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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

Amendment No. 1

(Mark one)

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2005

OR

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

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3505116**

(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
61 Moulton Street	
Cambridge, Massachusetts (Address of Principal Executive Offices)	**02138** (Zip Code)

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

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

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

Large accelerated filer ¨ Accelerated filer x 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 x No

As of November 11, 2005, there were 49,339,994 shares of the Registrant s common stock outstanding.

Table of Contents

EXPLANATORY NOTE:

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

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

QUARTERLY REPORT ON FORM 10-Q

INDEX

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

Table of Contents

Item 1. FINANCIAL STATEMENTS

CURIS, INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

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

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

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (unaudited)

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

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

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

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock in connection with conversion of note payable to Elan Pharma International, Limited (Note 10)	$ 3,305,523	$

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Business

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

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

2. Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed and do not include all disclosures required by accounting principles generally accepted in the United States for complete financial statements and should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the Securities and Exchange Commission on March 15, 2005.

In the opinion of the Company, the unaudited consolidated financial statements contain all adjustments (all of which were considered normal and recurring) necessary to present fairly the Company s financial position at September 30, 2005, the results of operations for the three- and nine-month periods ended September 30, 2005 and 2004, and cash flows for the nine-month periods ended September 30, 2005 and 2004. The preparation of the Company s consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include the carrying value of property and equipment and intangible assets and the value of certain liabilities. Actual results may differ from such estimates.

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

3. Restatement of Financial Statements

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

These adjustments are more fully described as follows:

Genentech license fee payments: The Company had been recognizing revenue in connection with $7,509,000 in license maintenance fee payments received from Genentech as of part of the June 2003 Hedgehog antagonist collaboration between the parties over an eight-year period based on the Company s belief that its participation on the steering committees would become inconsequential after the first product was approved in each of the two programs covered under this collaboration, and would therefore no longer represent a performance obligation. The Company has determined it should not have recognized any of this revenue in 2005, 2004, or 2003. Instead, the Company will defer the $7,509,000 in payments and recognize this amount as revenue only when the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company s steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of the Company s steering committee obligations is indefinite and the Company expects that it will not record any revenue related to these payments for at least several years.

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

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

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

8

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

4. Financial Statement Reclassifications

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

5. Revenue Recognition

The Company s business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company s product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. The Company follows the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104 (SAB No. 104), *Revenue Recognition*, Emerging Issues Task Force (EITF) Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables,* EITF Issue No. 99-19 (EITF 99-19), *Reporting Revenue Gross as a Principal Versus Net as an Agent,* and EITF Issue No. 01-9 (EITF 01-9), *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).*

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

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

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

12

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

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

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

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

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

6. Procter & Gamble Collaboration

(i) Collaboration Summary

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

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

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

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

(ii) Accounting Summary

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

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

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

15

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

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

7. Genentech April 2005 Drug Discovery Collaboration

(i) Collaboration Summary

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

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

(ii) Accounting Summary

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

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

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

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

17

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

8. Genentech April 2005 Hedgehog Antagonist Collaboration Amendment

(i) Agreement Summary

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

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

(ii) Accounting Summary

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

9. Genentech Collaboration Accounting

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

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

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

The Company has deferred the $7,509,000 in license and maintenance fee payments and will recognize it only when the Company can reasonably estimate when its contractual steering committee obligations will cease or after it no longer has contractual steering committee obligations under this agreement with Genentech. The contractual term of the Company s steering committee obligations extends for as long as Hedgehog antagonist products subject to this collaboration are being developed or commercialized by either of the parties. Accordingly, the contractual term of the Company s steering committee obligations is indefinite and the Company expects that it will not record any revenue related to these payments for at least several years.

19

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

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

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

20

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

10. Long-Term Debt and Capital Lease Obligations

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

Effective January 7, 2005, the Company entered into an amendment with the Boston Private Bank & Trust Company to extend the drawdown date by which it can request periodic financings up to $2,250,000 for qualifying purchases of equipment and leasehold improvements through April 30, 2005. On March 23, 2005, the Company drew down the remaining balance under this agreement bringing the total amount financed to $2,250,000 and exercised its option to convert the outstanding balance into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, the Company is required to make equal monthly payments of $62,500 plus any accrued interest beginning on May 1, 2005 extending through the 36-month term. The loan is collateralized by all of the Company s property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of September 30, 2005, the Company was in compliance with the sole covenant under this agreement. This covenant requires the Company to maintain a minimum modified working capital ratio. Should the Company fail to pay amounts when due or fail to maintain compliance with the covenant under this agreement, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

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

11. Accounting for Stock-Based Compensation

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

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

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

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

12. Loss of Subtenant Income

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

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

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

Table of Contents

CURIS, INC. AND SUBSIDIARY

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

and on the potential for future default by the subtenant, the Company recorded a charge of $500,000 in the General and administrative expense line item of its Consolidated Statement of Operations during the second quarter of 2005. This amount represents the Company s estimate of the total expected loss on the subleased space over the remaining term of the lease. There has been no change in the Company s estimate of the $500,000 liability, approximately $350,000 and $150,000 are included as current and long-term liabilities, respectively, in the Company s balance sheet as of September 30, 2005.

13. Subsequent Events

(a) Extension of research funding by Genentech

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

(b) Payment from former collaborator

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

14. New Accounting Standards

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

24

Table of Contents

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

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

Restatement of Financial Statements.

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

Overview

We are a therapeutic drug development company principally focused on the discovery, development and future commercialization of products that modulate key regulatory signaling pathways controlling the growth, repair and regeneration of human tissues and organs. Our product development approach involves using small molecules, proteins or antibodies to modulate these regulatory signaling pathways, for example, to increase the pathway signals when they are insufficient or to decrease them when they are excessive or unregulated. We have successfully used our product development approach to produce multiple compounds with potential use for several different disease indications. For example, we have developed a product candidate for the topical treatment of basal cell carcinoma, which is currently in a phase I clinical trial and under co-development with Genentech, Inc., or Genentech, a collaborator. We have also developed several promising preclinical product candidates in various fields, including cancer, neurological disorders, hair growth regulation and cardiovascular disease. We operate in a single reportable segment: developmental biology products. We expect that any successful products would be used in the health care industry and would be regulated in the United States by the U.S. Food and Drug Administration, or FDA, and in overseas markets by similar regulatory agencies.

Since our inception, we have funded our operations primarily through license fees, research and development funding from our strategic collaborators, the private and public placement of our equity securities, debt financings and the monetization of certain royalty rights. We have never been profitable and have incurred an accumulated deficit of $678,690,000 as of September 30, 2005. We expect to incur significant operating losses for the next several years as we devote substantially all of our resources to research and development of our product candidates. We will need to generate significant revenues to achieve profitability and do not expect to achieve profitability in the foreseeable future, if at all.

