

CURIS INC  
Form 10-Q  
April 30, 2008  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark one)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2008**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934**

Commission File Number: 000-30347

**CURIS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: CURIS INC - Form 10-Q

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

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

**45 Moulton Street**

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

**02138**  
(Zip Code)

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

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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company

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

As of April 28, 2008, there were 63,314,836 shares of the registrant's common stock outstanding.

---

**Table of Contents**

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

|  | <b>Page<br/>Number</b> |
|--|------------------------|
| <b><u>PART I. FINANCIAL INFORMATION</u></b>  |                        |
| Item 1. <u>Unaudited Financial Statements</u>  |                        |
| <u>Condensed Consolidated Balance Sheets as of March 31, 2008 and December 31, 2007</u>                                | 3                      |
| <u>Consolidated Statements of Operations and Comprehensive Loss for the Three Months ended March 31, 2008 and 2007</u> | 4                      |
| <u>Consolidated Statements of Cash Flows for the Three Months ended March 31, 2008 and 2007</u>                        | 5                      |
| <u>Notes to Condensed Consolidated Financial Statements</u>  | 6                      |
| Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                   | 13                     |
| Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>  | 22                     |
| Item 4. <u>Controls and Procedures</u>   | 22                     |
| <b><u>PART II. OTHER INFORMATION</u></b>   |                        |
| Item 1A. <u>Risk Factors</u>   | 23                     |
| Item 6. <u>Exhibits</u>  | 37                     |
| <u>SIGNATURE</u>   | 38                     |

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

|  | <b>March 31,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|--|---------------------------|------------------------------|
| <b>ASSETS</b>  |                           |                              |
| Current Assets:  |                           |                              |
| Cash and cash equivalents  | \$ 16,241,439             | \$ 17,396,599                |
| Marketable securities  | 18,990,208                | 24,062,577                   |
| Accounts receivable  | 221,132                   | 230,467                      |
| Prepaid expenses and other current assets  | 415,500                   | 349,453                      |
| <b>Total current assets</b>  | <b>35,868,279</b>         | <b>42,039,096</b>            |
| Property and equipment, net  | 2,355,664                 | 2,577,602                    |
| Long-term investment restricted  | 210,007                   | 210,007                      |
| Goodwill   | 8,982,000                 | 8,982,000                    |
| Other assets, net  | 7,980                     | 7,980                        |
|  | <b>\$ 47,423,930</b>      | <b>\$ 53,816,685</b>         |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                           |                              |
| Current Liabilities:   |                           |                              |
| Debt, current portion  | \$ 93,483                 | \$ 403,832                   |
| Accounts payable   | 1,892,001                 | 3,222,091                    |
| Accrued liabilities  | 880,632                   | 1,150,931                    |
| Deferred revenue, current portion  |                           | 1,852,518                    |
| <b>Total current liabilities</b>   | <b>2,866,116</b>          | <b>6,629,372</b>             |
| Other long-term liabilities  | 299,907                   | 342,750                      |
| <b>Total liabilities</b>   | <b>3,166,023</b>          | <b>6,972,122</b>             |
| Commitments  |                           |                              |
| Stockholders Equity:   |                           |                              |
| Common stock, \$0.01 par value 125,000,000 shares authorized; 64,362,543 and 63,314,836 shares issued and outstanding, respectively, at March 31, 2008 and 64,288,793 and 63,241,086 shares issued and outstanding, respectively, at December 31, 2007 | 643,625                   | 642,888                      |
| Additional paid-in capital   | 743,728,173               | 742,903,399                  |
| Treasury stock (at cost, 1,047,707 shares)   | (891,274)                 | (891,274)                    |
| Deferred compensation  | (51,793)                  | (46,286)                     |
| Accumulated deficit  | (699,278,405)             | (695,847,738)                |
| Accumulated other comprehensive income   | 107,581                   | 83,574                       |
| <b>Total stockholders equity</b>   | <b>44,257,907</b>         | <b>46,844,563</b>            |

\$ 47,423,930 \$ 53,816,685

The accompanying notes are an integral part of these consolidated financial statements.

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

|  | <b>Three Months Ended<br/>March 31,</b> |                |
|--|---|----------------|
|  | <b>2008</b>                             | <b>2007</b>    |
| <b>REVENUES:</b>                                   |   |                |
| Research and development contracts                 | \$ 215,065                              | \$ 1,282,873   |
| License fees                                       | 1,852,518                               | 1,079,913      |
| Total Revenues                                     | 2,067,583                               | 2,362,786      |
| <b>COSTS AND EXPENSES:</b>                         |   |                |
| Research and development                           | 3,475,812                               | 3,295,615      |
| General and administrative                         | 2,415,494                               | 2,951,585      |
| Total costs and expenses                           | 5,891,306                               | 6,247,200      |
| Loss from operations                               | (3,823,723)                             | (3,884,414)    |
| <b>OTHER INCOME (EXPENSE):</b>                     |   |                |
| Interest income                                    | 390,735                                 | 365,352        |
| Other income                                       | 6,131                                   | 11,264         |
| Interest expense                                   | (3,810)                                 | (32,975)       |
| Total other income, net                            | 393,056                                 | 343,641        |
| Net loss   | \$ (3,430,667)                          | \$ (3,540,773) |
| Net loss per common share (basic and diluted)      | \$ (0.05)                               | \$ (0.07)      |
| Weighted average common shares (basic and diluted) | 63,245,538                              | 49,354,125     |
| Net loss   | \$ (3,430,667)                          | \$ (3,540,773) |
| Unrealized (loss) gain on marketable securities    | 24,007                                  | (2,520)        |
| Comprehensive loss                                 | \$ (3,406,660)                          | \$ (3,543,293) |

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

|   | <b>Three Months Ended</b> |                      |
|---|---------------------------|----------------------|
|   | <b>March 31,</b>          |                      |
|   | <b>2008</b>               | <b>2007</b>          |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                           |                      |
| Net loss  | \$ (3,430,667)            | \$ (3,540,773)       |
| Adjustments to reconcile net loss to net cash used in operating activities- |                           |                      |
| Depreciation and amortization   | 256,091                   | 475,506              |
| Stock-based compensation expense  | 752,304                   | 915,263              |
| Gain on sale of assets  |                           | (68,329)             |
| Unrealized foreign currency exchange gain                                   |                           | (11,264)             |
| Changes in operating assets and liabilities:                                |                           |                      |
| Accounts receivable   | 9,335                     | 24,652               |
| Prepaid expenses and other assets   | (66,047)                  | 56,738               |
| Accounts payable and accrued liabilities                                    | (1,645,248)               | (217,922)            |
| Deferred revenue  | (1,852,518)               | (1,257,572)          |
| Total adjustments   | (2,546,083)               | (82,928)             |
| Net cash used in operating activities                                       | (5,976,750)               | (3,623,701)          |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                           |                      |
| Purchase of marketable securities   | (5,004,484)               | (5,459,103)          |
| Sale of marketable securities   | 10,100,860                | 7,041,796            |
| Purchases of property and equipment   | (34,153)                  | (20,769)             |
| Net proceeds from the sale of assets  |                           | 196,688              |
| Net cash provided by investing activities                                   | 5,062,223                 | 1,758,612            |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                           |                      |
| Proceeds from issuance of common stock                                      | 67,700                    | 44,252               |
| Repayments of obligations under notes payable                               | (308,333)                 | (509,962)            |
| Net cash used in financing activities                                       | (240,633)                 | (465,710)            |
| <b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>                            | <b>(1,155,160)</b>        | <b>(2,330,799)</b>   |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>                       | <b>17,396,599</b>         | <b>18,829,332</b>    |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>                             | <b>\$ 16,241,439</b>      | <b>\$ 16,498,533</b> |

See accompanying notes to unaudited condensed consolidated financial statements.

---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

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

**1. Nature of Business**

Curis, Inc. (the Company or Curis) is a drug discovery and development company that is committed to leveraging its innovative signaling pathway drug technologies in seeking to create new medicines, primarily for cancer. In expanding the Company's drug development efforts in the field of cancer through its targeted cancer drug development platform, Curis is building upon its past experiences in targeting signaling pathways for the development of next generation targeted cancer therapies.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

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

**2. Basis of Presentation**

The accompanying consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the United States of America for complete financial statements and should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission on March 14, 2008.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company's financial position at March 31, 2008 and the results of operations and cash flows for the three-month periods ended March 31, 2008 and 2007. The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities. Actual results may differ from such estimates.

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

**3. Revenue Recognition**

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, contingent cash payments based upon achievement of clinical development and sales objectives and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. For a complete discussion of the Company's revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 14, 2008.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the twelve-month period ended March 31, 2009 are classified as long-term



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

deferred revenue. As of March 31, 2008, the Company has no remaining short- and long-term deferred revenue related to its collaborations.

**Table of Contents****4. Stryker Corporation**

On December 27, 2007, the Company completed a transaction with Stryker Corporation, in which Stryker paid the Company \$1,750,000 in cash in exchange for the sale and assignment of all of the Company's remaining BMP assets. As a result of the transaction, Stryker has assumed all future BMP costs subsequent to the December 27, 2007 effective date, including those related to future development and maintenance and prosecution of the patent portfolio. As of December 31, 2007, the Company recorded the \$1,750,000 received as short-term deferred revenue because the Company had not delivered all of the assets to Stryker as required by the agreement as of that date. The Company completed the transfer of all assets during the first quarter of 2008, at which time no material ongoing performance obligations remained under the agreement. Accordingly, the Company recorded \$1,750,000 as license revenue within the Revenues section of the Consolidated Statement of Operations for the three months ended March 31, 2008.

