

CURIS INC  
Form 10-Q  
October 30, 2007  
Table of Contents

---

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

Washington, D.C. 20549

\_\_\_\_\_  
**FORM 10-Q**  
\_\_\_\_\_

(Mark one)

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007**

**OR**

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

**Commission File Number: 000-30347**

\_\_\_\_\_  
**CURIS, INC.**  
\_\_\_\_\_

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of

Incorporation or Organization)

**45 Moulton Street**

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

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

**04-3505116**  
(I.R.S. Employer

Identification No.)

**02138**  
(Zip Code)

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

---

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of October 26, 2007, there were 63,164,972 shares of the registrant's common stock outstanding.

---

**Table of Contents**

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

**INDEX**

	<b>Page Number</b>
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. <u>Unaudited Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006</u>	3
<u>Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2007 and 2006</u>	4
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
Item 4. <u>Controls and Procedures</u>	29
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	30
Item 6. <u>Exhibits</u>	43
<u>SIGNATURE</u>	44

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

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 17,881,406	\$ 18,829,332
Marketable securities	23,208,689	17,826,675
Accounts receivable	241,199	1,315,412
Prepaid expenses and other current assets	490,290	541,182
<b>Total current assets</b>	<b>41,821,584</b>	<b>38,512,601</b>
Property and equipment, net	2,837,937	4,393,604
Long-term investment restricted	210,007	201,844
Goodwill	8,982,000	8,982,000
Deposits and other assets, net	15,740	178,204
	<b>\$ 53,867,268</b>	<b>\$ 52,268,253</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Debt, current portion	\$ 714,377	\$ 1,246,289
Accounts payable	1,748,201	1,461,195
Accrued liabilities	1,167,629	1,529,337
Deferred revenue, current portion	557,579	1,755,160
<b>Total current liabilities</b>	<b>4,187,786</b>	<b>5,991,981</b>
Debt obligations, net of current portion		733,333
Deferred revenue, net of current portion	7,593,584	9,131,673
Other long-term liabilities	385,595	514,127
<b>Total liabilities</b>	<b>12,166,965</b>	<b>16,371,114</b>
Commitments		
Stockholders Equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized; 64,212,679 and 63,164,972 shares issued and outstanding, respectively, at September 30, 2007 and 50,381,561 and 49,333,854 shares issued and outstanding, respectively, at December 31, 2006	642,127	503,816
Additional paid-in capital	742,092,313	725,271,688
Treasury stock (at cost, 1,047,707 shares)	(891,274)	(891,274)
Deferred compensation	(58,701)	(111,390)
Accumulated deficit	(700,140,112)	(688,883,495)
Accumulated other comprehensive income	55,950	7,794
<b>Total stockholders equity</b>	<b>41,700,303</b>	<b>35,897,139</b>
	<b>\$ 53,867,268</b>	<b>\$ 52,268,253</b>

Edgar Filing: CURIS INC - Form 10-Q

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>REVENUES:</b>				
License fees	\$ 546,443	\$ 2,605,638	\$ 2,710,513	\$ 3,218,885
Research and development contracts	765,759	2,020,236	2,193,199	7,376,594
Gross Revenues	1,312,202	4,625,874	4,903,712	10,595,479
Contra-revenues from co-development with Genentech		(355,435)		(1,727,727)
Net Revenues	1,312,202	4,270,439	4,903,712	8,867,752
<b>COSTS AND EXPENSES:</b>				
Research and development	3,203,388	3,669,368	9,545,827	10,994,327
General and administrative	2,231,474	2,302,469	7,542,245	8,150,372
Amortization of intangible assets				27,050
Total costs and expenses	5,434,862	5,971,837	17,088,072	19,171,749
Loss from operations	(4,122,660)	(1,701,398)	(12,184,360)	(10,303,997)
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	423,174	404,542	1,117,483	1,172,702
Other expense	(889)	(178,532)	(114,700)	(178,532)
Interest expense	(17,925)	(61,239)	(75,040)	(199,989)
Total other income, net	404,360	164,771	927,743	794,181
Net loss	\$ (3,718,300)	\$ (1,536,627)	\$ (11,256,617)	\$ (9,509,816)
Net loss per common share (basic and diluted)	\$ (0.06)	\$ (0.03)	\$ (0.22)	\$ (0.19)
Weighted average common shares (basic and diluted)	57,534,767	49,146,609	52,129,126	49,012,538
Net loss	\$ (3,718,300)	\$ (1,536,627)	\$ (11,256,617)	\$ (9,509,816)
Unrealized gain on marketable securities	42,686	19,539	48,156	44,869
Comprehensive loss	\$ (3,675,614)	\$ (1,517,088)	\$ (11,208,461)	\$ (9,464,947)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (11,256,617)	\$ (9,509,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,046,692	968,418
Stock-based compensation expense	2,434,101	2,859,098
Gain on sale of assets	(87,761)	
Impairment of investment	145,000	164,020
Impairment of assets	347,084	
Amortization of intangible assets		27,050
Realized foreign currency exchange gain	(26,935)	
Changes in current assets and liabilities:		
Accounts receivable	1,101,148	(2,007,032)
Prepaid expenses and other assets	68,356	29,358
Accounts payable and accrued liabilities	(211,358)	(1,138,534)
Deferred contract revenue	(2,735,670)	424,782
Total adjustments	2,080,657	1,327,160
Net cash used in operating activities	(9,175,960)	(8,182,656)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of marketable securities	(29,785,765)	(30,880,091)
Sale of marketable securities	24,451,907	38,740,803
Increase in restricted cash	(8,163)	(5,846)
Purchases of property and equipment	(66,469)	(73,621)
Net proceeds from sale of assets	316,121	
Net cash provided by (used in) investing activities	(5,092,369)	7,781,245
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs	14,577,524	120,294
Repayments of notes payable	(1,257,121)	(925,000)
Net cash provided by (used in) financing activities	13,320,403	(804,706)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(947,926)	(1,206,117)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	18,829,332	22,310,298
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 17,881,406	\$ 21,104,181

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:</b>		

Edgar Filing: CURIS INC - Form 10-Q

Issuance of common stock in connection with conversion of note payable to Becton Dickinson	\$	\$ 2,605,280
--	----	--------------

See accompanying notes to unaudited condensed consolidated financial statements.



---

**Table of Contents**

**CURIS, INC. AND SUBSIDIARIES**

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

**1. Nature of Business**

Curis, Inc. (the Company or Curis) is a drug discovery and development company that is seeking to leverage its innovative signaling pathway drug technologies to create new targeted medicines primarily to treat cancer, and also to treat several other medical indications for which there are substantial unmet therapeutic needs. Signaling pathways are used by the body throughout life to repair and regulate human tissue. The Company's product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive. In expanding its drug development efforts in the field of cancer, the Company is building upon its previous experiences in targeting signaling pathways in its current programs in the areas of cancer, neurological disease and cardiovascular disease. The Company operates in a single reportable segment: developmental biology products. The Company expects that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

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

**2. Basis of Presentation**

The accompanying consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. The year-end condensed balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America for complete financial statements and should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the Securities and Exchange Commission on March 2, 2007.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company's financial position at September 30, 2007 and the results of operations for the three- and nine-month periods ended September 30, 2007 and 2006, and cash flows for the nine-month periods ended September 30, 2007 and 2006. The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include revenue recognition, the collectibility of receivables, the carrying value of property and equipment and intangible assets, and the value of certain investments and liabilities. Actual results may differ from such estimates.

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

**3. Private Placement of Common Stock**

On August 8, 2007, the Company completed a private placement of units, each with a purchase price of \$1.06375 and comprising one share of unregistered common stock and a warrant to purchase 0.35 shares of common stock. As a result of the unit offering, the Company issued an aggregate of 13,631,022 shares of common stock, and warrants to purchase 4,770,859 shares of common stock at a purchase price of \$1.02 per share, all of which has been accounted for as equity in accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. The private placement resulted in net proceeds to the Company of approximately \$14,422,000 after the deduction of offering expenses. The Company intends to use the net proceeds primarily to support the Company's research and development efforts and for other general corporate purposes.

Pursuant to the Registration Rights Agreement, as amended, the Company agreed to file a registration statement with the SEC within 30 days after the closing of the private placement to register the resale of the shares and the shares issuable upon exercise of the warrants. The Company

also agreed to use its best efforts to have the registration

---

**Table of Contents**

statement declared effective within 120 days after the filing date of the registration statement, or within 150 days of the filing date if the SEC determines to review the registration statement. In the event the registration statement is in default of these timelines, the Company agreed to pay each investor as liquidated damages an amount equal to 1% of the purchase price paid by each such investor in the private placement per 30-day period or portion thereof during which the registration default remains uncured thereafter, subject to an aggregate limit of 10% of the aggregate purchase price paid by each such investor in the private placement as liquidated damages. The Company filed a resale registration statement on Form S-3 on August 24, 2007 to register for resale the shares of common stock, and the shares of common stock underlying the warrants, held by the investors, which was declared effective on September 10, 2007 by the SEC. Accordingly, the Company will not pay any liquidated damages under the registration default provisions of the registration rights agreement.

The warrants are exercisable for cash until the fifth anniversary of the date of issuance, or August 8, 2012. In the event that the closing price of the Company's common stock as listed on NASDAQ equals or exceeds \$2.50 per share for thirty consecutive days, then at any time thereafter for a period of thirty days the Company may require the mandatory exercise of the warrants by providing at least twenty business days' prior written notice to the holder; provided that the Company simultaneously requires the mandatory exercise of all warrants then outstanding under this private placement.

**4. Revenue Recognition**

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The terms of the agreements typically include one or more of the following: non-refundable license fees; funding of research and development; contingent cash payments based upon achievement of clinical development objectives; and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*, EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent*, and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. For a complete discussion of the Company's revenue recognition policy, see Note 2(c) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 2, 2007.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized during the twelve-month period ended September 30, 2008 are classified as long-term deferred revenue. As of September 30, 2007, the Company has short- and long-term deferred revenue of \$558,000 and \$7,594,000, respectively, related to its collaborations.