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

25

Table of Contents

bone morphogenetic protein, or BMP, pathway portfolio to Ortho Biotech Products, a subsidiary of Johnson & Johnson, for systemic administration for all applications excluding orthopedic and dental therapeutic applications. Our strategic collaborations and license agreements generally provide for our research, development and commercialization programs to be either a majority or wholly funded by our collaborators and provide us with the opportunity to receive additional payments if specified milestones are achieved, as well as royalty payments upon the successful commercialization of any products based upon the collaboration. These strategic license and collaboration agreements included $18,500,000 in up-front payments, of which we received $6,629,000 from the sale of shares of our common stock, and also include potential future clinical development and regulatory approval milestones of approximately $750,000,000 in the aggregate, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are developed, and all milestone payments are received upon successful completion of specified research and/or development objectives and regulatory approvals. In the future, we plan to continue to seek corporate collaborators for the further development and commercialization of some of our other technologies.

In January 2005, pursuant to the terms of our Hedgehog pathway collaboration agreement with Genentech, we exercised a co-development option pursuant to which we will share equally in all U.S. development costs and will also share equally in any future net profits and/or losses derived from sales in the U.S. of a therapeutic product candidate for the topical treatment of basal cell carcinoma should this product be successfully developed and marketed. Genentech has primary responsibility for clinical trial design and management and we participate on a steering committee that oversees the clinical development of the basal cell carcinoma product candidate. As a result of our election to exercise our co-development option, we will forego U.S. development and drug approval milestones and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On March 31, 2005, Genentech filed an investigational new drug application with the FDA in order to initiate human clinical investigation of the basal cell carcinoma product candidate and, in the second quarter of 2005, the first patient was enrolled in our phase I clinical trial. We expect that by exercising this co-development and equal cost-sharing option we will incur approximately $20,000,000 in development expenses through the planned completion of phase II clinical trials. We anticipate that the phase II clinical trials will be completed in mid-2007, assuming that the basal cell carcinoma product candidate successfully completes its phase I clinical trial. We expect to incur additional costs to complete phase III clinical trials and the remainder of the regulatory approval process, assuming that Genentech and we successfully complete phase II clinical trials.

Financial Operations Overview

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

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

Table of Contents

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

Research and Development. Research and development expense consists of costs incurred to discover, research and develop our product candidates. These expenses consist primarily of salaries and related expenses for personnel, supplies and reagents, outside service costs including medicinal chemistry, consulting and sponsored research collaborations, and occupancy and depreciation charges. We expense research and development costs as incurred.

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

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

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

(1) Genentech has selected a lead clinical candidate for this program, a small molecule antagonist of the Hedgehog pathway.

(2)

We have incurred nominal expenses related to our cardiovascular disease program. Our preclinical data relating to this program has been primarily derived from studies conducted at Caritas St. Elizabeth s Medical Center in Boston,

Table of Contents

Massachusetts. Wyeth has a right of first negotiation to obtain an exclusive license to the cardiovascular applications. If Wyeth declines to exercise its option, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for this program. In the event Wyeth declines to exercise its option, we will actively explore other licensing opportunities for this program. Should we be successful in our efforts to license this program, either to Wyeth or to another collaborator, any investigational new drug filing will likely be the responsibility of the collaborator.

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

Genentech and we are co-developing a Hedgehog small molecule antagonist formulated for the topical treatment of basal cell carcinoma. Genentech and we will share equally in all U.S. development costs. As a result of our election to exercise our co-development option, we will forego U.S. development and drug approval milestones and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. On March 31, 2005, Genentech filed an investigational new drug application with the FDA. We expect that we will incur approximately $20,000,000 in development expenses through phase II clinical trials and we anticipate that these trials will be completed in mid-2007, assuming the successful advancement of the basal cell carcinoma product candidate through phase I and phase II clinical trials. We expect to incur additional costs to complete phase III clinical trials and the remainder of the regulatory approval process, assuming that Genentech and we successfully complete phase II clinical trials. Due to the uncertainties that are inherent to the drug discovery process, as more fully described below, we are not currently able to estimate the cost and timing to complete the phase III trial and receive regulatory approval of this product candidate, if ever.

Except for our basal cell carcinoma product candidate, all of our product development initiatives are in various stages of preclinical testing. Because of the early stages of these programs, the successful development of our preclinical product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the timing of when collaborators may make compounds that are subject to our retained rights available for our development;
- 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.

Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity. A discussion of risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth below in Risk Factors That May Affect Future Results.

Table of Contents

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. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services. Within facility costs, we have recorded a $500,000 charge resulting from our expected loss of subtenant income on an operating lease for the remainder of our lease term ending on April 30, 2007.

Strategic Alliances and License Agreements. Since inception, substantially all of our revenues have been derived from collaborations and other research and development arrangements with third parties. Our current strategic collaborations and key license agreements are with Genentech, Wyeth, P&G and Ortho Biotech Products. These strategic license and collaboration agreements included $18,500,000 in up-front payments, including $6,629,000 from the sale of shares of our common stock, and have potential future clinical development milestones of approximately $750,000,000 in the aggregate, assuming that all of the collaborations continue for their full terms, multiple products for multiple indications are successfully developed, and all milestone payments are received upon successful completion of specified research, development and regulatory approval objectives.

The collaborations and licenses are summarized as follows:

Genentech Hedgehog Antagonist Collaboration. In June 2003, we licensed our proprietary Hedgehog pathway antagonists to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop these molecules for cancer indications. The collaboration consists of two programs: the development of a small molecule Hedgehog antagonist formulated for the topical treatment for basal cell carcinoma; and the development of systemically administered small molecule and antibody Hedgehog antagonists for the treatment of certain other solid tumor cancers. Pursuant to the collaboration agreement, Genentech agreed to make specified cash payments, including up-front payments of $8,500,000, which consisted of a $3,509,000 non-refundable license fee payment and $4,991,000 in exchange for 1,323,835 shares of our common stock. Genentech also agreed to make license maintenance fee payments totaling $4,000,000 over the first two years of the collaboration and milestone payments at various intervals during the clinical development and regulatory approval process of small molecule and antibody Hedgehog antagonist product candidates, assuming specified clinical development and regulatory approval objectives are met. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales volume. As described below, in December 2004, we entered into an amendment to this agreement which modified the maintenance and the payment arrangement.