Under the terms of the agreement, the Company is entitled to contingent cash payments related to certain clinical development and sales objectives, if such objectives are achieved by Stryker. The Company believes that these contingent payments would not constitute substantive milestones since the successful achievement of these objectives would not meet each of the criteria set forth in the Company's revenue recognition policy related to substantive milestones. As such, and because the Company has no future deliverables under the agreement, the Company intends to recognize such contingent payments as revenue in "License Fees" within the Revenues section of the Consolidated Statement of Operations if and when any such objectives are achieved and the related contingent cash payment from Stryker is reasonably assured.

**5. Termination of January 2004 Wyeth Collaboration**

On January 12, 2004, the Company licensed its Hedgehog proteins and small molecule Hedgehog pathway agonists to Wyeth Pharmaceuticals, or Wyeth, for therapeutic applications in the treatment of neurological and other disorders. Pursuant to the collaboration agreement, Wyeth agreed to make specified cash payments, including up-front payments of \$3,000,000, which consisted of a \$1,362,000 non-refundable license fee payment and \$1,638,000 in exchange for 315,524 shares of the Company's common stock.

The Company applied the provisions of EITF 00-21 and determined that its performance obligations under this collaboration should be accounted for as a single unit of accounting. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company's level of effort required to complete its performance obligations, the Company estimated that Wyeth would elect twice to extend the research and development service period and related funding, each in one-year increments, for a total of four years. The agreement also provided for a one-year evaluation period immediately following the end of the research term, during which time the Company could have been obligated to serve on a steering committee that oversees the program and could have been required, at Wyeth's expense, to perform additional research and development services. The Company originally estimated that it would provide an equal number of full-time equivalents for the four-year research and development service term plus the one-year evaluation period. In developing this estimate, the Company assumed that Wyeth would maintain its initially elected number of eight full-time equivalents throughout the five-year period. The steering committee effort was also expected to be consistent over the five-year period. On November 3, 2006, Wyeth agreed to extend the research funding term by one year through February 9, 2008 but elected to fund only five researchers working on the program through the research term. Accordingly, the Company revised its estimated level of effort over the remaining performance period. In December 2007, Wyeth informed the Company that it would not extend the current contractual research funding term beyond February 2008. As a result, the Company changed its estimated performance period to coincide with the conclusion of the research term from its original estimate of February 2009.

On March 7, 2008, Wyeth provided the Company with written notice that it will terminate this license agreement effective May 6, 2008. On the termination date, the licenses granted by the Company to Wyeth terminate and all terminated license rights revert to the Company. The Company intends to seek to license this technology to a third party collaborator.

The \$1,362,000 up-front license fee plus \$7,250,000, which is the total amount of research funding the Company received for providing an average of 7.25 full-time equivalents over the four-year performance period at a rate of \$250,000 each, was attributed to the research services. Revenue was recognized as the research services were provided over the performance period of February 2004 through February 2008.

The Company recorded revenue under this collaboration of \$252,000 and \$530,000 during the three-month periods ended March 31, 2008 and 2007, respectively. Of this amount, approximately \$103,000 and \$76,000 was

## Table of Contents

attributed to the amortization of the \$1,362,000 up-front license fee and is included in License fees within the Revenues section of the Consolidated Statements of Operations for the three-month periods ended March 31, 2008 and 2007, respectively. Of the remaining amounts, \$134,000 and \$395,000 were related to research services performed by the Company's full-time equivalents for the three months ended March 31, 2008 and 2007, respectively, and \$15,000 and \$59,000 for the three months ended March 31, 2008 and 2007, respectively, related to expenses incurred on behalf of Wyeth by the Company for which Wyeth is obligated to reimburse the Company and have met the revenue recognition provisions of EITF 99-19. These amounts are included within the Research and development contracts line item within the Revenues section of the Consolidated Statements of Operations.

### **6. Fair Value Measurements**

On January 1, 2008, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*, (SFAS No. 157) and SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, (SFAS No. 159) for its financial assets and liabilities. The adoption of SFAS No. 157 did not have a material impact on the Company's financial position or results of operations. As permitted by FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, the Company elected to defer the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. GAAP and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets include cash and cash equivalents, investments in marketable securities, and a long-term restricted investment. As of March 31, 2008, the Company held cash and cash equivalents and marketable securities of \$16,241,000 and \$18,990,000, respectively. The Company's marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, and government obligations. These amounts are invested directly in commercial paper of financial institutions and corporations with A-/Aa3 or better long-term ratings and A-1/P-1 short term debt ratings, U.S. Treasury securities, U.S. Treasury money market funds and interest bearing bank accounts. The long-term restricted investment of \$210,000 as of March 31, 2008 was solely comprised of a one-year certificate of deposit.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company has no Level 2 assets or liabilities at March 31, 2008.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. The Company has no material Level 3 assets or liabilities at March 31, 2008.

**Table of Contents**

The Company's financial instruments consist mainly of cash and cash equivalents, marketable securities, short-term accounts receivable, common stock in privately-held companies, accounts payable and debt obligations. Short-term accounts receivable and accounts payable are reflected in the accompanying consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. While the Company believes its valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

**7. Accrued Liabilities**

Accrued liabilities consist of the following:

|                        | <b>March 31,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|------------------------|---------------------------|------------------------------|
| Accrued compensation   | \$ 397,000                | \$ 708,000                   |
| Professional fees      | 106,000                   | 73,000                       |
| Facility-related costs | 187,000                   | 192,000                      |
| Other                  | 191,000                   | 178,000                      |
| <b>Total</b>           | <b>\$ 881,000</b>         | <b>\$ 1,151,000</b>          |

**8. Debt**

Short-term debt, including accrued interest, consists of the following at March 31, 2008 and December 31, 2007:

|   | <b>March 31,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|---|---------------------------|------------------------------|
| Notes payable to financing agencies for capital purchases | \$ 93,000                 | \$ 404,000                   |
| Less current portion                                      | (93,000)                  | (404,000)                    |
| <b>Total long-term debt obligations</b>                   | <b>\$</b>                 | <b>\$</b>                    |

On March 23, 2005, the Company converted \$2,250,000 borrowed under an amended loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bore interest at a fixed rate of 7.36% for the repayment period. On December 9, 2005, the Company converted \$1,450,000 borrowed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bore interest at a fixed rate of 7.95% for the repayment period. As of March 31, 2008, the Company was in compliance with the sole covenant under each of the agreements with the Boston Private Bank & Trust Company, which requires the Company to maintain a minimum working capital ratio. On April 1, 2008, the Company made the final repayments due under each note.

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

As of March 31, 2008, the Company had three shareholder-approved, share-based compensation plans: the 2000 Stock Incentive Plan (the 2000 Plan), the 2000 Director Stock Option Plan (the 2000 Director Plan) and the 2000 Employee Stock Purchase Plan (the ESPP). For a complete discussion of the Company's share-based compensation plans, see Note 5 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as previously filed with the Securities and Exchange Commission on March 14, 2008.

During the quarter ended March 31, 2008, options to purchase 1,049,000 shares of the Company's common stock were issued under the 2000 Plan, all of which were granted to officers and employees of the Company. These options were granted on January 25, 2008, vest over a four-year period and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global

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

Market on the grant date. During the quarter ended March 31, 2008, the Company's board of directors also granted options to its non-employee directors to purchase 115,000 shares of common stock under the 2000 Plan and options to purchase 35,000 shares of common stock under the 2000 Director Plan. All of these options were fully vested on the January 25, 2008 grant date and bear exercise prices that are equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the date of grant. The table below summarizes options outstanding and exercisable under the 2000 Plan and the 2000 Director Plan at March 31, 2008:

**Table of Contents**

| Exercise Price Range | Options Outstanding |  |   | Options Exercisable |   |
|----------------------|---------------------|--|---|---------------------|---|
|                      | Number of Shares    | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price per Share | Number of Shares    | Weighted Average Exercise Price per Share |
| \$ 0.56- \$ 1.39     | 2,624,844           | 8.40   | \$ 1.33                                   | 632,842             | \$ 1.19                                   |
| 1.43 - 1.74          | 3,247,407           | 7.97   | 1.51                                      | 1,657,840           | 1.54                                      |
| 2.11 - 2.73          | 1,143,626           | 5.15   | 2.43                                      | 1,128,251           | 2.43                                      |
| 3.13 - 3.98          | 1,632,145           | 4.92   | 3.74                                      | 1,476,201           | 3.72                                      |
| 4.03 - 6.91          | 1,172,061           | 5.74   | 4.65                                      | 1,058,897           | 4.70                                      |
| 10.00 - 29.26        | 444,821             | 2.42   | 12.92                                     | 444,821             | 12.92                                     |
|                      | 10,264,904          | 6.79   | \$ 2.78                                   | 6,398,852           | \$ 3.48                                   |

**Employee and Director Grants**

In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model when applying the provisions of Statement of Financial Accounting Standards 123(R), Share-Based Payment (SFAS 123(R)). The Company calculated the Black-Scholes value of employee options awarded during the quarters ended March 31, 2008 and 2007 based on the assumptions noted in the following table:

|                                 | Three Months Ended March 31, |       |
|---------------------------------|------------------------------|-------|
|                                 | 2008                         | 2007  |
| Expected life (years) employees | 6                            | 6.25  |
| Expected life (years) directors | 7                            | N/A   |
| Risk-free interest rate         | 2.97-3.2%                    | 4.49% |
| Volatility                      | 90.4-93.4%                   | 96.2% |
| Dividends                       | None                         | None  |

The stock price volatility and expected terms utilized in the calculation involve management's best estimates at that time, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. In determining the expense recorded in the Company's consolidated statements of operations, the Company has applied an estimated forfeiture rate to the remaining unvested awards based on historical experience, as adjusted. This estimate is evaluated quarterly and the forfeiture rate is adjusted as necessary. If the actual number of forfeitures differs from management's estimates, additional adjustments to compensation expense may be required in future periods.