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

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

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

The Company applied the provisions of EITF 00-21 and determined that its deliverables represented a single unit of accounting. Because the Company believed that it could reasonably estimate its level of effort over the term of the arrangement, the Company accounted for the arrangement under the relative performance method. In developing its original estimate of the Company's level of effort required to complete its performance obligations, the Company



**Table of Contents**

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

As a result of Genentech's decision not to extend the research term, the Company's estimated performance period was changed during the fourth quarter of 2006 to coincide with the March 31, 2007 research term end date, and the Company accelerated amortization of the unamortized up-front license fee and the remaining amount of research funding to which the Company was entitled. Revenue for the three- and nine-month periods ended September 30, 2006 was recognized as the research services were provided assuming a four-year term through March 2009 at a rate of \$312,500 per full-time equivalent. Revenue for the three-month period ended March 31, 2007 was recognized as the research services were provided at a rate of \$562,500 per full-time equivalent, which includes the effect of accelerating revenue recognition on the unamortized portion of the up-front license fee.

The Company recorded revenue under this collaboration of \$1,577,000 and \$2,753,000 during the nine-month periods ended September 30, 2007 and 2006, respectively. Of this amount, approximately \$938,000 and \$563,000 were attributed to the amortization of the up-front license fee and is included in "License fees" within the Revenue section of the Company's Consolidated Statement of Operations for the nine-month periods ended September 30, 2007 and 2006, respectively. In addition, the Company recorded \$639,000 and \$2,190,000 related to research services performed by the Company's full-time equivalent researchers for the nine-month periods ended September 30, 2007 and 2006, respectively, and is included within "Research and development contracts" within the Revenues section of the Company's Consolidated Statement of Operations. No amounts were recorded as revenue under this collaboration for the three months ended September 30, 2007 and there was no remaining deferred revenue related to this collaboration as of September 30, 2007.

**6. Termination of September 2005 Procter & Gamble Collaboration**

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

Under the terms of the agreement, the Company granted Procter & Gamble an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate the Company's Hedgehog agonist technology. In accordance with the terms of the agreement, the parties agreed to jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by Procter & Gamble.

Under the agreement, Procter & Gamble paid the Company an up-front license fee of \$500,000 and agreed to fund up to \$600,000 for two Curis full-time equivalents providing research and development activities during the initial one-year research term. In September 2006, Procter & Gamble exercised an option to extend additional research funding through September 2007 for one-third of a full-time equivalent for \$83,000.

The Company applied the provisions of EITF No. 00-21 and determined that its deliverables represented a single unit of accounting. Because the Company could not reasonably estimate the total level of effort required over the performance period, it was recognizing revenue on a straight-line basis over the performance period, which it had originally estimated to be six years through September 2011. The original performance period was based on the Company's expectation that it would exercise a co-development option under the agreement, which provided that the Company would jointly fund development costs and participate on a clinical development steering committee through Phase IIb clinical trials. The steering committee effort was also expected to be consistent over the performance period. The Company has attributed an aggregate of \$2,183,000 to the undelivered research and steering committee services. This amount is comprised of (i) a \$500,000 up-front fee, (ii) \$683,000 in research funding, and (iii) a \$1,000,000 contingent cash payment that the Company received in March 2006 upon the achievement of a preclinical development objective.

On May 9, 2007, Procter & Gamble notified the Company of Procter & Gamble's decision to terminate the collaboration effective November 9, 2007. As a result of Procter & Gamble's decision to terminate the license agreement, the Company's estimated performance period was changed during the second quarter of 2007 to coincide with the November 9, 2007 termination date, and the Company accelerated amortization of the unamortized up-front license fee and the remaining amount of research funding to which the Company was entitled.



**Table of Contents**

The Company recorded revenue under this collaboration of \$1,548,000 and \$759,000 during the nine-month periods ended September 30, 2007 and 2006, respectively. Of this amount, approximately \$1,032,000 and \$168,000 was attributed to the amortization of the \$500,000 up-front license fee and a \$1,000,000 cash payment received in March 2006 and is included in License fees within the Revenue section of the Company's Consolidated Statement of Operations for the nine-month periods ended September 30, 2007 and 2006, respectively. Of the remaining amounts, \$453,000 and \$75,000 were related to research services performed by the Company's full-time equivalents for the nine months ended September 30, 2007 and 2006, respectively, and \$63,000 and \$516,000 for the nine months ended September 30, 2007 and 2006, respectively, related to expenses incurred on behalf of Procter & Gamble by the Company for which Procter & Gamble 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 Company's Consolidated Statement of Operations. As of September 30, 2007, the Company had recorded in its consolidated balance sheet \$304,000 in short-term deferred revenue related to this collaboration.

**7. Termination of November 2002 Ortho Biotech License Agreement**

In November 2002, the Company licensed certain of its broad bone morphogenetic protein, or BMP, technology portfolio to Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies. The transaction related to all of the Company's proprietary BMP compounds including BMP-7, which has been studied in animal models as a treatment for chronic kidney disease and systemic complications, such as renal osteodystrophy, a form of bone disease, and blood vessel complications that have been associated with chronic kidney disease.

On May 18, 2007, Ortho Biotech Products provided Curis with written notice that it intended to terminate the license agreement. Pursuant to the license agreement, the agreement terminated on August 16, 2007 and the licenses granted by Curis to Ortho Biotech Products terminated. The Company is seeking to enter into a transaction with a third party to continue development of this technology. No amounts were recorded as revenue under this collaboration for the three and nine months ended September 30, 2007 and 2006, and there is no remaining deferred revenue related to this collaboration as of September 30, 2007.

**8. Accrued Liabilities**

Accrued liabilities consist of the following:

	September 30, 2007	December 31, 2006
Accrued compensation	\$ 593,000	\$ 578,000
Professional fees	178,000	200,000
Facility-related costs	193,000	484,000
Other	204,000	267,000
<b>Total</b>	<b>\$ 1,168,000</b>	<b>\$ 1,529,000</b>

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

As of September 30, 2007, the Company holds equity investments in two privately-held former collaborators of the Company, Aegea Therapeutics and ES Cell International (ESI). Equity investments in privately-held companies are reflected in the accompanying consolidated financial statements at cost, as adjusted for impairment. On a quarterly basis, the Company re-evaluates its investments in privately-held companies to determine if the carrying values have been impaired. During the second quarter of 2007, the Company determined that the carrying value of ESI's stock recorded at the Company's consolidated balance sheet was in excess of the fair value of the asset. Accordingly, the Company recorded a charge to Other expense of \$145,000 by writing down the carrying value of its investment in ESI equity securities to \$5,000 during the nine months ended September 30, 2007.

**10. Property and Equipment**

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

In the fourth quarter of 2006, the Company initiated a realignment of its research programs, shifting its focus to its later-stage preclinical drug development programs and de-emphasizing its earlier-stage discovery research programs. The Company revised its estimates of the depreciable lives on the remaining equipment being used in its discovery screening research programs as a result of two of the Company's discovery programs ending during 2006. Beginning in the fourth quarter of 2006, equipment with a net book value of \$988,000 was being depreciated over a period ending in December 2008.



**Table of Contents**

In March 2007, the Company's BMP-7 small molecule screening agreement with Centocor (a Johnson & Johnson subsidiary) concluded in accordance with the terms of contract. Under the terms of the screening agreement, Centocor maintained an option to exclusively negotiate a broader BMP-7 screening agreement. However, during the second quarter of 2007, Centocor notified the Company that it would not opt to negotiate a further BMP-7 small molecule agreement. The BMP-7 small molecule screening program was the only remaining program utilizing the majority of the Company's existing discovery screening equipment.

The Company determined that it would not fund the program internally and, as a result, during the nine months ended September 30, 2007, recorded property and equipment impairment charges of \$318,000 because this discovery equipment could not be used on other ongoing programs. This impairment charge has been reported within the Research and development line item within the Expenses section of the Company's Consolidated Statement of Operations for the nine months ended September 30, 2007.

**11. Debt**

Short- and long-term debt, including accrued interest, consists of the following at September 30, 2007 and December 31, 2006:

	September 30, 2007	December 31, 2006
Notes payable to financing agencies for capital purchases	\$ 714,000	\$ 1,980,000
Less current portion	(714,000)	(1,246,000)
<b>Total long-term debt obligations</b>	<b>\$</b>	<b>\$ 734,000</b>

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

On December 9, 2005, the Company converted \$1,450,000 borrowed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006, and extending through April 2008, due to the early pre-payments of the principal obligation of \$332,000 during the nine-month period ended September 30, 2007.

During the nine months ended September 30, 2007, the Company sold certain of its assets with a net book value of \$229,000 after effect of impairment. Gross proceeds from the sale of these assets, as well as various lab supplies that had no book value, were \$332,000 and were directly remitted to Boston Private Bank & Trust and applied to the principal obligation outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement. The Company also recorded expenses of \$5,000 related to these sales resulting in a net gain on sale of assets of \$88,000, which was reflected as a reduction of Research and development expenses in the Company's Consolidated Statement of Operations for the nine-month period ended September 30, 2007. Any future proceeds from the sale of collateralized assets will be applied to the Company's outstanding principal obligations under its loan agreements with the Boston Private Bank & Trust Company.

These loans are collateralized by all of the Company's property and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of September 30, 2007, the Company is in compliance with the sole covenant under each of the agreements with the Boston Private Bank & Trust Company. The covenant requires the Company to maintain a minimum working capital ratio. Should the Company fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

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

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

As of September 30, 2007, the Company had three shareholder-approved, share-based compensation plans: the 2000 Stock Incentive Plan (the 2000 Plan), the 2000 Director Stock Option Plan (the 2000 Director Plan) and the 2000 Employee Stock Purchase Plan (the ESPP). For a complete discussion of the Company's share-based compensation plans, see Note 2(l) included in its annual report on Form 10-K, as previously filed with the Securities and Exchange Commission on March 2, 2007.

**Table of Contents**

During the quarter ended March 31, 2007, stock options to purchase 330,000 shares of common stock were issued under the 2000 Plan, of which stock options to purchase 280,000 shares of common stock were granted to employees, which vest over a four-year period, and stock options to purchase 50,000 shares of common stock were granted to non-employees. During the quarter ended June 30, 2007, the Company's Compensation Committee of its Board of Directors granted stock options to its employees and executive officers to purchase 1,795,000 shares of its common stock under the 2000 Plan. Of the employee options issued during the quarter ended June 30, 2007, stock options to purchase 151,500 shares of common stock will vest one year from their grant date, stock options to purchase 390,000 shares of common stock will vest over a two-year period and stock options to purchase 641,000 shares of common stock will vest over a four-year period. The remaining stock options to purchase 612,500 shares of common stock were issued to the executive officers of the Company with a performance condition and will vest on December 6, 2012 or upon the consummation of a collaboration, licensing or other similar agreement regarding the Targeted Cancer Drug Development Platform that includes an up-front cash payment of at least \$10,000,000 excluding any equity investment in the Company, whichever occurs first, subject to the officer's continued employment. During the quarter ended September 30, 2007, stock options to purchase 29,000 shares of common stock were issued under the 2000 Plan, of which stock options to purchase 4,000 shares of common stock were granted to employees, which vest over a four-year period, and stock options to purchase 25,000 shares of common stock were granted to non-employees. All employee stock options granted during 2007 were issued with exercise prices equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the respective grant dates.

