

CURIS INC  
Form 10-Q/A  
March 31, 2006  
Table of Contents

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

Washington, D.C. 20549

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**FORM 10-Q/A**

**Amendment No. 1**

(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, 2005**

**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

04-3505116

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(State or Other Jurisdiction of

(I.R.S. Employer

Incorporation or Organization)

Identification No.)

61 Moulton Street

Cambridge, Massachusetts  
(Address of Principal Executive Offices)

02138  
(Zip Code)

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

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Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  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 11, 2005, there were 49,339,994 shares of the Registrant's common stock outstanding.

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**Table of Contents**

**EXPLANATORY NOTE:**

This Amendment No. 1 on Form 10-Q/A is being filed to restate the September 30, 2005 and December 31, 2004 consolidated balance sheets contained herein to correct amounts reported in prepaid expenses and other current assets, deposits and other assets, short-term and long-term deferred revenues, additional paid-in capital, and accumulated deficit; and to restate the consolidated statements of operations for the three- and nine-month periods ended September 30, 2005 and September 30, 2004, to correct amounts reported in gross revenues and research and development expenses. As a result of these restatements, amounts in the consolidated statements of cash flows for the nine-month periods ended September 30, 2005 and 2004 have also been corrected.

A summary of the effects of this restatement to our financial statements included within this Amendment No. 1 on Form 10-Q/A is presented at Note 3, Restatement of Financial Statements.

This Amendment No. 1 amends Part I, Items 1 and 2 and Part II, Item 6 of the Quarterly Report on Form 10-Q for the three- and nine-month periods ended September 30, 2005. This Amendment No. 1 continues to reflect circumstances as of the date of the original filing of the Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 and we have not updated the disclosures contained herein to reflect events that occurred at a later date, except for items related to the restatement or where otherwise indicated.

We do not anticipate filing amended Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for any periods prior to the first quarter of 2005. Our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q from the second quarter of 2003 through fiscal 2004 have not been revised to reflect the restatement and the consolidated financial statements contained in those reports should not be relied upon. Instead, the consolidated financial statements for fiscal 2004 and 2003 included in our Annual Report on Form 10-K for the fiscal period ended December 31, 2005 should be relied upon.

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**Table of Contents**

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

**INDEX**

|   | <b>Page</b>          |
|---|----------------------|
|   | <b><u>Number</u></b> |
| <b>PART I. FINANCIAL INFORMATION</b>  |                      |
| Item 1. <u>Financial Statements</u>   |                      |
| <u>Condensed Consolidated Balance Sheets as of September 30, 2005 and December 31, 2004 (unaudited and as restated)</u>   | 4                    |
| <u>Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2005 and 2004 (unaudited and as restated)</u> | 5                    |
| <u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2005 and 2004 (unaudited and as restated)</u>                                  | 6                    |
| <u>Notes to Unaudited Condensed Consolidated Financial Statements</u>   | 7                    |
| Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>  | 25                   |
| <b>PART II. <u>OTHER INFORMATION</u></b>  |                      |
| Item 6. <u>Exhibits</u>   | 55                   |
| <u>SIGNATURE</u>  | 56                   |

**Table of Contents****Item 1. FINANCIAL STATEMENTS**

**CURIS, INC. AND SUBSIDIARY**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(unaudited)**

|  | September 30,<br>2005 | December 31,<br>2004 |
|--|-----------------------|----------------------|
|  | (as restated)         | (as restated)        |
| <b>ASSETS</b>                                      |                       |                      |
| Current Assets:                                    |                       |                      |
| Cash and cash equivalents                          | \$ 22,884,331         | \$ 22,679,924        |
| Marketable securities                              | 20,013,996            | 26,834,038           |
| Accounts receivable                                | 2,026,140             | 1,226,460            |
| Prepaid expenses and other current assets          | 1,004,128             | 796,618              |
| <b>Total current assets</b>                        | <b>45,928,595</b>     | <b>51,537,040</b>    |
| Property and Equipment, net                        | 5,015,497             | 3,416,620            |
| Other Assets:                                      |                       |                      |
| Long-term investments                              |                       | 2,606,681            |
| Long-term investments restricted                   | 195,998               | 193,166              |
| Goodwill, net                                      | 8,982,000             | 8,982,000            |
| Other intangible assets, net                       | 45,818                | 102,122              |
| Deposits and other assets                          | 475,664               | 494,413              |
| <b>Total other assets</b>                          | <b>9,699,480</b>      | <b>12,378,382</b>    |
|  | <b>\$ 60,643,572</b>  | <b>\$ 67,332,042</b> |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>         |                       |                      |
| Current Liabilities:                               |                       |                      |
| Debt, current portion                              | \$ 1,634,680          | \$ 1,141,294         |
| Convertible notes payable                          | 2,556,962             |                      |
| Accounts payable                                   | 1,320,839             | 1,643,219            |
| Accrued liabilities                                | 2,271,819             | 1,078,687            |
| Deferred revenue, current portion                  | 1,236,152             | 819,640              |
| <b>Total current liabilities</b>                   | <b>9,020,452</b>      | <b>4,682,840</b>     |
| Long-term debt obligations, net of current portion | 1,187,500             |                      |
| Convertible notes payable, net of current portion  |                       | 5,710,007            |
| Deferred revenue, net of current portion           | 10,440,558            | 8,356,134            |
| Other long-term liabilities                        | 763,800               | 271,058              |
| <b>Total liabilities</b>                           | <b>21,412,310</b>     | <b>19,020,039</b>    |

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|   | September 30, 2005   | December 31, 2004    |
|---|----------------------|----------------------|
| <b>Commitments</b>  |                      |                      |
| <b>Stockholders' Equity:</b>  |                      |                      |
| Common stock, \$0.01 par value  |                      |                      |
| 125,000,000 shares authorized; 49,333,495 and 48,285,788 shares issued and outstanding, respectively, at September 30, 2005 and 48,565,120 and 47,517,413 shares issued and outstanding, respectively, at December 31, 2004 | 493,335              | 485,652              |
| Additional paid-in capital  | 718,740,861          | 714,831,427          |
| Treasury stock (at cost, 1,047,707 shares at September 30, 2005 and December 31, 2004)  | (891,274)            | (891,274)            |
| Deferred compensation   | (386,699)            | (834,157)            |
| Accumulated deficit   | (678,689,593)        | (665,199,001)        |
| Accumulated other comprehensive loss  | (35,368)             | (80,644)             |
|   | <u>39,231,262</u>    | <u>48,312,003</u>    |
| <b>Total stockholders' equity</b>   | <b>\$ 60,643,572</b> | <b>\$ 67,332,042</b> |

See accompanying notes to unaudited condensed consolidated financial statements.