In January 2005, pursuant to the collaboration agreement we exercised an option to co-develop Hedgehog antagonist products in the field of basal call carcinoma in the U.S. We are now sharing equally in both U.S. development costs and any future U.S. net profits and/or losses resulting from the development and commercialization of our basal cell carcinoma product candidate. This co-development right includes basal cell carcinoma and any additional indications for which this product candidate may be developed in the U.S. As a result of participating in co-development, we will forego U.S. development milestone and royalty payments on potential future U.S. sales of the basal cell carcinoma product candidate. Should we determine that we cannot continue funding our equal share of the development expenses, we may opt out of the co-development structure and receive certain development and regulatory approval milestones and royalties on sales of the basal cell carcinoma product candidate, should any ever occur. On March 31, 2005, Genentech filed an investigational new drug application for the basal cell carcinoma product candidate with the FDA. In addition to our co-development rights in the U.S. marketplace, in certain major international markets, we will receive milestones if specific clinical development objectives are achieved and a royalty on any international sales of a basal cell carcinoma product candidate.

Under the systemic Hedgehog antagonist program of the collaboration, Genentech is also obligated to make milestone payments to us assuming the successful achievement of clinical development and drug approval objectives. In addition, Genentech will pay a royalty on potential future net product sales, which increases with increasing sales.

29

Table of Contents

Amendments to the Genentech Hedgehog Antagonist Collaboration. In December 2004 and April 2005, we entered into separate amendments to our June 2003 agreement with Genentech. We considered the provisions of EITF 00-21 and determined that these agreements were separate contracts from our June 2003 agreement since these agreements were not contemplated at the time of the June 2003 arrangement, were separately negotiated in order to increase the number of full-time equivalents providing research and development services and to provide xenograft tumor samples to Genentech, and were not entered into at or near the time of the June 2003 agreement.

The December 2004 amendment, effective from June 12, 2004 to June 11, 2005, increases our commitment of full-time equivalents providing research and development services for the systemic Hedgehog antagonist program from eight to sixteen, including six full-time equivalents that are employed by a third party but are managed by us, and increases Genentech s funding commitment from $2,000,000 to $4,000,000 for this period of which Genentech paid us $2,000,000 for research services in December 2004 and the remaining $2,000,000 for subsequent research services was paid in June 2005. Pursuant to the agreement, we also agreed to provide xenograft tumor samples to Genentech during the research period for which Genentech paid us $100,000 in December 2004. Also in accordance with the amendment, the second $2,000,000 maintenance payment due under the June 2003 arrangement was removed with no economic effect since it was replaced by a $2,000,000 payment for research services made to us in December 2004.

The April 2005 amendment, effective from June 12, 2005 to June 11, 2006, provides for up to sixteen of our full-time equivalent researchers, including six full-time equivalents that are employed by a third party but are managed by us, to provide research and development services for the systemic Hedgehog antagonist program for the period of June 12, 2005 until December 11, 2005, in exchange for an additional $2,000,000, which was paid in December 2005. The agreement also provides Genentech with the option to request that we provide up to sixteen full-time equivalent researchers to perform research services during the period of December 12, 2005 until June 11, 2006, provided that Genentech supplies us with adequate notice. In October 2005, Genentech requested that we provide ten full-time equivalent researchers, all of which are Curis employees, to work on the program from December 12, 2005 until June 11, 2006, in exchange for $1,250,000. The six full-time third party equivalents that were previously involved in the program are no longer needed, based on the progress made under the program, which included the selection of a lead clinical candidate, a small molecule antagonist of the Hedgehog pathway. The remaining $1,250,000 for subsequent research services is payable by Genentech in June 2006.

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

Under the terms of the agreement, we will have primary responsibility for drug discovery and research activities and Genentech will be responsible for clinical development, manufacturing, and commercialization of products that may result from the collaboration. Genentech paid us an up-front license fee of $3,000,000 and has agreed to fund up to $6,000,000 for research activities during the initial two-year research term, subject to certain termination rights. Genentech has also agreed to make cash payments to us that are contingent upon the successful achievement of certain preclinical and clinical development milestones and drug approval milestones. Excluding royalties on potential net product sales, the total potential cash payments from this collaboration could exceed $140,000,000, assuming that two products are commercialized in two indications each. Genentech has an option to extend the initial two-year research term for up to two additional years in one-year increments. Genentech will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed.

Table of Contents

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

Wyeth is also obligated to make milestone payments if the licensed programs successfully achieve clinical development and drug approval objectives and to pay us a royalty on net product sales, if any should occur, that escalates with increasing sales volume. Our agreement with Wyeth includes more than $170 million in milestone payments, assuming at least two products are successfully developed and commercialized.

In addition to these initial and potential future milestone payments, Wyeth is obligated to provide financial support of our research under the collaboration, at $250,000 per full-time equivalent researcher, for a period of up two years based on the number of full-time equivalent researchers performing services under the collaboration. We are obligated to dedicate between five and ten full-time equivalents to this program, as determined by the steering committee in six-month intervals, for two years. After the initial two-year period, Wyeth can, at its option, elect to extend our research obligation, and Wyeth s funding thereof, for an initial one-year extension on the same terms and conditions as the initial two-year term. Thereafter, the agreement may be extended for additional one-year periods upon recommendation of the steering committee and with the Company s consent with such full-time equivalent resources and related Wyeth funding obligations as may be consistent with fulfilling the objectives of the research plan. The senior Wyeth representative on the Joint Steering Committee has the deciding vote in the event the parties disagree on matters relating to the research program. The agreement provides for a one-year evaluation period immediately following the end of the research term, during which we may be obligated to serve on the steering committee and may be required, at Wyeth s expense, to perform additional research and development services. We currently estimate we will only be required to provide steering committee services during the evaluation period if we are also performing research services during that period.

As part of the agreement, we have retained development and licensing options for certain therapeutic applications of the Hedgehog agonist technologies, including topical treatment for skin diseases and disorders including hair growth regulation, ex vivo cell therapy, local delivery applications for treatment of cardiovascular disease, and those applications that qualify as orphan drug indications. Wyeth has a right of first negotiation to obtain an exclusive license to the orphan drug indications and the cardiovascular applications. If Wyeth declines to exercise its right, or if we are unable to reach an agreement with Wyeth on terms within the contractually specified period, we are free to seek another collaborator for these programs.

Procter & Gamble Hedgehog Agonist Collaboration for Hair Growth and Skin Disorders. On September 18, 2005, we entered into a collaboration, research and license agreement with P&G, to evaluate and develop potential treatments for hair growth regulation and skin disorders utilizing our Hedgehog agonist technology.