The aggregate intrinsic value of options outstanding at March 31, 2008 was \$232,000, of which \$146,000 related to exercisable options. The weighted average grant-date fair values of stock options granted during the quarters ended March 31, 2008 and 2007 were \$1.09 and \$1.07, respectively. As of March 31, 2008, there was approximately \$4,341,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 2.82 years. The intrinsic values of employee stock options exercised during the quarters ended March 31, 2008 and 2007 were \$34,000 and \$10,000, respectively. The total fair values of vested stock options for the quarters ended March 31, 2008 and 2007 were \$543,000 and \$764,000, respectively.

The Company recorded a total of \$13,000 and \$20,000 in compensation expense for the quarters ended March 31, 2008 and 2007, respectively, related to the ESPP. The Company calculated the fair value of shares expected to be purchased under the ESPP using the Black-Scholes model with the following assumptions:

|               | For the three months ended March 31, |          |
|---------------|--------------------------------------|----------|
|               | 2008                                 | 2007     |
| Expected term | 6 months                             | 6 months |

Edgar Filing: CURIS INC - Form 10-Q

|                         |       |       |
|-------------------------|-------|-------|
| Risk-free interest rate | 3.28% | 4.98% |
| Volatility              | 63.5% | 70%   |
| Dividends               | None  | None  |

**Table of Contents**

Stock-based compensation for employees, including expense related to the ESPP, for the quarters ended March 31, 2008 and 2007 of \$724,000 and \$864,000, respectively, was calculated using the above valuation models and has been included in the Company's results of operations. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is more likely than not that the net deferred tax asset will not be realized. Based on basic and diluted weighted average shares outstanding of 63,245,538 and 49,354,125 for the quarters ended March 31, 2008 and 2007, respectively, the effect on the Company's net loss per share of stock-based compensation expense recorded under SFAS 123(R) was approximately \$0.01 per share for the quarter ended March 31, 2008 and \$0.02 per share for the quarter ended March 31, 2007.

**Non-Employee Grants**

The Company has historically granted stock options to consultants for services. These options were issued at or above their fair market value on the date of grant and have various vesting dates from date of grant, ranging from 3.5 months to 4 years. Should the Company or the consultant terminate the consulting agreements, any unvested options will be cancelled. Options issued to non-employees are marked-to-market which means that as the Company's stock price fluctuates, the related expense either increases or decreases. The Company recognized expense of \$28,000 and \$51,000 related to non-employee stock options for the quarter ended March 31, 2008 and 2007, respectively. As of March 31, 2008, the Company had recorded \$52,000 in deferred compensation related to unvested non-employee options.

For the three months ended March 31, 2008 and 2007, the Company recorded employee and non-employee stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

|   | <b>For the three months ended<br/>March 31,</b> |                   |
|---|---|-------------------|
|   | <b>2008</b>                                     | <b>2007</b>       |
| Research and development expenses             | \$ 227,000                                      | \$ 242,000        |
| General and administrative expenses           | 525,000   | 673,000           |
| <b>Total stock-based compensation expense</b> | <b>\$ 752,000</b>                               | <b>\$ 915,000</b> |

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

The Company applies SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic and diluted net losses per share were determined by dividing net loss by the weighted average common shares outstanding during the period. Diluted net loss per common share is the same as basic net loss per common share for all periods presented, as the effect of the potential common stock equivalents is antidilutive due to the Company's net loss position for all periods presented. Antidilutive securities consist of stock options, warrants and shares issuable under the Company's 2000 Employee Stock Purchase Plan; all of which are weighted based on the number of days outstanding during the respective reporting period. Antidilutive securities as of March 31, 2008 and 2007, respectively, are as follows.

|  | <b>For the three months ended<br/>March 31,</b> |                   |
|--|---|-------------------|
|  | <b>2008</b>                                     | <b>2007</b>       |
| Weighted average stock options outstanding | 9,637,151                                       | 8,525,922         |
| Weighted average warrants outstanding      | 6,399,271                                       | 1,630,976         |
| Shares issuable under ESPP                 | 13,319  |                   |
| <b>Total antidilutive securities</b>       | <b>16,049,741</b>                               | <b>10,156,898</b> |

**11. Related Party Transactions**



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

Under its August 23, 2006 consulting agreement, as amended, and its September 14, 2006 scientific advisory and consulting agreement with Joseph M. Davie, Ph.D., M.D., a member of the Company's Board of Directors, the Company incurred \$6,000 in related consulting expenses in its consolidated statement of operations for each of the three-month periods ended March 31, 2008 and 2007, respectively. The August 2006 consulting agreement terminated in accordance with its term in June 2007, and the September 2006 consulting agreement extends through September 2011, unless terminated earlier in accordance with its terms.

**Table of Contents**

**12. New Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. FAS No. 141(R) will only have an impact on the Company's financial statements if it is involved in a business combination that occurs after January 1, 2009.

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company's financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Company has historically entered into collaborative arrangements in which this Issue would be applicable; however, the Company had no remaining joint operating activities under current collaborations at March 31, 2008. The Company will have to evaluate the impact of this Issue on future collaborations that the Company may enter into.

---

## **Table of Contents**

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

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

#### **Overview**

We are a drug discovery and development company that is committed to leveraging our innovative signaling pathway drug technologies in seeking to create new medicines, primarily for cancer. In expanding our drug development efforts in the field of cancer through our targeted cancer drug development platform, we are building upon our past experiences in targeting signaling pathways as we pursue the development of next generation targeted cancer therapies.

We seek to conduct research programs both internally and through strategic collaborations. Our most advanced program is our Hedgehog antagonist program that is under a June 2003 collaboration agreement with Genentech. In January 2007, Genentech began a phase I clinical trial to test GDC-0449, a systemically administered Hedgehog antagonist, in cancers. The primary objectives of the phase I clinical trial were to evaluate the safety and tolerability of escalating doses of GDC-0449 and to establish the maximum tolerated dose and dose limiting toxicities. In October 2007, Genentech notified us that these initial objectives of the dose escalation study were achieved and that Genentech had initiated a phase I clinical trial expansion cohort to enroll additional patients with advanced basal cell carcinoma, which includes patients with locally advanced, multifocal or metastatic basal cell carcinoma. The primary objective of the ongoing phase I expansion cohort is to assess preliminary signs of biological activity as well as to continue to accumulate phase I safety data.

In April 2008, Daniel D. Von Hoff, M.D., the principal phase I study investigator, presented phase I clinical trial data at the American Association for Cancer Research (AACR) Annual Meeting 2008. The data presented at AACR were from nine patients that had enrolled in either the phase I dose escalation or the phase I expansion cohort as of February 11, 2008 and included the following:

In five patients with metastatic basal cell carcinoma to the lungs, two patients had confirmed Response Evaluation Criteria in Solid Tumors, or RECIST, partial responses, two have ongoing stable disease and one had progressive disease. RECIST provides standard parameters to be used when documenting patient response for solid tumors.

In four patients with clinically evaluable locally advanced or multi-focal basal cell carcinoma, two patients exhibited complete response in subcutaneous masses by physical exam and two patients had improvement in skin lesions.

Genentech has indicated that it expects to present additional phase I data, including full toxicity data, at the upcoming ASCO Annual Meeting being held in Chicago, Illinois May 30, 2008 through June 3, 2008. Genentech has also indicated that it plans to initiate a phase II clinical trial of GDC-0449 in advanced basal cell carcinoma during the second half of 2008.

Genentech also plans to initiate a phase II clinical trial of GDC-0449 in metastatic colorectal cancer. As a result, Genentech will be obligated to make a \$3,000,000 cash payment to us under our June 2003 collaboration agreement within 30 days of such initiation. GDC-0449 will be evaluated in approximately 150 patients with metastatic colorectal cancer in combination with the current standard of care as first-line therapy in a randomized, placebo-controlled, double-blind phase II trial. Patients will receive either FOLFOX or FOLFIRI chemotherapy regimens in combination with bevacizumab and will be randomized to receive GDC-0449 or placebo. They will be stratified based on the chemotherapy regimen chosen and whether or not RECIST measurable disease is present at baseline. The primary objective of the phase II clinical trial is progression-free survival from randomization to disease progression or death. Secondary outcome measures include the measurement of Hedgehog protein expression in archival tissue and tracking of adverse events.

Genentech has also indicated that it plans to initiate an additional phase II clinical trial of GDC-0449 in an undisclosed advanced solid tumor of epithelial origin during the second half of 2008.

#### *Our Internal Research and Development Programs*

Our internal drug development efforts are focused on our proprietary targeted cancer drug development platform. This platform focuses on the development of single agent drug candidates targeting one or more molecular components within the signaling pathways associated with certain cancers. These programs are primarily focused on seeking to develop a number of proprietary, small molecule, single agent, multi-targeted inhibitor drug compounds, including CUDC-101, the first drug candidate selected as a development candidate from this platform. Each proprietary compound is being designed to inhibit



---

**Table of Contents**

validated cancer targets, including the epidermal growth factor receptor (EGFR), vascular endothelial growth factor receptor (VEGFR), heat shock protein 90 (Hsp90), epidermal growth factor 2 (Her2) and in combination with inhibition of histone deacetylase, or HDAC, which is a validated non-kinase cancer target. We are also seeking to use this platform to develop proprietary single agent, single target drug candidates for cancer indications, including an Hsp90 inhibitor. CUDC-101, our lead drug candidate under internal development, is being designed as a first-in-class therapeutic to inhibit HDAC, EGFR and Her2. In preclinical studies, we have demonstrated that CUDC-101 inhibits all three molecular targets resulting in the potent killing of a wide range of cancer cell lines that are representative of a variety of human cancer types, many of which have demonstrated resistance to various approved targeted agents. We are continuing to progress CUDC-101 towards an investigational new drug, or IND, application filing and expect to announce a development candidate from our Hsp90 compound class in the near future.