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

|   | Three Months Ended<br>September 30, |                              | Nine Months Ended<br>September 30, |                              |
|---|-------------------------------------|------------------------------|------------------------------------|------------------------------|
|   | 2005<br><u>(as restated)</u>        | 2004<br><u>(as restated)</u> | 2005<br><u>(as restated)</u>       | 2004<br><u>(as restated)</u> |
| <b>REVENUES:</b>  |                                     |                              |                                    |                              |
| License fees  | \$ 258,544                          | \$ 68,100                    | \$ 582,243                         | \$ 174,365                   |
| Research and development contracts                        | 2,626,072                           | 1,100,881                    | 7,358,750                          | 2,289,033                    |
| Substantive Milestones                                    |                                     |                              | 250,000                            | 50,000                       |
| <b>Gross Revenues</b>                                     | <b>2,884,616</b>                    | <b>1,168,981</b>             | <b>8,190,993</b>                   | <b>2,513,398</b>             |
| Contra-revenues from co-development with Genentech        | (819,491)                           |                              | (5,697,993)                        |                              |
| <b>Net Revenues</b>                                       | <b>2,065,125</b>                    | <b>1,168,981</b>             | <b>2,493,000</b>                   | <b>2,513,398</b>             |
| <b>COSTS AND EXPENSES:</b>                                |                                     |                              |                                    |                              |
| Research and development                                  | 3,691,261                           | 3,324,079                    | 10,409,583                         | 9,380,846                    |
| General and administrative                                | 1,832,802                           | 2,138,070                    | 6,141,013                          | 6,460,769                    |
| Amortization of intangible assets                         | 18,768                              | 18,768                       | 56,304                             | 56,304                       |
| <b>Total costs and expenses</b>                           | <b>5,542,831</b>                    | <b>5,480,917</b>             | <b>16,606,900</b>                  | <b>15,897,919</b>            |
| <b>Loss from operations</b>                               | <b>(3,477,706)</b>                  | <b>(4,311,936)</b>           | <b>(14,113,900)</b>                | <b>(13,384,521)</b>          |
| <b>OTHER INCOME (EXPENSE):</b>                            |                                     |                              |                                    |                              |
| Interest income   | 319,208                             | 116,358                      | 861,869                            | 332,530                      |
| Other income  |                                     | 39,500                       | 24,958                             | 232,845                      |
| Interest expense  | (92,843)                            | (102,474)                    | (263,519)                          | (306,753)                    |
| <b>Total other income, net</b>                            | <b>226,365</b>                      | <b>53,384</b>                | <b>623,308</b>                     | <b>258,622</b>               |
| <b>Net loss</b>   | <b>\$ (3,251,341)</b>               | <b>\$ (4,258,552)</b>        | <b>\$ (13,490,592)</b>             | <b>\$ (13,125,899)</b>       |
| <b>Net loss per common share (basic and diluted)</b>      | <b>\$ (0.07)</b>                    | <b>\$ (0.10)</b>             | <b>\$ (0.28)</b>                   | <b>\$ (0.32)</b>             |
| <b>Weighted average common shares (basic and diluted)</b> | <b>48,178,626</b>                   | <b>41,620,123</b>            | <b>47,998,663</b>                  | <b>41,398,656</b>            |
| <b>Net loss</b>   | <b>\$ (3,251,341)</b>               | <b>\$ (4,258,552)</b>        | <b>\$ (13,490,592)</b>             | <b>\$ (13,125,899)</b>       |
| Unrealized gain (loss) on marketable securities           | 25,585                              | 23,330                       | 45,276                             | (35,829)                     |
| <b>Comprehensive loss</b>                                 | <b>\$ (3,225,756)</b>               | <b>\$ (4,235,222)</b>        | <b>\$ (13,445,316)</b>             | <b>\$ (13,161,728)</b>       |

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See accompanying notes to unaudited condensed consolidated financial statements.



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

|   | Nine Months Ended<br>September 30, |                 |
|---|------------------------------------|-----------------|
|   | 2005                               | 2004            |
|   | (as restated)                      | (as restated)   |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                                    |                 |
| Net loss  | \$ (13,490,592)                    | \$ (13,125,899) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                    |                 |
| Depreciation and amortization   | 668,720                            | 833,045         |
| Stock-based compensation expense  | 193,004                            | 1,058,678       |
| Non-cash interest on notes payable  | 152,478                            | 293,549         |
| Amortization of intangible assets   | 56,304                             | 56,304          |
| Decrease/increase in long-term receivables                                  |                                    |                 |
| Changes in current assets and liabilities:                                  |                                    |                 |
| Accounts receivable   | (799,680)                          | (396,368)       |
| Prepaid expenses and other assets   | (188,761)                          | (101,713)       |
| Accounts payable and accrued liabilities                                    | 1,363,494                          | 251,008         |
| Deferred contract revenue   | 2,500,936                          | 3,546,348       |
| Total adjustments   | 3,946,495                          | 5,540,851       |
| Net cash used in operating activities                                       | (9,544,097)                        | (7,585,048)     |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                                    |                 |
| Purchase of marketable securities   | (24,904,025)                       | (17,383,387)    |
| Sale of marketable securities   | 31,769,343                         | 10,400,683      |
| Increase in restricted cash   | (2,832)                            |                 |
| Purchase of long-term investments   |                                    | (4,568,290)     |
| Sale of long-term investments   | 2,606,681                          | 5,350,350       |
| Purchases and dispositions of property and equipment                        | (2,267,597)                        | (1,042,801)     |
| Net cash provided by (used in) investing activities                         | 7,201,570                          | (7,243,445)     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                                    |                 |
| Proceeds from issuance of common stock                                      | 866,048                            | 3,409,560       |
| Proceeds from issuance of debt  | 1,993,386                          | 591,930         |
| Repayments of notes payable and capital leases                              | (312,500)                          | (332,056)       |
| Net cash provided by financing activities                                   | 2,546,934                          | 3,669,434       |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS                        | 204,407                            | (11,159,059)    |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD                              | 22,679,924                         | 27,734,548      |
| CASH AND CASH EQUIVALENTS, END OF PERIOD                                    | \$ 22,884,331                      | \$ 16,575,489   |

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:

Issuance of common stock in connection with conversion of note payable to Elan Pharma International, Limited (Note 10)

\$ 3,305,523

\$

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

**1. Nature of Business**

Curis, Inc. (the Company or Curis) is a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the repair and regeneration of human tissues and organs. The Company's product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways. The Company's lead product candidate, a topical therapy for the treatment of basal cell carcinoma, is currently in a phase I clinical trial and is being co-developed with Genentech, Inc., or Genentech, a collaborator. The Company is sharing equally in all U.S. development costs and will share equally in any future U.S. net profits and/or losses, should its basal cell carcinoma product candidate be successfully developed and marketed. The Company operates in a single reportable segment: developmental biology products. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by its competitors of new technological innovations, dependence on key personnel, its ability to protect proprietary technology, reliance on corporate collaborators and licensors to successfully research, develop and commercialize products based on the Company's technologies, its ability to comply with FDA government regulations and approval requirements as well as its ability to grow its business and obtain adequate financing to fund this growth.

**2. Basis of Presentation**

The accompanying 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, 2004, as filed with the Securities and Exchange Commission on March 15, 2005.

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, 2005, the results of operations for the three- and nine-month periods ended September 30, 2005 and 2004, and cash flows for the nine-month periods ended September 30, 2005 and 2004. 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. Restatement of Financial Statements**

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The Company has restated its September 30, 2005 and December 31, 2004 consolidated balance sheets to correct amounts in prepaid expenses and other current assets, deposits and other assets, short- and long-term deferred revenues, additional paid-in capital, and accumulated deficit. The Company has also restated

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**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

its consolidated statements of operations for the three-month and nine-month periods ended September 30, 2005 and September 30, 2004, to correct amounts in gross revenues and research and development expenses. As a result of these restatements, amounts in the consolidated statements of cash flows for the nine-month periods ended September 30, 2005 and 2004 have also been corrected. The correction of the accounting for the June 2003 Genentech collaboration and the January 2004 Wyeth collaboration agreements resulted in a \$1,629,000 decrease in net cash used in operating activities and a corresponding decrease in net cash provided by financing activities for the nine-month period ended September 30, 2005.

These adjustments are more fully described as follows:

*Genentech license fee payments:* The Company had been recognizing revenue in connection with \$7,509,000 in license maintenance fee payments received from Genentech as of part of the June 2003 Hedgehog antagonist collaboration between the parties over an eight-year period based on the Company's belief that its 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. The Company has determined it should not have recognized any of this revenue in 2005, 2004, or 2003. Instead, the Company will defer the \$7,509,000 in payments and recognize this amount as revenue only when the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company's 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 the Company's steering committee obligations is indefinite and the Company expects that it will not record any revenue related to these payments for at least several years.