During the quarter ended June 30, 2007, the Company's Board of Directors granted options to its Board of Directors to purchase 135,000 shares of common stock under the 2000 Plan and options to purchase 30,000 shares of common stock under the 2000 Director Plan, which fully vested on the grant date of June 6, 2007. The exercise price of each of these options is equal to the closing market price of the Company's common stock on the NASDAQ Global Market on the date of grant.

In addition, the Company's non-employee directors were granted a total of 60,000 shares of common stock under the 2000 Plan at par value, or \$0.01 per share. The closing market price of the Company's common stock on the NASDAQ Global Market on June 6, 2007, the date of the grant, was \$1.39 per share. There were no restrictions or vesting requirements related to these awards. Accordingly, the Company recognized \$83,000 in compensation expense related to the issuance of the 60,000 shares of common stock during the second quarter of 2007.

The table below summarizes options outstanding and exercisable under the 2000 Plan and the 2000 Director Plan at September 30, 2007:

Exercise Price Range	Number of Shares	Options Outstanding		Options Exercisable	
		Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
\$ 0.56 - \$ 1.34	819,594	6.57	\$ 1.15	491,094	\$ 1.06
1.39 - 1.95	4,099,407	8.46	1.48	1,377,219	1.54
2.11 - 3.95	2,254,823	4.95	2.99	2,234,073	3.00
3.96 - 5.89	1,805,374	6.72	4.41	1,366,948	4.49
6.91 - 17.94	446,063	2.90	12.53	446,063	12.53
20.00 - 31.15	12,564	2.85	21.89	12,564	21.89
	9,437,825	6.85	\$ 2.92	5,927,961	\$ 3.60

**Employee Grants**

The Company adopted the provisions of Statement of Financial Accounting Standards 123(R), *Share-Based Payment* (SFAS 123(R)), beginning January 1, 2006, using the modified prospective transition method. In determining the fair value of stock options, the Company generally uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee options awarded during the three and nine months ended September 30, 2007 and 2006 based on the assumptions noted in the following table:

**Table of Contents**

	For the nine months ended			
	For the three months ended		September 30,	
	2007	2006	2007	2006
Expected term (years) Employees	6.25	6.25	5.5-7	5.5-6.25
Expected term (years) Directors	N/A	5	7	5
Risk-free interest rate	4.3%	4.5%	4.3-4.9%	4.5-5.2%
Volatility	91%	95-100%	91-97%	95-102%
Dividends	None	None	None	None

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

The aggregate intrinsic value of options outstanding at September 30, 2007 was \$20,000, of which all related to exercisable options. The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2007 and 2006 were \$1.10 and \$1.64, respectively. As of September 30, 2007, there was approximately \$4,200,000, including the impact of estimated forfeitures, of unrecognized compensation cost related to unvested employee and director stock option awards outstanding under the 2000 Plan and 2000 Director Plan that is expected to be recognized as expense over a weighted average period of 3.89 years. The intrinsic value of employee stock options exercised during the nine months ended September 30, 2007 and 2006 was \$13,000 and \$22,000, respectively.

For employee stock options with a market performance condition, which was used for a limited number of stock options issued in June 2002 that remained unvested as of January 1, 2006, the Company uses a lattice-based option valuation model. These awards accounted for \$15,000 and \$18,000 of the employee stock-based compensation expense recorded by the Company for the three months ended September 30, 2007 and 2006, respectively, and \$34,000 and \$54,000 for the nine months ended September 30, 2007 and 2006, respectively. All outstanding unvested market performance condition awards will be fully vested in November 2007. The lattice model utilizes assumptions including a 7-year expected life, 2.10% risk-free rate, 116% volatility, and a 0% dividend rate.

During the three- and nine-month periods ended September 30, 2007 and 2006, the Company recorded compensation expense related to its ESPP and 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			
	September 30,		For the Nine Months Ended	
	2007	2006	2007	2006
Compensation expense recognized under ESPP	\$ 19,000	\$ 18,000	\$ 57,000	\$ 57,000
Expected term	6 months	6 months	6 months	6 months
Risk-free interest rate	4.8%	5.3%	4.8-5.0%	4.6-5.3%
Volatility	64%	70%	64-71%	70-85%
Dividends	None	None	None	None

Stock-based compensation for employees for the three and nine months ended September 30, 2007 was calculated using the above valuation models and has been included in the Company's results of operations. No income tax benefit has been recorded as the Company has recorded a full valuation allowance and management has concluded that it is not likely that the net deferred tax asset will be realized.

**Non-Employee Grants**

During the nine-month periods ended September 30, 2007 and 2006, the Company granted stock options to consultants for services. These options were issued at or above their fair market value on the date of grant and have various vesting dates, ranging from 3.5 months to 4 years from date of grant. Should the Company terminate the consulting agreements, any unvested options will be cancelled. Options issued to non-employees are marked-to-market at each reporting period, which means that as the Company's stock price fluctuates, the liability and related



**Table of Contents**

expense either increases or decreases. The Company recognized expense of \$3,000 and \$68,000 related to non-employee stock options for the three and nine months ended September 30, 2007, respectively. The Company recognized expense of \$15,000 and reversed expense of \$148,000 related to non-employee stock options for the three and nine months ended September 30, 2006, respectively, as a result of a decline in the Company's stock price. As of September 30, 2007, the Company had recorded \$59,000 in deferred compensation related to unvested non-employee options.

**Total Stock-Based Compensation Expense**

For the three and nine months ended September 30, 2007 and 2006, the Company recorded stock-based compensation expense to the following line items in its Costs and Expenses section of the Consolidated Statements of Operations and Comprehensive Loss:

	For the three months ended September 30,		For the nine months ended September 30,	
	2007	2006	2007	2006
Research and development expenses	\$ 200,000	\$ 342,000	\$ 528,000	\$ 826,000
General and administrative expenses	436,000	641,000	1,906,000	2,033,000
Total stock-based compensation expense	\$ 636,000	\$ 983,000	\$ 2,434,000	\$ 2,859,000

**13. Loss of Subtenant Income**

In August 2006, the Company's subtenant to its 61 Moulton Street facility defaulted on the sublease and vacated the property. The Company was responsible for the lease payments upon default by the subtenant for which it established a reserve for estimated costs through the lease term which ended April 30, 2007. As of December 31, 2006, this reserve was \$245,000 and consisted of the Company's remaining lease obligations and an estimate of other related facility costs through April 30, 2007.

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

The subtenant's total obligation to the Company through the April 30, 2007 sublease term was \$368,000. On April 16, 2007, the Company entered into a settlement agreement with the subtenant under which it has received approximately \$262,000 during the second quarter of 2007. The Company increased the reserve by \$50,000 for final estimated costs associated with its obligations through the lease term of April 30, 2007. The remaining \$212,000 was applied against General and administrative expenses in the Company's consolidated statement of operations for the nine-month period ended September 30, 2007.

During the nine months ended September 30, 2007, the Company charged \$271,000 against the reserve, which represented the rent obligations and other related facility expenses incurred by the Company related to the leased space, which is no longer in use. The remaining reserve of \$24,000 was reversed during the quarter ended September 30, 2007 and applied against General and administrative expenses in the Company's consolidated statement of operations as the Company has no remaining obligations under the lease.

The subtenant will receive additional contingent cash payments upon the achievement of certain contractually defined preclinical and clinical development objectives assuming the third party does not terminate the agreement. If the first such objective is achieved and upon the subtenant's receipt of such contingent cash payment, the subtenant would pay the Company its remaining obligation of \$106,000. As of September 30, 2007, the Company does not believe that the collection of this amount is reasonably probable and therefore no amounts have been recorded as a receivable in the consolidated financial statements.

**14. Income Taxes**

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

On January 1, 2007, the Company adopted FASB Interpretation ( FIN ) No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of *FASB Statement 109* which was issued in July 2006. FIN 48 prescribes a comprehensive model for recognizing, measuring, presenting and disclosing in the financial statements tax positions taken or expected to be taken on a tax return, including a decision whether to file or not to file in a particular

**Table of Contents**

jurisdiction. If there are changes in net assets as a result of application of FIN 48, these will be accounted for as an adjustment to retained earnings. There were no unrecognized tax benefits as of January 1, 2007, the date FIN 48 was adopted.

For the three and nine months ended September 30, 2007 and 2006, respectively, the Company did not record any federal or state tax expense given its continued net operating loss position. As required by Statement of Financial Accounting Standards ( SFAS ) No. 109, *Accounting for Income Taxes*, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating losses ( NOL ), capitalized research and development expenditures and research and development credits ( R&D credits ). Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a full valuation allowance was maintained at September 30, 2007 and December 31, 2006.

As of December 31, 2006, the Company had federal and state NOL carryforwards and federal and state R&D credit carryforwards, which may be available to offset future federal and state income tax liabilities, which expire at various dates starting in 2007 and extending through 2026. Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions (both pre- and post-initial public offering) which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation because the Company continues to maintain a full valuation allowance on its NOL and R&D credit carryforwards. In addition, there could be additional changes in control in the future and the Company does not expect to have any taxable income for the foreseeable future. If the Company has experienced a change of control at any time since its formation, utilization of its NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no amounts accrued for interest and penalties at September 30, 2007.

**15. 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 calculated using the treasury stock method, which is weighted based on the number of days outstanding during the respective reporting period, and warrants and shares issuable under the Company's 2000 Employee Stock Purchase Plan. Antidilutive securities were 15,362,779 and 9,748,838 as of September 30, 2007 and 2006, respectively, consisting of the following:

	<b>For the nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Weighted average stock options outstanding	8,955,911	8,117,862
Warrants outstanding	6,401,835	1,630,976
Shares issuable under ESPP	5,033	
 Total antidilutive securities	 15,362,779	 9,748,838





---

**Table of Contents**

**16. Related Party Transactions**

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 and \$20,000 in related consulting expenses in its consolidated statement of operations for the three- and nine-month periods ended September 30, 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.

