

CURIS INC  
Form 10-Q  
November 09, 2006  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 SEPTEMBER 30, 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

of Incorporation or Organization)

61 Moulton Street

Cambridge, Massachusetts  
(Address of Principal Executive Offices)

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

04-3505116  
(I.R.S. Employer

Identification No.)

02138  
(Zip Code)

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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.  Yes  No

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

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

As of November 6, 2006, there were 49,234,657 shares of the registrant's common stock outstanding.

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

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

|  | September 30,<br>2006 | December 31,<br>2005 |
|--|-----------------------|----------------------|
| <b>ASSETS</b>  |                       |                      |
| Current Assets:  |                       |                      |
| Cash and cash equivalents  | \$ 21,104,181         | \$ 22,310,298        |
| Marketable securities  | 14,083,181            | 21,899,024           |
| Accounts receivable  | 3,009,543             | 1,002,511            |
| Prepaid expenses and other current assets  | 769,380               | 680,320              |
| <b>Total current assets</b>  | <b>38,966,285</b>     | <b>45,892,153</b>    |
| Property and Equipment, net  | 4,452,842             | 5,347,639            |
| Other Assets:  |                       |                      |
| Long-term investments restricted   | 201,844               | 195,998              |
| Goodwill, net  | 8,982,000             | 8,982,000            |
| Deposits and other assets  | 186,975               | 496,463              |
|  | <b>\$ 52,789,946</b>  | <b>\$ 60,914,253</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                       |                      |
| Current Liabilities:   |                       |                      |
| Debt, current portion  | \$ 1,247,822          | \$ 1,260,045         |
| Convertible notes payable, current portion   |                       | 2,605,280            |
| Accounts payable   | 1,316,447             | 1,361,752            |
| Accrued liabilities  | 2,089,269             | 2,897,042            |
| Deferred revenue, current portion  | 1,974,828             | 1,756,959            |
| <b>Total current liabilities</b>   | <b>6,628,366</b>      | <b>9,881,078</b>     |
| Debt obligations, net of current portion   | 1,041,667             | 1,966,667            |
| Deferred revenue, net of current portion   | 10,443,638            | 10,236,725           |
| Other long-term liabilities  | 556,971               | 830,204              |
| <b>Total liabilities</b>   | <b>18,670,642</b>     | <b>22,914,674</b>    |
| Commitments  |                       |                      |
| Stockholders' Equity:  |                       |                      |
| Common stock, \$0.01 par value 125,000,000 shares authorized; 50,212,652 and 49,164,945 shares issued and outstanding, respectively, at September 30, 2006 and 49,374,345 and 48,326,638 shares issued and outstanding, respectively, at December 31, 2005 | 502,127               | 493,743              |
| Additional paid-in capital   | 724,232,920           | 718,732,982          |
| Treasury stock (at cost, 1,047,707 shares)   | (891,274)             | (891,274)            |
| Deferred compensation  | (165,947)             | (242,297)            |
| Accumulated deficit  | (689,563,989)         | (680,054,173)        |
| Accumulated other comprehensive gain (loss)  | 5,467                 | (39,402)             |
| <b>Total stockholders' equity</b>  | <b>34,119,304</b>     | <b>37,999,579</b>    |

\$ 52,789,946      \$ 60,914,253

See accompanying notes to unaudited condensed consolidated financial statements.

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

|   | Three Months Ended    |                       | Nine Months Ended     |                        |
|---|-----------------------|-----------------------|-----------------------|------------------------|
|   | September 30,<br>2006 | September 30,<br>2005 | September 30,<br>2006 | September 30,<br>2005  |
| <b>REVENUES:</b>  |                       |                       |                       |                        |
| License fees  | \$ 2,605,638          | \$ 258,544            | \$ 3,218,885          | \$ 582,243             |
| Research and development contracts                        | 2,020,236             | 2,626,072             | 7,376,594             | 7,358,750              |
| Substantive milestones                                    |                       |                       |                       | 250,000                |
| <b>Gross Revenues</b>                                     | <b>4,625,874</b>      | <b>2,884,616</b>      | <b>10,595,479</b>     | <b>8,190,993</b>       |
| Contra-revenues from co-development with Genentech        | (355,435)             | (819,491)             | (1,727,727)           | (5,697,993)            |
| <b>Net Revenues</b>                                       | <b>4,270,439</b>      | <b>2,065,125</b>      | <b>8,867,752</b>      | <b>2,493,000</b>       |
| <b>COSTS AND EXPENSES:</b>                                |                       |                       |                       |                        |
| Research and development                                  | 3,669,368             | 3,691,261             | 10,994,327            | 10,409,583             |
| General and administrative                                | 2,302,469             | 1,832,802             | 8,150,372             | 6,141,013              |
| Amortization of intangible assets                         |                       | 18,768                | 27,050                | 56,304                 |
| <b>Total costs and expenses</b>                           | <b>5,971,837</b>      | <b>5,542,831</b>      | <b>19,171,749</b>     | <b>16,606,900</b>      |
| <b>Loss from operations</b>                               | <b>(1,701,398)</b>    | <b>(3,477,706)</b>    | <b>(10,303,997)</b>   | <b>(14,113,900)</b>    |
| <b>OTHER INCOME (EXPENSE):</b>                            |                       |                       |                       |                        |
| Interest income   | 404,542               | 319,208               | 1,172,702             | 861,869                |
| Other income (expense)                                    | (178,532)             |                       | (178,532)             | 24,958                 |
| Interest expense  | (61,239)              | (92,843)              | (199,989)             | (263,519)              |
| <b>Total other income, net</b>                            | <b>164,771</b>        | <b>226,365</b>        | <b>794,181</b>        | <b>623,308</b>         |
| <b>Net loss</b>   | <b>\$ (1,536,627)</b> | <b>\$ (3,251,341)</b> | <b>\$ (9,509,816)</b> | <b>\$ (13,490,592)</b> |
| <b>Net loss per common share (basic and diluted)</b>      | <b>\$ (0.03)</b>      | <b>\$ (0.07)</b>      | <b>\$ (0.19)</b>      | <b>\$ (0.28)</b>       |
| <b>Weighted average common shares (basic and diluted)</b> | <b>49,146,609</b>     | <b>48,178,626</b>     | <b>49,012,538</b>     | <b>47,998,663</b>      |
| <b>Net loss</b>   | <b>\$ (1,536,627)</b> | <b>\$ (3,251,341)</b> | <b>\$ (9,509,816)</b> | <b>\$ (13,490,592)</b> |
| Unrealized gain (loss) on marketable securities           | 19,539                | 25,585                | 44,869                | 45,276                 |
| <b>Comprehensive loss</b>                                 | <b>\$ (1,517,088)</b> | <b>\$ (3,225,756)</b> | <b>\$ (9,464,947)</b> | <b>\$ (13,445,316)</b> |

See accompanying notes to unaudited condensed consolidated financial statements.

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

|  | <b>Nine Months Ended September 30,</b> |                 |
|--|--|-----------------|
|  | <b>2006</b>                            | <b>2005</b>     |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>   |  |                 |
| Net loss   | \$ (9,509,816)                         | \$ (13,490,592) |
| Adjustments to reconcile net loss to net cash used in operating activities:                                  |  |                 |
| Depreciation and amortization  | 968,418                                | 668,720         |
| Stock-based compensation expense   | 2,859,098                              | 193,004         |
| Impairment of investment   | 164,020                                |                 |
| Non-cash interest on notes payable   |  | 152,478         |
| Amortization of intangible assets  | 27,050                                 | 56,304          |
| Changes in current assets and liabilities:   |  |                 |
| Accounts receivable  | (2,007,032)                            | (799,680)       |
| Prepaid expenses and other assets  | 29,358                                 | (188,761)       |
| Accounts payable and accrued liabilities   | (1,138,534)                            | 1,363,494       |
| Deferred contract revenue  | 424,782                                | 2,500,936       |
| Total adjustments  | 1,327,160                              | 3,946,495       |
| Net cash used in operating activities  | (8,182,656)                            | (9,544,097)     |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |  |                 |
| Purchase of marketable securities  | (30,880,091)                           | (24,904,025)    |
| Sale of marketable securities  | 38,740,803                             | 31,769,343      |
| Increase in restricted cash  | (5,846)                                | (2,832)         |
| Sale of long-term investments  |  | 2,606,681       |
| Purchases of property and equipment  | (73,621)                               | (2,267,597)     |
| Net cash provided by investing activities  | 7,781,245                              | 7,201,570       |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |  |                 |
| Proceeds from issuance of common stock under stock plans   | 120,294                                | 866,048         |
| Proceeds from issuance of debt   |  | 1,993,386       |
| Repayments of notes payable  | (925,000)                              | (312,500)       |
| Net cash provided by (used in) financing activities  | (804,706)                              | 2,546,934       |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS   | (1,206,117)                            | 204,407         |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD   | 22,310,298                             | 22,679,924      |
| CASH AND CASH EQUIVALENTS, END OF PERIOD   | \$ 21,104,181                          | \$ 22,884,331   |
| <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 6)      | \$ 2,605,280                           | \$              |
| 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 SUBSIDIARIES**

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

**1. Nature of Business**

Curis, Inc. (the Company or Curis ) is a therapeutic drug development company focusing on cancer, neurological and dermatological disease indications, with technologies that modulate certain biological pathways that control the growth, repair and regeneration of tissues and organs. Curis' product development involves the use of small molecules, proteins or antibodies to modulate these pathways, for example by increasing the pathway signals when they are insufficient or by decreasing them when they are up-regulated or unregulated. The Company has successfully used this technology and product development approach to produce several drug product candidates. This technology and approach have been used in the fields of cancer (under two collaborations with Genentech, as well as under internal preclinical development for new proprietary cancer programs that target multiple validated cancer pathways), neurological disorders (under collaboration with Wyeth), hair growth (under collaboration with Procter & Gamble), kidney and other diseases (licensed to Ortho Biotech Products and under development at Centocor, both subsidiaries of Johnson & Johnson), as well as cardiovascular disease. 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 unaudited 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 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. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

In the opinion of the Company, the unaudited consolidated financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company's financial position at September 30, 2006, the results of operations for the three- and nine-month periods ended September 30, 2006 and 2005, and cash flows for the nine-month periods ended September 30, 2006 and 2005. The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States 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 the carrying value of property and equipment and intangible assets 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 the full year or subsequent interim periods.