*Expenses due to university licensors:* The Company is restating previously reported research and development expenses associated with \$410,000 in license fee payments that were payable by the Company to university licensors in connection with the June 2003 Hedgehog antagonist collaboration with Genentech. The Company had previously capitalized this amount as Prepaid expenses and other current assets and Deposits and other assets in its consolidated balance sheets and amortized this amount to research and development expense as the related license fee was recognized. The Company has determined that it should have instead recognized the entire \$410,000 immediately as research and development expense in June 2003.

*Correction of previously identified immaterial errors Allocation of up-front payments received from Genentech and Wyeth:* In connection with the restatement, the Company will also correct other previously identified immaterial errors which had previously been corrected through a cumulative adjustment to the consolidated financial statements in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005. The restatement will allocate the adjustment among the correct periods.

These errors relate to the Company's sale of shares of its common stock in connection with the June 2003 Genentech and January 2004 Wyeth collaboration agreements. In each case, the Company calculated the value of the common stock using the negotiated price (which was less than the closing market price on the agreement date). Because of this, the Company understated additional paid-in capital and overstated deferred revenues by \$1,629,000. During the third quarter of 2005, prior to restating, the Company recorded a cumulative adjustment as a result of these errors to reverse previously recorded license fee revenue of \$460,000 for the years ended December 31, 2004 and 2003 and through the nine-month period ended September 30, 2005. The overstatement of deferred revenues resulted in an overstatement of license fee revenues because, in



**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

each case, the Company amortized deferred revenue over the estimated performance period to revenues in its consolidated statements of operations. The Company will correct its accounting for these common stock sales by allocating the fair value of the common stock sold to its additional paid-in capital accounts at the date of sale and by removing the effect of any license fee revenue that had been previously recorded as a result of these errors. The correction of the accounting for the January 2004 Wyeth collaboration agreement resulted in a \$138,000 increase in net cash used in operating activities and a corresponding increase in net cash provided by financing activities for the nine months ended September 30, 2004.

The following is a summary of the effects of the changes described above:

|   | <u>As Previously<br/>Reported</u> | <u>Adjustments</u> | <u>As Restated</u> |
|---|-----------------------------------|--------------------|--------------------|
| <b><u>Consolidated Balance Sheets</u></b>           |                                   |                    |                    |
| <b>September 30, 2005</b>                           |                                   |                    |                    |
| Prepaid expenses and other current assets           | \$ 1,068,822                      | \$ (64,694)        | \$ 1,004,128       |
| Total current assets                                | 45,993,289                        | (64,694)           | 45,928,595         |
| Total assets  | 60,708,266                        | (64,694)           | 60,643,572         |
| Deferred revenue, current portion                   | 2,152,210                         | (916,058)          | 1,236,152          |
| Total current liabilities                           | 9,936,510                         | (916,058)          | 9,020,452          |
| Deferred revenue, net of current portion            | 7,290,927                         | 3,149,631          | 10,440,558         |
| Accumulated deficit                                 | (676,391,326)                     | (2,298,267)        | (678,689,593)      |
| Total stockholders' equity                          | 41,529,529                        | (2,298,267)        | 39,231,262         |
| Total liabilities and stockholders' equity          | 60,708,266                        | (64,694)           | 60,643,572         |
| <b>December 31, 2004</b>                            |                                   |                    |                    |
| Prepaid expenses and other current assets           | \$ 843,198                        | \$ (46,580)        | \$ 796,618         |
| Total current assets                                | 51,583,620                        | (46,580)           | 51,537,040         |
| Deposits and other assets                           | 750,604                           | (256,191)          | 494,413            |
| Total other assets                                  | 12,634,573                        | (256,191)          | 12,378,382         |
| Total assets  | 67,634,813                        | (302,771)          | 67,332,042         |
| Deferred revenue, current portion                   | 1,939,708                         | (1,120,068)        | 819,640            |
| Total current liabilities                           | 5,802,908                         | (1,120,068)        | 4,682,840          |
| Deferred revenue, net of current portion            | 6,941,545                         | 1,414,589          | 8,356,134          |
| Additional paid-in capital                          | 713,202,427                       | 1,629,000          | 714,831,427        |
| Accumulated deficit                                 | (662,972,709)                     | (2,226,292)        | (665,199,001)      |
| Total stockholders' equity                          | 48,909,295                        | (597,292)          | 48,312,003         |
| Total liabilities and stockholders' equity          | 67,634,813                        | (302,771)          | 67,332,042         |
| <b><u>Consolidated Statements of Operations</u></b> |                                   |                    |                    |
| <b>Three months ended September 30, 2005</b>        |                                   |                    |                    |
| License fee revenues                                | \$ 8,561                          | \$ 249,983         | \$ 258,544         |
| Gross revenues                                      | 2,634,633                         | 249,983            | 2,884,616          |
| Net revenues  | 1,815,142                         | 249,983            | 2,065,125          |
| Research and development expenses                   | 3,820,650                         | (129,389)          | 3,691,261          |
| Total costs and expenses                            | 5,672,220                         | (129,389)          | 5,542,831          |
| Loss from operations                                | (3,857,078)                       | 379,372            | (3,477,706)        |

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|   |             |         |             |
|---|-------------|---------|-------------|
| Net loss                                      | (3,630,713) | 379,372 | (3,251,341) |
| Net loss per common share (basic and diluted) | \$ (0.08)   | \$ 0.01 | \$ (0.07)   |



**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

|   | <u>As Previously<br/>Reported</u> | <u>Adjustments</u> | <u>As Restated</u> |
|---|-----------------------------------|--------------------|--------------------|
| <b>Three months ended September 30, 2004</b>  |                                   |                    |                    |
| License fee revenues                          | \$ 385,345                        | \$ (317,245)       | \$ 68,100          |
| Gross revenues                                | 1,486,226                         | (317,245)          | 1,168,981          |
| Net revenues                                  | 1,486,226                         | (317,245)          | 1,168,981          |
| Research and development expenses             | 3,288,472                         | 35,607             | 3,324,079          |
| Total costs and expenses                      | 5,445,310                         | 35,607             | 5,480,917          |
| Loss from operations                          | (3,959,084)                       | (352,852)          | (4,311,936)        |
| Net loss                                      | (3,905,700)                       | (352,852)          | (4,258,552)        |
| Net loss per common share (basic and diluted) | \$ (0.09)                         | \$ (0.01)          | \$ (0.10)          |
| <b>Nine months ended September 30, 2005</b>   |                                   |                    |                    |
| License fee revenues                          | \$ 892,295                        | \$ (310,052)       | \$ 582,243         |
| Gross revenues                                | 8,501,045                         | (310,052)          | 8,190,993          |
| Net revenues                                  | 2,803,052                         | (310,052)          | 2,493,000          |
| Research and development expenses             | 10,647,659                        | (238,076)          | 10,409,583         |
| Total costs and expenses                      | 16,844,976                        | (238,076)          | 16,606,900         |
| Loss from operations                          | (14,041,924)                      | (71,976)           | (14,113,900)       |
| Net loss                                      | (13,418,616)                      | (71,976)           | (13,490,592)       |
| Net loss per common share (basic and diluted) | \$ (0.28)                         | \$ (0.00)          | \$ (0.28)          |
| <b>Nine months ended September 30, 2004</b>   |                                   |                    |                    |
| License fee revenues                          | \$ 1,123,067                      | \$ (948,702)       | \$ 174,365         |
| Gross revenues                                | 3,462,100                         | (948,702)          | 2,513,398          |
| Net revenues                                  | 3,462,100                         | (948,702)          | 2,513,398          |
| Research and development expenses             | 9,448,534                         | (67,688)           | 9,380,846          |
| Total costs and expenses                      | 15,965,607                        | (67,688)           | 15,897,919         |
| Loss from operations                          | (12,503,507)                      | (881,014)          | (13,384,521)       |
| Net loss                                      | (12,244,885)                      | (881,014)          | (13,125,899)       |
| Net loss per common share (basic and diluted) | \$ (0.30)                         | \$ (0.02)          | \$ (0.32)          |