Under the terms of the agreement, we granted to P&G an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate our Hedgehog agonist technology. In accordance with the terms of the agreement, the parties shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by P&G. P&G is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program, provided however, that at the time that P&G determines to file the first investigational new drug application with the U.S. Food and Drug Administration for a product candidate, we shall have the option, at our sole discretion, to co-develop a product candidate through phases I and II of clinical development. We, however, would

Table of Contents

receive a higher royalty in the event that we exercise our co-development option and subsequently share in development expense through phase II clinical trials. Should we elect to exercise this co-development option, we will forego development milestones that would otherwise be payable during the period from investigational new drug application filing through the completion of a phase II clinical trial. P&G has paid us an up-front license fee of $500,000 and has agreed to fund up to $600,000 for two of our full-time equivalent employees providing research and development activities during the initial one-year research term, subject to its termination rights. P&G has an option to extend the initial one-year research term for up to three additional years in one-year increments.

P&G has also agreed to make cash payments to us that are contingent upon the successful achievement of certain research, development, clinical and drug approval milestones. P&G will also pay us royalties on net product sales if product candidates derived from the collaboration are successfully developed. We will receive a higher royalty in the event that we exercise our co-development option and subsequently share in development expenses through phase II clinical trials.

Ortho Biotech Products BMP License. In November 2002, we licensed our broad bone morphogenetic protein, or BMP, technology portfolio to Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies. Two of Ortho Biotech Products research affiliates, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Centocor Research & Development, also members of the Johnson & Johnson family of companies, will have joint responsibility for further research and development of our licensed BMP technology portfolio.

The transaction relates to all of our proprietary BMP compounds including BMP-7, which has been studied in animal models in various disease indications, including 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. Use of our BMPs for the repair or regeneration of local musculoskeletal tissue defects and dental defects is the subject of an exclusive agreement with Stryker and is not included as part of this transaction.

Pursuant to the agreement, Ortho Biotech paid us an up-front payment of $3,500,000, in December 2002, and has agreed to make milestone payments at various intervals during the U.S. and European regulatory approval process assuming the first two therapeutic indications are successfully developed. These milestones include a $30,000,000 payment if Ortho Biotech achieves U.S. regulatory approval of a product for the treatment of kidney disease or associated complications. The agreement further specifies that we will receive a royalty on net sales of products that incorporate our BMP technologies. Unless terminated earlier, the agreement shall remain in effect until the expiration of Ortho Biotech s obligation to pay royalties to us under the agreement.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires that we make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at our balance sheet date. Such estimates and judgments include the carrying value of property and equipment and intangible assets, revenue recognition and the value of certain liabilities. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to understanding the judgments and estimates we use in preparing our financial statements:

Revenue recognition. Our business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our

32

Table of Contents

product candidates. The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of clinical development milestones and royalties on product sales. We follow the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, Emerging Issues Task Force, or EITF, Issue No. 00-21*, Accounting for Revenue Arrangements with Multiple Deliverables,* EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent,* and EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).*

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

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

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

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

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete its performance obligations under an arrangement. In addition, if we are involved in a steering committee as part of a multiple element arrangement that is accounted for as a single unit of accounting, we assess whether our involvement constitutes a performance

Table of Contents

obligation or a right to participate. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

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

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and,
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

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

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

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

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

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

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

Table of Contents

month period ended September 30, 2006 are classified as long-term deferred revenue. As of September 30, 2005, we have short- and long-term deferred revenue of $1,236,000 and $10,441,000, respectively, related to our collaborations.

Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, in connection with our existing collaboration agreements, we have recorded on our balance sheet short- and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue, or applied against future co-development costs, by September 30, 2006. Amounts that we expect will not be recognized prior to September 30, 2006 are classified as long-term deferred revenue. However, this estimate is based on our current operating plan as of September 30, 2005. If our operating plan should change in the future, we may recognize a different amount of deferred revenue over the twelve-month period from October 1, 2005 through September 30, 2006.

The estimate of deferred revenue also reflects management s estimate of the periods of our involvement in certain of our collaborations. Our performance obligations under these collaborations consist of participation on steering committees and the performance of other research and development services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in future periods.

Goodwill. We assess the impairment of goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. In addition, we perform a goodwill impairment test annually. If we determined that the carrying value of goodwill might not be recoverable based upon the existence of one or more indicators of impairment, we would measure any impairment based on a projected cash flow method.

Valuation of investments in privately held companies. We have investments in Aegera, Micromet and ES Cell International with carrying values of $167,000, $100,000 and $150,000, respectively. These investments are included in the Deposits and other assets category of our consolidated balance sheets. At each balance sheet date, we review these investments to determine whether the fair value of these investments is less than the carrying value and, if so, whether we should write-down the investment. These companies are not publicly traded and, therefore, determining the fair value of our investments in these companies involves significant judgment. We consider available information in estimating the fair value of these investments and, as of September 30, 2005, we believe that the fair value of these investments is not less than their carrying value.

If the financial condition or results of Aegera, Micromet or ES Cell decline significantly, the fair value of these investments would likely decline and, as a result, we may have to record an impairment charge to the extent such impairment is deemed other than temporary.

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

Table of Contents

Results of Operations

Three-Month Periods Ended September 30, 2005 and September 30, 2004

Revenues. Total revenues are summarized as follows:

	For the Three Months Ended September 30,		Percentage Increase/ (Decrease)
	2005	2004	
	(as restated)	(as restated)	
REVENUES:			
Research and development contracts			
Genentech	$ 1,791,000	$ 301,000	495%
Wyeth	561,000	661,000	(15%)
Spinal Muscular Atrophy Foundation	205,000	139,000	47%
Procter & Gamble	7,000		100%
Other	62,000		100%
Subtotal	2,626,000	1,101,000	139%
License fees			
Genentech	187,000		100%
Wyeth	68,000	68,000	0%
Procter & Gamble	3,000		100%
Subtotal	258,000	68,000	279%
Gross Revenues	2,884,000	1,169,000	147%
Contra-revenues from co-development with Genentech	(819,000)		(100%)
Net Revenue	$ 2,065,000	$ 1,169,000	77%

The 77% increase in net revenues for the three months ended September 30, 2005 as compared to the same period in the prior year, was primarily due to gross revenues from our research and development contracts, which increased from $1,101,000 for the three months ended September 30, 2004 to $2,626,000 for the three months ended September 30, 2005, an increase of $1,525,000. Research and development contract revenues for three months ended September 30, 2005 increased $1,737,000 from three new agreements entered into during 2005 a new drug discovery collaboration with Genentech entered into April 2005, an agreement to extend research services to Genentech under our solid tumor program entered into April 2005, and a collaboration with Procter & Gamble entered into September 2005. The increases in research and development contract revenue were partially offset by a decrease in such revenues under our Wyeth collaboration of $100,000 for the three months ended September 30, 2005 as compared to the same period in the prior year.