**3. Creation of Curis Shanghai**

In August 2006, the Company established a wholly-owned subsidiary in Shanghai, China called Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. Upon establishment of the subsidiary, the Company is

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required by the Chinese government to contribute \$2,100,000 to Curis Shanghai, of which the first contribution of \$420,000 is due in November 2006. The remaining capital must be funded by August 2008 and the Company expects to fund Curis Shanghai as needed to meet its obligations. Once capital has been contributed to Curis Shanghai, it will be restricted for use to satisfy only those obligations incurred in China and cannot be transferred back to Curis, Inc. The Company has not made any payments to Curis Shanghai to date.

As of September 30, 2006, Curis Shanghai was not operational. There were no transactions, including any intercompany transactions, at Curis Shanghai for the quarter ended September 30, 2006. Curis Shanghai currently has no employees and the Company does not plan to hire any subsidiary employees for the foreseeable future. The Company currently expects that certain operational aspects, including oversight of the third party chemistry provider, will be managed from the Company's Cambridge, Massachusetts location. It is anticipated that payments made to the third party chemistry provider will be made by Curis Shanghai from the Company's capital contributions.

**4. Revenue Recognition**

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development objectives 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 Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. For a complete discussion of the Company's revenue recognition policy, see Note 4(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 31, 2006.

*(i) Genentech Collaborations*

*Basal Cell Carcinoma Co-Development Accounting.* The Company has two collaboration agreements with Genentech. The first agreement, entered into in June 2003, relates to the development of Hedgehog antagonist technologies, including the development of a basal cell carcinoma product candidate, for which, prior to September 2006, the Company was sharing development costs equally with Genentech. The second agreement, entered into in April 2005, relates to the development of drug candidates that modulate another signaling pathway that plays an important role in cell proliferation and has been implicated in certain cancers.

In July 2006, the Company and Genentech elected to halt a Phase I clinical trial on the basal cell carcinoma product candidate. Effective August 31, 2006, the Company elected to cease its participation in the co-development of this drug candidate and, as of August 31, 2006, Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. The Company does not expect to incur any additional costs related to co-development of this drug candidate. The June 2003 and April 2005 collaborations are both continuing to progress and the Company believes that its decision to opt out of co-development does not otherwise impact these ongoing collaborations. Should Genentech determine to proceed with development of a topically administered Hedgehog antagonist for the treatment of basal cell carcinoma, the Company would be eligible for cash payments on the achievement of certain future clinical development objectives, if any, as well as a royalty on future product sales.

In connection with its co-development arrangement with Genentech under the June 2003 agreement, the Company has recorded cumulative revenues under both of its collaboration agreements with Genentech of

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\$11,308,000 through September 30, 2006. In addition, at September 30, 2006, the Company's deferred revenue under its collaborations with Genentech totaled \$9,722,000. For the period July, 1, 2006 through August 31, 2006, the Company incurred \$355,000 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 through the co-development termination date. The cumulative costs incurred on this program were \$8,727,000 as of September 30, 2006. Since the sum of cumulative revenue recorded through September 30, 2006 of \$11,308,000 and the deferred revenue of \$9,722,000 at September 30, 2006 exceeded cumulative co-development costs incurred through September 30, 2006 of \$8,727,000, the Company has recorded a reduction to revenues, or contra-revenue, of \$355,000 and \$1,728,000 in its consolidated statements of operations and comprehensive loss for the three- and nine-month periods ended September 30, 2006, respectively.

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

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

The Company determined that this payment does not constitute a substantive milestone payment for accounting purposes because it did not meet all of the conditions outlined in the Company's revenue recognition policy. Accordingly, the Company considered this payment as part of the single unit of accounting for its Procter & Gamble collaboration and the Company is recognizing the payment 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. The original note had been received as partial payment for a technology license. Under the amended note, Micromet is obligated to pay Curis a total amount of \$4,500,000, subject to certain conditions. This note had been fully written down by the Company in 2003.

The Company received two equal payments of \$1,250,000 in 2004 and 2005. The remaining \$2,000,000 under the amended note payable is due upon the achievement by Micromet of certain financing objectives or upon an exit event, as defined in the agreement. The Company believed that \$533,000 of the remaining \$2,000,000 became due as a result of Micromet's achievement of a financing milestone. The Company also believed that the merger of Micromet with CancerVax, Inc., a U.S. publicly traded biotechnology company, obligated Micromet to pay Curis the remaining \$1,467,000 within 30 days of the merger's May 5, 2006 closing date. Micromet had disputed this claim and the Company filed suit in Germany in the second quarter of 2006.

In September 2006, the Company agreed to a court-proposed settlement agreement with Micromet, pursuant to which Micromet is required to repay a note receivable in two installments of \$1,000,000, on each of November 1, 2006 and May 31, 2007. Under the terms of the settlement agreement, should Micromet make the second payment on or before April 30, 2007, the second payment would decrease to \$800,000. The Company believes that it is probable that Micromet will honor its obligation under the court ruling and pay Curis \$1,000,000 (approximately \$1,269,000 at September 30, 2006) by November 1, 2006 and \$800,000 (approximately \$1,015,000 at September 30, 2006) by April 30, 2007, to take advantage of the 30-day discount term offered by the German court. As a result of this recovery of amounts owed under the note, the Company has recorded license fee revenues of \$2,284,000 for the three- and nine-month periods ended September 30, 2006 based on the Euro-to-U.S. dollar exchange rate as of September 30, 2006. Corresponding amounts related to

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these payments are included under Accounts receivable within Current assets in the Company's consolidated balance sheet as of September 30, 2006. The first payment of 1,000,000, or \$1,252,000, was received on October 17, 2006.

**5. Investments in Privately-Held Companies**

As of September 30, 2006, the Company holds equity investments in two privately-held former collaborators of the Company, Aegera Therapeutics and ES Cell International. Equity investments in privately-held companies are reflected in the accompanying consolidated financial statements at a value based on the Company's best estimate of the fair value of such investments. When determining the fair values of such investments, the Company generally considers such factors as the fair value paid by outside investors for similar equity in such companies, the liquidity of the investment and both company-specific and macroeconomic factors that may have affected values since the last such investment by outside investors. On a quarterly basis, the Company reevaluates the book valuation of its investments in privately-held companies to determine if its carrying value should be changed.

In September 2006, the Company was notified of Aegera's need to secure additional financing at a value that was significantly less than the current carrying value of Aegera stock recorded at the Company's consolidated balance sheet. The Company believes that the terms of any future financing will adversely affect the carrying value of the equity investment in Aegera. Accordingly, during the quarter ended September 30, 2006, the Company, recorded a charge to Other expense of \$164,000 by writing down the carrying value of its investment in Aegera equity securities to \$3,000 from \$167,000.

At December 31, 2005, the Company held an equity investment in Micromet AG, a privately-held former collaborator, valued at \$100,000. In May 2006, Micromet merged with CancerVax, Inc., a U.S. publicly traded biotechnology company. The shares the Company held in Micromet were converted to shares of the combined company, Micromet, Inc., which began trading on the NASDAQ market on May 8, 2006. During the quarter ended September 30, 2006, the Company sold its equity investment in Micromet for proceeds totaling \$85,000, recognizing a loss of \$15,000 reflected in Other expense in the consolidated statement of operations.

**6. Long-Term Debt Obligations**

Long-term debt obligations, including accrued interest, consisted of the following at September 30, 2006 and December 31, 2005:

|   | September 30, | December 31, |
|---|---------------|--------------|
|   | 2006          | 2005         |
| Notes payable to financing agency for capital             | \$ 2,290,000  | \$ 3,227,000 |
| Convertible subordinated note payable to Becton Dickinson |               | 2,605,000    |
|   | 2,290,000     | 5,832,000    |
| Less current portion                                      | (1,248,000)   | (3,865,000)  |
| Total long-term debt obligations                          | \$ 1,042,000  | \$ 1,967,000 |

*Boston Private Bank & Trust Company.* 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.

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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 September 30, 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.

*Becton Dickinson.* 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.

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

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *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 nine-month period ended September 30, 2006 includes (i) 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 (ii) 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.

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***2000 Stock Incentive Plan***

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 options to purchase the Company's common stock as well as the issuance of restricted shares of common stock. 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 September 30, 2006, the number of shares of common stock reserved for issuance under the 2000 Plan is 16,000,000 and 2,568,948 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 equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the grant date.

On May 31, 2006, the Company granted stock options to its employees to purchase 540,000 shares of its common stock, which vest over one to two years. On June 1, 2006, the Company also granted options to its Board of Directors to purchase 145,000 shares of its common stock, which fully vested on the grant date, and options to the executive officers of the Company to purchase 700,000 shares of its common stock, which vest over a four-year period. All of these grants were issued at exercise prices equal to the closing market price of the Company's common stock on the NASDAQ Global Market on date of grant.

On May 31, 2006, the Board of Directors granted to the Chief Executive Officer a restricted stock award under the 2000 Plan for 10,000 shares of common stock at a purchase price of \$0.01 per share. The restricted common stock is subject to a right of repurchase by the Company, which lapses after one-year. The Company does not intend to exercise its repurchase right to these shares. The closing price of the common stock on May 31, 2006 was \$1.57 per share, which is also the weighted average grant date fair value of the restricted stock. The only substantive restriction on the award relates to a one-year service condition. Accordingly, the Company will recognize \$16,000 in compensation expense over a one-year period, assuming a 0% forfeiture rate. For the three- and nine-month periods ended September 30, 2006, the Company recognized \$4,000 and \$5,000, respectively, related to this award.

On June 1, 2006, the Company's non-employee directors were granted a total of 60,000 shares of common stock under the 2000 Plan at par value, or \$0.01 per share. The market value of the common stock on June 1, 2006 was \$1.67 per share. There were no restrictions or vesting requirements related to these awards. Accordingly, the Company recognized \$100,000 in related compensation expense during the second quarter of 2006.