**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

|   | <u>As Previously<br/>Reported</u> | <u>Adjustments</u> | <u>As Restated</u> |
|---|-----------------------------------|--------------------|--------------------|
| <b><u>Consolidated Statements of Cash Flows</u></b>                 |                                   |                    |                    |
| <b>Nine months ended September 30, 2005</b>                         |                                   |                    |                    |
| Net loss  | \$ (13,418,616)                   | \$ (71,976)        | \$ (13,490,592)    |
| Changes in operating assets and liabilities:                        |                                   |                    |                    |
| Prepaid expenses and other assets                                   | 49,316                            | (238,077)          | (188,761)          |
| Deferred revenue  | 561,884                           | 1,939,052          | 2,500,936          |
| Total adjustments   | 2,245,519                         | 1,700,976          | 3,946,495          |
| Net cash used in operating activities                               | (11,173,097)                      | 1,629,000          | (9,544,097)        |
| Reclassification of deferred revenues to additional paid-in capital | 1,629,000                         | (1,629,000)        |                    |
| Net cash provided by financing activities                           | 4,175,934                         | (1,629,000)        | 2,546,934          |
| <b>Nine months ended September 30, 2004</b>                         |                                   |                    |                    |
| Net loss  | \$ (12,244,885)                   | \$ (881,014)       | \$ (13,125,899)    |
| Increase in long-term receivables                                   | 2,000,000                         | (2,000,000)        |                    |
| Changes in operating assets and liabilities:                        |                                   |                    |                    |
| Prepaid expenses and other assets                                   | (234,023)                         | 132,310            | (101,713)          |
| Accounts payable and accrued liabilities                            | 451,006                           | (199,998)          | 251,008            |
| Deferred revenue  | 735,646                           | 2,810,702          | 3,546,348          |
| Total adjustments   | 4,797,837                         | 743,014            | 5,540,851          |
| Net cash used in operating activities                               | (7,447,048)                       | (138,000)          | (7,585,048)        |
| Proceeds from issuance of common stock                              | 3,271,560                         | 138,000            | 3,409,560          |
| Net cash provided by financing activities                           | 3,531,434                         | 138,000            | 3,669,434          |

**4. Financial Statement Reclassifications**

The Company has reclassified \$368,000 and \$1,059,000, respectively, for the three- and nine-month periods ended September 30, 2004 from Stock-based compensation expense to Research and development expenses and General and administrative expenses in the Company's costs and expenses section of its consolidated statements of operations and comprehensive loss to conform with the current period presentation. Of these amounts, \$342,000 and \$864,000 were reclassified to Research and development expenses and \$26,000 and \$195,000 were reclassified to General and administrative expenses for the three- and nine-month periods ended September 30, 2004, respectively.

**5. 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 milestones and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF 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)*.

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Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably

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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements are analyzed to determine whether the deliverables, which often include a license and performance obligations such as research and steering committee services can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The Company recognizes revenue using the relative performance method provided that the Company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Direct labor hours or full-time equivalents are typically used as the measure of performance. Revenue recognized under the relative performance method would be determined by multiplying the total payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of level of effort incurred to date to estimated total level of effort required to complete the Company's performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the Company cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or become inconsequential.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. In addition, if the Company is involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, the Company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.



**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

Collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

the milestone payments are non-refundable;

achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;

substantive effort is involved in achieving the milestone;

the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,

a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above. In addition, the determination that one such payment was not a substantive milestone would prevent the Company from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments would also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable.

Reimbursement of costs is recognized as revenue provided the provisions of EITF 99-19 are met, the amounts are determinable, and collection of the related receivable is reasonably assured.

Royalty revenue is recognized upon the sale of the related products, provided that the royalty amounts are fixed or determinable, collection of the related receivable is reasonably assured and the Company has no remaining performance obligations under the arrangement. If royalties are received when the Company has remaining performance obligations, the royalty payments would be attributed to the services being provided under the arrangement and therefore would be recognized as such performance obligations are performed under either the relative performance or straight line methods, as applicable, and in accordance with these policies as described above.

For revenue-generating arrangements where the Company, as a vendor, provides consideration to a licensor or collaborator, as a customer, the Company applies the provisions of EITF 01-9. EITF 01-9 addresses the accounting for revenue arrangements where both the vendor and the customer make cash payments to each other for services and/or products. A payment to a customer is presumed to be a reduction of the selling

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price unless the Company receives an identifiable benefit for the payment and the Company can reasonably estimate the fair value of the benefit received. Payments to a customer that are deemed a reduction of selling price are recorded first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and of probable future revenues, which include any unamortized deferred revenue balances, under all arrangements with such customer and then as an expense. Payments that are not deemed to be a reduction of selling price would be recorded as an expense.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during

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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

the twelve-month period ended September 30, 2006 are classified as long-term deferred revenue. As of September 30, 2005, the Company has short- and long-term deferred revenue of \$1,236,000 and \$10,448,000, respectively, related to its collaborations.

The Company received a grant award during 2004 from the Spinal Muscular Atrophy Foundation. Revenue under this grant is being recognized as the services are provided and when payment is reasonably assured under the terms of the grant.

**6. Procter & Gamble Collaboration**

*(i) Collaboration Summary*

On September 18, 2005, the Company entered into a collaboration, research and license agreement with the Procter & Gamble Company, or P&G, to evaluate and seek to develop potential treatments for hair growth regulation and skin disorders utilizing the Company's Hedgehog agonist technology.

Under the terms of the agreement, the Company granted P&G an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate the Company's Hedgehog agonist technology. In accordance with the terms of the agreement, the parties shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by P&G. P&G is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program. At the time that P&G determines to file the first investigational new drug application with the U.S. Food and Drug Administration for a product candidate, the Company shall have the option, at its sole discretion, to co-develop a product candidate through phases I and II of clinical development at a 20% or 50% participation rate. Should the Company elect to exercise its co-development option, the Company will forego development milestones that would otherwise be payable during the period from investigational new drug application filing through the completion of a phase II clinical trial. The Company, however, would receive a higher royalty in the event that it exercises its co-development option and subsequently shares in development expense through phase II clinical trials. The amount of the royalty increase is based on the co-development percentage elected by the Company. Under the agreement, P&G paid the Company an up-front license fee of \$500,000 and has agreed to fund up to \$600,000 for two Curis full-time equivalents providing research and development activities during the initial one-year research term, subject to its termination rights. P&G has an option to extend the initial one-year research term for up to three additional years in one-year increments. P&G has also agreed to make cash payments to the Company that are contingent upon the successful achievement of certain research, development, clinical and drug approval milestones, including \$2,800,000 in preclinical milestones. P&G will also pay the Company royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Unless terminated earlier in accordance with the terms of the agreement, the agreement shall continue until six months after the expiration of the last to expire of any patent rights covering a product being sold under the agreement. Early termination rights are as follows:

During the first twelve months, the agreement may not be terminated by either party, except in the case of breach, as discussed below, or failure of all, or all but one, of the licensed compounds to demonstrate acceptable results in certain tests as specified in the agreement and the research plan. In the event of such failure, P&G may terminate the agreement and the



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related research obligations (full-time equivalent reimbursement) without cause, with 45 days prior written notice.

Following the initial twelve-month period, P&G shall have the right to terminate the agreement without cause upon at least six months prior written notice.

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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

Upon or after the uncured breach of any material provision of the agreement by a party, the other party may terminate the agreement immediately upon written notice to the defaulting party.

If P&G terminates the agreement without cause or the Company terminates the agreement as a result of P&G's material breach, then, among other things, all licenses granted to P&G shall terminate. The Company shall have the exclusive option to acquire from P&G all data generated by P&G and all regulatory approvals and other regulatory filings and submissions, clinical data, promotional, advertising, marketing and distribution rights or contracts, and other similar information and items related to the compounds developed during the collaboration by P&G, on commercially reasonable terms to be mutually agreed to by the parties. Upon termination of the agreement by P&G as a result of a material breach by the Company, all rights and licenses granted to P&G under the agreement shall terminate.