**17. New Accounting Pronouncements**

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

In June 2007, the FASB issued EITF Issue No. 07-3 ( EITF 07-3 ), *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-3 is limited to non-refundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. The EITF affirms that these payments should be capitalized and deferred until the goods have been delivered or the related services have been performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, and interim periods in those fiscal years. The Company does not expect the adoption of EITF 07-3 to have a material impact on its consolidated financial statements.

**18. Subsequent Events**

In October 2007, Genentech notified the Company that it had initiated an expansion cohort in its ongoing Phase I clinical trial of a systemically administered Hedgehog antagonist. As a result, the Company received a \$3,000,000 cash payment from Genentech under the parties' June 2003 collaboration agreement. Genentech is obligated to make the payment because it determined that the Phase I clinical trial expansion cohort satisfied the criteria for a Phase II clinical trial under the parties' collaboration agreement.

Pursuant to the collaboration, Genentech began a Phase I clinical trial in January 2007, which is designed as an open-label study of a systemic Hedgehog antagonist in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for whom no standard therapies exist. The primary objectives of the Phase I trial are to evaluate the safety and tolerability of escalating doses of the Phase I molecule, to establish the maximum tolerated dose and dose limiting toxicities and to characterize the pharmacokinetic and pharmacodynamic properties of the drug candidate. The initial objectives of the Phase I clinical trial have been achieved and the Phase I clinical trial expansion cohort is expected to enroll additional patients for preliminary signs of clinical response as well as the continued accumulation of Phase I safety data.

---

## **Table of Contents**

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

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

#### **Overview**

We are a drug discovery and development company that is seeking to leverage our innovative signaling pathway drug technologies to create new targeted medicines primarily in the field of cancer, and also to treat several other medical indications for which there are substantial unmet therapeutic needs. Signaling pathways are used by the body throughout life to repair and regulate human tissue. In certain diseases such as cancer, signaling pathways may be abnormally activated or de-activated. Our product development approach involves using small molecules, proteins or antibodies to modulate these signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive. In expanding our drug development efforts in the field of cancer, we are building upon our previous experiences in targeting signaling pathways under our current programs in the areas of cancer, neurological disease and cardiovascular disease.

Since our inception, we have funded our operations primarily through license fees, research and development funding from our strategic collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable and have incurred an accumulated deficit of \$700,140,000 as of September 30, 2007. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to research and development of our product candidates. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all. Key drivers to our success include our ability to successfully advance the preclinical development of CUDC-101, which is a multi-target inhibitor that is designed to inhibit HDAC, EGFR and Her2, three validated cancer targets. Other potential success drivers include our ability to advance the preclinical development of the other small molecule cancer drug candidates that we are developing under our Targeted Cancer Drug Development Platform, to commence and complete clinical trials, both for our internally developed programs and our programs under development in collaboration with our strategic collaborators, and to successfully commercialize products on the basis of these programs.

#### *Our Proprietary Research and Development Programs*

Our internally developed Targeted Cancer Drug Development Platform programs are primarily focused upon seeking to develop a number of proprietary, small molecule, multi-target inhibitor drug compounds, including CUDC-101. Each compound is designed to inhibit one or more validated cancer targets, such as Hsp90, Bcr-Abl/Src, CDK2, BCL, MEK, VEGFR and others along with inhibition of histone deacetylase, or HDAC, which is a validated non-kinase cancer target.

We believe that HDAC inhibition is a very promising non-kinase target for cancer therapy. Currently there is one FDA-approved HDAC inhibitor and several other HDAC targeted drug candidates in clinical trials for cancer. There is substantial preclinical evidence demonstrating synergistic induction of cancer cell death when HDAC inhibitors are combined with a diverse range of other targeted therapies or standard chemotherapeutic agents, potentially making HDAC inhibition more broadly effective in the treatment of cancer when integrated with other inhibitory activities.

We have filed a number of patents including a broad omnibus application that covers the drug design concept that is the basis for the Targeted Cancer Drug Development Platform as well as numerous species filings relating to specific classes of compounds which we believe will constitute novel compositions from a patentability standpoint. We expect that we will continue to file additional patent applications covering new compositions in the future.

CUDC-101 is our lead multi-target inhibitor drug candidate under development. CUDC-101 is being designed to inhibit HDAC, EGFR and Her2, three validated cancer targets. We believe that CUDC-101 is the first-in-class compound under development to simultaneously inhibit HDAC, EGFR and Her2.

We have been actively working toward our goal of filing an IND for CUDC-101 by the end of the first quarter of 2008. IND-enabling studies are currently under way. Preliminary preclinical toxicology studies have shown CUDC-101 to be well tolerated and we recently initiated formal preclinical toxicology testing.

We are concurrently engaged in potential collaboration discussions with several companies and remain optimistic that we may consummate a collaboration for CUDC-101 or another one of our multi-target inhibitors during 2008, although we



---

## **Table of Contents**

can not assure that such a collaboration will occur in the time frame expected, or at all. When evaluating potential collaborative opportunities, we are seeking a corporate collaboration that will provide us with the opportunity for significant involvement in at least the early stages of human clinical testing. We are currently meeting with potential collaborators for CUDC-101 as well as for our Hsp90 single target inhibitor as well as our Hsp90/HDAC multi-target inhibitor, but we are not in advanced stages of negotiations, with new or existing collaborators, relating to these programs.

We are also seeking to advance other small molecule drug candidates in our Targeted Cancer Drug Development Platform. Currently, the more advanced of these programs include a multi-target inhibitor that is designed to inhibit HDAC, Bcr-Abl and Src kinases, an inhibitor that seeks to inhibit HDAC and Hsp90, an inhibitor of Hsp 90 as well as an inhibitor of HDAC and CDK2. We anticipate that in late 2007 or early 2008 we will select one of these compounds as the second development candidate from our Targeted Cancer Drug Development Platform. Assuming that we meet this selection date and that subsequent IND-enabling preclinical studies are successful, we anticipate that we would file an IND for this second development candidate by the end of 2008. We currently also plan to select a third development candidate from this platform during 2008.

Going forward, assuming that we continue to successfully advance our Targeted Cancer Drug Development Platform, we intend to hire clinical development and regulatory employees and we currently plan to advance one or more of our proprietary multi-target cancer programs into at least the early stages of clinical testing on our own. We will also continue our efforts to establish a corporate collaboration for the further development and commercialization of at least one of our multi-target cancer programs from this platform.

### *Our Research and Development Programs under Collaboration*

Our current collaborations, which include our two agreements with Genentech and our collaboration with Wyeth generally provide 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. We are also entitled to receive royalty payments upon the successful commercialization of any products based upon the collaborations. These strategic collaboration and license agreements include over \$500,000,000 in contingent cash payments that are tied principally to the achievement of future development objectives and regulatory approval objectives. We cannot assure that any of such objectives will be achieved in a timely manner, if at all. As of September 30, 2007, we have received \$3,250,000 in such cash payments under our existing collaborations.

### **Hedgehog Collaborations**

We currently have strategic collaborations with Genentech and Wyeth to develop therapeutics that modulate the signaling of the Hedgehog pathway. Our June 2003 collaboration with Genentech includes our most advanced program, a small molecule antagonist of the Hedgehog signaling pathway that is currently enrolling patients in an expansion cohort of its Phase I clinical trial. This Phase I expansion cohort began in October 2007. As a result, in October 2007 we received a \$3,000,000 cash payment from Genentech. Genentech was obligated to make the \$3,000,000 cash payment because it determined that the Phase I clinical trial expansion cohort satisfied the criteria for a Phase II clinical trial under the parties' collaboration agreement.

Genentech began a Phase I clinical trial in January 2007, which is designed as an open-label study of a systemic Hedgehog antagonist in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for whom no standard therapies exist. The primary objectives of the Phase I trial are to evaluate the safety and tolerability of escalating doses of the Phase I molecule, to establish the maximum tolerated dose and dose limiting toxicities and to characterize the pharmacokinetic and pharmacodynamic properties of the drug candidate. The initial objectives of the Phase I clinical trial have been achieved and the Phase I clinical trial expansion cohort is expected to enroll additional patients for preliminary signs of clinical response as well as the continued accumulation of Phase I safety data.

Our January 2004 collaboration with Wyeth is currently focused on the development of Hedgehog agonists, which include both small molecule and Hedgehog protein-based therapeutic candidates, for use in treating neurologic disorders such as stroke and for cardiovascular disease indications. Both of these programs are currently in preclinical development with research being conducted at Wyeth and Curis. Wyeth is currently providing research funding for five researchers under this collaboration through February 9, 2008.

### **Other Collaborations**

In addition to our Hedgehog antagonist collaboration, in April 2005 we entered into a second collaboration with Genentech focused on the discovery and development of small molecule compounds that modulate the Wnt signaling



---

## **Table of Contents**

pathway. We conducted research activities under this collaboration from April 2005 until March 2007, at which time Genentech assumed further responsibility for any future development of this program. We do not expect that we will receive future research funding under this program.

We have the right to receive contingent cash payments under the agreement assuming that Genentech pursues the development of one or more drug candidates and specified development objectives are achieved. We are also eligible to receive royalties on product sales, should any products under this collaboration be successfully commercialized. If Genentech does not advance drug candidates generated under this collaboration beyond the discovery research stage, we are not entitled to receive any future cash payments under this collaboration. We can not predict whether Genentech will pursue the further development of drug candidates under the agreement and/or whether any development objectives for which we may be entitled to a cash payment will be successfully achieved.

In September 2005, we entered into a collaboration agreement with Procter & Gamble, which was principally focused on the development of topically applied Hedgehog agonist compounds for hair growth regulation. On May 9, 2007, Procter & Gamble notified us of its decision to terminate this collaboration agreement. Pursuant to the collaboration agreement, the agreement will terminate in six months from the date of notice, or November 9, 2007. We currently do not expect to further develop Hedgehog agonist compounds for topical use for hair growth regulation.

In November 2002, we entered into an agreement with Ortho Biotech Products in which Ortho Biotech obtained the exclusive rights to develop and commercialize products based on our BMP-7 technology. On May 18, 2007, Ortho Biotech Products provided us with written notice that it intends to terminate this license agreement. Pursuant to the license agreement, the agreement terminated on August 16, 2007. On the termination date, the licenses granted by us to Ortho Biotech Products terminated and we are now free to re-license the technology. We intend to seek to enter into a transaction with a third party to continue development of this technology.