In furtherance of the development of our targeted cancer drug development platform, since May 2006, we have outsourced certain medicinal chemistry-based research functions to a leading provider of such services in Shanghai, China. More recently, we have engaged another provider in Beijing, China to perform certain biology-based research functions. We have developed these relationships with Chinese providers to support our U.S. operations and we are currently engaging 27 chemists and six biologists in China.

Since our inception, we have funded our operations primarily through license fees, contingent cash payments, research and development funding from our strategic collaborators, the private and public placement of our equity securities and debt financings. We have never been profitable and have incurred an accumulated deficit of \$699,278,000 as of March 31, 2008. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to our research and development programs. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. We believe that key drivers to our success will include our ability to:

successfully complete the requisite pre-IND studies and file an IND application for CUDC-101;

successfully advance an Hsp90 inhibitor compound to development status, complete IND application filing requirements and file an IND application for this compound in 2009;

advance the preclinical development of other small molecule cancer drug candidates that we are developing under our targeted cancer drug development platform;

commence and complete clinical trials, both for our internally developed programs, our Hedgehog small molecule antagonist program being studied in phase I clinical trials by our collaborator, Genentech, and any future programs we may pursue in collaboration with others in the future; and

successfully commercialize products on the basis of our and any current or planned collaborators' drug development programs. Going forward, we intend to add clinical development and regulatory capacities in 2008 and we will seek to advance one or more of our proprietary targeted cancer programs into the early stages of clinical testing. We also plan to continue to seek corporate collaborators for the further development and commercialization of at least one class of small molecules from our targeted cancer drug development platform. When evaluating potential collaborative opportunities, we plan to seek to retain significant rights and involvement or control in at least the early stages of clinical development.

*Our Research and Development Programs under Collaboration*

We are currently a party to a June 2003 collaboration with Genentech relating to our Hedgehog signaling pathway antagonist technologies and to an April 2005 collaboration with Genentech relating to the Wnt signaling pathway. Our past and current collaborations have generally provided for research, development and commercialization programs to be wholly or majority funded by our collaborators and provide us with the opportunity to receive additional payments principally if specified development and regulatory approval objectives are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaborations. As of March 31, 2008, we are not receiving any research funding, and we do not expect to receive such funding in the future, from our existing collaborations with Genentech.

**Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, if any, the timing of the receipt of payments from new or existing collaborators and the cost and outcome of any preclinical development or clinical trials then being

**Table of Contents**

conducted. We anticipate that existing capital resources at March 31, 2008, should enable us to maintain current and planned operations into the fourth quarter of 2009. Our ability to continue funding our planned operations is dependent upon the success of our collaborations with Genentech, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt, new collaborations or other sources of financing. A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under Part II, Item 1A Risk Factors.

*Revenue.* We do not expect to generate any revenue from the sale of products for several years, if ever. Substantially all of our gross revenues to date have been derived from license fees, research and development payments, and other amounts that we have received from our strategic collaborators and licensees.

We currently have two collaborations, both of which are with Genentech. We currently receive no research funding for our programs under collaboration with Genentech and we do not expect to receive such funding in the future under such collaborations. Accordingly, our only source of cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of development objectives, if any are met, under new collaborations or our existing collaborations with Genentech and royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter.

*Research and Development.* Research and development expense consists of costs incurred to discover, research and develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense. Research and development expenses also include the costs of supplies and reagents, outside service costs including medicinal chemistry, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We believe that our research and development expenses will increase in 2008 as compared to prior years as we continue to seek to progress our drug product candidates under our targeted cancer drug development platform into clinical trials. Although we have historically incurred research and development expenses under our collaborations with Genentech, we are currently incurring only nominal expenses for these programs which are limited to the maintenance of third-party licenses. For each contingent payment, if any, received under our collaborations with Genentech, we would be obligated to make payments to these third parties and recognize the related expense. Our research and development programs, both internal and under collaboration, are summarized in the following table:

| <b>Product Candidate</b>  | <b>Primary Indication(s)</b>                          | <b>Collaborator/Licensee</b> | <b>Status</b>                |
|---|---|------------------------------|------------------------------|
| <b><i>Hedgehog systemic antagonist</i></b><br>GDC-0449                        | Metastatic colorectal cancer                          | Genentech                    | (1)                          |
|   | Advanced basal cell carcinoma                         |                              | Phase I expansion cohort (1) |
|   | Undisclosed advanced solid tumor of epithelial origin |                              | (1)                          |
| Small molecule and antibody<br><b><i>Targeted cancer drug development</i></b> | Cancer  | Genentech                    | Preclinical                  |
| <b><i>platform</i></b>  |   |                              |                              |
| CUDC-101 (HDAC, EGFR, Her2Cancer inhibitor)                                   |   | Internal development         | Development candidate        |
| Hsp90 inhibitors  | Cancer  | Internal development         | Preclinical                  |
| Other targeted cancer programs  | Cancer  | Internal development         | Preclinical                  |
| Hedgehog protein/agonist  | Stroke  | Wyeth (2)                    | Preclinical                  |

- (1) On March 14, 2008, Genentech indicated that it plans to initiate phase II clinical trials of GDC-0449 in metastatic colorectal cancer, advanced basal cell carcinoma and in an undisclosed advanced solid tumor of epithelial origin during 2008.
- (2) Our collaboration agreement with Wyeth terminates in May 2008. On the termination date, the licenses granted by us to Wyeth shall terminate and we intend to pursue other collaboration or licensing opportunities for this program.





## **Table of Contents**

In the chart above, **Phase I expansion cohort** means that our collaborator is currently treating human patients in an expanded phase I clinical trial, the principal purpose of which is to evaluate the safety and biological activity of the compound being tested in a specific solid tumor type at a defined dose. **Development candidate** means that from our testing in several preclinical models of human disease of various compounds from a particular compound class, we have selected a single lead candidate for potential future clinical development and are seeking to complete the relevant safety, toxicology, and other data required to submit an IND application with the FDA seeking to commence a phase I clinical trial.

**Preclinical** means we are seeking to obtain evidence of therapeutic efficacy in preclinical models of human disease of one or more compounds within a particular class of drug candidates.

Because of the early stages of development of these programs, our ability and that of our collaborator to successfully complete preclinical and clinical studies of these drug product candidates, and the timing of completion of such programs, is highly uncertain, there are numerous risks and uncertainties associated with developing drugs which may affect our and our collaborators' future results, including:

the scope, quality of data, rate of progress and cost of clinical trials and other research and development activities undertaken by us or our collaborators;

the results of future preclinical and clinical trials;

the cost and timing of regulatory approvals;

the cost and timing of establishing sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

the effect of competing technological and market developments; and

the cost and effectiveness of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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

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

*General and Administrative.* General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology, corporate communications and human resource functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Patent costs include certain patents covered under collaborations, a portion of which are reimbursed by collaborators and a portion of which are borne by Curis.

## **Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the collectibility of receivables and the value of certain investments and liabilities. We base our estimates on historical experience and on various

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

other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We set forth our critical accounting policies and estimates in our annual report on Form 10-K for the year ended December 31, 2007, which is on file with the SEC. The following sets forth material changes in our critical accounting policies and estimates described therein.

## **Table of Contents**

*Fair Value Measurements.* Effective January 1, 2008, we adopted the provisions of SFAS (SFAS) No. 157, *Fair Value Measurements*, and SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, (SFAS No. 159) for our financial assets and financial liabilities. The adoption of SFAS No. 157 did not have a material impact on our financial position or results of operations. In accordance with Financial Accounting Standards Board Staff Position (FSP) No. 157-2, *Effective Date of FASB Statement No. 157*, we will delay application of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option for eligible financial instruments under SFAS No. 159.

SFAS No. 157 provides a framework for measuring fair value under U.S. generally accepted accounting principles and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact.

SFAS No. 157 requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets and liabilities. The income approach uses valuation techniques to convert future amounts, such as cash flows or earnings, to a single present amount on a discounted basis. The cost approach is based on the amount that currently would be required to replace the service capacity of an asset (replacement cost). Valuation techniques should be consistently applied. SFAS No. 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Our cash, cash equivalents and marketable securities have been classified as Level 1 assets. We do not hold any asset-backed or auction rate securities. Short-term accounts receivable and accounts payable are reflected in the consolidated financial statements at cost, which approximates fair value due to the short-term nature of these instruments. In general, fair value is based upon quoted market prices, where available. If such quoted market prices are not available, fair value is based upon internally developed models that primarily use, as inputs, observable market-based parameters. Valuation adjustments may be made to ensure that financial instruments are recorded at fair value. These adjustments may include unobservable parameters. Any such valuation adjustments would then be applied consistently over time. Our valuation methodologies may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. While we believe our valuation methodologies are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Our discussion of our critical accounting policies is not intended to be a comprehensive discussion of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

### **Recently Issued Accounting Standards**

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)). SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS No. 141(R) also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS No. 141(R) is effective for fiscal years beginning after December 15, 2008. FAS No. 141(R) will only have an impact on our financial statements if we are involved in a business combination that occurs after January 1, 2009.