(ii) *Accounting Summary*

The Company considers its arrangement with P&G to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include an exclusive license to evaluate and develop potential treatments for hair growth regulation and skin disorders and certain performance obligations, including research and development services for at least one year and participation on at least one steering committee. The Company applied the provisions of Emerging Issues Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21) to determine whether the performance obligations under this collaboration can be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these performance obligations represented a single unit of accounting, since the Company believes that the license does not have stand-alone value to P&G without the Company's research services and steering committee participation during certain phases of the development process and because objective and reliable evidence of the fair value of the Company's research and steering committee participation could not be determined.

The Company's ongoing performance obligations under this collaboration consist of participation on a steering committee and the performance of preclinical research services. The Company cannot reasonably estimate the total level of effort required over the performance period and, therefore, is recognizing revenue on a straight-line basis over the performance period, which it has estimated to be six years. In developing its estimate of the period to complete its performance obligations, the Company estimates the time required to complete phase II clinical trials of a product candidate under the collaboration to be six years. The performance period was determined based on management's estimate of its involvement through co-development of phase IIB clinical trials since, should Curis exercise its co-development option, Curis' last deliverable under this arrangement would be its participation on the clinical development steering committee through phase IIB. The steering committee effort is also expected to be consistent over the six-year period.

The Company has attributed the \$500,000 up-front fee plus \$600,000, the total amount of currently committed research funding which the Company expects to receive for providing two full-time equivalents at \$300,000 each over the first year of the collaboration, to the undelivered research and steering committee services. The \$1,100,000 in total payments is being recognized as revenue over the Company's performance period of six years under the collaboration. If the research period, number of full-time equivalents requested by P&G, or the estimate to complete phase II clinical trials changes, then the Company will update its estimated level of effort and total expected payments under the arrangement. During the three months ended September 30, 2005, the Company recorded revenue of approximately \$10,000. Of this amount, approximately \$3,000 was attributed to the amortization of the up-front license fee and is included in the "License fees" line item within the Revenues section of the Company's Consolidated Statement of Operations for the three months



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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

ended September 30, 2005. The remaining \$7,000 was related to research services performed by the Company's two full-time equivalents and is included within the "Research and development contracts" line item within the Revenues section of the Company's Consolidated Statement of Operations.

The Company expects that some of the preclinical, clinical development and drug approval milestones under this collaboration with P&G to be substantive milestones provided that the successful achievement of these milestones meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a milestone payment for the achievement of a preclinical milestone or P&G's filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related milestone payments would be recorded as revenue upon achievement of the milestone in "Substantive milestones" in the Revenues section of its Consolidated Statement of Operations.

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, the Company will recognize such contingent payments as revenue ratably over the remaining performance period at the time such contingent payment is received.

As of September 30, 2005, the Company has not provided any consideration, such as payments under co-development arrangements, to P&G.

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

*(i) Collaboration Summary*

On April 1, 2005, the Company entered into a drug discovery collaboration agreement with Genentech for the discovery and development of small molecule compounds that modulate a signaling pathway that plays an important role in cell proliferation. This pathway is a regulator of tissue formation and repair, the abnormal activation of which is associated with certain cancers. Under the terms of the agreement, the Company has granted Genentech an exclusive, royalty-bearing license to make, use and sell the small molecule compounds that are modulators of the pathway. Curis has retained the rights for ex vivo cell therapy, except in the areas of oncology and hematopoiesis.

Under the terms of the agreement, the Company will have primary responsibility for research and development activities and Genentech will be responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration. Genentech paid the Company an up-front license fee of \$3,000,000 and has agreed to fund up to \$6,000,000 for research and development activities during the initial two-year research term, subject to its termination rights described below. Genentech will also make cash payments to the Company that are contingent upon the successful achievement of certain preclinical and clinical development milestones and drug approval milestones.

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Genentech has an option to extend the initial two-year research term for up to two additional years in one-year increments. Genentech will also pay the Company royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Each party has the right to terminate the agreement for uncured material breach by the other party. Genentech has the right to terminate the agreement without cause at any time after the first anniversary of

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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

the effective date, upon six months prior written notice, if such termination is to be effective prior to the end of the initial research term, and upon sixty days prior written notice otherwise. In the event of termination by Genentech without cause or if the agreement is terminated by Genentech due to material breach, the Company would be entitled to receive only a reduced royalty for those products that are covered by a subset of certain intellectual property rights, in lieu of the standard contract royalties that would otherwise apply.

(ii) *Accounting Summary*

The Company considers this arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include an exclusive license to its technologies in this signaling pathway and certain performance obligations, including research services for at least two years and participation on a steering committee. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration can be accounted for separately or as a single unit or multiple units of accounting. The Company determined that these deliverables represented a single unit of accounting, since the Company believes that the license does not have stand-alone value to Genentech without the Company's research services and steering committee participation during certain phases of research and because objective and reliable evidence of the fair value of the Company's research and steering committee participation could not be determined.

The Company's ongoing performance obligations under this collaboration consist of participation on a steering committee and the performance of research services. Because the Company can reasonably estimate its level of effort over the term of the arrangement, the Company is accounting for the arrangement under the relative performance method. In developing its estimate of the Company's level of effort required to complete its performance obligations, the Company estimated that Genentech would elect twice to extend the research service period and related funding, each in one-year increments, although there can be no assurance Genentech will, in fact, make such an election. The Company estimates that it will provide an equal number of full-time equivalents for the four-year research and development service term. In developing this estimate, the Company assumed that Genentech will maintain its initially elected number of twelve full-time equivalent researchers throughout the four-year period. The steering committee effort is also expected to be consistent over the four-year period. The \$3,000,000 up-front fee plus \$12,000,000, the total amount of research funding which the Company will be entitled to for providing twelve full-time equivalents at \$250,000 each over four years, is therefore being attributed to the research services. Revenue is being recognized as the research services are provided over the four-year period through March 2009 at a rate of \$312,500 per full-time equivalent. If the research period is changed or the number of full-time equivalents requested by Genentech changes, then the Company will update its estimated level of effort and total expected payments under the arrangement.

The Company expects that some of the preclinical, clinical development and drug approval milestones under this collaboration with Genentech to be substantive milestones provided that the successful achievement of these milestones meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a milestone payment for the achievement of a preclinical milestone or Genentech's filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related milestone payments would be recorded as revenue upon achievement of the milestone in Substantive milestones in the Revenues section of its Consolidated Statement of Operations.

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may not constitute substantive milestones since the



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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, the Company will recognize such contingent payments as revenue ratably over the remaining performance period at the time such contingent payment is received.

The Company recorded revenue under this collaboration of \$944,000 and \$1,533,000, respectively, during the three- and nine-month periods ended September 30, 2005. Of this amount, approximately \$187,000 and \$375,000, respectively, was attributed to the amortization of the up-front license fee and is included in the License fees line item within the Revenue section of the Company's Consolidated Statement of Operations for the three- and nine-month periods ended September 30, 2005, respectively. The remaining \$757,000 and \$1,158,000, respectively, were related to research services performed by the Company's full-time equivalent researchers and are included within the Research and development contracts line item within the Revenues section of the Company's Consolidated Statement of Operations.

As of September 30, 2005, the Company has provided cash consideration to Genentech in the form of co-development payments for the Company's equal share of U.S. development costs of a basal cell carcinoma product candidate that is being developed under a separate collaboration with Genentech.

**8. Genentech April 2005 Hedgehog Antagonist Collaboration Amendment**

*(i) Agreement Summary*

On April 13, 2005, the Company entered into a second amendment to the Collaborative Research, Development and License Agreement with Genentech dated June 11, 2003. The effective date of the amendment was April 11, 2005.