License fees increased $190,000 over the prior year period primarily due to the recognition of $187,000 license fees associated with a new drug discovery collaboration with Genentech entered into April 2005.

Research and development and license fee revenues were offset by $819,000 in contra-revenue, or a reduction to gross revenues, related to our co-development payments to Genentech. This reduction in gross revenue represents amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma therapeutic product candidate.

Table of Contents

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

Research and Development Program	Primary Indication	For the Three Months Ended September 30, 2005	For the Three Months Ended September 30, 2004	Percentage Increase/ (Decrease)
		(as restated)	(as restated)	
Hh small molecule and antibody antagonist	Cancer	$ 955,000	$ 1,041,000	(8)%
Hh small molecule agonist	Nervous system disorders	708,000	643,000	10%
Hh small molecule agonist	Hair loss	218,000	225,000	(3)%
Discovery research	Spinal muscular atrophy	578,000	139,000	316%
Discovery research	Various	1,061,000	932,000	14%
Other	Various	7,000	2,000	250%
Stock-based compensation	N/A	164,000	342,000	(52)%
Total research and development expense		$ 3,691,000	$ 3,324,000	11%

The increase of $367,000 in research and development expenses for the three-month period ended September 30, 2005 was primarily due to an increase in spending of $568,000 on our discovery research programs, one of which is under a grant with the Spinal Muscular Atrophy Foundation and another of which is under collaboration with Genentech.

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

	For the Three Months Ended September 30, 2005	For the Three Months Ended September 30, 2004	Percentage Increase/ (Decrease)
Personnel	$ 771,000	$ 749,000	3%
Occupancy and depreciation	170,000	136,000	25%
Legal services	423,000	568,000	(26)%
Consulting and professional services	223,000	481,000	(54)%
Insurance costs	107,000	114,000	(6)%
Other general and administrative expenses	137,000	64,000	114%
Stock-based compensation	2,000	26,000	(92)%
Total general and administrative expenses	$ 1,833,000	$ 2,138,000	(14)%

The decrease in general and administrative expenses of $305,000 for the three-month period ended September 30, 2005 was primarily due to decreases in professional services and legal services of $258,000 and $145,000 respectively, offset by increases in other expenses of $73,000.

Amortization of Intangibles. Amortization of intangible assets was $19,000 for each of the three-month periods ended September 30, 2005 and 2004.

Interest Income. Interest income for the three-month period ended September 30, 2005 was $319,000 as compared to $116,000 for the three-month period ended September 30, 2004, an increase of $203,000, or 175%. The increase in interest income resulted from higher interest rates and a higher available investment balance for the period ended September 30, 2005 as compared to the three-month period ended September 30, 2004.

Other Income. We recorded no other income for the three months ended September 30, 2005. Other income was $40,000 for the three-month period ended September 30, 2004, which primarily consisted of a gain recognized on currency rate fluctuations on a Euro-denominated note receivable from a former collaborator.

Table of Contents

Interest Expense. Interest expense of $93,000 for the three-month period ended September 30, 2005, was comparable to interest expense of $102,000 for the three-month period ended September 30, 2004.

Net Loss. As a result of the foregoing, we incurred a net loss of $3,251,000 for the three-month period ended September 30, 2005 as compared to a net loss of $4,259,000 for the three-month period ended September 30, 2004.

Nine-Month Periods Ended September 30, 2005 and September 30, 2004

Revenues. Total revenues are summarized as follows:

	For the Nine Months Ended September 30		Percentage Increase/ (Decrease)
	2005 (as restated)	2004 (as restated)	
REVENUES:			
Research and development contracts			
Genentech	$ 4,119,000	$ 625,000	559%
Wyeth	1,745,000	1,525,000	14%
Spinal Muscular Atrophy Foundation	1,425,000	139,000	925%
Procter & Gamble	7,000		100%
Other	63,000		100%
Subtotal	7,359,000	2,289,000	221%
License fees			
Genentech	375,000		100%
Wyeth	204,000	174,000	17%
Procter & Gamble	3,000		100%
Subtotal	582,000	174,000	234%
Substantive milestones	250,000	50,000	400%
Gross Revenues	8,191,000	2,513,000	226%
Contra-revenues from co-development with Genentech	(5,698,000)		(100%)
Net Revenue	$ 2,493,000	$ 2,513,000	(1%)

The 1% decrease in net revenues for the three months ended September 30, 2005 as compared to the same period in the prior year, was primarily due to $5,698,000 in contra-revenues, or a reduction to gross revenues, that were recorded by the Company related to our co-development payments to Genentech. This reduction in gross revenue represents amounts owed for the reimbursement of our equal share of costs incurred by Genentech under our collaboration related to the co-development of a basal cell carcinoma therapeutic product candidate.

Amounts recorded as contra-revenues were mostly offset by an increase of $5,070,000 recorded in research and development contract revenues during the nine months ended September 30, 2005 as compared to the same period in the prior year. This increase was primarily due to research and development contract revenues recorded from two new agreements entered into during 2005 a new drug discovery collaboration with Genentech entered into April 2005, and an agreement to extend research services to Genentech under our solid tumor program entered into April 2005. In addition, the Company began to record revenue under its September 2005 collaboration with Procter & Gamble.

License fees increased $408,000 over the prior year period primarily due to the recognition of $375,000 license fees associated with the new drug discovery collaboration with Genentech entered into April 2005.

Table of Contents

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

Research and Development Program	Primary Indication	For the Nine Months Ended September 30, 2005	For the Nine Months Ended September 30, 2004	Percentage Increase/ (Decrease)
		(as restated)	(as restated)	
Hh small molecule and antibody antagonist	Cancer	$ 2,810,000	$ 3,158,000	(11)%
Hh small molecule agonist	Nervous system disorders	2,189,000	2,243,000	(2)%
Hh small molecule agonist	Hair loss	664,000	603,000	10%
Discovery research	Spinal muscular atrophy	2,046,000	139,000	1,372%
Discovery research	Various	2,488,000	2,301,000	8%
Other	Various	25,000	73,000	(66)%
Stock-based compensation	N/A	188,000	864,000	(78)%
Total research and development expense		$ 10,410,000	$ 9,381,000	11%

The increase of $1,029,000 in research and development expenses for the nine-month period ended September 30, 2005, was primarily due to an increase in spending of $1,907,000 on one of our discovery research programs which is under a sponsored research agreement with the Spinal Muscular Atrophy Foundation. This program began in mid-September 2004 and we incurred costs of $139,000 during the nine-month period ended September 30, 2004. Reduced spending of $348,000 in our Hedgehog small molecule and antibody antagonist for cancer programs partially offset this increase. This increase was further offset by a decrease in stock-based compensation, which was $188,000 as compared to $864,000 for the nine-month periods ended September 30, 2005 and 2004, respectively. The decrease was primarily attributable to a decrease of compensation expense recorded on options to purchase common stock that were issued to employees with exercise prices below fair market value in August 2000 that became fully vested as of August 2004. No related additional expense was recognized for these August 2000 stock options beyond August 2004.