**Table of Contents**

In December 2007, the EITF issued Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and shall be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date that include a joint operating activity (i.e., co-development) and that are operated as a virtual joint venture. This Issue includes enhanced disclosure requirements regarding the nature and purpose of the arrangement, rights and obligations under the arrangement, accounting policy, amount and income statement classification of collaboration transactions between the parties. This Issue also requires that transactions with third parties (i.e., parties that do not participate in the collaborative arrangement) should be reported in the appropriate line item in each company's financial statement pursuant to the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. We have historically entered into collaborative arrangements in which this Issue would be applicable; however, we had no remaining joint operating activities under current collaborations at March 31, 2008. Management will have to evaluate the impact of this Issue on future collaborations that we may enter into.

**Results of Operations****Three Months Ended March 31, 2008 and March 31, 2007**

*Revenues. Total revenues are summarized as follows:*

|   | <b>For the Three Months Ended<br/>March 31,</b> |                     | <b>Percentage<br/>Increase/<br/>(Decrease)</b> |
|---|---|---------------------|--|
|   | <b>2008</b>                                     | <b>2007</b>         |  |
| <b>REVENUES:</b>                          |   |                     |  |
| <i>Research and development contracts</i> |   |                     |  |
| Genentech                                 | \$ 54,000                                       | \$ 718,000          | (92)%  |
| Wyeth                                     | 149,000   | 454,000             | (67)%  |
| Procter & Gamble                          |   | 32,000              | (100)%   |
| Other                                     | 12,000  | 79,000              | (85)%  |
| Subtotal                                  | 215,000   | 1,283,000           | (83)%  |
| <i>License fees</i>                       |   |                     |  |
| Genentech                                 |   | 938,000             | (100)%   |
| Wyeth                                     | 103,000   | 76,000              | 36%  |
| Procter & Gamble                          |   | 66,000              | (100)%   |
| Stryker                                   | 1,750,000                                       |                     | 100%   |
| Subtotal                                  | 1,853,000                                       | 1,080,000           | 72%  |
| <b>Total revenues</b>                     | <b>\$ 2,068,000</b>                             | <b>\$ 2,363,000</b> | <b>(12)%</b>                                   |

Total revenues decreased by \$295,000 to \$2,068,000 for the three months ended March 31, 2008 from \$2,363,000 for the same prior year period. Research and development contracts decreased \$1,068,000 as all research funding for programs under collaboration concluded at various times beginning in March 2007. The conclusion of research funding under our Wnt signaling pathway discovery collaboration with Genentech in March 2007 and under our Hedgehog agonist collaboration with Wyeth in February 2008 accounted for \$944,000 of the decrease. We currently receive no research funding for our programs under past or current collaborations. As a result of the foregoing changes, we expect that our future research and development contract revenues will be limited to expenses that we incur on behalf of our collaborators for which the collaborator is obligated to reimburse us.

Offsetting the decrease in research and development contract revenue, our license revenues increased by \$773,000 to \$1,853,000 in the first quarter of 2008 from \$1,080,000 for the same period in 2007. The increase is due to \$1,750,000 in license revenue recognized for the sale and assignment of our remaining BMP assets to Stryker Corporation during the quarter ended March 31, 2008, offset in part by a decrease of \$938,000 in license revenue recognized under our Wnt signaling pathway discovery collaboration with Genentech.

**Table of Contents**

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

| Research and Development Program       | Primary Indication                                  | Collaborator         | For the Three Months Ended<br>March 31, |              | Percentage<br>Increase/<br>(Decrease) |
|--|---|----------------------|---|--------------|---------------------------------------|
|  |   |                      | 2008                                    | 2007         |                                       |
| Hh systemic small molecule antagonist  | Cancer  | Genentech            | \$ 20,000                               | \$ 35,000    | (43)%                                 |
| CUDC-101 (HDAC, EGFR, Her2 inhibitor)  | Cancer  | Internal             | 1,716,000                               |              | 100%                                  |
| Other targeted cancer programs         | Cancer  | Internal             | 1,204,000                               | 1,705,000    | (29)%                                 |
| Hh agonist                             | Nervous system disorders/<br>cardiovascular disease | Wyeth (1)            | 186,000                                 | 443,000      | (58)%                                 |
| Wnt signaling pathway                  | Cancer  | Genentech            |   | 626,000      | (100)%                                |
| Hh small molecule agonist              | Hair loss   | Procter & Gamble (2) |   | 18,000       | (100)%                                |
| Discovery research                     | Various   | Various/internal     | 123,000                                 | 295,000      | (58)%                                 |
| Gain on sale of assets                 | N/A   |                      |   | (68,000)     | (100)%                                |
| Stock-based compensation               | N/A   |                      | 227,000                                 | 242,000      | (6)%                                  |
| Total research and development expense |   |                      | \$ 3,476,000                            | \$ 3,296,000 | 5%                                    |

(1) On March 7, 2008, Wyeth provided us with written notice that this collaboration agreement will terminate on May 6, 2008. On the termination date, the licenses granted by us to Wyeth shall terminate and we intend to pursue other collaboration or lecturing opportunities for this program.

(2) Our collaboration with Procter & Gamble terminated effective November 9, 2007.

Our research and development expenses increased by \$180,000, or 5%, to \$3,476,000 for the three months ended March 31, 2008 as compared to \$3,296,000 for the same period in the prior year due to increased spending on our targeted cancer drug development platform programs offset by decreased spending on programs under collaborations. Our lead targeted cancer development candidate, CUDC-101, was selected in March 2007 and accounted for an increase in spending of \$1,716,000 when compared to the same prior year period. Our spending on other targeted cancer programs decreased by \$501,000 from the prior year period as we continue to allocate resources to CUDC-101 in an effort to move this candidate toward an IND filing and clinical development. Further offsetting this increase, spending on our collaborator-funded programs with (i) Genentech for the Wnt signaling pathway; (ii) Wyeth for the Hedgehog agonist; and (iii) Centocor for BMP-7 small molecule agonists decreased by an aggregate amount of \$1,145,000 as a result of the conclusion of the research funding for each of these programs at various times between March 2007 and February 2008. Certain of these resources were reallocated to our internal targeted cancer drug development platform programs.

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

|   | For the Three Months Ended<br>March 31, |              | Percentage<br>Increase/<br>(Decrease) |
|---|---|--------------|---------------------------------------|
|   | 2008                                    | 2007         |                                       |
| Personnel                                 | \$ 719,000                              | \$ 704,000   | 2%                                    |
| Occupancy and depreciation                | 91,000                                  | 74,000       | 23%                                   |
| Legal services                            | 371,000                                 | 761,000      | (51)%                                 |
| Professional and consulting services      | 325,000                                 | 330,000      | (2)%                                  |
| Insurance costs                           | 98,000                                  | 123,000      | (20)%                                 |
| Other general and administrative expenses | 286,000                                 | 287,000      | %                                     |
| Stock-based compensation                  | 525,000                                 | 673,000      | (22)%                                 |
| Total general and administrative expenses | \$ 2,415,000                            | \$ 2,952,000 | (18)%                                 |

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

General and administrative expenses decreased by \$537,000, or 18%, to \$2,415,000 for the three months ended March 31, 2008 as compared to \$2,952,000 for the same period in the prior year primarily due to decreased spending for legal services. Legal services decreased \$390,000 during the three months ended March 31, 2008, primarily due to costs associated with foreign patent applications in the prior year period. We expect that our patent costs will continue to fluctuate from quarter-to-quarter in the future. In addition, stock-based compensation expense decreased by \$148,000 in the first quarter of 2008 as compared to the same period in the prior year as a result of a decline in the grant date fair values of stock options expensed in the quarter ended March 31, 2008 as compared to the quarter ended March 31, 2007.

---

**Table of Contents**

**Liquidity and Capital Resources**

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

At March 31, 2008, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$35,232,000, excluding restricted long-term investments of \$210,000. Our cash and cash equivalents are highly liquid investments with a maturity of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions, short-term commercial paper, and government obligations. We also maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances because the balances are invested in highly rated securities. Our marketable securities are investments with expected maturities of greater than three months, but less than twelve months, and consist of commercial paper, corporate debt securities, and government obligations. We do not hold any asset-backed or auction rate securities.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees and legal fees.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. As a result of the conclusion of all research funding, the majority of our research and development effort and expense has shifted from our programs that were funded under collaborations relating to the Hedgehog pathway and various discovery programs to the development of programs under our targeted cancer drug development platform, particularly for our lead targeted cancer development candidate, CUDC-101. While we are seeking a corporate collaborator for one or more of the programs in this platform, we are currently progressing the research and development of these programs on our own. We believe that our research and development expenses will increase in 2008 in connection with our plan to initiate phase I clinical testing for CUDC-101, and to select at least one additional development candidate from our proprietary platform.

In general, our only source of cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of development objectives, if any are met, under new collaborations or our existing collaborations with Genentech and royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was \$5,977,000 for the three-month period ended March 31, 2008 as compared to \$3,624,000 for the three-month period ended March 31, 2007. Cash used in operating activities during the three-month period ended March 31, 2008 was primarily the result of our net loss for the period of \$3,431,000. In addition, changes in certain operating assets and liabilities affected operating cash during the three-month period ended March 31, 2008, including a decrease in deferred revenue of \$1,853,000 as a result of both the recognition of the \$1,750,000 license fee that we received in December 2007 under our BMP transaction with Stryker Corporation and a decrease of \$1,645,000 in our accounts payable and accrued liabilities. Offsetting these decreases were noncash items stock-based compensation expense of \$752,000 and depreciation of \$256,000.