During the quarter ended September 30, 2006, 154,000 shares were issued to employees under the 2000 Plan on various dates, all of which vest over a four-year period and were issued with exercise prices that were equal to the closing price of the Company's common stock on the NASDAQ Global Market on the grant date. On August 13, 2006, the Company also granted an additional option to purchase 10,000 shares of its common stock to one of its non-employee directors, which was granted at the closing price on the date of grant and was fully vested on the grant date.

***2000 Director Stock Option Plan***

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 grant of

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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 closing price of the Company's common stock on the 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 and becomes exercisable upon the grant date and that is issued with an exercise price that is equal to the closing price of the Company's common stock on the grant date.

On June 1, 2006, the Company's non-employee directors received the annual grant of options to purchase a total of 35,000 shares of common stock. During the quarter ended September 30, 2006, no shares were issued under the 2000 Director Plan. As of September 30, 2006, the number of shares of common stock subject to issuance under the 2000 Director Plan is 500,000 and there are 105,000 shares available for grant under the 2000 Director Plan.

**2000 Employee Stock Purchase 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 purchase period, as defined. The Company has two six-month purchase periods per year. During the quarter ended September 30, 2006, no shares were issued under the ESPP and there are 670,601 shares available for future purchase under the ESPP.

A summary of stock option activity under the 2000 Plan and the 2000 Director Plan for the nine months ended September 30, 2006 is presented below:

|                                  | Number of<br>Shares | Exercise Price<br>per Share | Contractual<br>Term |
|----------------------------------|---------------------|-----------------------------|---------------------|
| Balance, January 1, 2006         | 9,340,769           | \$ 4.35                     | 6.71                |
| Granted employees                | 1,954,000           | \$ 2.02                     | 9.63                |
| Granted non-employees            | 467,500             | \$ 1.45                     | 9.95                |
| Exercised                        | (37,195)            | \$ 0.92                     |                     |
| Cancelled (Forfeited or expired) | (1,176,462)         | \$ 4.35                     |                     |
| Outstanding, September 30, 2006  | 10,548,612          | \$ 3.80                     | 6.75                |
| Exercisable, September 30, 2006  | 6,849,537           | \$ 4.47                     | 5.73                |

The table below summarizes options outstanding and exercisable at September 30, 2006:

| Exercise Price Range | Number of<br>Shares | Options Outstanding | Weighted       | Options Exercisable | Weighted       |
|----------------------|---------------------|---------------------|----------------|---------------------|----------------|
|                      |                     | Weighted<br>Average | Average        | Number of<br>Shares | Average        |
|                      |                     | Remaining           | Exercise Price |                     | Exercise Price |
|                      |                     | Contractual         | per Share      |                     | per Share      |

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|         |         | Life (in years) |      |         |           |         |
|---------|---------|-----------------|------|---------|-----------|---------|
| \$ 0.56 | \$ 1.29 | 552,833         | 6.07 | \$ 1.04 | 546,895   | \$ 1.04 |
| 1.50    | 1.95    | 3,091,055       | 8.00 | 1.56    | 1,031,430 | 1.56    |
| 2.11    | 3.95    | 3,323,431       | 5.78 | 2.97    | 2,906,510 | 3.01    |
| 3.96    | 5.89    | 2,649,733       | 7.73 | 4.38    | 1,433,142 | 4.53    |
| 6.91    | 17.94   | 882,997         | 3.83 | 13.47   | 882,997   | 13.47   |
| 20.00   | 31.15   | 48,563          | 1.56 | 27.02   | 48,563    | 27.02   |
|         |         | 10,548,612      | 6.75 | \$ 3.80 | 6,849,537 | \$ 4.47 |

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The aggregate intrinsic value of options outstanding at September 30, 2006 was \$182,000, of which \$180,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2006 and 2005 were \$1.64 and \$2.95, respectively. As of September 30, 2006, there was approximately \$5,832,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 3.47 years. The intrinsic value of employee stock options exercised during the nine-month periods ended September 30, 2006 and 2005, were \$22,000 and \$923,000, respectively. The total fair value of vested stock options for the nine-month periods ended September 30, 2006 and 2005 were \$180,000 and \$7,933,000, 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. The Black-Scholes option pricing model employs the following key assumptions for option grants.

|                         |           | Nine Months Ended     |      |
|-------------------------|-----------|-----------------------|------|
|                         |           | September 30,<br>2006 | 2005 |
| Expected term (years)   | Employees | 5.5-6.25              | 5    |
| Expected term (years)   | Directors | 5                     | 5    |
| Risk-free interest rate |           | 4.53-5.16%            | 3.8% |
| Volatility              |           | 95-102%               | 95%  |
| Dividends               |           | None                  | None |

For the period ended September 30, 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, for grants issued during the three and nine months ended September 30, 2006, the Company assigned an expected term of 6.25 years for grants with four-year graded vesting and 5.5 years for grants with one- and two-year vesting. For the three and nine months ended September 30, 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 three and nine months ended September 30, 2006, expected volatility is based on the annualized daily historical volatility of the Company's stock price through the end of the reporting period for a time period consistent with the expected term of a grant. Management believes that the historical volatility of the Company's stock price best represents the volatility of the stock price. For the three and nine months ended September 30, 2005, the expected volatility of the options granted was calculated using an estimate of historical volatility as calculated under SFAS 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 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 third 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.

Under SFAS 123(R), 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. These awards

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accounted for \$18,000 and \$54,000 of the employee stock-based compensation expense recorded by the Company for the three- and nine-month periods ended September 30, 2006, respectively. 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 \$18,000 and \$57,000 in compensation expense for the three and nine months ended September 30, 2006, respectively, related to the ESPP. The Company calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model with the following assumptions:

|                         | <b>Nine Months Ended<br/>September 30, 2006</b> |
|-------------------------|---|
| Expected term           | 6 months  |
| Risk-free interest rate | 4.55-5.31%                                      |
| Volatility              | 70-85%  |
| Dividends               | None  |

Stock-based compensation for employees for the three and nine months ended September 30, 2006 of \$968,000 and \$3,007,000, respectively, was calculated using the above valuation models and has been included in the Company's results of operations. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is not likely that the net deferred tax asset will be realized. Based on basic and diluted weighted average shares outstanding of 49,146,609 and 49,012,538, respectively, for the three and nine months ended September 30, 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 and \$0.06, respectively per share.

The following table shows the pro forma effect on the Company's net income and net income per share for the three and nine months ended September 30, 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>Three months ended<br/>September 30, 2005</b> | <b>Nine months ended<br/>September 30, 2005</b> |
|--|--|---|
| Net loss, as reported  | \$ (3,251,000)                                   | \$ (13,491,000)                                 |
| Add back: employee stock based compensation included in net loss, as reported                            | 2,000  | 6,000   |
| Less: stock-based employee compensation expense determined under fair value based methods for all awards | (1,148,000)                                      | (3,713,000)                                     |
| Pro forma net loss   | \$ (4,397,000)                                   | \$ (17,198,000)                                 |
| Net loss per common share (basic and diluted)  |  |   |
| As reported  | \$ (0.07)  | \$ (0.28)                                       |
| Pro forma  | \$ (0.09)  | \$ (0.36)                                       |

**8. 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. During the second quarter of 2006, the Company discontinued use 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. No other terms of the sublease agreement were changed. In August 2006, the subtenant defaulted on the sublease and vacated the property. The subtenant is attempting to sell its assets and is currently in discussions with various third parties. The Company currently cannot reasonably estimate the likelihood that the subtenant can successfully sell its assets, or if successful, whether the proceeds generated by the sale of the subtenant's assets would be sufficient to enable the subtenant to satisfy its obligations under the sublease.

In July 2005, the Company estimated that it did not expect to utilize the space for its current or future operations, if vacated by the current tenant due to default of the amended sublease terms. 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. During the second quarter of 2006, the Company wrote off \$93,000 against this reserve, which represented the net book value of the leasehold improvements related to the leased space, which are no longer in use. The Company had originally estimated that the subtenant would pay its obligations, including rent and related facility expenses, through August 31, 2006. As a result of the default by the subtenant on August 1, 2006, the Company increased its reserve by \$48,000 in the third quarter of 2006.

During the quarter ended September 30, 2006, \$104,000 has been charged against the reserve representing the rent obligations and other related facility expenses incurred by the Company. Accordingly, the remaining \$401,000 is included under Accrued liabilities within Current liabilities in the Company's consolidated balance sheet as of September 30, 2006. The remaining reserve consists of the Company's remaining lease obligations and an estimate of other related facility costs through April 2007, as it does not expect to be able to sublet the space for the remaining lease term and cannot reasonably predict the outcome of the subtenant's efforts to sell its assets and satisfy its obligations under the lease.

**9. Basic and Diluted Loss Per Common Share**

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share were determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company's net loss position for all periods presented. Securities consisting of stock options, warrants, shares issuable under the Company's ESPP and convertible debt outstanding throughout 2005 were excluded from diluted net loss per common share as they were antidilutive under the if converted method. Antidilutive securities were 12,680,681 and 12,021,324 as of September 30, 2006 and 2005, respectively.

**10. Related Party Transactions**

The Company and Joseph M. Davie, Ph.D., M.D., a member of the Company's Board of Directors, entered into a consulting agreement, which was approved by the Board on August 23, 2006 with an effective date of June 19, 2006, the date on which Dr. Davie commenced the performance of consulting services for the Company as the Interim Chief Scientific Officer. The term of the Agreement is one year from the effective date. Either party may terminate the Agreement by providing thirty days' written notice to the other party. In consideration for the services rendered by Dr. Davie to the Company, the Company agreed to pay Dr. Davie compensation in the amount of \$4,000 per day for each day of consulting work, or \$500 per hour for portions thereof, not to exceed an aggregate of \$40,000 for the term of the agreement. For the three and nine month periods ended September 30, 2006, the Company had incurred \$33,000 in related consulting expenses in its consolidated statement of operations.

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On October 30, 2006, the Company and Dr. Davie entered into an amendment to the consulting agreement, which eliminated the \$40,000 cap on aggregate compensation to be paid by the Company to Dr. Davie under the consulting agreement.

