order to produce products which 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 operation 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 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 dilute our existing shareholder ownership interest in us.**

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:

fund our portion of the U.S. development costs for a basal cell carcinoma drug candidate pursuant to our equal cost-sharing co-development arrangement with Genentech;

support our research and development activities for our internal programs, including our program in cardiovascular disease and any unfunded portion of our small molecule discovery screening programs;

expand our infrastructure; and

fund our general and administrative costs and expenses.

We believe that our existing cash and working capital should be sufficient to fund our operations until at least the second half of 2007; however, our future capital requirements may vary from what we expect. There are factors that may 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:

continued progress in our research and development programs, as well as the magnitude of these programs;

the time and cost, including unplanned cost, involved in advancing clinical trials for the basal cell carcinoma drug candidate being co-developed with Genentech;

the cost of additional facilities requirements;

our ability to establish and maintain collaborative arrangements;

the timing, receipt and amount of research funding and milestone, license, royalty, profit-sharing and other payments, if any, from collaborators;

the timing, payment and amount of research funding and milestone, 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 receive from our product candidates in the market; and

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

We expect to seek additional funding through public or private financings of debt or equity and may seek additional funding from additional strategic collaborators or additional foundations, such as the funding that we were awarded under our Spinal Muscular Atrophy Foundation research grant. However, the market for biotechnology stocks in general, and the market for our common stock in particular, is highly volatile. Due to various factors, including market conditions and the 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.

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**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 Risk Factors. As disclosed in our annual report on Form 10-K, we have 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.

### **RISKS RELATING TO OUR COLLABORATIONS**

**If the clinical trial for our lead product candidate currently under co-development with Genentech for the treatment of basal cell carcinoma is terminated or is otherwise unsuccessful, then we may not be able to successfully develop and commercialize a product based upon this technology and the market price of our common stock could decline.**

We have devoted a substantial portion of our working capital to our co-development program with Genentech, pursuant to which we are co-developing a topical antagonist of the Hedgehog signaling pathway for the treatment of basal cell carcinoma. This product candidate is the only compound of ours that is currently in clinical trials. The product candidate is currently the subject of a phase I clinical trial and the trial is expected to be completed in the first half of 2006. The primary objective of the phase I clinical trial was to obtain data about the safety and tolerability of a four-week regimen of the drug candidate. In addition, Genentech and we are evaluating the clinical activity of the drug candidate, where activity is defined as the complete eradication of the treated basal cell carcinoma lesion and is determined by clinical and microscopic examinations of the lesions. In January 2006, we announced that preliminary results of the first of three segments of the study in which less clinical activity was observed than anticipated. Based on these data, the internal data review board recommended that Genentech and we temporarily suspend further enrollment in the second segment of the trial, in which additional patients were to be treated at the highest dose level from the dose escalation segment. The companies will determine to re-open enrollment in this segment based on a secondary interim analysis that will occur at a later date. The internal data review board also recommended that a third segment of the trial that is evaluating biological activity using a pharmacodynamic endpoint be enrolled as planned.

Genentech and we expect to have final results from the phase I clinical trial during the second half of 2006. When the final results are obtained, Genentech and we will determine whether this drug candidate should proceed to phase II clinical trials. Should this drug candidate not progress into phase II clinical trials, we and Genentech will evaluate various criteria, including the data from the biological activity segment of the trial, and determine the alternatives for the basal cell carcinoma program. Possible scenarios include, but are not limited to the following:

extending the duration of the treatment regimen of the existing drug candidate,

developing a new topical formulation of the existing drug candidate,

selection of a new drug candidate,

negotiation of the return of the compounds to us for our further development, or

termination of the basal cell carcinoma drug program.

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If we and Genentech determine that the results of the phase I trial are unfavorable or only marginally favorable or otherwise determine to terminate the basal cell carcinoma drug program then our ability to successfully develop and commercialize products on the basis of this technology 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 may decline.

**We are dependent on collaborators for the development and commercialization of many of our product candidates and for a significant portion 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 product candidates depends upon our ability to form and maintain productive strategic collaborations. We currently have strategic collaborations with Genentech, Wyeth, Procter & Gamble, Centocor, and Ortho Biotech Products. During the three month period ended March 31, 2006 and the year ended December 31, 2005, \$2.4 million and \$9.6 million, or 84% and 85%, respectively, of our gross revenue was derived from licensing and research and development payments received from these collaborators. We hope to enter into additional collaborations in the future. 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 they will apply to the collaboration. The timing and amount of any future royalty, profit-sharing and milestone revenue that we may receive under such collaborative arrangements will depend on, among other things, such 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 available to independently undertake product development, manufacturing and commercialization and we may not have the funds or capability to do this, 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 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 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. 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 additional strategic collaborations or other alternative arrangements. Our research and development pipeline may be insufficient or our programs may be deemed 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 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, with Procter & Gamble in the field of hair growth regulation, is highly competitive. A number of entities are seeking to identify and patent randomly sequenced genes and gene

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fragments, typically without specific knowledge of the function that such genes or gene fragments perform. 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 DNA 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. As a result, they may be more successful in commercialization and/or may develop competing products more rapidly and at a lower cost. For those programs that are subject to a collaboration agreement, competitors may discover, develop and commercialize products which render our products non-competitive or obsolete.

We expect competition to intensify in genomics research and regulatory signaling pathways as technical advances in the field are made and become more widely known.