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

	For the Nine Months Ended September 30, 2005	For the Nine Months Ended September 30, 2004	Percentage Increase/ (Decrease)
Personnel	$ 2,549,000	$ 2,273,000	12%
Occupancy and depreciation	946,000	500,000	89%
Legal services	1,019,000	1,443,000	(29)%
Consulting and professional services	797,000	1,137,000	(30)%
Insurance costs	319,000	378,000	(16)%
Other general and administrative expenses	506,000	535,000	(5)%
Stock-based compensation	5,000	195,000	(97)%
Total general and administrative expenses	$ 6,141,000	$ 6,461,000	(5)%

The decrease of $320,000 in general and administrative expenses for the nine-month period ended September 30, 2005 was due to decreases in most cost categories, offset by an increase in personnel costs and by the recognition of a $500,000 charge resulting from the expected loss of subtenant income under an operating lease for the remainder of our lease term.

Amortization of Intangibles. Amortization of intangible assets was $56,000 for each of the nine-month periods ended September 30, 2005 and 2004.

Table of Contents

Interest Income. Interest income for the nine-month period ended September 30, 2005 was $862,000 as compared to $333,000 for the nine-month period ended September 30, 2004, an increase of $529,000, or 159%. The increase in interest income resulted from higher interest rates and a higher available investment balance for the period ended September 30, 2005 as compared to September 30, 2004.

Other Income. Other income for the nine-month period ended September 30, 2005 was $25,000 as compared to $233,000 for the nine-month period ended September 30, 2004. For the nine-month period ended September 30, 2004, other income primarily consisted of an adjustment to an estimate of an amount payable to a former collaborator.

Interest Expense. Interest expense for the nine-month period ended September 30, 2005 was $264,000 as compared to $307,000 for the nine-month period ended September 30, 2004, a decrease of $43,000, or 14%. The decrease resulted from lower outstanding debt obligations at September 30, 2005 as compared to September 30, 2004.

Net Loss. As a result of the foregoing, we incurred a net loss of $13,491,000 for the nine-month period ended September 30, 2005 as compared to a net loss of $13,126,000 for the nine-month period ended September 30, 2004.

Liquidity and Capital Resources

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

At September 30, 2005, our principal sources of liquidity consisted of cash, cash equivalents, and marketable securities of $42,898,000, excluding restricted long-term investments of $196,000. 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. However, 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 clinical trials, preclinical studies, laboratory supplies, consulting fees, and legal fees. To date, the source of our cash flows from operations has been payments received from our collaborators and liaisons. In general, our only source of cash flows from operations for the foreseeable future will be the up-front license payments, if any, payments for the achievement of milestones, if any, and funded research and development that we may receive under collaboration agreements. The timing of any new collaboration agreements and any payments under existing collaboration agreements cannot be easily predicted and may vary significantly from quarter to quarter.

Net cash used in operating activities was $9,544,000 for the nine-month period ended September 30, 2005 as compared to $7,585,000 for the nine-month period ended September 30, 2004. Cash used in operating activities during the nine-month period ended September 30, 2005 was primarily the result of our net loss for the period partially offset by non-cash charges including stock-based compensation, depreciation and non-cash interest expense. In addition, increases in operating cash resulted from changes in certain current assets and liabilities during the

nine-month period ended September 30, 2005, including the receipt of payments from our collaborators including, a $3,000,000 license fee from Genentech associated with our April 2005 discovery research agreement and $2,000,000 from Genentech for our research and development services under our Hedgehog agonist collaboration. Net cash used in operating activities during the nine-month period ended September 30, 2004 was primarily the result of our net loss for the period partially offset by non-cash charges

Table of Contents

including stock-based compensation, depreciation and non-cash interest expense. In addition, increases in operating cash as a result of changes in certain current assets and liabilities during the nine-month period ended September 30, 2004, including a $1,362,000 up-front payment received for a licensing agreement with Wyeth and a $2,000,000 maintenance fee payment received from Genentech, further offset our net loss.

We expect to continue to use cash in operations as we continue to develop our products in clinical trials and advance new products into preclinical development. In addition, in the future we may owe royalties and other contingent payments to our licensees based on the achievement of developmental milestones, product sales and specified other objectives.

Investing activities provided $7,202,000 of cash for the nine-month period ended September 30, 2005 as compared to $7,243,000 used in the nine-month period ended September 30, 2004. Cash provided by investing activities resulted principally from $9,470,000 in net investment sales offset by $2,268,000 in fixed asset purchases for the nine-month period ended September 30, 2005. For the nine-month period ended September 30, 2004, cash used in investing activities resulted principally from $6,201,000 in net investment purchases and $1,043,000 in fixed asset purchases.

Financing activities provided approximately $2,547,000 of cash for the nine-month period ended September 30, 2005, principally resulting from net proceeds of $1,681,000 from the issuance of debt for the purchase of fixed assets and proceeds of $866,000 received upon stock option exercises. Financing activities provided approximately $3,669,000 of cash for the nine-month period ended September 30, 2004 resulting primarily from the sale of $3,410,000 of our common stock, including $1,638,000 from the sale of 315,524 shares to Wyeth and $1,567,000 in proceeds received upon stock option exercises. In addition, proceeds from the issuance of debt for the purchase of fixed assets provided $592,000 for the nine-month period ended September 30, 2004. These increases were offset by $332,000 in repayments of obligations under capital leases.

Pursuant to our co-development arrangement with Genentech, we will forego U.S. development and drug approval milestones and royalty payments on potential future U.S. sales. We will now share equally in U.S. development costs and any future net profits and/or losses derived from sales in the U.S. of a therapeutic product candidate for the topical treatment of basal cell carcinoma. We expect to incur approximately $20,000,000 in development expenses through phase II clinical trials, of which $4,879,000 was paid through the third quarter of 2005 and an additional $819,000 has been accrued. Genentech filed an investigational new drug application with the FDA on March 31, 2005 in order to initiate human clinical investigation of the basal cell carcinoma product candidate. The basal cell carcinoma product candidate is currently being tested in a phase I clinical trial. Assuming the successful advancement of the basal cell carcinoma product candidate through phase I and phase II clinical trials, we expect that the phase II clinical trial will be completed in mid-2007. We expect to incur additional costs to complete phase III clinical trials and complete the regulatory approval process, assuming that Genentech and we successfully complete phase II clinical trials.