Under the terms of the amendment, Genentech will provide to the Company \$2,000,000 of funding to continue development of therapeutics to treat solid tumor cancers, and the research term has been extended until December 11, 2005 (previously June 11, 2005), at which time the \$2,000,000 will be paid. At Genentech's option, the research term may be extended for an additional six-month period to June 11, 2006, upon written notice delivered to the Company by October 2005. Genentech notified the Company in October 2005 of its decision to extend the research term, and will now fund ten Curis full-time equivalents through June 11, 2006. Genentech will pay the Company \$1,250,000 in June 2006, provided that Curis has performed the required research services. Other than the change to the period of the research term and payments associated with such research, the amendment has not changed the terms of the June 2003 agreement, which remains in full force and effect.

*(ii) Accounting Summary*

The Company considered the provisions of EITF 00-21 and determined that this agreement is a separate contract from its June 2003 agreement, and a previous amendment entered into between the Company and Genentech in December 2004, since it was not contemplated at the time of the June 2003 arrangement, was separately negotiated in order to increase the number of full-time equivalents providing research and development services and to provide xenograft tumor samples to Genentech, and was not entered into at or near the time of the June 2003



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agreement. The Company's performance obligations under this agreement are to provide research services and xenograft tumor samples to Genentech through June 11, 2006. Since Genentech elected to exercise its option and extend the research services, the Company's performance obligations would extend for an additional period from December 2005 through June 2006. The Company has applied the provisions of SAB No. 104 and is recognizing the research funding as

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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

revenues under this collaboration as such research services are performed. The amount payable to the Company and, accordingly, the amount of revenue to be recognized will vary if the Company provides less than the required sixteen full-time equivalents through December 2005 or the ten full-time equivalents through June 2006.

**9. Genentech Collaboration Accounting**

In June 2003, the Company licensed its proprietary Hedgehog pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit, or antagonize, the Hedgehog pathway for the treatment of various cancers. The collaboration consists of two programs: the development of a small molecule Hedgehog antagonist formulated for the topical treatment for basal cell carcinoma; and the development of systemically administered small molecule and antibody Hedgehog antagonists for the treatment of certain other solid tumor cancers. Pursuant to the collaboration agreement, Genentech agreed to make specified cash payments, including up-front payments of \$8,500,000, which consisted of a \$3,509,000 non-refundable license fee payment and \$4,991,000 in exchange for 1,323,835 shares of our common stock. Genentech also agreed to make license maintenance fee payments totaling \$4,000,000 over the first two years of the collaboration and substantive milestone payments at various intervals during the clinical development and regulatory approval process of small molecule and antibody Hedgehog antagonist product candidates, assuming specified clinical development and regulatory approval objectives are met. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume.

The Company considers its June 2003 arrangement with Genentech to be a revenue arrangement with multiple deliverables. The Company's deliverables under this collaboration include an exclusive license to its Hedgehog antagonist technologies, research and development services for the first two years of the collaboration, and participation on steering committees. The Company applied the provisions of EITF 00-21 to determine whether the performance obligations under this collaboration could be accounted for separately or should be accounted for as a single unit of accounting. The Company determined that the deliverables, specifically, the license, research and development services and steering committee participation, represented a single unit of accounting because the Company believes that the license, although delivered at the inception of the arrangement, does not have stand-alone value to Genentech without the Company's research and development services and steering committee participation and because objective and reliable evidence of the fair value of the Company's research and development services and steering committee participation could not be determined.

The Company has attributed the \$3,509,000 up-front fee and the \$4,000,000 of maintenance fees to the undelivered research and development services and steering committee participation. The Company did not consider the \$4,000,000 in maintenance fees to be substantive milestone payments because receipt of the maintenance fee payments did not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones (See Note 5).

The Company has deferred the \$7,509,000 in license and maintenance fee payments and will recognize it only when the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company's 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 the Company's steering committee obligations is indefinite and the Company expects that it will not record any revenue related to these payments for at least several years.



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**Table of Contents**

**CURIS, INC. AND SUBSIDIARY**

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

The Company expects that some of the clinical development and drug approval milestones under this collaboration with Genentech will be considered to be substantive milestones provided that the successful achievement of these milestones meets each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. For example, the Company believes that a milestone payment for the filing of an investigational new drug application would be substantive since the requirements of its revenue recognition policy would have been met. Should the company ever successfully achieve any substantive milestones under this collaboration agreement, any related milestone payments would be recorded as revenue upon achievement of the milestone in Substantive milestones in the Revenues section of its Consolidated Statement of Operations.

The Company believes that certain contingent payments tied to later stage clinical development and drug approval objectives under this collaboration may not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones (i.e., the Company does not expect to incur substantive effort in achieving late-stage clinical and drug approval objectives). Accordingly, all such contingent payments will be deferred until the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech.

Under the collaboration agreement, the Company has the option to elect to co-develop Hedgehog antagonist products in the field of basal cell carcinoma in the U.S. In January 2005, the Company elected to exercise this co-development option and will now share equally in both U.S. development costs and any future U.S. net profits and/or losses resulting from the development and commercialization of its basal cell carcinoma product candidate. This co-development right includes basal cell carcinoma and any additional indications for which this product candidate may be developed in the U.S. As a result of participating in co-development, the Company will forego U.S. development milestone and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. Should the Company determine that it cannot continue funding its equal share of the development expenses, the Company may opt out of the co-development structure and receive certain development and regulatory approval milestones and royalties on sales of the basal cell carcinoma product candidate, should any ever occur. In addition, in certain major international markets, the Company will receive milestones if specific clinical development objectives are achieved and a royalty on any international sales of any basal cell carcinoma product candidate.

In connection with its election to exercise its co-development option related to its basal cell carcinoma program under development with Genentech (see Note 6(a)), the Company has applied the provisions of EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*, or EITF 01-9, which addresses the accounting for revenue arrangements where both the vendor and the customer make cash payments to each other for services and/or products, as is the case with the Company's collaboration agreements with Genentech. EITF 01-9 states that situations in which a vendor (the Company) is paying its customer (Genentech) must be evaluated in order to determine if the vendor payment can be treated as expense or as a reduction to revenues generated by the customer relationship. EITF 01-9 also requires that all transactions with a customer be considered when determining the appropriate accounting treatment, including separate collaborations with the same customer.

The Company has entered into two collaborations with Genentech, including the June 2003 license to its Hedgehog antagonist technologies and an April 2005 license relating to another signaling pathway. Under these collaboration agreements with Genentech, the Company, as the vendor, sold licenses to Genentech and received or may receive from Genentech, as the customer, license fees, development and drug approval milestones, royalties on potential future product sales, payments for research services, and



**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

reimbursement for certain patent expenses and other costs. In addition, the Company also makes co-development payments to Genentech in connection with the basal cell carcinoma product candidate. The payments made by the Company to reimburse Genentech for co-development payments are considered by the Company to be within the scope of EITF 01-9 because the Company considers these payments to be payments from a vendor made to a customer, and the Company has concluded that such payments did not meet any of the scope exceptions outlined in EITF 01-9.

The Company will follow the provision of EITF 01-09 and expects to record its future co-development payments first as a reduction of revenue, to the extent of both cumulative revenue recorded to date and of probable future revenues, which includes any unamortized deferred revenue balances, under all arrangements with Genentech and then as an expense.

As of September 30, 2005, the Company has recorded cumulative co-development costs of \$5,698,000 and cumulative revenues under its collaborations with Genentech of \$5,152,000. In addition, the Company's unamortized deferred revenues under its collaborations with Genentech were \$10,264,000. Since the sum of the cumulative revenue recorded to date and the unamortized deferred revenue exceed the cumulative co-development costs incurred to-date, the Company has recorded a reduction to revenues, or contra revenue, of \$820,000 and \$5,698,000 in the Company's consolidated statement of operations and comprehensive loss for the three-and six-month periods ended September 30, 2005.