**While many of our technologies are subject to collaborations, our remaining technologies that are available for internal programs have several potential applications. We have limited resources and are pursuing a strategy of undertaking foundation-funded research for orphan disease indications. The limited markets that are associated with such indications as well as conditions of funding arrangements may result in our failure to capitalize on other potentially profitable applications of our technologies.**

We have limited financial and managerial resources to devote to new internal programs. These limitations have led us to adopt a strategy where we have undertaken funded research for certain orphan disease indications and to forego the exploration of other product opportunities. While our new technologies may permit us to work in multiple areas, resource commitments may require trade-offs resulting in delays in the development of certain programs or research areas, which may place us at a competitive disadvantage. In addition, our funded research includes screening of compounds that are not proprietary to us and may result in identification of a drug candidate that would not result in a commercially viable product and/or may divert resources away from other market opportunities, which ultimately prove to be more profitable.

**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.

**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 and developing human health care products, could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. 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 maintain product liability insurance coverage for the clinical trials of our products under development, it is possible that we will not be able to obtain additional product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage will not prove to be adequate to protect us from all potential claims.

**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 highly depend upon our senior management and scientific staff. 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. Key members of our senior management team include Daniel R. Passeri, our President and Chief Executive Officer and Dr. Lee L. Rubin, our Executive Vice President and Chief Scientific Officer. Our executive officers, including these individuals, can terminate their employment with us at any time. The loss of the services of any of our executive





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officers may significantly delay or prevent the achievement of product research and development and other business objectives. 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.

**If we make any acquisitions, we will incur a variety of costs and may never successfully integrate the acquired business into ours.**

We may attempt to acquire businesses, technologies, services or products that we believe are a strategic complement to our business model. We may encounter operating difficulties and expenditures relating to integrating an acquired business, technology, service or product. These acquisitions may also absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. We may also make dilutive issuances of equity securities, incur debt, experience a decrease in the cash available for our operations, or incur contingent liabilities in connection with any future acquisitions.

### **RISKS RELATING TO INTELLECTUAL PROPERTY**

**If we or any of our licensees and 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 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 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 which the United States Patent and Trademark Office uses to grant patents, and the standards which 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 enterprise 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

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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 which 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

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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 which 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;

participation in interference or opposition proceedings to determine the priority of invention if our competitors file patent applications that claim technology also claimed by us;

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 which 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 agreements with our employees, consultants and other third-party contractors as well as through other security measures. These confidentiality 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**

\*

**We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates as well as certain preclinical testing. If clinical trials are not successful, or if our collaborators decide to terminate development efforts for a particular compound, or if we or our collaborators are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates.**

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. We have limited experience in conducting clinical trials and expect to rely primarily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials, if any, of our product candidates under development may not be successful. We and our collaborators could experience delays in preclinical or clinical trials of any of our product candidates which obtain

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unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. 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. The results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials. Furthermore, the timing and completion of clinical trials, if any, 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.

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. Also, 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. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials.

For example, in January 2006, we announced preliminary results of the first of three segments of our phase I clinical trial of a basal cell carcinoma product candidate, under co-development with Genentech, in which less clinical activity was observed than anticipated. Based on these data, the internal data review board recommended that Genentech and we temporarily suspend further enrollment in the second segment of the trial, in which additional patients were to be treated at the highest dose level from the dose escalation segment. The internal data review board also recommended that a third segment of the trial that is evaluating biological activity using a pharmacodynamic endpoint be enrolled as planned. Genentech and we expect to have final results from the phase I clinical trial during the first half of 2006. When the final results are obtained, Genentech and we will determine whether this drug candidate should proceed to phase II clinical trials.

The failure of our phase I clinical trial under co-development with Genentech, or the failure of any other clinical trials we may undertake in the future, could adversely affect our ability to successfully develop and commercialize products on the basis of our technologies, our reputation and our ability to raise additional capital and the value of an investment in our stock price may decline.

**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 will substantially decline.**

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product.

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.

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

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

If there is a failure to comply with applicable regulatory requirements, we or our collaborator may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, 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 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 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 PRODUCT 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 products, apply for regulatory approvals, and commercialize our products, we or our collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, at acceptable quality and cost 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 on a timely basis or at all or are contaminated or otherwise lost, 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.

Any contract manufacturers that we enter into manufacturing arrangements with 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. Failure of contract manufacturers or 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,



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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 these 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 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 which 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.

### **RISKS RELATED TO OUR COMMON STOCK**

**Our stock price will 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 \$2.28 per share for the period January 1, 2004 through March 31, 2006. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical- and biotechnology-based company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

announcements regarding new technologies by us or our competitors;



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market conditions in the biotechnology and pharmaceutical sectors;

rumors relating to us or our competitors;

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

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

actual or anticipated changes to our research and development plans;

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

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

any intellectual property lawsuits involving us;

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sales of large blocks of our common stock;

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

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

FDA or international regulatory actions; and

general market conditions.

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. As of March 31, 2006, we had outstanding approximately 49.0 million shares of common stock. Substantially all of these shares may also be resold in the public market at any time. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized blank check preferred stock and our stockholders are limited in their ability to call special stockholder meetings. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control transaction.

**Item 6. EXHIBITS**

(a) Exhibits.

See exhibit index.

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**SIGNATURE**

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

CURIS, INC.

Dated: May 10, 2006

By:

/s/ MICHAEL P. GRAY

**Michael P. Gray**

Vice President of Finance and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
31.1	Certification of the Chief Executive Officer
31.2	Certification of the Chief Financial Officer
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to 906 of the Sarbanes-Oxley Act of 2002