## **Financial Operations Overview**

*General.* Our future operating results will largely depend on the magnitude of payments from our current and potential future corporate collaborators and the progress of other product candidates currently in our research and development pipeline. The results of our operations will vary significantly from year to year and quarter to quarter and depend on, among other factors, the timing of our entry into new collaborations, the timing of the receipt of payments from collaborators and the cost and outcome of any clinical trials then being conducted. We anticipate that existing capital resources at September 30, 2007, together with the \$3,000,000 cash payment that we recently received from Genentech and assuming the payment of all contractually-defined research funding payments from Wyeth, but excluding any cash payments that are contingent upon the achievement of defined development objectives under our collaborations with Genentech and Wyeth, should enable us to maintain current and planned operations into mid-2009. Our ability to continue funding our planned operations is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity, debt or other sources of financing. A discussion of certain risks and uncertainties that could affect our liquidity, capital requirements and ability to raise additional funds is set forth under 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 current and former strategic collaborators and licensees.

Our current third-party research funding consists solely of payments by Wyeth for five researchers through February 9, 2008. Accordingly, for the majority of our programs under collaboration, our future revenues are limited to (i) the amortization of previously received license payments, (ii) potential future cash payments, if any, that are contingent upon the successful completion principally of contractually defined development and regulatory approval objectives, and (iii) royalty payments upon the successful commercialization of any products based upon the collaboration.

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

**Table of Contents**

*Research and Development.* Research and development expense consists of costs incurred to discover, research and develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel including stock-based compensation expense for employee share-based payments. Research and development expenses also include the costs of supplies and reagents, outside service costs including medicinal chemistry, consulting, and occupancy and depreciation charges. We expense research and development costs as incurred. We believe that our research and development expenses will neither increase nor decrease significantly in 2007 as compared to 2006; however, we do expect that our fourth quarter 2007 expenses will increase as compared to prior quarters in 2007.

Recently, a majority of our research and development effort and expense has shifted from our work primarily in the Hedgehog pathway and our various discovery programs to the development of programs under our Targeted Cancer Drug Development Platform. We are seeking to advance one or more of our drug candidates from this platform into at least the early stages of clinical testing through our internal efforts. We plan to file an IND for CUDC-101 in the first quarter of 2008 and, assuming that this IND application is not rejected or otherwise delayed by the FDA, we expect to begin a Phase I clinical trial of CUDC-101 early in the second quarter of 2008. Should we begin clinical evaluations of CUDC-101 or another of these drug candidates, we expect that our research and development costs would increase significantly as we increase our clinical development and regulatory capacities. In addition, in the near-term we expect to continue contracting between 20-30 medicinal chemists in an effort to rapidly advance our programs under the Targeted Cancer Drug Development Platform.

The table below summarizes our primary research and development programs, including the current development status of each program. The terms used in the chart below are as follows:

**Phase I expansion cohort** means that we or a collaborator are 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 one or more tumor types;

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

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

<b>Product Candidate</b>	<b>Primary Indication</b>	<b>Collaborator/Licensee</b>	<b>Status</b>
Hedgehog systemic small molecule	Cancer	Genentech	Phase I expansion cohort
CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Internal development	Development candidate
Single and multi-target inhibitors	Cancer	Internal development	Preclinical
Hedgehog systemic antibody antagonist	Cancer	Genentech	Preclinical
Hedgehog small molecule agonist or protein	Nervous system disorders	Wyeth	Preclinical
Hedgehog protein/agonist	Cardiovascular disease	Wyeth	Preclinical

During the fourth quarter of 2006, research funding concluded on our SMA program under a sponsored research agreement with the SMA Foundation. In March 2007, our BMP-7 small molecule screening agreement with Centocor (a Johnson & Johnson subsidiary) concluded in accordance with the terms of the contract. Under the terms of the screening agreement, Centocor maintained an option to exclusively negotiate a broader BMP-7 screening agreement. However, during the second quarter of 2007, Centocor notified us that it would not opt to negotiate a further BMP-7 small molecule agreement. In May 2007, Procter & Gamble notified us of its decision to terminate its collaboration agreement focused on the development of topically applied Hedgehog agonist compounds for hair growth regulation, which will be effective November



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

2007. We do not expect to recognize any additional material revenues or incur additional research expenses for these programs subsequent to their termination dates.

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

In addition to the research and development programs in the above table, we have a Wnt signaling pathway program that is under collaboration with Genentech and a Bone Morphogenetic Protein, or BMP, program that we are not currently developing internally but for which we are seeking a third-party licensee.

Under our Wnt signaling pathway work, we and Genentech have generated small molecule compounds during the research term of our April 2005 Wnt signaling pathway collaboration agreement. We conducted research activities under this

## **Table of Contents**

collaboration from April 2005 until March 2007, at which time, Genentech assumed further responsibility for any future development of this program. We have the right to receive contingent cash payments under the agreement assuming that Genentech pursues the development of one or more drug candidates and specified development objectives are achieved. We are also eligible to receive royalties on product sales, should any products under this collaboration be successfully commercialized. If Genentech does not advance drug candidates generated under this collaboration beyond the discovery research stage, we are not entitled to receive any future cash payments under this collaboration. We can not predict whether Genentech will pursue the further development of drug candidates under the agreement and/or whether any development objectives for which we may be entitled to a cash payment will be successfully achieved.

Our BMP-7 program was licensed to Ortho Biotech Products from November 2002 until August 2007. On the August termination date, the licenses granted by Curis to Ortho Biotech Products terminated. We are not currently developing our BMP-7 technologies internally and instead are working to license this program to another third party.

Because of the early stages of development of these programs, our ability and that of our collaborators and licensors to successfully complete preclinical and clinical studies of these product candidates, and the timing of completion of such programs, is highly uncertain. There are numerous risks and uncertainties associated with developing drugs, including:

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

the results of future clinical trials;

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

the cost and timing of regulatory approvals;

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

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

the effect of competing technological and market developments; and

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

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

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

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

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

*Strategic Collaborations and License Agreements.* Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties. As of September 30, 2007, we have ongoing collaborations with Genentech (June 2003 Hedgehog Antagonist, April 2005 Wnt Signaling) and Wyeth Pharmaceuticals (February 2004 Hedgehog Agonist). For a detailed discussion of these arrangements, please see Management's Discussion and Analysis of Financial Condition and Results of Operations Strategic Alliances and License Agreements in our annual report on Form 10-K for the year ended December 31, 2006, which is on file with the Securities and Exchange Commission, or SEC.

---

**Table of Contents****Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition, the collectibility of receivables and the value of certain investments and liabilities. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We set forth our critical accounting policies and estimates in our annual report on Form 10-K for the year ended December 31, 2006, which is on file with the SEC. The following sets forth material changes in our critical accounting policies and estimates described therein.

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

We assess the impairment of identifiable long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If it were determined that the carrying value of our other long-lived assets might not be recoverable based upon the existence of one or more indicators of impairment, we would measure an impairment based on application of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. During 2006, we initiated a realignment of our research programs, shifting our focus on later-stage preclinical drug development programs and de-emphasizing our earlier discovery research programs. As a result, in 2006 we recorded an impairment charge of \$148,000 related to certain of our equipment that was no longer used in our discovery or other programs. In addition, we revised our estimates of the depreciable lives on the remaining equipment currently being used in our discovery research programs as a result of the conclusion of two of our discovery screening programs in late 2006 and early 2007.

In March 2007, our BMP-7 small molecule screening agreement with Centocor (a Johnson & Johnson subsidiary) concluded in accordance with the terms of contract. Under the terms of the screening agreement, Centocor maintained an option to exclusively negotiate a broader BMP-7 screening agreement. However, during the second quarter of 2007, Centocor notified us that it would not opt to negotiate a further BMP-7 small molecule agreement. The BMP-7 small molecule screening program was the only remaining program utilizing the majority of our existing discovery screening equipment. During the second quarter of 2007, we determined that we would not fund the BMP small molecule program internally. As a result, during the nine months ended September 30, 2007, we recorded additional property and equipment impairment charges of \$347,000, which is net of estimated proceeds of \$100,000, because this discovery equipment could not be used on other ongoing programs. This impairment charge has been reported within the Research and development line item within the Expenses section of the Company's Consolidated Statement of Operations for the nine months ended September 30, 2007. We received net proceeds of \$316,000 during the nine months ended September 30, 2007 from the sale of the impaired equipment, which was applied to our outstanding debt obligations with the Boston Private Bank & Trust Company. We will continue to review our estimates of remaining useful lives related to assets currently being used on our remaining programs. Any future changes to the estimated useful lives of our assets could have a material impact on our financial statements.

As of September 30, 2007, we also hold equity investments in two privately-held former collaborators, Aegera Therapeutics and ES Cell International (ESI). Equity investments in privately-held companies are reflected in the accompanying consolidated financial statements at a value based on our best estimate of the fair value of such investments. When determining the fair values of such investments, we generally consider such factors as the fair value paid by outside investors for similar equity in such companies, the liquidity of the investment and both company-specific and macroeconomic factors that may have affected values since the last such investment by outside investors. On a quarterly basis, we re-evaluate our investments in privately-held companies to determine if its carrying value has been impaired. During the second quarter of 2007, we determined that the carrying value of ESI's stock was in excess of the fair value of the asset. Accordingly, we recorded a charge of \$145,000 by writing down the carrying value of our investment in ESI equity securities to \$5,000 during the nine months ended September 30, 2007.

**Table of Contents****Recently Issued Accounting Standards**

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

In June 2007, the FASB issued EITF Issue No. 07-3 (EITF 07-3), *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. EITF 07-3 is limited to non-refundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. The EITF affirms that these payments should be capitalized and deferred until the goods have been delivered or the related services have been performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, and interim periods in those fiscal years. We do not expect the adoption of EITF 07-3 to have a material impact on our consolidated financial statements.