**10. Long-Term Debt and Capital Lease Obligations**

The Company believes that the carrying value of its debt obligations approximate the market value since the underlying interest rates approximate the current market rates for similar debt securities. Long-term debt obligations consisted of the following at September 30, 2005 and December 31, 2004:

|  | <b>September 30,<br/>2005</b> | <b>December 31,<br/>2004</b> |
|--|-------------------------------|------------------------------|
|  | <u>                    </u>   | <u>                    </u>  |
| Note payable to financing agency for capital purchases   | \$ 2,822,000                  | \$ 1,141,000                 |
| Convertible promissory note agreement with Elan Pharma International, Limited including approximately \$298,000 of accrued interest at December 31, 2004   |                               | 3,298,000                    |
| Convertible subordinated note payable to Becton Dickinson, net of \$40,000 and \$80,000 discount and including \$597,000 and \$492,000 of accrued interest at September 30, 2005 and December 31, 2004, respectively | 2,557,000                     | 2,412,000                    |
|  | <u>                    </u>   | <u>                    </u>  |
|  | 5,379,000                     | 6,851,000                    |
| Less current portion   | (4,192,000)                   | (1,141,000)                  |
|  | <u>                    </u>   | <u>                    </u>  |
| <b>Total long-term debt obligations</b>  | <b>\$ 1,187,000</b>           | <b>\$ 5,710,000</b>          |
|  | <u>                    </u>   | <u>                    </u>  |

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Effective June 9, 2005, the Company entered into a loan agreement with the Boston Private Bank & Trust Company to finance up to \$1,450,000 in purchases of equipment and facility leasehold improvements. Under the terms of the loan agreement, the Company can request periodic financings for qualifying purchases of equipment and leasehold improvements during the period from June 9, 2005 until December 9, 2005. Until December 9, 2005, the Company will pay interest only on any borrowings on a monthly basis in arrears. On or before December 9, 2005, the Company will convert the then outstanding balance into a 36-month term note that bears interest at either a variable rate (7.75% as of September 30, 2005) or a fixed rate (7.66% as of September 30, 2005) for the repayment period. The loan will be collateralized by any equipment and leasehold improvements financed thereunder. As of September 30, 2005, the Company has financed \$866,000 in equipment purchased under this loan agreement.

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**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

Effective January 7, 2005, the Company entered into an amendment with the Boston Private Bank & Trust Company to extend the drawdown date by which it can request periodic financings up to \$2,250,000 for qualifying purchases of equipment and leasehold improvements through April 30, 2005. On March 23, 2005, the Company drew down the remaining balance under this agreement bringing the total amount financed to \$2,250,000 and exercised its option to convert the outstanding balance 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 extending through the 36-month term. The 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. As of September 30, 2005, the Company was in compliance with the sole covenant under this agreement. This covenant requires the Company to maintain a minimum modified working capital ratio. Should the Company fail to pay amounts when due or fail to maintain compliance with the covenant under this agreement, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

On January 7, 2005, Elan Pharma International Limited, or EPIL, elected to convert the entire balance of its outstanding convertible note into shares of the Company's common stock. As of January 7, 2005, the outstanding balance of the EPIL note, including interest, was \$3,305,523. In accordance with the terms of the amended and restated convertible note payable with EPIL, 330,552 shares of the Company's common stock were issued to EPIL based on a conversion rate of \$10.00 per share. The Company has no further obligations to EPIL.

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

The Company has two stock option plans. In December 2004, the FASB issued SFAS No. 123(R), *Accounting for Stock-Based Compensation*, 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 historical financial statements as services are performed. Prior to adopting SFAS No. 123(R), only certain pro forma disclosures of fair value are required. The provisions of SFAS No. 123(R) are effective for the first annual reporting period beginning after June 15, 2005. Early adoption is encouraged and retroactive application of the provisions of SFAS 123(R) to the beginning of the fiscal year that includes the effective date is permitted, but not required. The Company will implement the revised standard in the first quarter of fiscal year 2006. Currently, the Company accounts for its share-based payment transactions under the provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, which does not necessarily require the recognition of compensation cost in the financial statements. The Company is evaluating its current compensation strategies as they relate to stock-based compensation. Management is assessing the implications of this revised standard which will materially impact the Company's results of operations in the first quarter of fiscal year 2006 and thereafter.

For the three- and nine-month periods ended September 30, 2005, the Company applied APB No. 25 and related interpretations, including FASB Interpretation No. 44, in accounting for qualifying options granted to its employees and directors under its plans and applies SFAS No. 123, as amended by FASB No. 148, for disclosure purposes only. The SFAS 123 disclosures include pro forma net loss and net loss per share as if the fair value method of accounting had been used. Stock issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.



**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

The following are the pro forma net loss and net loss per share, as if compensation expense for the option plans had been determined based on the fair value at the date of grant, consistent with SFAS 123:

|  | <b>Three months ended September 30,</b> |                       | <b>Nine months ended September 30,</b> |                        |
|--|---|-----------------------|--|------------------------|
|  | <b>2005</b>                             | <b>2004</b>           | <b>2005</b>                            | <b>2004</b>            |
|  | <b>(As Restated)</b>                    | <b>(As Restated)</b>  | <b>(As Restated)</b>                   | <b>(As Restated)</b>   |
| Net loss, as reported  | \$ (3,251,000)                          | \$ (4,259,000)        | \$ (13,491,000)                        | \$ (13,126,000)        |
| Add back: employee stock based compensation included in net loss, as reported                            | 2,000                                   | 89,000                | 6,000                                  | 598,000                |
| Less: stock-based employee compensation expense determined under fair value based methods for all awards | (1,148,000)                             | (1,595,000)           | (3,713,000)                            | (5,773,000)            |
| <b>Pro forma net loss</b>  | <b>\$ (4,397,000)</b>                   | <b>\$ (5,765,000)</b> | <b>\$ (17,198,000)</b>                 | <b>\$ (18,301,000)</b> |
| <b>Net loss per common share (basic and diluted)</b>   |   |                       |  |                        |
| As reported  | \$ (0.07)                               | \$ (0.10)             | \$ (0.28)                              | \$ (0.32)              |
| Pro forma  | \$ (0.09)                               | \$ (0.14)             | \$ (0.36)                              | \$ (0.44)              |

The effects on the three- and nine month periods ended September 30, 2005 and 2004 pro forma net loss and net loss per share of the estimated fair value of stock options are not necessarily representative of the effects on the results of operations in the future. In addition, the estimates made utilize a pricing model developed for traded options with relatively short lives. The Company's option grants typically have a life of up to ten years and are generally not transferable, therefore, the actual fair value of a stock option grant may be different from these estimates. The Company believes that its estimates incorporate all relevant information and represent a reasonable approximation in light of the difficulties involved in valuing non-traded stock options.

**12. Loss of Subtenant Income**

Effective August 15, 2002, the Company sublet approximately 12,000 square feet, or 67%, of the rentable square footage of its facility at 61 Moulton Street, Cambridge, MA. The original subtenant's lease bears a contracted rate of \$40.00 per square foot through the end of the Company's lease term of April 30, 2007. In addition to the sublease payments, the subtenant is required to pay its pro rata share of all building operating costs. The sublease income exceeded the Company's cost of the sublet space so the Company did not record a loss on the lease at the time the Company ceased using the space. The Company has continued to use a portion of the remaining 33% of the leased space.

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

The Company does not expect to utilize the space, if vacated by the current tenant due to default of the amended sublease terms, for its current or future operations. In addition, the Company believes that its costs under the lease will exceed any future sublease income for the duration of the lease. Based on these factors

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**Table of Contents****CURIS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited) (continued)**

and on the potential for future default by the subtenant, 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. This amount represents the Company's estimate of the total expected loss on the subleased space over the remaining term of the lease. There has been no change in the Company's estimate of the \$500,000 liability, approximately \$350,000 and \$150,000 are included as current and long-term liabilities, respectively, in the Company's balance sheet as of September 30, 2005.