On September 14, 2006, the Company and Dr. Davie entered into a Scientific Advisory and Consulting Agreement pursuant to which Dr. Davie agreed to serve as Chairman of the Company's Scientific Advisory Board (SAB). The term of this agreement is for a period of five years. Either party may terminate this agreement by providing thirty days' written notice to the other party. In consideration for the services rendered by Dr. Davie to the Company, the Company agreed to pay Dr. Davie an annual retainer of \$25,000, such retainer to become effective only upon the termination or expiration of the consulting agreement, dated as of June 19, 2006. As of September 30, 2006, the Company had not made any cash payments to Dr. Davie in his role as Chairman of the SAB.

In connection with the SAB agreement, the Board also granted to Dr. Davie an option, pursuant to the 2000 Plan, to purchase 35,000 shares of common stock of the Company at an exercise price equal to \$1.72, which was the closing price of the common stock of the Company on the NASDAQ Global Market on the date of grant. These options will vest quarterly over a four-year period.

### **11. New Accounting Standards**

In July 2006, the FASB issued FASB Interpretation (FIN) No. 48 Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement 109. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 is effective for fiscal years beginning after December 15, 2006. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. The Company expects the adoption of FIN 48 will not have a material impact on its consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 establishes a common definition for fair value to be applied to US GAAP guidance requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. While the Company is currently evaluating the provisions of SFAS No. 157, the adoption is not expected to have a material impact on its consolidated financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin (SAB) 108 Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 requires that public companies utilize a dual-approach to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. The guidance in SAB 108 must be applied to annual financial statements for fiscal years ending after November 15, 2006. The Company but does not expect that the adoption of SAB 108 will have a material effect on the Company's consolidated financial position or results of operations.

### **12. Subsequent Events**

#### *(i) Preclinical payment received from Genentech*

On October 2, 2006, Genentech filed an investigational new drug application with the FDA to initiate Phase I clinical testing of a systemically administered small molecule Hedgehog antagonist for the treatment of cancer covered by the Company's June 2003 collaboration agreement with Genentech. This clinical development objective triggered the payment of \$3,000,000 by Genentech, which the Company received on October 6, 2006.

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*(ii) Research funding extension from Wyeth*

On November 3, 2006, Wyeth exercised its option under the 2004 agreement to extend funding to continue development of therapeutic applications of the Hedgehog agonist with a primary focus on neurological disorders. By exercising this option, Wyeth has agreed to extend the research term by one year through February 9, 2008 (previously February 9, 2007). Under terms of the updated agreement, Wyeth can terminate the relationship within 60 days of written notice. Wyeth has elected to fund five researchers working on the program through the research term.

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

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

**Overview**

We are a therapeutic drug development company focusing on cancer, neurological and dermatological disease indications, with technologies that modulate certain biological pathways that control the growth, repair and regeneration of tissues and organs. Our product development involves the use of small molecules, proteins or antibodies to modulate these pathways, for example by increasing the pathway signals when they are insufficient or by decreasing them when they are up-regulated or unregulated. We have successfully used this technology and product development approach to produce several promising drug product candidates in the fields of cancer (under two collaborations with Genentech, as well as new proprietary cancer programs that target multiple validated cancer pathways), neurological disorders (under collaboration with Wyeth), hair growth (under collaboration with Procter & Gamble), kidney and other diseases (licensed to Ortho Biotech Products and under development at Centocor, both subsidiaries of Johnson & Johnson), as well as cardiovascular disease. 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 \$689,564,000 as of September 30, 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.

In June 2006, we announced the initiation of a new strategic focus seeking to more rapidly develop later-stage drug development programs and to deemphasize our earlier-stage discovery research. As part of this transition, we are winding down certain discovery-stage research activities, such as our spinal muscular atrophy discovery research program, and have initiated development on new mid-preclinical stage cancer drug candidates.

As part of this strategic shift, we have also initiated changes in our scientific leadership. Our current board member, Dr. Joseph Davie, has been serving as interim chief scientific officer and will temporarily oversee our drug programs while also assisting us in our efforts to build a more development-focused scientific team. During the third quarter of 2006, we continued to make progress on building a development-focused company. We augmented our scientific advisory board by adding three recognized leaders in research and clinical development of cancer therapies. We have enhanced our internal chemistry capacity by hiring two Ph.D.-level chemists who are working closely to oversee the work of approximately 20 chemists at a third-party Chinese chemistry provider. We expect to continue building our internal capacities; we are actively seeking a Chief Scientific Officer and expect to begin building a small clinical development group in the near future.

Our research programs are conducted both internally and through strategic collaborations. We recently initiated pre-clinical development on several classes of new proprietary small molecule cancer drug candidates, each of which is designed to target at least one and preferably multiple distinct molecular pathways that are known to be involved in the growth and/or metastasis of various cancers. These new drug programs are currently in preclinical testing and we expect that a significant amount of our research efforts will be aimed at advancing these assets into later preclinical and clinical stages of development. We will seek to progress several classes of compounds simultaneously through preclinical development. Assuming successful preclinical development, we

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expect to select a lead clinical candidate during the first half of 2007 and to file an investigational new drug, or IND, application by the end of 2007 or early 2008. We currently plan to retain ownership of either all or a majority of these drug candidate classes.

In addition to our proprietary cancer programs, we currently have strategic collaborations with Genentech, Procter & Gamble, and Wyeth Pharmaceuticals to develop therapeutics that modulate the signaling of the Hedgehog pathway. We have a second collaboration with Genentech focusing on the discovery and development of small molecule modulators of 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.

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 development objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic collaboration and license agreements included \$18,500,000 in up-front payments, of which we received \$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 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 relating to a hair growth product candidate in exchange for a higher royalty rate under our dermatological Hedgehog agonist collaboration with Procter & Gamble, 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.

### **Recent Developments**

*Hedgehog antagonist IND filing:* In October 2006, Genentech filed an IND application with the Food and Drug Administration to initiate Phase I clinical testing of a systemically administered small molecule Hedgehog antagonist for the treatment of cancer. Pursuant to the terms of our June 2003 collaboration agreement, Genentech paid us a \$3,000,000 after filing the IND application. Should this small molecule drug candidate successfully continue its development into subsequent stages of clinical testing and regulatory approval, we would be eligible for additional cash payments. Should this drug candidate be commercialized, we would also receive royalties on any product sales.

*Initiation of new cancer programs:* In September 2006, we announced that we are seeking to develop several classes of new proprietary small molecule drug candidates, each of which is being designed to target at least one and preferably multiple distinct molecular pathways. We believe that some of the most effective currently marketed therapies are those that attack cancer from multiple directions simultaneously. Our drugs are being developed as single molecules that preferably target multiple distinct molecular pathways that we believe will provide anti-tumor activity across a broad range of hematological (i.e., blood) and solid tumor cancers.

We anticipate that our multi-targeted pathway inhibitors may improve efficacy, prevent the emergence of drug resistance, and/or decrease the dose-limiting toxicities, possibly by virtue of the ability to reduce dosing

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frequency or amount, and/or avoid adverse drug-drug interactions that can result from the use of multiple chemotherapeutic agents. Further, we believe that these new inhibitors may represent a new paradigm in rational multi-pathway targeting cancer drug development.

These new drug programs are currently in preclinical testing. We will seek to progress several classes of compounds simultaneously through preclinical development. Factors to be considered in prioritizing potential drug candidates include efficacy, pharmacology, patient needs, path to regulatory approval, scale-up of compound synthesis, and freedom to operate. Assuming successful preclinical development, we expect to select a lead clinical candidate during the first half of 2007 and to file an IND application by the end of 2007 or early 2008.

*Establishment of Chinese operation:* In August 2006, we established a wholly-owned subsidiary in Shanghai, China called Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. Upon establishment of the subsidiary, we are required by the Chinese government to contribute \$2,100,000 to Curis Shanghai, of which the first contribution of \$420,000 is due in November 2006. The remaining capital must be funded by August 2008 and we expect to fund Curis Shanghai as needed to meet its obligations. Once capital has been contributed to Curis Shanghai, it will be restricted for use to satisfy only those obligations incurred in China and cannot be transferred back to us. We have not made any payments to Curis Shanghai to date.

We have engaged approximately 20 chemists, through a Chinese third party chemistry provider, to work to advance our multi-targeted pathway inhibitor cancer programs. We anticipate that payments made to the third party chemistry provider will be made by Curis Shanghai from our capital contributions. In the near term, oversight of the medicinal chemistry services that are being conducted by the third party provider will be managed from our Cambridge, Massachusetts location.

As of September 30, 2006, Curis Shanghai was not operational. There were no transactions, including any intercompany transactions, at Curis Shanghai for the quarter ended September 30, 2006. Curis Shanghai has no employees and, currently, we do not plan to hire any subsidiary employees. In the future, we will evaluate whether it would be more advantageous to hire our own scientists and administrative staff in China for the purposes of performing the medicinal chemistry services that are currently provided by the third party provider.

*Termination of basal cell carcinoma co-development program:* On August 31, 2006, and pursuant to the terms of our June 2003 collaboration agreement with Genentech, we elected to cease our participation in the co-development of a basal cell carcinoma drug candidate. We previously announced that the parties had halted enrollment in the basal cell carcinoma phase I clinical trial and had made a decision not to move forward with the phase I molecule in its current formulation. While data from the phase I trial revealed no significant safety concerns in four weeks of topical treatment, the observed clinical and histological clearance of the basal cell carcinoma was far less than anticipated. The results from a final segment of the study showed that the molecule in its current formulation did not downregulate the targeted pharmacodynamic marker in this tumor, one possible explanation being that the drug candidate did not adequately penetrate human skin. We believe that the Phase I trial was halted due to a formulation/penetration problem and does not call into question the role of the Hedgehog pathway in basal cell carcinoma or other cancers.

Effective as of the August 31, 2006 co-development termination date, Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. Should Genentech determine to proceed with development of a topically administered Hedgehog antagonist for the treatment of basal cell carcinoma, we would be eligible for cash payments on the achievement of certain future clinical development objectives, if any, as well as a royalty on future product sales.