Cash used in operating activities during the three-month period ended March 31, 2007 was primarily the result of our net loss for the quarter of \$3,541,000. Increases in operating cash resulting from non-cash charges, including stock-based compensation expense of \$915,000 and depreciation of \$476,000 during the three-month period ended March 31, 2007, were offset by a decrease of \$1,258,000 in deferred revenue as a result of license fee amortization under our various collaborations.

We expect to continue to use cash in operations as we continue to seek to advance our targeted cancer drug development platform programs through preclinical development and into clinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and specified other objectives.

Investing activities provided cash of \$5,062,000 for the three-month period ended March 31, 2008 as compared to \$1,759,000 for the three-month period ended March 31, 2007. Cash generated in investing activities resulted principally from



## **Table of Contents**

\$5,096,000 and \$1,583,000 in net investment sales for the three months ended March 31, 2008 and 2007, respectively. In addition, for the quarter ended March 31, 2007, we received \$197,000 in net proceeds from the sale of certain of our assets. We currently do not expect to undertake any significant capital projects during 2008.

Financing activities used cash of approximately \$241,000 for the three-month period ended March 31, 2008, resulting from repayment of \$308,000 on our notes with the Boston Private Bank & Trust Company. This decrease in cash was offset by cash received of \$68,000 upon the exercise of stock options. Financing activities used cash of approximately \$466,000 for the three-month period ended March 31, 2007, resulting from repayment of \$510,000 on our notes with the Boston Private Bank & Trust Company, including proceeds from the sale of certain of our assets during the quarter. As of April 1, 2008, our two loan agreements with the Boston Private Bank & Trust Company have been paid in full and we do not expect to secure any significant debt financing in the near term.

We anticipate that existing capital resources at March 31, 2008, should enable us to maintain current and planned operations into the fourth quarter of 2009. This projection excludes any contingent cash payments other than those stated above. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials, for the foreseeable future. Our ability to continue funding planned operations beyond the fourth quarter of 2009 is dependent upon, among other things, the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through additional corporate collaborations, equity or debt financings, or from other sources of financing. We are seeking additional collaborative arrangements and also anticipate that we will seek to raise funds through one or more financing transactions, if conditions permit. Due to our significant long-term capital requirements, we intend to seek to raise funds through the sale of debt or equity securities when conditions are favorable, even if we do not have an immediate need for additional capital at such time. Additional financing may not be available or, if available, it may not be available on favorable terms. In addition, the sale of additional debt or equity securities could result in dilution to our stockholders. If substantial additional funding is not available, our ability to fund research and development and other operations will be significantly affected and, accordingly, our business will be materially and adversely affected. See Part II, Item 1A Risk Factors, for a further discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional capital.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of March 31, 2008.

### **Inflation**

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

**Table of Contents**

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There have been no material changes to the information provided under Item 7A Quantitative and Qualitative Disclosures About Market Risk set forth in our Annual Report on form 10-K for the year ended December 31, 2007.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls & Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in Internal Control Over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede the risk factors previously disclosed in Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2007.

**RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING**

**We have incurred substantial losses, we expect to continue to incur substantial losses for the foreseeable future and we may never generate significant revenue or achieve profitability.**

As of March 31, 2008, we had an accumulated deficit of approximately \$699,278,000. We have not successfully commercialized any products to date, either alone or in collaboration with others. If we are not able to successfully commercialize any products, whether alone or with a collaborator, we will not achieve profitability. All of our product candidates are in early stages of development. As a result, for the foreseeable future, we will need to spend significant capital, particularly on our internally funded targeted cancer drug development platform, in an effort to produce products that we can commercialize. As such, we expect to incur substantial operating losses for the foreseeable future.

We have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. Research funding related to our ongoing Hedgehog antagonist and Wnt signaling pathway collaborations with Genentech concluded in the fourth quarter of 2006 and the first quarter of 2007, respectively. In addition, research funding under our Hedgehog agonist collaboration with Wyeth concluded in February 2008 and, pursuant to notice provided by Wyeth, this collaboration will terminate effective May 6, 2008. Accordingly, we have no current source of research funding revenue and our only source of cash flows from operations for the foreseeable future will be up-front license payments and funded research and development that we may receive under new collaboration agreements, if any, contingent cash payments for the achievement of development objectives, if any are met, under new collaborations or our existing collaborations with Genentech, and royalty payments that are contingent upon the successful commercialization of any products based upon collaborations. The timing of or entrance into any new collaboration agreements and any contingent cash payments under our existing collaboration agreements with Genentech are not assured, cannot be easily predicted and may vary significantly from quarter to quarter. Moreover, the pursuit and achievement of any development or commercialization objectives is substantially within the collaborator's or licensee's sole control. In addition, there is considerable inherent uncertainty in the successful development and commercialization of pharmaceutical drugs. As a result, we cannot assure you that we will attain any further revenue under any collaborations or licensing arrangements.

We will need to generate significant revenues in order to fund our operations and achieve profitability. We cannot be certain whether or when this will occur because of the significant uncertainties that affect our business, including the various risks described in this section titled "Risk Factors". Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our research and development programs or continue our operations.

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

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

support our research and development activities for CUDC-101 and other small molecules that we are seeking to develop under our targeted cancer drug development platform;

fund our general and administrative costs and expenses; and

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

potentially expand our infrastructure.

We anticipate that existing capital resources at March 31, 2008, should enable us to maintain current and planned operations into the fourth quarter of 2009. This projection excludes any contingent cash payments other than those stated above. Our future capital requirements, however, may vary from what we currently expect. There are factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing. These factors, many of which are outside our control, include the following:

unanticipated costs in our research and development programs;

**Table of Contents**

the timing and cost of obtaining regulatory approvals for our product candidates;

the cost of additional facility requirements;

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

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

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

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

We expect to seek additional funding through public or private financings of debt or equity as well as from additional strategic collaborations. The market for emerging life science stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research and development activities will be adversely affected.

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

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

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

the cost of research and development that we engage in;

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

the entry into, or termination of, collaboration agreements;

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

the scope, duration and effectiveness of our collaborative arrangements;

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

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

the ability to operate without infringing upon the proprietary rights of others;

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting estimates, policies or principles; and

the introduction of competitive products and technologies by third parties.

Except for our systemically administered Hedgehog antagonist program, which is currently being evaluated by our collaborator, Genentech, in an expansion cohort of an ongoing phase I clinical trial, all of our programs are in various stages of preclinical drug development. Accordingly, our revenues from sales of approved products may not occur for several years, if at all. While we may receive contingent cash payments upon the achievement of certain objectives defined within our collaboration agreements with Genentech, the timing of such payments is uncertain. In addition, the amount of these payments and the methodology that we would record such payments to revenue vary for each of our collaborator agreements. As a result, we may experience fluctuations in our operating results from quarter to quarter and continue to generate losses. Quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of our future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a drop of our stock price.

---

**Table of Contents**

**RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS**

**We depend on our collaborative relationship with Genentech for the development and commercialization of certain product candidates based upon our technologies, including our most advanced product candidate. If Genentech fails or delays in developing or commercializing these product candidates, our business prospects and operating results would suffer and our stock price would likely decline.**

The success of our strategy for development and commercialization of certain licensed product candidates depends upon our ability to form and maintain productive and successful strategic collaborations. We currently have two collaborations with Genentech pursuant to which we have granted to Genentech exclusive rights to develop and commercialize products based upon our technologies in defined fields of use, including GDC-0449, an orally-administered small molecule antagonist of the hedgehog signaling pathway. Genentech is currently testing GDC-0449 in an expansion cohort of an ongoing phase I clinical trial and has stated that it plans to initiate up to three phase II clinical trials of GDC-0449 in 2008. Our collaborations with Genentech are our only current collaborations, and these collaborations may not be scientifically or commercially successful due to a number of factors, including the following:

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

Our strategic collaboration agreements with Genentech permit Genentech wide discretion in deciding which product candidates to advance through the clinical trial process. It is possible for Genentech to reject product candidates at any point in the research, development and clinical trial process, without triggering a termination of the collaboration agreement with us. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress product candidates ourselves.

Genentech may develop and commercialize, either alone or with others, products that are similar to or competitive with the product candidates that are the subject of its collaborations with us.

Genentech may change the focus of its development and commercialization efforts or pursue higher-priority programs. Our ability to successfully commercialize product candidates under collaboration with Genentech could be limited if Genentech decreases or fails to increase spending related to such product candidates.

Genentech may, under specified circumstances, terminate its collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the scientific and financial communities.

If Genentech fails to successfully develop and commercialize our product candidates under collaboration, we may not be able to develop and commercialize these candidates independently or successfully enter into one or more alternative collaborations, in which event our financial condition, results of operations and stock price may be adversely affected.

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

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new strategic collaborations for the development and commercialization of products in our development pipeline. For example, we are currently seeking a corporate collaboration for one or more programs that we are developing under our proprietary targeted cancer drug development platform and also intend to seek a collaborative partner for our Hedgehog agonist program. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a collaboration or other alternative arrangements for any of these programs because, for example, our research and development pipeline may be insufficient or our programs may be deemed to be at too early of a stage of development for collaborative effort. Even if we are successful in our efforts to

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

establish new collaborations, the terms that we agree upon may not be favorable to us. Finally, any such strategic alliances or other arrangements may not result in the successful development and commercialization of products and associated revenue.