**Results of Operations****Three-Month Periods Ended September 30, 2007 and September 30, 2006**

*Revenues.* Total revenues are summarized as follows:

	<b>For the Three Months Ended September 30,</b>		<b>Percentage Increase/ (Decrease)</b>
	<b>2007 (unaudited)</b>	<b>2006 (unaudited)</b>	
<b>REVENUES:</b>			
<b>Research and development contracts</b>			
Genentech	\$ 142,000	\$ 988,000	(86)%
Wyeth	362,000	524,000	(31)%
Procter & Gamble	242,000	217,000	12%
Centocor		100,000	(100)%
Spinal Muscular Atrophy Foundation		191,000	(100)%
Other	20,000		100%
Subtotal	766,000	2,020,000	(62)%
<b>License fees</b>			
Genentech		187,000	(100)%
Wyeth	63,000	68,000	(7)%
Procter & Gamble	483,000	66,000	632%
Micromet		2,284,000	(100)%
Subtotal	546,000	2,605,000	(79)%
<b>Gross Revenues</b>	<b>1,312,000</b>	<b>4,625,000</b>	<b>(72)%</b>
<b>Contra-revenues from co-development with Genentech</b>		<b>(355,000)</b>	<b>(100)%</b>
<b>Net Revenue</b>	<b>\$ 1,312,000</b>	<b>\$ 4,270,000</b>	<b>(69)%</b>

Gross revenues decreased by \$3,313,000 to \$1,312,000 for the three months ended September 30, 2007 from \$4,625,000 for the same prior year period. Research funding for our Hedgehog antagonist program under collaboration with Genentech and our research agreement with the Spinal Muscular Atrophy Foundation concluded during the fourth quarter of 2006. Research funding under our April 2005 collaboration with Genentech for the Wnt signaling pathway and under our screening agreement with Centocor concluded during the first quarter of 2007. The termination of research funding under these four arrangements accounted for \$1,137,000 of the decrease in research and development contract

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

revenues. In addition, research funding from Wyeth under our Hedgehog agonist program decreased during the first quarter of 2007. As a result of the foregoing changes to our research and development contracts, we expect that our revenues will continue to decline for the remainder of 2007.

**Table of Contents**

Our license revenues decreased by \$2,059,000 to \$546,000 in the third quarter of 2007 from \$2,605,000 for the same period in 2006 primarily as the result of \$2,284,000 in license fee revenue recognized in 2006 as part of a settlement agreement with Micromet. Offsetting this decrease, we accelerated approximately \$417,000 in license fee revenue resulting from a change in our estimated performance period from September 2011 to November 2007 under our collaboration with Procter & Gamble.

Contra-revenues decreased by \$355,000 for the three months ended September 30, 2007 as compared to the same prior year period because we ceased our co-development arrangement with Genentech of a basal cell carcinoma drug candidate on August 31, 2006.

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

Research and Development Program	Primary Indication	Collaborator	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
			2007 (unaudited)	2006 (unaudited)	
Hh systemic small molecule CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Genentech	\$ 19,000	\$ 326,000	(94)%
Single and multi-target inhibitors	Cancer	Internal	1,433,000		100%
Hh small molecule agonist or protein	Nervous system disorders/ cardiovascular disease	Internal	1,170,000	752,000	56%
Wnt signaling pathway	Cancer	Wyeth	360,000	625,000	(42)%
Hh small molecule agonist	Hair loss	Genentech	2,000	596,000	(100)%
Discovery research	Various	Procter & Gamble		181,000	(100)%
Impairment of assets	N/A	Various/internal	10,000	847,000	(99)%
Stock-based compensation	N/A		10,000		100%
			199,000	342,000	(42)%
Total research and development expense			\$ 3,203,000	\$ 3,669,000	(13)%

Our research and development expenses decreased by \$466,000 to \$3,203,000 for the three months ended September 30, 2007 as compared to \$3,669,000 for the same period in the prior year. During the fourth quarter of 2006 and first quarter of 2007, research funding concluded on our Hedgehog antagonist and our Wnt signaling pathway programs under separate collaborations with Genentech, our SMA program under a sponsored research agreement with the SMA Foundation and our BMP-7 small molecule screening agreement with Centocor. As a result, our spending on these programs decreased \$1,444,000 for the three-month period ended September 30, 2007 as compared to the same prior year period.

As the research funding concluded on programs under collaboration, we reallocated certain of these resources to our internal Targeted Cancer Drug Development Platform programs, including CUDC-101 and other single- and multi-target inhibitor drug candidates, which were initiated in the first half of 2006 and accounted for \$2,603,000, or 81%, of our third quarter 2007 research expense compared to \$752,000 for the same prior year period, an increase of \$1,851,000. Spending on our collaborator-funded programs with Wyeth for the Hedgehog systemic agonist and Procter & Gamble for our Hedgehog topical agonist decreased \$446,000 as a result of fewer researchers supporting the respective programs.



**Table of Contents**

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

	<b>For the Three Months Ended</b>		<b>Percentage Increase/ (Decrease)</b>
	<b>September 30,</b>		
	<b>2007</b>	<b>2006</b>	
	<b>(unaudited)</b>	<b>(unaudited)</b>	
Personnel	\$ 571,000	\$ 676,000	(16)%
Occupancy and depreciation	67,000	171,000	(61)%
Legal services	573,000	167,000	243%
Consulting and professional services	241,000	341,000	(29)%
Insurance costs	107,000	120,000	(11)%
Other general and administrative expenses	236,000	186,000	27%
Stock-based compensation	436,000	641,000	(32)%
<b>Total general and administrative expenses</b>	<b>\$ 2,231,000</b>	<b>\$ 2,302,000</b>	<b>(3)%</b>

The decrease in general and administrative expenses of \$71,000 for the three-month period ended September 30, 2007 was due to decreases in most spending areas offset by increases in legal services. Occupancy costs decreased \$104,000 as a result of the end of our lease on our 61 Moulton Street facility on April 30, 2007, which reduced our overall facilities-related costs during the three months ended September 30, 2007. Consulting services also decreased \$100,000 primarily due to technology evaluations and review of business development opportunities in China, both which occurred in the prior year period. Finally, stock-based compensation expense decreased by \$205,000 in the three months ended September 30, 2007 as compared to the same period in the prior year as a result of a decline in the grant date fair value of stock options issued in 2007 as compared to 2006 and an increase in forfeitures, both of which resulted in lower compensation expense.

Offsetting these decreases, legal services increased \$406,000 as a result of increased spending related to our patent portfolio, including filings for CUDC-101, other programs under our Targeted Cancer Drug Development Platform and foreign patent applications.

***Nine-Month Periods Ended September 30, 2007 and September 30, 2006***

*Revenues.* Total revenues are summarized as follows:

	<b>For the Nine Months Ended</b>		<b>Percentage Increase/ (Decrease)</b>
	<b>September 30</b>		
	<b>2007</b>	<b>2006</b>	
	<b>(unaudited)</b>	<b>(unaudited)</b>	
<b>REVENUES:</b>			
<b><i>Research and development contracts</i></b>			
Genentech	\$ 905,000	\$ 3,670,000	(75)%
Wyeth	1,189,000	1,749,000	(32)%
Procter & Gamble	516,000	591,000	(13)%
Centocor	73,000	300,000	(76)%
Spinal Muscular Atrophy Foundation		1,055,000	(100)%
Other	48,000	12,000	300%
<b>Subtotal</b>	<b>2,731,000</b>	<b>7,377,000</b>	<b>(63)%</b>
<b><i>License fees</i></b>			
Genentech	938,000	563,000	67%
Wyeth	203,000	204,000	0%
Procter & Gamble	1,032,000	168,000	514%
Micromet		2,284,000	(100)%

Edgar Filing: CURIS INC - Form 10-Q

Subtotal	2,173,000	3,219,000	(32)%
<b>Gross Revenues</b>	4,904,000	10,596,000	(54)%
<b>Contra-revenues from co-development with Genentech</b>		(1,728,000)	(100)%
<b>Net Revenue</b>	\$ 4,904,000	\$ 8,868,000	(45)%

**Table of Contents**

Gross revenues decreased by \$5,692,000 to \$4,904,000 for the nine months ended September 30, 2007 from \$10,596,000 for the same prior year period. This decrease was primarily the result of a decrease in research funding under four collaborations that ended in the fourth quarter of 2006 and first quarter of 2007. The termination of research funding under these arrangements accounted for \$4,047,000 of the decrease in research and development contract revenues. In addition, research funding from Wyeth under our Hedgehog agonist program decreased during the first quarter of 2007. As a result of the foregoing, we expect that revenues under our research and development contracts will continue to decline for the remainder of 2007.

Our license revenues also decreased by \$1,046,000 to \$2,173,000 in the nine month period ended September 30, 2007 from \$3,219,000 for the same period in 2006, primarily as the result of \$2,284,000 in license fee revenue recognized in 2006 as part of a settlement agreement with Micromet. Offsetting this decrease, accelerated amortization of license fee revenue resulting from changes in our estimated performance periods of our April 2005 Wnt signaling pathway collaboration with Genentech and our September 2005 topical Hedgehog agonist for hair growth regulation with Procter & Gamble resulted in additional revenue of \$1,239,000 for the nine months ended September 30, 2007.

Contra-revenues decreased by \$1,728,000 for the nine months ended September 30, 2007 as compared to the same prior year period because we ceased our participation in a co-development arrangement with Genentech of a basal cell carcinoma drug candidate on August 31, 2006.

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

Research and Development Program	Primary Indication	Collaborator	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
			2006 (unaudited)	2006 (unaudited)	
Hh systemic small molecule CUDC-101 (HDAC, EGFR, Her2 inhibitor)	Cancer	Genentech	\$ 75,000	\$ 1,326,000	(94)%
Single and multi-target inhibitors	Cancer	Internal	2,499,000		100%
Hh small molecule agonist or protein	Cancer	Internal	3,837,000	1,137,000	237%
Wnt signaling pathway	Nervous system disorders/ cardiovascular disease	Wyeth	1,201,000	1,886,000	(36)%
Hh small molecule agonist	Cancer	Genentech	637,000	2,145,000	(70)%
Discovery research	Hair loss	Procter & Gamble	20,000	741,000	(97)%
Impairment of assets	Various	Various/internal	489,000	2,933,000	(83)%
Stock-based compensation	N/A		260,000		100%
			528,000	826,000	(36)%
Total research and development expense			\$ 9,546,000	\$ 10,994,000	(13)%

Our research and development expenses decreased by \$1,448,000 to \$9,526,000 for the nine months ended September 30, 2007 as compared to \$10,994,000 for the same period in the prior year primarily as a result of several funded programs concluding. During the fourth quarter of 2006 and first quarter of 2007, research funding concluded on our Hedgehog antagonist and our Wnt signaling pathway programs under separate collaborations with Genentech, our SMA program under a sponsored research agreement with the SMA Foundation and our BMP-7 small molecule screening agreement with Centocor. As a result, our spending on these programs decreased \$4,506,000 for the nine-month period ended September 30, 2007 as compared to the same prior year period.

As the research funding concluded on programs under collaboration and as we shifted our focus from discovery research, we reallocated certain of these resources to our internal Targeted Cancer Drug Development Platform programs, including CUDC-101, which were initiated in the first half of 2006. These new programs accounted for \$6,336,000, or 66%, of our 2007 research expense through September 30, 2007 compared to \$1,137,000 for the same prior year period, an increase of \$5,199,000.