*Settlement on amended note payable from Micromet AG:* In October 2006, we entered into a court-proposed settlement agreement with Micromet, a former collaborator. In accordance with the settlement, Micromet has

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agreed to repay a note receivable by paying to us 1,000,000, due on November 1, 2006, and 1,000,000, due on May 31, 2007. Should Micromet make the second payment on or before April 30, 2007, the second payment would decrease to 800,000. Using September 30, 2006 currency exchange rates, the total amount Micromet has agreed to pay us is approximately \$2,500,000, or \$2,300,000 if Micromet elects to prepay the second installment. Future changes in currency exchange rates may increase or decrease the actual amount of U.S. dollars received by us. We received the first payment of 1,000,000, or \$1,252,000, on October 17, 2006.

*Research funding extension from Wyeth:* On November 3, 2006, Wyeth exercised its option under the 2004 agreement to extend funding to continue development of therapeutic applications of the Hedgehog agonist with a primary focus on neurological disorders. By exercising this option, Wyeth has agreed to extend the research term by one year through February 9, 2008 (previously February 9, 2007). Under terms of the updated agreement, Wyeth can terminate the relationship within 60 days of written notice. Wyeth has elected to fund five researchers working on the program through the research term.

## **Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, the timing of the receipt of payments from collaborators and the cost and outcome of any clinical trials then being conducted. We believe that our existing capital resources at September 30, 2006, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, and Procter & Gamble, assuming these programs continue as planned, should enable us to maintain current and planned operations into the second half of 2008. Our ability to continue funding our planned operations into the second half of 2008 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt or other sources of financing. A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth 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, and other amounts that we have received from our strategic collaborators and licensees, including Genentech, Wyeth, Ortho Biotech Products/Centocor and Procter & Gamble. Our share of the basal cell carcinoma co-development costs have been recorded as a reduction to any revenue recognized under our collaborations with Genentech in accordance with EITF 01-9 through the termination date of August 31, 2006. We do not expect to record any additional contra-revenues, as we do not expect to incur any additional costs under this co-development program. Since we have opted out of co-development, Genentech will be solely responsible for all development costs subsequent to August 31, 2006, and we would be entitled to cash payments upon the occurrence of certain development objectives and royalties on product sales, if any should occur. In the future, we will seek to generate revenues from a combination of license fees, research and development funding, milestone payments and royalties resulting from 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.* 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

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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 nor decrease significantly in the short-term. Longer-term changes in these expenses are contingent upon our then-current operating plan.

Except for our Hedgehog systemic small molecule antagonist, all 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 below, the term discovery means that we are searching for compounds that may be relevant for treating a particular disease area and preclinical means we are seeking to obtain demonstrations of therapeutic efficacy in preclinical models of human disease. IND means that we or our collaborator have filed an IND with the FDA but have not yet initiated Phase I clinical trials.

All of our estimates below regarding planned filing dates for investigational new drug applications for 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 clinical and preclinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain.

| Product Candidate                                       | Primary Indication                            | Collaborator/Licensee                 | Status                    |
|---|---|---------------------------------------|---------------------------|
| Hedgehog systemic small molecule or antibody antagonist | Cancer  | Genentech                             | IND                       |
| Multi-target inhibitors                                 | Cancer  | Internal Development                  | Preclinical               |
| Undisclosed pathway                                     | Cancer  | Genentech                             | Discovery                 |
| Hedgehog small molecule agonist or protein              | Nervous system disorders                      | Wyeth                                 | Preclinical/Discovery (1) |
| Hedgehog small molecule agonist                         | Hair growth                                   | Procter & Gamble                      | Preclinical               |
| BMP-7 protein   | Kidney disease and other disorders            | Ortho Biotech Products/<br>Centocor   | Preclinical               |
| Discovery research                                      | Spinal muscular atrophy (2)                   | Spinal Muscular Atrophy<br>Foundation | Discovery                 |
| Hedgehog agonist/gene                                   | Cardiovascular disease (local administration) | Internal development (3)              | Preclinical               |
| BMP-7 small molecule agonists                           | Kidney disease and other disorders            | Centocor                              | Discovery                 |

- (1) Curis and Wyeth are currently evaluating drug candidates in a particular class of agonist small molecule compounds. This class of compounds is currently in 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. Wyeth is also evaluating the use of the protein for neurological and other therapeutic indications.
- (2) We anticipate that we will enter into an agreement with the Spinal Muscular Atrophy, or SMA, Foundation to conclude our SMA discovery-stage research program. We anticipate that the remaining work for SMA will be completed by the end of November 2006 and that all direct costs through such date will be fully funded by the SMA Foundation.
- (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.

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Because of the early stages of these programs, the successful development of our product candidates is highly uncertain 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.

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

A further discussion of some of the risks and uncertainties associated with completing our 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 in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. These expenses include stock-based compensation expense for employee share-based payments beginning on January 1, 2006. 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 nor 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. We currently have collaborations with Genentech, Procter & Gamble, Wyeth Pharmaceuticals, and Ortho Biotech Products, as well as a screening program with Centocor. For a detailed discussion of these arrangements, please see Management's Discussion and Analysis of Financial Condition and Results of Operations Strategic Alliances and License Agreements in our annual report on Form 10-K for the year ended December 31, 2005, which is on file with the Securities and Exchange Commission, or SEC. For an update on certain of our programs with Genentech and the SMA program, see Recent Developments of this Quarterly Report on Form 10-Q.

## **Critical Accounting Policies and Estimates**

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

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

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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 estimates described therein.

*Stock-based compensation.* Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment (SFAS 123(R))*. 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 \$968,000 and \$3,007,000, respectively, for the three- and nine-month periods ended September 30, 2006. Stock-based compensation expense of \$2,000 and \$6,000 for the same periods in 2005 was recorded applying APB 25. We are estimating that we will record approximately \$3,600,000 to \$4,100,000 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

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- and nine-month periods ended September 30, 2006 relates to continued vesting of stock options that were granted prior to January 1, 2006. In accordance with the transition provisions of 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.



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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 we ultimately expect will 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, we amended a note receivable with Micromet, a former collaborator. Under the amended note, Micromet is obligated to pay Curis a total amount of 4,500,000, subject to certain conditions. This note had been fully written down in 2003. We received payments totaling 2,500,000 from Micromet in 2004 and 2005. The remaining 2,000,000 due under the amended note was payable to us upon the achievement by Micromet of certain financing objectives or upon an exit event, as defined in the amended note. We asserted that the conditions precedent to the payment of the remaining 2,000,000 had been achieved through Micromet's recent merger with CancerVax, a claim that Micromet disputed. As a result, we filed a lawsuit in Germany during the second quarter of 2006.

In September 2006, we agreed to a court-proposed settlement agreement with Micromet to resolve this claim. In accordance with the settlement, Micromet has agreed to pay us 1,000,000, due on November 1, 2006, and 1,000,000, due on May 31, 2007. Should Micromet make the second payment on or before April 30, 2007, the second payment would decrease to 800,000. Using September 30, 2006 currency exchange rates, the total amount Micromet has agreed to pay us is approximately \$2,538,000, or \$2,284,000 if Micromet elects to prepay the second installment. Future changes in currency exchange rates may increase or decrease the actual amount of U.S. dollars received by us.

In our judgment, the 2,000,000 was not reasonably assured of collection prior to this settlement. We have reevaluated the probability of collection as a result of the settlement of the suit and have concluded that payment of 1,800,000 by Micromet is now probable. Accordingly, we have recorded a receivable in our consolidated balance sheet and related license revenue in our consolidated statement of operations as of September 30, 2006.

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 July 2006, the FASB issued FASB Interpretation (FIN) No. 48 Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement 109. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 is effective for fiscal years beginning after December 15, 2006. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. We expect the adoption of FIN 48 will not have a material impact on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157). SFAS No. 157 establishes a common definition for fair value to be applied to US GAAP guidance requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value

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measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. While we are currently evaluating the provisions of SFAS No. 157, the adoption is not expected to have a material impact on our consolidated financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin (SAB) 108 Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 requires that public companies utilize a dual-approach to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. The guidance in SAB 108 must be applied to annual financial statements for fiscal years ending after November 15, 2006. We do not expect that the adoption of SAB 108 will have a material effect on our consolidated financial position or results of operations.

**Results of Operations****Three-Month Periods Ended September 30, 2006 and September 30, 2005**

*Revenues.* Total revenues are summarized as follows:

|   | <b>For the Three Months</b>                 |                         | <b>Percentage Increase/ (Decrease)</b> |
|---|---|-------------------------|--|
|   | <b>Ended September 30, 2006 (unaudited)</b> | <b>2005 (unaudited)</b> |  |
| <b>REVENUES:</b>  |   |                         |  |
| <i>Research and development contracts</i>                 |   |                         |  |
| Genentech   | \$ 988,000                                  | \$ 1,791,000            | (45%)                                  |
| Wyeth   | 524,000                                     | 561,000                 | (7%)                                   |
| Procter & Gamble  | 217,000                                     | 7,000                   | 3,000%                                 |
| Centocor  | 100,000                                     |                         | 100%                                   |
| Spinal Muscular Atrophy Foundation                        | 191,000                                     | 205,000                 | (7%)                                   |
| Other   |   | 62,000                  | (100%)                                 |
| <b>Subtotal</b>   | <b>2,020,000</b>                            | <b>2,626,000</b>        | <b>(23%)</b>                           |
| <i>License fees</i>                                       |   |                         |  |
| Genentech   | 187,000                                     | 187,000                 | 0%                                     |
| Wyeth   | 68,000                                      | 68,000                  | 0%                                     |
| Procter & Gamble  | 66,000                                      | 3,000                   | 2,100%                                 |
| Micromet  | 2,284,000                                   |                         | 100%                                   |
| <b>Subtotal</b>   | <b>2,605,000</b>                            | <b>258,000</b>          | <b>910%</b>                            |
| <b>Gross Revenues</b>                                     | <b>4,625,000</b>                            | <b>2,884,000</b>        | <b>60%</b>                             |
| <b>Contra-revenues from co-development with Genentech</b> | <b>(355,000)</b>                            | <b>(819,000)</b>        | <b>(57%)</b>                           |
| <b>Net Revenue</b>  | <b>\$ 4,270,000</b>                         | <b>\$ 2,065,000</b>     | <b>107%</b>                            |

Gross revenues increased primarily as the result of \$2,284,000 in license fee revenue recognized as part of a settlement agreement with Micromet on an amended note payable from Micromet due to us. We had written off the corresponding receivable related to this note in prior periods. Research and development contract revenues for the three months ended September 30, 2006 decreased \$606,000 primarily due to decreased funding of the Hh antagonist solid tumor program under collaboration with Genentech. Seven researchers were supporting this program for the three-month period ended September 30, 2006 compared to sixteen researchers in the same prior year period. Funding of the research services is tied to the number of researchers supporting the program.