**13. Subsequent Events****(a) Extension of research funding by Genentech**

In October 2005, Genentech exercised its option under the April 2005 Hedgehog antagonist collaboration amendment with the Company to extend funding of ten full-time equivalents performing research services to continue development of therapeutics to treat solid tumor cancers. Genentech had previously supported a total of sixteen Curis and additional third party resources managed by Curis scientists. The progress made by the two companies had reduced the need for the third party resources. By exercising this option, Genentech has agreed to extend the research term by six months through June 11, 2006 (previously December 11, 2005). As a result of the extension, Genentech will provide to the Company up to an additional \$1,250,000 of funding for research services performed from December 12, 2005 through June 11, 2006 payable in June 2006.

**(b) Payment from former collaborator**

On October 21, 2004, the Company amended a note receivable with Micromet, a former collaborator. Under the amended note, Micromet is obligated to pay Curis a total amount of EUR 4,500,000, subject to certain conditions, of which EUR 1,250,000 was paid in November 2004. Pursuant to the payment terms of the amended note, Micromet made a second payment of EUR 1,250,000 on October 27, 2005, which resulted in revenues of \$1,500,000 based on the EUR-to-US dollar foreign exchange rate. This revenue will be recorded in the License Fees line item at the Revenues section of the Company's Consolidated Statement of Operations during the fourth quarter of 2005.

**14. New Accounting Standards**

On June 2, 2005, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154), which will require entities that voluntarily make a change in accounting principle to apply that change retrospectively to prior periods' financial statements, unless this would be impracticable. FAS 154 supersedes Accounting Principles Board Opinion No. 20, *Accounting Changes* (APB 20), which previously required that most voluntary changes in accounting principle be recognized by including in the current period's net income the cumulative effect of changing to the new accounting principle. FAS 154 also makes a distinction between retrospective application of an accounting principle and the restatement of financial statements to reflect the correction of an error. Another significant change in practice under the FAS 154 will be that if an entity changes its method of depreciation, amortization, or depletion for long-lived, non-financial assets, the change must be accounted for as a change in accounting estimate. Under APB 20, such a change would have been reported as a change in accounting principle. FAS 154 applies to accounting changes and error corrections that are made in fiscal years beginning after December 15, 2005.



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**Table of Contents**

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

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

**Restatement of Financial Statements.**

In this Quarterly Report on 10Q/A we are restating our September 30, 2005 and December 31, 2004 consolidated balance sheets contained herein to correct amounts in prepaid expenses and other current assets, deposits and other assets, short- and long-term deferred revenues, additional paid-in capital, and accumulated deficit and to restate the consolidated statements of operations for the three- and nine-month periods ended September 30, 2005 and September 30, 2004, to correct amounts reported in gross revenues and research and development expenses. As a result of these restatements, amounts in the consolidated statements of cash flows for the nine-month periods ended September 30, 2005 and 2004 have also been corrected. Our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q from the second quarter of 2003 through fiscal 2004 have not been revised to reflect the restatement and the consolidated financial statements contained in those reports should not be relied upon. Instead, the consolidated financial statements for fiscal 2004 and 2003 included in our Annual Report on Form 10-K for the fiscal period ended December 31, 2005 should be relied upon. For additional information regarding the restatement, refer to Note 3 Restatement of our Financial Statements in the Notes to Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q/A. Management's discussion and analysis of the financial condition and our results of operations have been updated to reflect these restated amounts.

**Overview**

We are a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. Our product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive or unregulated. We have successfully used our product development approach to produce multiple compounds with potential use for several different disease indications. For example, we have developed a product candidate for the topical treatment of basal cell carcinoma, which is currently in a phase I clinical trial and under co-development with Genentech, Inc., or Genentech, a collaborator. We have also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders, hair growth regulation and 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 \$678,690,000 as of September 30, 2005. 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.

We currently have strategic collaborations with Genentech, Wyeth Pharmaceuticals, or Wyeth, and the Procter & Gamble Company, or P&G, to develop therapeutics which modulate the signaling of the Hedgehog, or Hh, pathway and, as of April 1, 2005, an additional collaboration with Genentech to develop therapeutics that modulate another signaling pathway that plays an important role in cell proliferation. We have also licensed our



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**Table of Contents**

bone morphogenetic protein, or BMP, pathway portfolio to Ortho Biotech Products, a subsidiary of Johnson & Johnson, for systemic administration for all applications excluding orthopedic and dental therapeutic applications. Our strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be either a majority or wholly funded by our collaborators and provide us with the opportunity to receive additional payments if specified milestones are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic license and collaboration agreements included \$18,500,000 in up-front payments, of which we received \$6,629,000 from the sale of shares of our common stock, and also include potential future clinical development and regulatory approval milestones of approximately \$750,000,000 in the aggregate, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are developed, and all milestone payments are received upon 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 January 2005, pursuant to the terms of our Hedgehog pathway collaboration agreement with Genentech, we exercised a co-development option pursuant to which we will share equally in all U.S. development costs and will also share equally in 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 should this product be successfully developed and marketed. Genentech has primary responsibility for clinical trial design and management and we participate on a steering committee that oversees the clinical development of the basal cell carcinoma product candidate. As a result of our election to exercise our co-development option, we will forego U.S. development and drug approval milestones and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On March 31, 2005, Genentech filed an investigational new drug application with the FDA in order to initiate human clinical investigation of the basal cell carcinoma product candidate and, in the second quarter of 2005, the first patient was enrolled in our phase I clinical trial. We expect that by exercising this co-development and equal cost-sharing option we will incur approximately \$20,000,000 in development expenses through the planned completion of phase II clinical trials. We anticipate that the phase II clinical trials will be completed in mid-2007, assuming that the basal cell carcinoma product candidate successfully completes its phase I clinical trial. We expect to incur additional costs to complete phase III clinical trials and the remainder of the regulatory approval process, assuming that Genentech and we successfully complete phase II clinical trials.

**Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend upon, among other factors, the timing of our entry into new collaborations, the timing of the receipt of payments from collaborators and the cost and outcome of clinical trials. We believe that our existing capital resources at September 30, 2005, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, P&G and the SMA Foundation, assuming these programs continue as planned, should enable us to maintain current and planned operations into the second half of 2007, including expected spending related to our co-development of our lead product candidate for the treatment of basal cell carcinoma. Our ability to continue funding our planned operations beyond into the second half of 2007 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt or other sources of financing. A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth below under the heading Risk Factors that May Affect Results.

*Revenue.* We do not expect to generate any revenue from the sale of products for several years, if ever. Substantially all of our gross revenues to date have been derived from license fees, research and development payments, milestone payments and other amounts that we have received from our strategic collaborators and licensees, including Genentech, Wyeth, Ortho Biotech Products, and P&G, as well as royalty revenue and

**Table of Contents**

payments received upon monetization of certain royalty rights from Stryker Corporation. Since our equal share of the basal cell carcinoma co-development costs will be recorded as a reduction to any revenue recognized under our collaborations with Genentech in accordance with EITF 01-9, we do not expect to generate any net revenue from our two collaborations with Genentech until we obtain FDA approval to commercialize our basal cell carcinoma product candidate. In the future, we will seek to generate revenues from a combination of license fees, research and development funding and milestone payments, royalties resulting from the sale of products that incorporate our intellectual property in connection with strategic licenses and collaborations, and sales of any products we successfully develop and commercialize, either alone or in collaboration with third parties. We expect that any revenues we generate will fluctuate from quarter to quarter as a result of the timing and amount of payments received under our strategic collaborations, and the amount and timing of payments we receive upon the sale of our products, to the extent that any are successfully commercialized.

*Research and Development.* 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, supplies and reagents, outside service costs including medicinal chemistry, consulting and sponsored research collaborations, and occupancy and depreciation charges. We expense research and development costs as incurred.

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

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

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