---

**Table of Contents**

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

In order to obtain regulatory approval for the commercial sale of our product candidates, we and any current or planned collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective. Our lead product candidate, GDC-0449, is currently being tested by our collaborator, Genentech, in an ongoing phase I clinical trial and Genentech has stated that it expects to initiate up to three phase II clinical trials of GDC-0449 in 2008. In addition, we expect to file an IND to commence a phase I clinical trial of CUDC-101, our lead preclinical candidate under internal development, in mid-2008. Development, including preclinical and clinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials of our product candidates under development may not be successful. We, Genentech and any future collaborators could experience delays or failures in preclinical or clinical trials of any of our product candidates for a number of reasons. For example:

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

the results from preclinical studies and early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

we may encounter difficulties or delays in manufacturing sufficient quantities of the product candidate used in any preclinical study or clinical trial;

the timing and completion of clinical trials of our product candidates depend on, among other factors, the number of patients required to be enrolled in the clinical trials and the rate at which those patients are enrolled, and any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or program termination;

our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use;

institutional review boards or regulators, including the FDA, or any collaborators may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including failure to achieve established success criteria, noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks; and

we, along with any of our current or planned collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA's Application Integrity Policy. Employment of such a debarred person may result in delays in FDA's review or approval of our products, or the rejection of data developed with the involvement of such person(s).

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

**We have very limited experience in conducting clinical trials. We are currently recruiting clinical/regulatory management but we expect to rely primarily on a combination of collaborative partners, consultants and contract research organizations for the performance and**

**management of any clinical trials of our product candidates. If such third parties fail to perform then we will not be able to successfully develop and commercialize product candidates and grow our business.**

We have limited experience in conducting clinical trials. We expect to rely to varying degrees on third parties to conduct our clinical trials and provide services in connection with such clinical trials. For example, we have granted development and commercialization rights to Genentech under our existing collaboration agreements with Genentech and we expect that any future collaboration partners may similarly be fully responsible for conducting clinical trials of product candidates. In some instances, such as product candidates associated with new programs that successfully advance into the clinic, we may be responsible for clinical trials. While we are currently seeking to add clinical/regulatory employees, we expect that hiring such employees will be difficult since competition for skilled clinical and regulatory employees is intense. In the near term, we are likely to rely primarily on third parties such as consultants, contract research organizations and other

---

## **Table of Contents**

similar entities to complete IND-enabling preclinical studies, create and submit IND applications, enroll qualified subjects, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If any such events were to occur, efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

In addition, for those product candidates where we expect to be responsible for clinical trials, we must ensure that each such clinical trial is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of the third-party contractors on whom we may in the future rely do not comply with good clinical practices or other applicable regulatory requirements, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approvals for and commercialize our product candidates may be delayed.

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

We, Genentech and any planned collaborative partners will be required to obtain regulatory approval in order to successfully advance our product candidates through the clinic and prior to marketing and selling such products. The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. With respect to internal programs to date, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations may restrict the size of the market for the product and affect reimbursement by third-party payors. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke or significantly modify previously granted approvals.

We are subject to, and our current and planned collaborative partners are, or will be, subject to, numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing may be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

In addition, regulatory agencies may change existing requirements or adopt new requirements or policies. We and any collaborative partners may be slow to adapt or may not be able to adapt to these changes or new requirements.

As a result of these factors, we and any collaborators may not successfully begin or complete clinical trials and/or obtain regulatory approval to market and sell our product candidates in the time periods estimated, if at all. Moreover, if we or any collaborators incur costs and delays in development programs or fail to successfully develop and commercialize products based upon our technologies, we may not become profitable and our stock price could decline.

**Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute products after approval.**

On September 27, 2007, the President of the United States signed the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute products after approval.

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

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

Even if we or any current or planned collaborators obtain regulatory approval of a product candidate, the approval may be subject to limitations on the indicated uses for which the product is marketed or require costly post-marketing follow-up

---

## **Table of Contents**

studies. After marketing approval for any product is obtained, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other regulatory agencies. The subsequent discovery of previously unknown problems with the product, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If there is a failure to comply with applicable regulatory requirements, we or any collaborator may be subject to fines, refusal to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, refusal to permit the import or export of our products and criminal prosecution.

**We and Genentech are, and any planned collaborators will be, subject to governmental regulations in connection with the research, development and commercialization of our product candidates in addition to those imposed by the FDA. We and any such collaborators may not be able to comply with these regulations, which could subject us, or such collaborators, to penalties and otherwise result in the limitation of our or such collaborators' operations.**

In addition to regulations imposed by the FDA, we, our current collaborator, Genentech, and any planned collaborators are subject to regulation under, among other laws, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, as well as regulations administered by the Nuclear Regulatory Commission, national restrictions on technology transfer, import, export and customs regulations and certain other local, state or federal regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of pharmaceutical and biotechnology applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with all applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury caused by these materials.

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

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

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

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies, initiation and completion of clinical trials, and other developments and milestones under our proprietary programs and those programs being developed under collaboration agreements. For example, we currently estimate that we will seek to submit an IND application to commence clinical trials of CUDC-101 in mid-2008. We continue to expect that we will select a second development candidate from our targeted cancer drug development platform in the first half of 2008. Genentech has also made public statements regarding its expectations for the clinical development of GDC-0449. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our and our current and planned collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us and our current and planned collaborators' and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that our or our current and planned collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we or they announce or expect, that we or our current and planned collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our current and planned collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or any collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

---

## **Table of Contents**

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

Our product candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the Hedgehog signaling pathway is increasingly competitive. We are developing Hedgehog-based therapies under our collaborations with Genentech in the field of cancer. Competitors may discover, characterize and develop Hedgehog antagonist drug candidates before we do or which compete with us in the same market sector.

In addition, our small molecule drug development candidates being developed under our targeted cancer drug development platform, which are focused primarily on clinically validated cancer targets, face significant competition from marketed drugs and drugs under development that seek to inhibit the same targets as our drug candidates.

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

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

We expect competition to intensify in cancer generally and, specifically, in targeted approaches to develop potential cancer therapies as technical advances in the field are made and become more widely known. If we are not able to compete effectively, then we may not be able, either alone or with others, to advance the development and commercialization of our product candidates, which would adversely affect our ability to grow our business and become profitable.

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

Product liability claims inherent in the process of researching, developing and commercializing human health care products could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. Product liability insurance is expensive to procure for emerging life science companies such as ours. Product liability claims would require us to spend significant time, money and other resources to defend such claims and could ultimately result in the payment of a significant damage award. Because we are not currently conducting any clinical trials or commercializing any products, we do not currently carry any product liability insurance. We plan to purchase product liability insurance for our expected phase I clinical trial of CUDC-101, which we expect will begin in mid-2008. Although we would seek to obtain and maintain product liability insurance coverage for this and any other future clinical trials of our products under development, it is possible that we will not be able to obtain this product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage would not prove to be adequate to protect us from all potential claims.

### **If we are not able to attract and retain key management and scientific personnel and advisors, we may not successfully develop our product candidates or achieve our other business objectives.**

We depend upon our senior management and scientific staff, including Daniel R. Passeri, our President and Chief Executive Officer, Michael P. Gray, our Chief Operating Officer and Chief Financial Officer, and Changgeng Qian, Ph.D., M.D., our Vice President, Discovery and Preclinical Development. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Our officers can terminate their employment with us at any time, although we are not aware of any present intention of any of these individuals to leave our company. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency. We do not maintain key man life insurance on any of these executive officers.



---

## **Table of Contents**

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

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

We may seek to expand our operations in the future, including without limitation through internal growth and/or the acquisition of businesses and technologies that we believe are a strategic complement to our business model. We may not be able to identify suitable acquisition candidates or expansion strategies and successfully complete such acquisitions or successfully execute any such other expansion strategies. We may never realize the anticipated benefits of any efforts to expand our business. Furthermore, the expansion of our business, either through internal growth or through acquisitions, poses significant risks to our existing operations, financial condition and operating results, including:

a diversion of management from our existing operations;

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

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

incurrence of debt, other liabilities and contingent liabilities; and

dilutive stock issuances.

**Any business that we conduct in China will expose us to the risk of adverse changes in political, legal and economic policies of the Chinese government, which changes could impede our preclinical efforts in China and materially and adversely affect the development of our Targeted Cancer Drug Development platform.**

We are developing our targeted cancer drug development platform using standard medicinal chemistry approaches to create proprietary targeted cancer drugs. In order to satisfy the platform's extensive medicinal chemistry requirements, we currently engage 25 to 30 medicinal chemists in Shanghai, China pursuant to an agreement with a medicinal chemistry provider in Shanghai. The economics of doing business in China allow us to engage approximately five chemists for the same price as one chemist at U.S. or European chemistry providers. We also currently engage approximately six biologists at another third-party provider in Beijing, China. In addition, we have a subsidiary in China, Curis Shanghai, which is currently licensed but is not operational.

Conducting business in China exposes us to a variety of risks and uncertainties that are unique to China. The economy of China has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the Chinese government. In addition, the Chinese government continues to play a significant role in regulating industrial development. It also exercises significant control over China's economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Efforts by the Chinese government to slow the pace of growth of the Chinese economy could result in interruptions of our development efforts in China. If our research and development efforts in China are delayed due to such interruptions, we may not realize the reductions in costs anticipated from engaging chemists in China. We would also have to consider moving our chemistry and/or biology research that is currently conducted in China to U.S. or European providers, thereby either increasing our overall costs for such services or reducing the total number of chemists and or/biologists that we could engage.

In addition, the Chinese legal system is a civil law system based on written statutes. Unlike common law systems, it is a system in which decided legal cases have little precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations



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

governing economic matters in general. Accordingly, we cannot predict the effect of future developments in the Chinese legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. Our business could be materially harmed by any changes in the political, legal or economic climate in China or the inability to enforce applicable Chinese laws and regulations.