Contra-revenues represent amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma therapeutic product candidate through August 31, 2006. Contra-revenues for the third quarter of 2005 were significantly higher than



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the same period in 2006 due to reduced clinical activity during the third quarter of 2006 as compared to the third quarter of 2005. In addition, we elected to cease our participation in the co-development of this drug candidate as of August 31, 2006, thereby incurring only two months of co-development costs during the third quarter of 2006. Beginning September 1, 2006, Genentech is solely responsible for all future costs and development decisions regarding the basal cell carcinoma program.

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

| Research and Development Program          | Primary Indication       | Collaborator     | For the Three Months Ended<br>September 30, |                     | Percentage<br>Increase/<br>(Decrease) |
|---|--------------------------|------------------|---|---------------------|---------------------------------------|
|   |                          |                  | 2006<br>(unaudited)                         | 2005<br>(unaudited) |                                       |
| Hh small molecule and antibody antagonist | Cancer                   | Genentech        | \$ 326,000                                  | \$ 963,000          | (66%)                                 |
| Multi-target inhibitors                   | Cancer                   | Internal         | 752,000                                     |                     | 100%                                  |
| Undisclosed pathway                       | Cancer                   | Genentech        | 596,000                                     | 721,000             | (17%)                                 |
| Hh small molecule agonist                 | Nervous system disorders | Wyeth            | 625,000                                     | 708,000             | (12%)                                 |
| Hh small molecule agonist                 | Hair growth              | Procter & Gamble | 181,000                                     | 218,000             | (17%)                                 |
| Discovery research                        | Spinal muscular atrophy  | SMA Foundation   | 320,000                                     | 578,000             | (45%)                                 |
| BMP-7 small molecule agonists             | Kidney disease and other | Centocor         | 223,000                                     |                     | 100%                                  |
| Discovery research                        | Various                  | Internal         | 304,000                                     | 339,000             | (10%)                                 |
| Stock-based compensation                  | N/A                      |                  | 342,000                                     | 164,000             | 109%                                  |
| Total research and development expense    |                          |                  | \$ 3,669,000                                | \$ 3,691,000        | (1%)                                  |

Our spending in research remained consistent from period to period due to the reallocation of resources to various programs, specifically to discovery programs, and decreases in outside services. Outside medicinal chemistry costs decreased from the prior year period by \$360,000 for our cancer program under collaboration with Genentech and by \$120,000 for our program under collaboration with Wyeth as product candidates under these two programs advanced beyond the need for further medicinal chemistry. Additional medicinal chemistry may be reinstated on either of these programs in the future.

In addition, we initiated a new internal, mid-preclinical program focusing on multi-targeted inhibitors in the second quarter of 2006. We incurred expenses of approximately \$752,000 during the three months ended September 30, 2006 for this program. We also incurred \$223,000 during the third quarter of 2006 under our December 2005 BMP small molecule screening agreement with Centocor. The increase in stock-based compensation of \$178,000 is primarily a result of the adoption of SFAS 123R on January 1, 2006.

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

|   | For the Three Months Ended<br>September 30, |                     | Percentage<br>Increase/<br>(Decrease) |
|---|---|---------------------|---------------------------------------|
|   | 2006<br>(unaudited)                         | 2005<br>(unaudited) |                                       |
| Personnel                                 | \$ 676,000                                  | \$ 771,000          | (12%)                                 |
| Occupancy and depreciation                | 171,000                                     | 170,000             | 1%                                    |
| Legal services                            | 167,000                                     | 423,000             | (61%)                                 |
| Consulting and professional services      | 341,000                                     | 223,000             | 53%                                   |
| Insurance costs                           | 120,000                                     | 107,000             | 12%                                   |
| Other general and administrative expenses | 186,000                                     | 137,000             | 36%                                   |
| Stock-based compensation                  | 641,000                                     | 2,000               | 31,950%                               |
| Total general and administrative expenses | \$ 2,302,000                                | \$ 1,833,000        | 26%                                   |



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The increase in general and administrative expenses of \$469,000 for the three-month period ended September 30, 2006 was primarily due to an increase in employee stock-based compensation expense of \$639,000 offset by decreased legal services of \$256,000 due to decreased patent costs. Consulting and professional services increased \$118,000 during the three-month period ended September 30, 2006 as compared to the same prior year period due primarily to specialized tax and audit advice related to the formation of our Chinese subsidiary.

*Interest Income.* Interest income for the three-month period ended September 30, 2006 was \$405,000 as compared to \$319,000 for the three-month period ended September 30, 2005, an increase of \$86,000, or 27%. The increase in interest income resulted from higher interest rates for the three-month period ended September 30, 2006 as compared to the three-month period ended September 30, 2005.

*Other Expense.* Other expense for the three-month period ended September 30, 2006 was \$179,000. During the quarter ended September 30, 2006, we wrote down the carrying value of our investment in Aegera equity securities from \$167,000 to \$3,000, recognizing a charge of \$164,000. In addition, we sold our Micromet common stock for proceeds totaling \$85,000, recognizing a loss of \$15,000 during the three-month period ended September 30, 2006. We recorded no other income for the three-month period ended September 30, 2005.

*Interest Expense.* Interest expense for the three-month period ended September 30, 2006 was \$61,000 as compared to \$93,000 for the three-month period ended September 30, 2005, a decrease of \$32,000, or 34%. The decrease resulted from lower outstanding debt obligations at September 30, 2006 as compared to September 30, 2005.

**Nine-Month Periods Ended September 30, 2006 and September 30, 2005**

*Revenues.* Total revenues are summarized as follows:

|   | For the Nine Months                       |                     | Percentage<br>Increase/<br>(Decrease) |
|---|---|---------------------|---------------------------------------|
|   | Ended September 30<br>2006<br>(unaudited) | 2005<br>(unaudited) |                                       |
| <b>REVENUES:</b>  |   |                     |                                       |
| <i>Research and development contracts</i>                 |   |                     |                                       |
| Genentech   | \$ 3,670,000                              | \$ 4,119,000        | (11%)                                 |
| Wyeth   | 1,749,000                                 | 1,745,000           | 0%                                    |
| Procter & Gamble  | 591,000                                   | 7,000               | 8,343%                                |
| Centocor  | 300,000                                   |                     | 100%                                  |
| Spinal Muscular Atrophy Foundation                        | 1,055,000                                 | 1,425,000           | (26%)                                 |
| Other   | 12,000                                    | 63,000              | (81%)                                 |
| Subtotal  | 7,377,000                                 | 7,359,000           | 0%                                    |
| <i>License fees</i>                                       |   |                     |                                       |
| Genentech   | 563,000                                   | 375,000             | 50%                                   |
| Wyeth   | 204,000                                   | 204,000             | 0%                                    |
| Procter & Gamble  | 168,000                                   | 3,000               | 5,500%                                |
| Micromet  | 2,284,000                                 |                     | 100%                                  |
| Subtotal  | 3,219,000                                 | 582,000             | 453%                                  |
| <i>Substantive milestones</i>                             |   | 250,000             | (100%)                                |
| <b>Gross Revenues</b>                                     | <b>10,596,000</b>                         | <b>8,191,000</b>    | <b>29%</b>                            |
| <b>Contra-revenues from co-development with Genentech</b> | <b>(1,728,000)</b>                        | <b>(5,698,000)</b>  | <b>(70%)</b>                          |
| <b>Net Revenue</b>  | <b>\$ 8,868,000</b>                       | <b>\$ 2,493,000</b> | <b>256%</b>                           |

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Gross revenues increased primarily as the result of \$2,284,000 in license fee revenue recognized as part of a settlement agreement with Micromet. Research and development contract revenues for the nine months ended September 30, 2006 were consistent with the same prior year period.

In addition, during 2006 there was a decrease of \$250,000 in substantive milestone revenues. During the first quarter of 2005, we achieved a preclinical milestone under our Wyeth collaboration. We did not achieve any such milestones during the third quarter of 2006.

Contra-revenues represent amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma therapeutic product candidate through August 31, 2006. Contra-revenues for the nine months ended September 30, 2005 were significantly higher than the same period in 2006 due to significant preclinical costs that had been incurred by Genentech prior to our election to exercise our co-development option in January 2005. Upon our decision to exercise this co-development option, 50% of such costs were payable by us in the first quarter of 2005. In addition, we elected to cease our participation in the co-development of this drug candidate in the third quarter of 2006 and, as of the August 31, 2006 termination date, Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program.

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

| Research and Development Program          | Primary Indication       | Collaborator     | For the Nine Months Ended September 30, |                  | Percentage Increase/ (Decrease) |
|---|--------------------------|------------------|---|------------------|---------------------------------|
|   |                          |                  | 2006 (unaudited)                        | 2005 (unaudited) |                                 |
| Hh small molecule and antibody antagonist | Cancer                   | Genentech        | \$ 1,326,000                            | \$ 2,828,000     | (53%)                           |
| Multi-target inhibitors                   | Cancer                   | Internal         | 1,137,000                               |                  | 100%                            |
| Undisclosed pathway                       | Cancer                   | Genentech        | 2,145,000                               | 1,230,000        | 74%                             |
| Hh small molecule agonist                 | Nervous system disorders | Wyeth            | 1,886,000                               | 2,189,000        | (14%)                           |
| Hh small molecule agonist                 | Hair growth              | Procter & Gamble | 741,000                                 | 664,000          | 12%                             |
| Discovery research                        | Spinal muscular atrophy  | SMA Foundation   | 1,530,000                               | 2,046,000        | (25%)                           |
| BMP-7 small molecule agonists             | Kidney disease and other | Centocor         | 652,000                                 |                  | 100%                            |
| Discovery research                        | Various                  | Internal         | 751,000                                 | 1,265,000        | (41%)                           |
| Stock-based compensation                  | N/A                      |                  | 826,000                                 | 188,000          | 339%                            |
| Total research and development expense    |                          |                  | \$ 10,994,000                           | \$ 10,410,000    | 6%                              |

The increase of \$584,000, or 6%, in research and development expenses in the nine months ended September 30, 2006 was primarily due to an increase in stock-based compensation expense of \$638,000. Our spending in research remained consistent from period to period due to the reallocation of resources to various programs, including our new proprietary cancer programs and certain collaborator-funded discovery programs. In addition, our outside service costs decreased, largely due to decreases in medicinal chemistry costs, which decreased from the prior year period by \$1,080,000 for our Hedgehog antagonist cancer program under collaboration with Genentech and by \$360,000 for our Hedgehog agonist stroke program under collaboration with Wyeth. These decreases resulted from product candidates under these two programs advancing beyond the need for further medicinal chemistry. Additional medicinal chemistry may be reinstated on either of these programs in the future.