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

Effective January 7, 2005, we entered into an amendment with the Boston Private Bank & Trust Company to extend the drawdown date under which we can request periodic financings up to $2,250,000 for qualifying purchases of equipment and facility leasehold improvements through April 30, 2005. On March 23, 2005, we drew down the remaining balance under this agreement bringing the total amount financed to $2,250,000 and

41

Table of Contents

exercised our option to convert the outstanding balance into a 36-month term note that bears interest at a fixed rate of 7.36% for the repayment period. Under the terms of the note payable, we are required to make equal monthly payments of $62,500 plus any accrued interest beginning on May 1, 2005 extending through the 36-month term. The loan is collateralized by all of our property, plant and equipment assets, except for fixtures and those that are purchased after March 23, 2005 under purchase money arrangements with equipment lenders. As of September 30, 2005, we were in compliance with the sole covenant under this agreement. This 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 this agreement, the entire obligation becomes immediately due at the option of the Boston Private Bank & Trust Company.

On June 26, 2001, we received $2,000,000 from Becton Dickinson under a convertible subordinated note payable. The note is repayable at any time up to its maturity date of June 26, 2006 by us, at our discretion, in either cash or upon issuance to Becton Dickinson of shares of our common stock. The note bears interest at 7%. As of September 30, 2005, there was approximately $2,597,000, including approximately $597,000 in accrued interest, outstanding under the note.

Since August 2002, we have sublet 11,980 of the 17,600 square fee of our facility at 61 Moulton Street in Cambridge, Massachusetts. Under the terms of our sublease, as amended, we receive sublease payments which total $365,000 per year. In addition, we receive approximately $50,000 for facilities-related services and a pro-rata portion of the 61 Moulton Street facility overhead, including real estate taxes and utilities. In July 2005, our subtenant informed us that it would like to amend the terms of our sublease to reduce its sublease rate and that it would likely vacate the space in December 2005. Our lease obligation on our 61 Moulton Street facility extends to April 2007 and our lease obligation from October 2005 to April 2007 is approximately $750,000. Should our current subtenant vacate the 61 Moulton facility, as expected, we will seek to sublet all or part of the facility. There is no guarantee that we will be able to sublease the premises or on terms that are similar to our current sublease.

Contractual Obligations

In addition to our loan agreement with Boston Private Bank & Trust Company, we also have contractual obligations related to our facility lease, research services agreements, consulting agreements, and license agreements. The following table summarizes our contractual obligations due by the period indicated at September 30, 2005:

	(amounts in 000 s)(1)						
	Remainder of 2005	2006	2007	2008	2009	Thereafter	Total
Convertible subordinated long-term debt(2)	$	$ 2,805	$	$	$	$	$ 2,805
Debt obligations under note payable	1,095	853	798	254			3,000
Operating lease obligations	203	1,323	1,105	948	948	948	5,475
Outside service obligations(3)	662	163					825
Licensing obligations	99	146					245
Total future obligations(4)	$ 2,059	$ 5,290	$ 1,903	$ 1,202	$ 948	$ 948	$ 12,350

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

(2) Convertible subordinated debt is convertible into either shares of our common stock or cash at our option.

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

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

Table of Contents

We anticipate that existing capital resources at September 30, 2005, together with the payment of all contractually-defined payments under our collaborations and research programs with Genentech, Wyeth, P&G and the SMA Foundation, assuming these programs continue as planned, should enable us to maintain current and planned operations into the second half of 2007, including spending related to the co-development of our basal cell carcinoma product candidate under development with Genentech. We expect to incur substantial additional research and development and other costs, including costs related to preclinical studies and clinical trials for the foreseeable future. Our ability to continue funding planned operations beyond into the second half of 2007 is dependent upon the success of our collaborations, our ability to control our cash burn rate and our ability to raise additional funds through equity or debt financings, or from other sources of financing. Our ability to generate sufficient cash flows depends on a number of factors, including the ability of either us, or our collaborators, to obtain regulatory approval to market and commercialize products to treat indications in major commercial markets. We are seeking additional collaborative arrangements and also expect 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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of September 30, 2005.

Inflation

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

Forward-Looking Statements

This Quarterly Report on Form 10Q/A includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the forward-looking statements we make. These important factors include the risk factors set forth below under the caption Factors That May Affect Future Results. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this quarterly report.

Table of Contents

Factors That May Affect Future Results

RISKS RELATING TO OUR FINANCIAL RESULTS AND NEED FOR FINANCING

We have incurred substantial losses, we expect to continue to incur substantial losses and we may never 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, 2005, we had an accumulated deficit of approximately $678,690,000. Other than OP-1, which we and Stryker discovered under a former collaboration and Stryker has subsequently commercialized, we have not commercialized any products to date, either alone or with a third party collaborator. All of our product candidates are in early stages of development. If we are not able to commercialize any products, whether alone or with a collaborator, we will not achieve profitability. Even if our collaboration agreements provide funding for a portion of our research and development expenses for some of our programs, we expect to spend significant capital to fund our research and development programs for the foreseeable future. As a result, we will need to generate significant revenues in order to 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 Factors That May Affect Results . Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We will require additional financing, which may be difficult to obtain and may dilute our existing shareholder ownership interest in us.

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

- fund our portion of the U.S. development costs for a basal cell carcinoma drug candidate pursuant to our equal cost-sharing co-development arrangement with Genentech;
- support our research and development activities for our internal programs, including our program in cardiovascular disease and any unfunded portion of our small molecule discovery screening programs;
- expand our infrastructure; and
- fund our general and administrative costs and expenses.

We believe that our existing cash and working capital should be sufficient to fund our operations until mid-2007; however, our future capital requirements may vary from what we expect. There are factors that may affect our planned future capital requirements and accelerate our need for additional financing. These factors, many of which are outside our control, include the following:

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

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

the cost of additional facilities requirements;

our ability to establish and maintain collaborative arrangements;

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

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

the timing, receipt and amount of sales revenues and associated royalties to us, if any, from our product candidates in the market; and

Table of Contents

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

We expect to seek additional funding through public or private financings of debt or equity and may seek additional funding from additional strategic collaborators or additional foundations, such as the funding that we were awarded under our Spinal Muscular Atrophy Foundation research grant. However, the biotechnology market in general, and the market for our common stock, in particular, is highly volatile. Due to various factors, including market conditions and the status of our development pipeline, additional funding may not be available to us on acceptable terms, if at all. If we fail to obtain such additional financing on a timely basis, our ability to continue all of our research and development activities will be adversely affected.