Spending on our collaborator-funded programs with Wyeth for the Hedgehog agonist and Procter & Gamble for our Hedgehog topical agonist decreased \$1,406,000 as a result of fewer researchers supporting the respective programs.



**Table of Contents**

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

	For the Nine Months Ended September 30,		Percentage Increase/ (Decrease)
	2007 (unaudited)	2006 (unaudited)	
Personnel	\$ 1,999,000	\$ 2,185,000	(9)%
Occupancy and depreciation	48,000	577,000	(92)%
Legal services	1,624,000	1,258,000	29%
Consulting and professional services	924,000	1,161,000	(20)%
Insurance costs	352,000	329,000	7%
Other general and administrative expenses	689,000	607,000	14%
Stock-based compensation	1,906,000	2,033,000	(6)%
Total general and administrative expenses	\$ 7,542,000	\$ 8,150,000	(7)%

The decrease in general and administrative expenses of \$608,000 for the nine-month period ended September 30, 2007 was primarily due to a decrease in occupancy costs of \$529,000. During the nine months ended September 30, 2007, we received \$262,000 in proceeds under an April 2007 settlement agreement entered into with a former subtenant that had defaulted on a sublease of our 61 Moulton Street facility, of which \$212,000 was recorded as a reduction of expense. In addition, our lease on our 61 Moulton Street facility concluded on April 30, 2007, which reduced our overall facilities-related costs. Professional and consulting services decreased \$237,000 as a result of expenses incurred for the restatement of our prior financial statements during the first quarter of 2006 and costs incurred during 2006 associated with the formation of the Chinese subsidiary, including technology evaluations and review of business development opportunities in China. In addition, personnel costs decreased \$186,000.

Offsetting these decreases, legal services increased \$366,000 as a result of increased spending related to our patent portfolio, including filings for CUDC-101, other programs under our Targeted Cancer Drug Development Platform and foreign patent applications.

**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 September 30, 2007, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of \$41,090,000, 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.

The use of our cash flows for operations has primarily consisted of salaries and wages for our employees, facility and facility-related costs for our office and laboratory, fees paid in connection with preclinical studies, laboratory supplies, consulting fees, legal fees and our equal share of co-development expenses under a co-development arrangement with Genentech that we opted out of in August 2006.

To date, the primary source of our cash flows from operations has been payments received from our collaborators and licensors. Recently, however, a majority of our research and development effort and expense has shifted from our work funded under collaborations in Hedgehog pathway and our various discovery programs to the development of programs under our Targeted Cancer Drug Development Platform. While we believe that our research and development expenses will neither increase nor decrease significantly in 2007 as compared to 2006, we believe that we will be required to use more cash to fund these research and development programs in 2007 since we are responsible for 100% of the research and development costs. In addition, we are seeking to advance one or more of our drug candidates from this platform into at least the early stages of clinical testing ourselves. We plan to file an IND application for CUDC-101 in the first quarter of 2008 and, assuming that this IND application is not rejected or otherwise delayed by the FDA, we are seeking to begin our Phase I clinical trial of CUDC-101 early in the second quarter of 2008. Should we begin clinical evaluations of CUDC-101 or another of these drug candidates, we expect that our research and

development costs would increase significantly.

---

**Table of Contents**

In general, our only source of cash flows from operations for the foreseeable future will be up-front license payments from new collaborations, contingent cash payments for the achievement of development objectives, if any are met, and funded research and development that we may receive under collaboration agreements. Except for five researchers who are funded by Wyeth through February 9, 2008, substantially all of our research staff is working on developing drug candidates from our Targeted Cancer Drug Development Platform. The timing of or entrance into any new collaboration agreements and any contingent cash payments under existing collaboration agreements are not assured, cannot be easily predicted and may vary significantly from quarter to quarter. Potential future cash payments, if any, are contingent upon the successful completion principally of contractually defined development and regulatory approval objectives under existing collaborations, and royalty payments are contingent upon the successful commercialization of any products based upon the collaboration.

Net cash used in operating activities was \$9,176,000 for the nine-month period ended September 30, 2007 as compared to \$8,183,000 for the nine-month period ended September 30, 2006. Cash used in operating activities during the nine-month period ended September 30, 2007 was primarily the result of our net loss of \$11,257,000 offset by increases in operating cash resulting from non-cash charges, including stock-based compensation expense of \$2,434,000, depreciation of \$1,047,000 and impairment of assets of \$492,000 during the nine-month period ended September 30, 2007. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during the nine months ended September 30, 2007. Specifically, our accounts payable and accrued liabilities decreased \$211,000 and our deferred revenue decreased \$2,736,000 as a result of accelerated license fee amortization under our Genentech and Procter & Gamble collaborations. We also collected \$1,101,000 of our accounts receivable primarily related to our Micromet settlement.

Cash used in operating activities during the nine-month periods ended September 30, 2006 was primarily the result of our net loss for the period partially offset by non-cash charges including stock-based compensation, depreciation and non-cash interest expense. In addition, changes in certain operating assets and liabilities offset these increases in operating cash during the nine-month period ended September 30, 2006. Our accounts receivable increased \$2,007,000 primarily as a result of our settlement with Micromet. In addition, our accounts payable and accrued liabilities decreased \$1,139,000 primarily as a result of payment of co-development costs incurred under our collaboration with Genentech.

We expect to continue to use cash in operations as we continue to research and develop our existing product candidate and advance our Targeted Cancer Drug Development Platform programs through preclinical development and, we expect, into clinical development. In addition, in the future we may owe royalties and other contingent payments to our licensors based on the achievement of developmental milestones, product sales and specified other objectives. We also expect that the increase in cash used will be partially offset by anticipated payments made under our collaboration with Wyeth through February 9, 2008, assuming this collaboration continues in accordance with its terms.

Investing activities used cash of \$5,092,000 for the nine-month period ended September 30, 2007 as compared to cash of \$7,781,000 generated in the nine-month period ended September 30, 2006. Cash used by investing activities resulted principally from \$5,334,000 in net investment purchases for the nine months ended September 30, 2007 primarily related to investment of funds received from our August 2007 private placement. In addition, for the nine months ended September 30, 2007, we received \$316,000 in net proceeds from the sale of certain of our assets. We currently do not expect to undertake any significant capital projects during 2007. Cash provided by investing activities resulted principally from \$7,861,000 in net investment sales offset by \$74,000 in fixed asset purchases for the nine-month period ended September 30, 2006.

Financing activities provided cash of \$13,320,000 for the nine-month period ended September 30, 2007, resulting primarily from \$14,578,000 received in issuances of common stock, including net proceeds of \$14,422,000 from our August 2007 private placement of common stock and \$156,000 received upon the exercise of stock options. Offsetting these increases in cash, we repaid \$1,257,000 on our term debt with the Boston Private Bank & Trust Company. Financing activities used \$805,000 of cash for the nine-month period ended September 30, 2006, resulting from debt repayments of \$925,000 on our term debt with the Boston Private Bank & Trust Company and proceeds of \$120,000 received upon stock option exercises.

On August 8, 2007, we completed a private placement of units, each with a purchase price of \$1.06375 per share and comprising one share of common stock and a warrant to purchase 0.35 shares of common stock. As a result, we issued an aggregate of 13,631,022 shares of common stock and warrants to purchase an additional 4,770,859 shares of common stock. We intend to use the \$14,422,000 in net proceeds from the private placement primarily to support our clinical and research and development efforts, working capital and other general corporate purposes. The warrants have an exercise price of \$1.02

---

## **Table of Contents**

per share and expire on August 8, 2012. We can require the mandatory exercise of the warrants in the event that our stock closing price on NASDAQ exceeds \$2.50 per share for a period of 30 days. We filed a resale registration statement in Form S-3, which was declared effective by the SEC on September 10, 2007, to register for resale the shares of common stock, and the shares of common stock underlying the warrants, held by the investors.

On March 23, 2005, we converted \$2,250,000 financed under an amended loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, we are required to make equal monthly payments of \$62,500 plus any accrued interest beginning on May 1, 2005 extending through April 2008, unless the outstanding principal is paid in full earlier.

On December 9, 2005, we converted \$1,450,000 financed under a separate loan agreement with the Boston Private Bank & Trust Company into a 36-month term note that bears interest at a fixed rate of 7.95% for the repayment period. During the nine months ended September 30, 2007, we sold certain of our assets and lab supplies for which we received \$321,000 in gross proceeds for the assets and \$11,000 for the lab supplies. The total proceeds of \$332,000 were remitted to Boston Private Bank & Trust and were applied to the principal obligation outstanding under this loan agreement. None of the terms of the loan were changed as a result of the sale of assets collateralized under this agreement. Under the terms of the note payable, we are required to make equal monthly payments of \$40,278 plus any accrued interest beginning on January 1, 2006 extending through the repayment period, which is July 2008 after giving effect to the \$332,000 in additional principal payments, which resulted from our sale of certain of our pledged assets during 2007.

These loans are collateralized by all of our property and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of September 30, 2007, we were in compliance with the sole covenant under each of these financing agreements. The covenant requires us to maintain a minimum working capital ratio. Should we fail to pay amounts when due or fail to maintain compliance with the covenant under the agreements, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

We anticipate that existing capital resources at September 30, 2007, together with the cash payment of \$3,000,000 that we recently received from Genentech and assuming the payment of all contractually-defined research funding payments from Wyeth, but excluding any cash payments that are contingent upon the achievement of defined development objectives under our collaborations and with Genentech and Wyeth, assuming this contract is not earlier terminated, should enable us to maintain current and planned operations into mid-2009. 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 mid-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 September 30, 2007.

### **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, 2006.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls & Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in Internal Control Over Financial Reporting*

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

---

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 1A. Risk Factors**

You should carefully consider the following risk factors, in addition to other information included in this quarterly report on Form 10-Q, in evaluating Curis and our business. If any of the following risks occur, our business, financial condition and operating results could be materially adversely affected. The following risk factors restate and supersede the risk factors previously disclosed in Item 1A. of our Annual Report on Form 10-K for the year ended December 31, 2006.