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We initiated a new internal, preclinical program focusing on multi-targeted inhibitors in the second quarter of 2006. We incurred expenses of approximately \$1,137,000 during the nine months ended September 30, 2006 related to this program. Our spending under our April 2005 discovery collaboration with Genentech increased by \$915,000, to \$2,145,000 during the nine months ended September 30, 2006, as compared to \$1,230,000 for the same period in 2005. We also incurred expenses of \$652,000 during the first nine months of 2006 under our December 2005 BMP small molecule screening agreement with Centocor.

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

|   | For the Nine Months Ended<br>September 30, |                     | Percentage<br>Increase/<br>(Decrease) |
|---|--|---------------------|---------------------------------------|
|   | 2006<br>(unaudited)                        | 2005<br>(unaudited) |                                       |
| Personnel                                 | \$ 2,185,000                               | \$ 2,549,000        | (14%)                                 |
| Occupancy and depreciation                | 577,000                                    | 946,000             | (39%)                                 |
| Legal services                            | 1,258,000                                  | 1,019,000           | 23%                                   |
| Consulting and professional services      | 1,161,000                                  | 797,000             | 46%                                   |
| Insurance costs                           | 329,000                                    | 319,000             | 3%                                    |
| Other general and administrative expenses | 607,000                                    | 506,000             | 20%                                   |
| Stock-based compensation                  | 2,033,000                                  | 5,000               | 40,560%                               |
| Total general and administrative expenses | \$ 8,150,000                               | \$ 6,141,000        | 33%                                   |

The increase in general and administrative expenses of \$2,009,000 for the nine-month period ended September 30, 2006 was primarily due to an increase in stock-based compensation expense of \$2,028,000. In addition, legal costs increased \$239,000 and professional and consulting services increased \$364,000 related to the restatement of our financial statements in the first quarter of 2006 and costs associated with the formation of the Chinese subsidiary. These increases were offset by decreases in personnel costs of \$364,000 and lower occupancy costs of \$369,000. The decrease in personnel costs relates to executive bonuses incurred in 2005. We also recognized a \$500,000 loss in 2005 on an operating lease resulting from the loss of subtenant income.

*Interest Income.* Interest income for the nine-month period ended September 30, 2006 was \$1,173,000 as compared to \$862,000 for the nine-month period ended September 30, 2005, an increase of \$311,000, or 36%. The increase in interest income resulted from higher interest rates for the period ended September 30, 2006 as compared to September 30, 2005.

*Other Income/Expense.* Other expense for the nine-month period ended September 30, 2006 was \$179,000 as compared to other income of \$25,000 for the nine-month period ended September 30, 2005. During the nine-month period ended September 30, 2006, we wrote down the carrying value of our investment in Aegera equity securities, recognizing a charge of \$164,000. In addition, we sold our equity investment in Micromet for proceeds totaling \$85,000, recognizing a loss of \$15,000 for the period ended September 30, 2006.

*Interest Expense.* Interest expense for the nine-month period ended September 30, 2006 was \$200,000 as compared to \$264,000 for the nine-month period ended September 30, 2005, a decrease of \$64,000, or 24%. The decrease resulted from lower outstanding debt obligations at September 30, 2006 as compared to September 30, 2005.

**Liquidity and Capital Resources**

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

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At September 30, 2006, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$35,187,000, excluding restricted long-term investments of \$202,000. 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 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 and for the nine months ended September 30, 2006, we have incurred 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. On August 31, 2006, we opted out of co-development of the basal cell carcinoma product candidate and Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program. For the nine months ended September 30, 2006, we recorded \$1,728,000 in contra-revenues at our consolidated statement of operations in connection with these co-development costs. To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. In general, our only source of cash flows from operations for the foreseeable future will be up-front license payments from new collaborations, payments for the achievement of milestones if any are met and funded research and development that we may receive under collaboration agreements. The timing of or entrance into any new collaboration agreements and any payments under existing collaboration agreements cannot be easily predicted and may vary significantly from quarter to quarter. We are not currently in any advanced negotiations with new or existing collaborators.

Net cash used in operating activities was \$8,183,000 for the nine-month period ended September 30, 2006 as compared to \$9,544,000 for the nine-month period ended September 30, 2005. Cash used in operating activities during the nine-month periods ended September 30, 2006 and 2005 was primarily the result of our net loss for the period partially offset by non-cash charges including stock-based compensation, depreciation and non-cash interest expense. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during the nine-month period ended September 30, 2006. Our accounts receivable increased \$2,007,000 primarily as a result of our settlement with Micromet, of which \$1,252,000 was paid in October 2006. Micromet is obligated to pay an additional 1,000,000 by May 31, 2007, which will be reduced to 800,000 if Micromet pays by April 30, 2007. In addition, our accounts payable and accrued liabilities decreased \$1,139,000 primarily as a result of payment of co-development costs incurred under our collaboration with Genentech. As of August 31, 2006, we will no longer be responsible for development costs incurred for a basal cell carcinoma product candidate.

We expect to continue to use cash in operations as we continue to research and develop our product candidates and advance new product candidates into preclinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and specified other objectives. We also expect that the increase in cash used will be partially offset by anticipated payments made under our collaborations with Genentech and Wyeth, assuming these collaborations and research programs continue in accordance with their terms.

Investing activities provided \$7,781,000 of cash for the nine-month period ended September 30, 2006 as compared to \$7,202,000 in the nine-month period ended September 30, 2005. Cash provided by investing activities resulted principally from \$7,861,000 in net investment sales offset by \$74,000 in fixed asset purchases for the nine-month period ended September 30, 2006. Cash provided by investing activities resulted principally from \$9,470,000 in net investment sales offset by \$2,268,000 in fixed asset purchases for the nine-month period ended September 30, 2005.

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Financing activities used \$805,000 of cash for the nine-month period ended September 30, 2006, resulting from debt repayments of \$925,000 on our notes with the Boston Private Bank & Trust Company and proceeds of \$120,000 received upon stock option exercises. Financing activities provided approximately \$2,547,000 of cash for the nine-month period ended September 30, 2005, principally resulting from net proceeds of \$1,681,000 from the issuance of debt for the purchase of fixed assets and proceeds of \$866,000 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 September 30, 2006, 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 17,600 square feet of our facility at 61 Moulton Street in Cambridge, Massachusetts. Under the terms of our sublease, as amended, we received sublease payments, which totaled approximately \$320,000 per year. In addition, we received approximately \$50,000 for facilities-related services and 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. In August 2006, the subtenant defaulted on the sublease and vacated the facility. Our lease obligation on our 61 Moulton Street facility extends to April 2007 and our lease obligation from October 2006 to April 2007 is approximately \$275,000. As of September 30, 2006, we have \$401,000 reflected under accrued liabilities at our consolidated balance sheet consisting of our remaining lease obligations and an estimate of other related facility costs through April 2007, as we do not expect to be able to sublet the space for the remaining lease term.

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 \$1,728,000 in development expenses through the nine-month period ended September 30, 2006. On August 31, 2006, we opted out of co-development of the basal cell carcinoma product candidate. Genentech will be solely responsible for all future costs and development decisions regarding the basal cell carcinoma program, and we would be entitled to cash payments upon the occurrence of certain development objectives and royalties on product sales, if any should occur.

In August 2006, we established a wholly-owned subsidiary in Shanghai, China called Curis Pharmaceuticals (Shanghai) Co., Ltd., or Curis Shanghai. Curis Shanghai currently has no employees and the Company does not plan to hire any subsidiary employees for the foreseeable future. The Company currently expects that certain operational aspects, including oversight of the third party chemistry provider, will be managed from the Company's Cambridge, Massachusetts location. It is anticipated that payments made to the third party chemistry provider will be made by Curis Shanghai from the Company's capital contributions. Upon establishment of the subsidiary, we are required by the Chinese government to contribute \$2,100,000 to Curis Shanghai, of which the first contribution of \$420,000 is due in November 2006. The remaining capital must be funded by August 2008 and we expect to fund Curis Shanghai as needed to meet its obligations. Once capital has been contributed to

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Curis Shanghai, it will be restricted for use to satisfy only those obligations incurred in China and cannot be transferred back to us. We have not made any payments to Curis Shanghai to date.

We anticipate that existing capital resources at September 30, 2006, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech and Wyeth, assuming these contracts are not earlier terminated, should enable us to maintain current and planned operations into the second half of 2008. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials, for the foreseeable future. Our ability to continue funding planned operations beyond into the second half of 2008 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity 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.