---

## **Table of Contents**

### **If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates elsewhere in this quarterly report on Form 10-Q.

### **Compliance with changing regulation of corporate governance and public disclosure as well as potential new accounting pronouncements is likely to impact our future financial position or results of operations.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New accounting pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies, for example the 2006 requirement under Statement of Financial Accounting Standards No. 123 (revised 2004), or SFAS 123(R), to expense stock options.

Our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. We expect these efforts to require the continued commitment of significant resources. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

### **Failure to maintain effective internal controls in accordance with section 404 of the Sarbanes-Oxley act could have a material adverse effect on our business and stock price.**

Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal controls, and attestations of the effectiveness of our internal controls by our independent auditors. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of section 404 of the Sarbanes-Oxley Act, as such standards are modified, supplemented or amended from time to time, could have a material adverse effect on our business, operating results and stock price.

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

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

We are a party to intellectual property out-licenses, collaborations and agreements that are important to our business, including our June 2003 and April 2005 collaboration agreements with Genentech and our December 2007 assignment agreement with Stryker Corporation, and we expect to enter into similar agreements with third parties in the future. Under these agreements, we generally license or transfer intellectual property to third parties and impose various research, development, commercialization, sublicensing, royalty, indemnification, insurance, and other obligations on them. If a third party breaches its responsibilities under these agreements, we generally retain the right to terminate the agreement, and to bring a legal action in court or in arbitration. In the event of breach, we may need to enforce our rights under these agreements by resorting to arbitration or litigation. During the period of arbitration or litigation, we may be unable to effectively use, assign or license the relevant intellectual property rights and may be deprived of current or future revenues that are associated with such intellectual property.



---

## **Table of Contents**

**We in-license certain of our principal proprietary technologies, and if we fail to comply with our obligations under any of the related agreements, or fail to secure any required new licenses, we could lose license rights that are necessary to commercializing our product candidates.**

We are party to various license agreements that give us rights to commercialize various technologies, particularly our Hedgehog pathway technologies, and to use technologies in our research and development processes. Our most significant in-license agreements are with Harvard University, Columbia University, the Johns Hopkins University both alone and with the University of Washington, and Leland Stanford Junior University. Some of these license agreements impose various development, commercialization, funding, royalty, diligence, and other obligations on us, which provide that our failure to meet any agreed upon requirements may allow the licensor to terminate the agreement. Some of our license agreements grant us exclusive licenses to the underlying technologies. If our licensors terminate our license agreements or if we are unable to maintain the exclusivity of our exclusive license agreements, we may be unable to continue to develop and commercialize our product candidates. In addition, continued development and commercialization of our product candidates may require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

**We may not be able to obtain patent protection for our technologies and the patent protection we do obtain may not be sufficient to stop our competitors from using similar technology.**

The patent positions of pharmaceutical and life science companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The procedures and standards that the United States Patent and Trademark Office and various foreign intellectual property offices use to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and may be changed in a significant way and are expected to continue to change. Consequently, the level of protection, if any, that will be obtained and provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our business depends in significant part on our ability to:

obtain patents to protect our technologies and discoveries;

protect trade secrets from disclosure to third-party competitors;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficient to protect our technology from exploitation by our competitors. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and abroad are maintained in secrecy until 18 months after filing, it is possible that third parties have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our knowledge.

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

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

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management, and could result in significant monetary or equitable judgments against us. For example, lawsuits by employees, licensors, licensees, suppliers, distributors, stockholders, or competitors could be very costly and substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure that we will always be able to resolve such disputes out of court or on terms favorable to

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

us. Any claims, with or without merit, and regardless of whether we prevail in the dispute, would be time-consuming, could result in costly litigation and the diversion of technical and management personnel.

---

## **Table of Contents**

In recent years, there have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and life science industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

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

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

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

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

initiation of foreign opposition proceedings by third parties that seek to limit or eliminate the scope of our patent protection in a foreign jurisdiction;

initiation of litigation by third parties claiming that our processes or product candidates or the intended use of our product candidates infringe their patent or other intellectual property rights; and

initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property that may be important to our business.

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

### **Our commercial success will depend in part on our ability to obtain and maintain protection of our intellectual property in China.**

We rely on trade secrets, proprietary know-how and other non-patentable technology, which we seek to protect through agreements containing non-disclosure and intellectual property assignment provisions with the chemists and biologists we have engaged in China. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets, proprietary know-how and other non-patentable technology will not otherwise become known to, or be independently developed by, our competitors.

Implementation and enforcement of Chinese intellectual property-related laws has historically been inconsistent and damages assessed fail to reflect the true value of the infringed technology and its market. Accordingly, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we might need to resort to litigation to enforce or defend patents issued to us or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of Chinese courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require significant expenditure of cash and management efforts and could harm our business, financial condition and results of operations. An adverse determination in any such litigation will impair our intellectual property rights and may harm our business, prospects and reputation.

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

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through confidentiality and intellectual property license or assignment provisions in agreements with our employees, consultants and other third-party contractors as well as through other security measures. The confidentiality and intellectual property provisions of our agreements and security measures may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

---

**Table of Contents**

**RISKS RELATING TO MANUFACTURING AND SALES**

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

We have no manufacturing experience or manufacturing capabilities. In order to continue to develop product candidates, apply for regulatory approvals, and commercialize our products under development, we or any collaborators must be able to manufacture products in adequate clinical and commercial quantities, in compliance with regulatory requirements, including those related to quality control and quality assurance, at acceptable costs and in a timely manner. The manufacture of our product candidates may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If supplies of any of our product candidates or related materials become unavailable or are not delivered on a timely basis or at all, or are contaminated or otherwise lost, certain preclinical studies and/or clinical trials by us and any collaborators could be seriously delayed. This is due to the fact that such materials are time-consuming to manufacture and cannot be readily obtained from third-party sources.

To the extent that we or any collaborators seek to enter into manufacturing arrangements with third parties, we and such collaborators will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current good manufacturing practices and other governmental regulations and corresponding foreign standards. Any failure by our contract manufacturers, any collaborators or us to comply with applicable regulations could result in sanctions being imposed, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including;

we and any collaborators may not be able to initiate or continue certain preclinical and/or clinical trials of products that are under development;

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

we and any collaborators may not be able to meet commercial demands for any approved products.

**We have no sales or marketing experience and, as such, will depend significantly on third parties who may not successfully sell our products.**

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech, we have granted Genentech the exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on terms that are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.



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

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

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

---

**Table of Contents**

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

our direct sales and marketing efforts may not be successful.

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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

**Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell our products, if approved, and impair our ability to derive revenue from these products.**

Legislation has been introduced in the U.S. Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States. This could include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenue. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales.

**RISKS RELATED TO OUR COMMON STOCK**

**If we fail to meet the requirements for continued listing on the NASDAQ Global Market, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.**

Our common stock is currently listed for quotation on the NASDAQ Global Market. We are required to meet specified financial requirements in order to maintain our listing on the NASDAQ Global Market. One such requirement is that we maintain a minimum closing bid price of at least \$1.00 per share for our common stock. Our common stock has recently closed at prices that are below the minimum bid price requirement. If our stock price falls below \$1.00 per share for 30

**Table of Contents**

consecutive business days, we will receive a deficiency notice from NASDAQ advising us that we have 180 days to regain compliance by maintaining a minimum bid price of at least \$1.00 for a minimum of ten consecutive business days. Under certain circumstances, NASDAQ could require that the minimum bid price exceed \$1.00 for more than ten consecutive days before determining that a company complies with its continued listing standards. If in the future we fail to satisfy the NASDAQ Global Market's continued listing requirements, our common stock could be delisted from the NASDAQ Global Market, in which case we may transfer to the NASDAQ Capital Market, which generally has lower financial requirements for initial listing or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the NASDAQ Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as \$4.10 and as low as \$0.86 per share for the period January 1, 2006 through March 31, 2008. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical- and biotechnology-based company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

announcements regarding new technologies by us or our competitors;

market conditions in the biotechnology and pharmaceutical sectors;

rumors relating to us or our competitors;

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

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

actual or anticipated changes to our research and development plans;

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

entering into new collaboration agreements or termination of existing collaboration agreements;

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

any intellectual property or other lawsuits involving us;

third-party sales of large blocks of our common stock;

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

equity sales by us of our common stock to fund our operations;

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

FDA or international regulatory actions; and

general market conditions.

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

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

As of March 31, 2008, we had outstanding approximately 63.3 million shares of common stock, most of which can be traded without restriction at any time. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

---

**Table of Contents**

**Insiders have substantial control over us and could delay or prevent a change in corporate control.**

As of March 31, 2008, our directors, executive officers and principal stockholders, together with their affiliates, owned, in the aggregate, approximately 38% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, if acting together, will have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

Provisions of our certificate of incorporation, our bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. For example, we have divided our board of directors into three classes that serve staggered three-year terms, we may issue shares of our authorized blank check preferred stock and our stockholders are limited in their ability to call special stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. These provisions could discourage, delay or prevent a change in control transaction.

**Item 6. EXHIBITS**

(a) Exhibits.

See exhibit index.

**Table of Contents**

**SIGNATURE**

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

CURIS, INC.

Dated: April 30, 2008

By:

/s/ MICHAEL P. GRAY  
**Michael P. Gray**  
Chief Operating Officer and Chief Financial Officer  
(Principal Financial and Accounting Officer)

38

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

| <b>Number</b> | <b>Description</b>   |
|---------------|--|
| 31.1          | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act                            |
| 31.2          | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act                            |
| 32.1          | Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 |
| 32.2          | Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350 |