**Factors That May Affect Results**

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

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

We expect to incur substantial operating losses for the foreseeable future, and we have no current sources of material ongoing revenue. As of September 30, 2007, we had an accumulated deficit of approximately \$700,140,000. If we are not able to 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 proprietary research and development programs in an effort to produce products that we can commercialize. We have historically derived a substantial portion of our revenue from the research funding portion of our collaboration agreements. During the years ended December 31, 2005 and 2006, and the nine months ended September 30, 2007, we recorded \$10,500,000, \$9,300,000, and \$2,200,000, respectively, in research and development contract revenues. 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 ongoing Hedgehog agonist collaboration with Wyeth was reduced from 8 to 5 researchers during the first quarter of 2007. We expect that our research and development contracts revenues from will continue to decline for the remainder of 2007. Accordingly, for the majority of our programs currently under collaboration, our future revenues are limited to (i) the amortization of previously received license payments, (ii) potential future cash payments, if any, that are contingent upon the successful completion principally of contractually defined development and regulatory approval objectives, and (iii) royalty payments upon the successful commercialization of any products based upon the collaboration. Moreover, the pursuit and achievement of any development or commercialization objectives is substantially within the collaborators' sole control. In addition, there is considerable inherent uncertainty in the successful development and commercialization of pharmaceutical drugs and, as such, we can not assure you that any such objectives will be achieved or that any further revenue will be attained by us. Even if our current and planned collaboration arrangements provide future revenue, 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 additional financing, which may be difficult to obtain and may result in stockholder dilution.**

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

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

fund our general and administrative costs and expenses; and

potentially expand our infrastructure.

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

We believe that our existing cash, together with the payment of all contractually-defined research funding payments under our collaboration and research program with Wyeth, assuming this contract is not earlier terminated, and working capital should be sufficient to fund our operations into the second quarter of 2009; however, our future capital requirements may vary from what we currently expect. There are factors that may adversely affect our planned future capital requirements and accelerate our need for additional financing. These factors, many of which are outside our control, include the following:

**Table of Contents**

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

the cost of additional facility requirements;

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

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

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

the timing, receipt and amount of sales revenues and/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 collaborators. The market for biotechnology stocks in general, and the market for our common stock in particular, is highly volatile. Due to this and various other factors, including general market conditions and the early-stage status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research and development activities will be adversely affected.

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

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

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

the cost of research and development that we engage in;

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

the scope, duration and effectiveness of our collaborative arrangements;

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

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

costs to comply with changes in government regulations;

changes in management and reductions or additions of personnel;

changes in accounting policies or principles; and

the introduction of competitive products and technologies by third parties.

Except for our systemically administered Hedgehog antagonist program, which is in an expansion cohort of its Phase I clinical trial, all of our programs are in various stages of preclinical drug development. Accordingly, our revenues from the sales of any products resulting from our research and development efforts 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, 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**

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

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

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

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

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges taken by us and related disclosure. Such estimates and judgments include the carrying value of our property, equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements. For example, during the second quarter of 2007, Procter & Gamble terminated our collaboration agreement, which was focused on seeking to develop topically-applied Hedgehog agonist compounds for hair growth regulation. We had originally estimated that our performance period under this collaboration was six years and we were recognizing the payments received under this collaboration over this six-year period, ending September 2011. The termination of this collaboration agreement caused us to change our estimated performance period to coincide with the termination date of November 2007. Accordingly, recognition of deferred revenue related to our Procter & Gamble collaboration is being accelerated and recognized based on the updated performance period ending November 2007.

## **RISKS RELATING TO OUR COLLABORATIONS**

**We depend on collaborators for the development and commercialization of product candidates based upon our technologies and plan to enter into additional collaborations in the future. If any of these collaborators terminate our agreements, or if they fail or delay in developing or commercializing our product candidates, our anticipated product pipeline and operating results would suffer.**

The success of our strategy for development and commercialization of certain licensed product candidates depends upon our ability to form and maintain productive and successful strategic collaborations. We currently have two collaborations with Genentech as well as a collaboration with Wyeth Pharmaceuticals, pursuant to which we have granted to Genentech and Wyeth exclusive rights to develop and commercialize products based upon our technologies in defined fields of use. In addition, we are seeking to enter into additional collaborations in the future, including a potential collaboration related to the development of CUDC-101, the first development candidate from our Targeted Cancer Drug Development Platform or another program from this platform. Our existing and any future collaborations may not be scientifically or commercially successful.



---

## **Table of Contents**

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

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

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

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

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

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

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

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

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the commencement and completion of preclinical studies and clinical trials, anticipated regulatory approval dates and other developments and milestones under our collaboration agreements. For example, we have estimated that we will seek to file an IND to commence clinical trials of CUDC-101 in the first quarter of 2008 and select a second development candidate from our Targeted Cancer Drug Platform in late 2007. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or our collaborators' preclinical studies or clinical trials, the amount of time, effort and resources committed to our programs by us or our collaborators and the uncertainties inherent in the regulatory approval process. There can be no assurance that our or our collaborators' preclinical studies and clinical trials will advance or be completed in the time frames we announce or expect, that we or our collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or our collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our internal or collaborative programs. If we or our collaborators fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

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



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

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 and with Wyeth in the field of neurology. Competitors may discover, characterize and develop Hedgehog-based drug candidates before we do.

---

## **Table of Contents**

In addition, our multi-target inhibitors 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 than we have. Efforts by other biotechnology, medical device and pharmaceutical companies could render our programs or products uneconomical or result in therapies superior to those that we develop alone or with a collaborator.

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

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

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

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

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

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

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

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

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



## **Table of Contents**

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

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

a diversion of management from our existing operations;

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

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

incurrence of debt, other liabilities and contingent liabilities; and

dilutive stock issuances.

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

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

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

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

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The procedures and standards that the United States Patent and Trademark Office uses to grant patents, and the standards that courts use to interpret patents, are not always applied predictably or uniformly and have recently 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 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 collaborative partners may be required to obtain licenses under third-party patents to develop and commercialize some of our product candidates. If we are unable to secure licenses to such patented technology on acceptable terms, we or our collaborative partners will not be able to develop and commercialize the affected product candidate or candidates.

---

## **Table of Contents**

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

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

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

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

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

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 our collaborative partners may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. Moreover, we may not be able to obtain required licenses on commercially acceptable terms or any terms at all. In addition, we could be held liable for lost profits if we are found to have infringed a valid patent, or liable for treble damages if we are found to have willfully infringed a valid patent. Litigation results are highly unpredictable and we or our collaborative partners may not prevail in any patent litigation or other proceeding in which we may become involved. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could damage our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and expense.

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

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

## **RISKS RELATING TO PRECLINICAL, CLINICAL AND REGULATORY MATTERS**

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

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective. 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 and our collaborators could experience delays or failures in preclinical or clinical trials of any of our product candidates for a number of reasons. For example:

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

---

**Table of Contents**

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

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

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

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

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

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

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

**We have very limited experience in conducting clinical trials. We are currently recruiting clinical/regulatory management but we expect to rely primarily on collaborative partners for our programs under collaboration and, to a lesser extent, consultants and contract research organizations for our internal programs for the performance and management of clinical trials of our product candidates. If such third parties fail to perform then we will not be able to successfully develop and commercialize product candidates and grow our business.**

We have limited experience in conducting clinical trials. We expect to rely to varying degrees on third parties to conduct our clinical trials and provide services in connection with such clinical trials. For example, we have granted development and commercialization rights under our existing agreements with Genentech and Wyeth. In most instances, such collaboration partners are fully responsible for conducting clinical trials of product candidates. We have also reserved limited rights to further develop and commercialize products that are subject to current collaborations. In these instances and for product candidates associated with new programs, we will be responsible for clinical trials. While we expect that we will add clinical/regulatory employees, we 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 similar entities to completed IND-enabling preclinical studies, create and file INDs, enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If any such events were to occur, efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

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



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

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

---

## **Table of Contents**

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

We and our collaborative partners will be required to obtain regulatory approval in order to successfully advance our product candidates through the clinic and prior to marketing and selling such products.

The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. With respect to internal programs to date, we have limited experience in filing and prosecuting applications to obtain marketing approval.

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

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

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

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

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

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

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

**We and our collaborators are subject to governmental regulations other than those imposed by the FDA. We and our collaborators may not be able to comply with these regulations, which could subject us, or such collaborators, to penalties and otherwise result in the limitation of our or such collaborators' operations.**

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

---

## **Table of Contents**

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

### **RISKS RELATING TO MANUFACTURING AND SALES**

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

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

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

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

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

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

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

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

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

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

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

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.

## Table of Contents

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

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

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

our direct sales and marketing efforts may not be successful.

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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

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

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

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

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as \$6.59 and as low as \$0.91 per share for the period January 1, 2004 through September 30, 2007. The stock market, particularly in recent years, has experienced significant volatility with respect to pharmaceutical- and biotechnology-based company stocks. Prices for our stock will be determined in the marketplace and may be influenced by many factors, including:

announcements regarding new technologies by us or our competitors;

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;

**Table of Contents**

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 our collaborators;

any intellectual property 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 September 30, 2007, we had outstanding approximately 63.2 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.

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

As of September 30, 2007, 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:

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

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.

**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 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



**Table of Contents**

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.

**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.

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 6. 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: October 30, 2007

By:

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

44

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

**Number Description**

3.1	Amendment to Amended and Restated By-laws (incorporated by reference to Exhibit 3.1 to Form 8-K filed on September 24, 2007).
10.1	Common Stock Purchase Agreement, dated as of August 6, 2007, by and among the Company and the Purchasers (as defined therein), as amended by Amendment to Common Stock Purchase Agreement and Waiver, dated August 7, 2007 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 9, 2007).
10.2	Common Stock Purchase Agreement, dated as of August 7, 2007, by and among the Company and the Purchasers (as defined therein) (incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 9, 2007).
10.3	Registration Rights Agreement, dated as of August 6, 2007, by and among the Company and the Purchasers (as defined therein), as amended by Amendment to Registration Rights Agreement, dated August 7, 2007 (incorporated by reference to Exhibit 10.3 to Form 8-K filed on August 9, 2007).
10.4	Form of Warrant, dated August 8, 2007, issued pursuant to the Common Stock Purchase Agreement, dated as of August 6, 2007, as amended on August 7, 2007 (incorporated by reference to Exhibit 10.4 to Form 8-K filed on August 9, 2007).
10.5	Form of Warrant, dated August 8, 2007, issued pursuant to the Common Stock Purchase Agreement, dated as of August 7, 2007 (incorporated by reference to Exhibit 10.5 to Form 8-K filed on August 9, 2007).
10.6	Employment Agreement, dated September 18, 2007, by and between the Company and Daniel R. Passeri (incorporated by reference to Exhibit 10.1 to Form 8-K filed on September 24, 2007).
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