**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 September 30, 2006:

|                                      | (amounts in 000 s)(1) |                 |                 |               |               |            | Total           |
|--------------------------------------|-----------------------|-----------------|-----------------|---------------|---------------|------------|-----------------|
|                                      | Remainder<br>of 2006  | 2007            | 2008            | 2009          | 2010          | Thereafter |                 |
| Debt obligations under note payable  | \$ 350                | 1,342           | 758             |               |               |            | 2,450           |
| Operating lease obligations          | \$ 355                | 1,105           | 948             | 948           | 948           |            | 4,304           |
| Outside service obligations (2)      | \$ 809                | 171             |                 |               |               |            | 980             |
| Licensing obligations                | \$ 322                | 182             |                 |               |               |            | 504             |
| <b>Total future obligations (3).</b> | <b>\$ 1,836</b>       | <b>\$ 2,800</b> | <b>\$ 1,706</b> | <b>\$ 948</b> | <b>\$ 948</b> | <b>\$</b>  | <b>\$ 8,238</b> |

(1) Obligations do not include amounts we will owe Genentech under our co-development arrangement, which was terminated on August 31, 2006. All amounts owed to Genentech were accrued as of September 31, 2006.

(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 September 30, 2006.

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**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.

As of September 30, 2006, we held EURO-denominated assets on our balance sheet totaling \$2,284,000. The underlying assets are expected to have a holding period of eight months or less. The value of these assets could fluctuate based on changes in the exchange rate between the dollar and EURO. The Company has not entered into any hedging agreements relating to this risk.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls & Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 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 September 30, 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 September 30, 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 incurred substantial losses, we expect to continue to incur substantial losses for the foreseeable future and we may never generate significant revenue or achieve profitability.**

We expect to incur substantial operating losses for the foreseeable future, and we have no current sources of material ongoing revenue. As of September 30, 2006, we had an accumulated deficit of approximately \$689,564,000. If we are not able to commercialize any products, whether alone or with a collaborator, we will not achieve profitability. Other than OP-1, a bone-inducing protein developed for use in orthopedic and other therapeutic applications, which we and Stryker Corporation discovered under a former collaboration and 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 an effort to produce products that we can commercialize. Even if our collaboration agreements provide funding for a portion of our research and development expenses, we will need to generate significant revenues in order to fund our 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 titled Risk Factors . Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

We will require substantial funds to continue our research and development programs and to fulfill our planned operating goals. In particular, our currently planned operating and capital requirements primarily include the need for working capital to:

support our research and development activities for our internal programs, including our program in cardiovascular disease and our focus on small molecule multi-targeting inhibitors;

costs related to operating a wholly-owned subsidiary in China;

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 the beginning of 2008; however, our future capital requirements may vary from what we currently 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:

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



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the cost of additional facilities requirements or increased facility costs due to loss of subtenant income;

the unplanned or early termination of any of our 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 may receive in the future from our product candidates in the market;

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

additional costs associated with our Chinese subsidiary including incremental legal, accounting and patent-related expenses.

We expect to seek additional funding through public or private financings of debt or equity and may seek funding from additional strategic collaborators. The market for biotechnology stocks in general, and the market for our common stock in particular, is highly volatile. Due to 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.

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

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

the amount of research and development we engage in;

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

our ability to expand our facilities to support our operations, as needed;

the scope, duration and effectiveness of our collaborative arrangements;

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

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting policies or principles; and

release of successful products into the market by our competitors.

Our potential products currently are primarily in research or pre-clinical development, and revenues from the sales of any products resulting from this research and development may not occur for several years, if at all. A significant amount of our expenses are fixed costs such as lease obligations. As a result, we may experience fluctuations in our operating results from quarter to quarter and continue to generate losses.

Quarterly

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

**We have 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 2003, 2004 or 2005. Instead, we have deferred the \$7,509,000 in payments and will recognize this amount as revenue only when we can reasonably estimate when our contractual steering committee obligations will cease or after we no longer have contractual steering committee obligations under this agreement with Genentech. The contractual term of our steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of our steering committee obligations is indefinite and we expect that we will not record any revenue related to these payments for at least several years.

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 that 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 would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our business, results of operations and financial condition.

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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 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. 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**

We currently have collaborations with Genentech, Procter & Gamble, Wyeth Pharmaceuticals and Ortho Biotech Products as well as a screening program with Centocor.

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

The success of our strategy for development and commercialization of certain licensed product candidates depends upon our ability to form and maintain productive strategic collaborations. We currently have strategic collaborations with Genentech, Wyeth, Procter & Gamble, Centocor and Ortho Biotech Products. Three of these collaborations, Ortho Biotech, Centocor and Procter & Gamble have involved limited development effort and corresponding funding by us. To date, the Genentech and Wyeth collaborations have involved substantial development effort and related funding by us, in order to assist the collaborators to advance the programs. These collaborations are now moving into a development phase where our effort will be minimized or eliminated. Accordingly, the funding associated with such development effort will be reduced or eliminated. We will need to reassign development personnel who have been working on such programs to new programs. Some new programs may be retained by us and others may be licensed and thus subject to funding by new collaborators. We may not be successful in transferring all current personnel to new programs due to lack of specific skills and training. In addition, we may not be successful in obtaining funding for new development programs, either from new collaborators or the capital markets.

During the nine-month period ended September 30, 2006 and the year ended December 31, 2005, \$7.2 million and \$9.6 million, or 68% and 85%, respectively, of our gross revenue was derived from licensing and research and development payments received from our current collaborators. We hope to enter into additional collaborations in the future. Our existing and any future collaborations may not be scientifically or commercially successful.

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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 or capability to independently undertake product development, manufacturing and commercialization, which could result in a discontinuation of such program.

Our strategic collaboration agreements permit our collaborators wide discretion in terms of deciding which product candidates to advance 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 to be too early for collaborative effort. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us. Finally, any such strategic alliances or other arrangements may not result in the successful development and commercialization of products and associated revenue.

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

**We and our collaborators may not achieve our projected research and development goals in the time frames we announce and expect, which could have an adverse impact on our business and could cause our stock price to decline.**

We set goals for and make public statements regarding the timing of certain accomplishments, such as the commencement and completion of preclinical studies and clinical trials, anticipated regulatory approval dates and other developments and milestones under our collaboration agreements. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or our collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by our collaborators and the uncertainties inherent in the regulatory approval process. There can be no assurance that our or our collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we announce.

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or expect, that we or our collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or our collaborators fail to achieve one or more of these milestones as planned, our business will be materially adversely affected and the price of our common stock could decline.

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

Our product candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the fields of regulatory signaling pathways and functional genomics, which includes our work with Genentech in the field of cancer, with Wyeth in the field of neurology and with Procter & Gamble in the field of hair growth regulation, is highly competitive. Our competitors may discover, characterize and develop important inducing molecules or genes before we do. We also face competition from these and other entities in gaining access to human tissue samples used in our research and development projects.

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

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

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

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

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

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

Product liability claims, inherent in the process of researching, developing and commercializing human health care products, could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. Although we do not currently commercialize any products, claims could be made against us based upon the use of our drug candidates in clinical trials. Product liability claims

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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 any 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 depend upon our senior management and scientific staff. The loss of the service of any of the key members of our senior management, such as the departure in July 2006 of Dr. Lee L. Rubin, our former Executive Vice President and Chief Scientific Officer, may significantly delay or prevent the achievement of product development and other business objectives. Our executive officers, including Daniel R. Passeri, our President and Chief Executive Officer, can terminate their employment with us at any time. We are not aware of any present intention of any of these individuals to leave our company. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency. We do not maintain key man life insurance on any of these executive officers.

Our ability to operate successfully will depend on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

**\*We may seek to acquire complementary businesses and technologies in the future or otherwise seek to expand our operations to grow our business which may divert management resources and adversely affect our financial condition and operating results.**

We expect to expand our operations in the future, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. For example, in September 2006, we formed a wholly-owned subsidiary in China in an effort to leverage China's cost-efficient medicinal chemistry industry as a means to broaden our drug discovery pipeline. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute in any such other expansion strategies. In connection with our expansion efforts in China, we will need to integrate operations and cultures that are different and unfamiliar. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating result, including:

a diversion of management from our existing operations;

increased operating complexity of our business, requiring greater personnel and resources;

significant additional cash expenditures to expand our operations and acquire and integrate new businesses and technologies;

incurrence of debt and other contingent liabilities;

dilutive stock issuances.

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**RISKS RELATING TO OUR INTELLECTUAL PROPERTY**

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

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business and expect to enter into similar agreements with third parties in the future. Under these agreements, we 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 that the United States Patent and Trademark Office uses to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our 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 license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge.

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

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

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

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Situations that may give rise to patent litigation or other disputes over the use of our intellectual property include:

initiation of litigation or other proceedings against third parties to enforce our patent rights;

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

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 that may be important to our business.

The costs associated with any patent litigation or other proceeding, even if resolved favorably, will likely be substantial. Some of our competitors may be able to sustain the cost of such litigation or other proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably, we or our collaborative partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or our collaborative partners may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of, the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and expense.

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

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through confidentiality 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 design and 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.



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

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

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

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

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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 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 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

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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 with which we enter into manufacturing arrangements, will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. 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, 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 that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

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

we may not be able to attract and build a significant and skilled marketing staff or sales force;

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the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and

our direct sales and marketing efforts may not be successful.

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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

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

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as \$6.59 and as low as \$0.91 per share for the period January 1, 2004 through September 30, 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;

market conditions in the biotechnology and pharmaceutical sectors;

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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;

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 September 30, 2006, we had outstanding approximately 49.2 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.**

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

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**PART II OTHER INFORMATION**

**Item 6. EXHIBITS**

See exhibit index.

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**SIGNATURE**

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

CURIS, INC.

Dated: November 9, 2006

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

Senior Vice President of Finance and Chief Financial Officer

(Principal Financial and Accounting Officer)

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**EXHIBIT INDEX**

**Exhibit**

| <b>Number</b> | <b>Description</b>  |
|---------------|---|
| 10.1          | Consulting Agreement dated June 19, 2006 by and between the Company and Joseph M. Davie, Ph. D., M.D. (incorporated herein by reference to the Company's Current Report on Form 8-K filed on August 29, 2006).                  |
| 10.2          | Consulting Agreement dated September 13, 2006 by and between the Company and Lee Rubin, Ph. D. (incorporated herein by reference to the Company's Current Report on Form 8-K filed on September 19, 2006).                      |
| 10.3          | Scientific Advisory Agreement dated September 14, 2006 by and between the Company and Joseph M. Davie, Ph. D., M.D. (incorporated herein by reference to the Company's Current Report on Form 8-K filed on September 19, 2006). |
| 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   |