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

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 prove to be incorrect. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements. For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Critical Accounting Policies and Estimates above.

RISKS RELATING TO OUR COLLABORATIONS

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

The success of our strategy for development and commercialization of product candidates depends upon our ability to form and maintain productive strategic collaborations. We currently have strategic collaborations with Genentech, Wyeth, P&G, and Ortho Biotech Products. Through the third quarter of 2005 and for the year ended December 31, 2004, $6.8 million and $3.1 million, or 83% and 85%, respectively, of our gross revenue was derived from licensing and research and development payments received from these collaborators. We expect to enter into additional collaborations in the future. Our existing and any future collaborations may not be scientifically or commercially successful.

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

Each of our collaborators has significant discretion in determining the efforts and resources that they will apply to the collaboration. The timing and amount of any future royalty, profit-sharing and milestone revenue that we may receive under such collaborative arrangements will depend on, among other things, such collaborator s efforts and allocation of resources.

Table of Contents

All of our strategic collaboration agreements are for fixed terms and are subject to termination under various circumstances, including in some cases, on short notice without cause. If any collaborator were to terminate an agreement, we may be required to undertake product development, manufacturing and commercialization and we may not have the funds or capability to do this, which could result in a discontinuation of such program.

Our 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 reach their potential could be limited if our collaborators decrease or fail to increase spending related to such product candidates.

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

As an integral part of our ongoing research and development efforts, we periodically review opportunities to establish new strategic collaborations for the development and commercialization of products in our development pipeline. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish additional strategic collaborations or other alternative arrangements. Even if we are successful in our efforts to establish a collaboration or agreement, the terms that we establish may not be favorable to us. Finally, any such strategic alliances or other arrangements may not result in the successful development and commercialization of products and associated revenue.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

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

Our product candidates face competition from existing and new technologies and products being developed by biotechnology, medical device and pharmaceutical companies, as well as universities and other research institutions. For example, research in the fields of regulatory signaling pathways and functional genomics, which includes our work with Genentech in the field of cancer, with Wyeth in the field of neurology, with Procter & Gamble in the field of hair growth regulation, is highly competitive. A number of entities are seeking to identify and patent randomly sequenced genes and gene fragments, typically without specific knowledge of the function that such genes or gene fragments perform. Our competitors may discover, characterize and develop important inducing molecules or genes in advance of us. We also face competition from these and other entities in gaining access to DNA samples used in our research and development projects.

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

For those programs that we have selected for internal development, we face competition from companies that are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. As a result, they may develop competing

products more rapidly and at a lower cost. For those programs that are subject to a collaboration agreement, competitors may discover, develop and commercialize products which render our products non-competitive or obsolete.

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

Table of Contents

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

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

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

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

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

Product liability claims, inherent in the process of researching and developing human health care products, could expose us to significant liabilities and prevent or interfere with the development or commercialization of our product candidates. Product liability claims would require us to spend significant time, money and other resources to defend such claims and could ultimately lead to our having to pay a significant damage award. Product liability insurance is expensive to procure for biopharmaceutical companies such as ours. Although we maintain product liability insurance coverage for the clinical trials of our products under development, it is possible that we will not be able to obtain additional product liability insurance on acceptable terms, if at all, and that our product liability insurance coverage will not prove to be adequate to protect us from all potential claims.

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

We highly depend upon our senior management and scientific staff. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of product development and other business objectives. Key members of our senior management team include Daniel R. Passeri, our president and chief executive officer and Dr. Lee L. Rubin, our senior vice president and chief scientific officer. Our executive officers, including these individuals, can terminate their employment with us at any time. The loss of the services of any of our executive officers may significantly delay or prevent the achievement of product research and development and other business objectives. We are not aware of any present intention of any of these individuals to leave our company. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to research, develop and successfully commercialize products in our areas of core competency. We do not maintain key man

life insurance on any of these executive officers.

Our ability to operate successfully will depend on our ability to attract and retain qualified personnel, consultants and advisors. We face intense competition for qualified individuals from numerous pharmaceutical

Table of Contents

and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

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

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

RISKS RELATING TO INTELLECTUAL PROPERTY

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

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

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

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal, scientific and factual questions. The standards which the United States Patent and Trademark Office uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. The long-term success of our enterprise depends in significant part on our ability to:

- obtain patents to protect our technologies and discoveries;
- protect trade secrets from disclosure to third-party competitors;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

Patents may not issue from any of the patent applications that we own or license. If patents do issue, the type and extent of patent claims issued to us may not be sufficiently broad to protect our technology from exploitation by our competitors. In addition, issued patents that we own or 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.

Table of Contents

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

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

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

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

- initiation of litigation or other proceedings against third parties to enforce our patent rights;
- initiation of litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our product candidates do not infringe the third parties patents;
- participation in interference or opposition proceedings to determine the priority of invention if our competitors file patent applications that claim technology also claimed by us;
- initiation of litigation by third parties claiming that our processes or product candidates or the intended use of our product candidates infringe their patent or other intellectual property rights; and
- initiation of litigation by us or third parties seeking to enforce contract rights relating to intellectual property which may be important to our business.

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

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

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

Table of Contents

RISKS RELATING TO CLINICAL AND REGULATORY MATTERS

We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates. If these clinical trials are not successful, or if we or our collaborators are not able to obtain the necessary regulatory approvals, we will not be able to commercialize our product candidates.

In order to obtain regulatory approval for the commercial sale of our product candidates, we and our collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective. We have limited experience in conducting clinical trials and expect to rely primarily on collaborative partners and contract research organizations for their performance and management of clinical trials of our product candidates.

Clinical development, including preclinical testing, is a long, expensive and uncertain process. Accordingly, preclinical testing and clinical trials, if any, of our product candidates under development may not be successful. We and our collaborators could experience delays in preclinical or clinical trials of any of our product candidates obtain unfavorable results in a development program, or fail to obtain regulatory approval for the commercialization of a product. Preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. The results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials. Furthermore, the timing and completion of clinical trials, if any, of our product candidates depend on, among other factors, the number of patients we will be required to enroll in the clinical trials and the rate at which those patients are enrolled.

Any increase in the required number of patients, decrease in recruitment rates or difficulties retaining study participants may result in increased costs, program delays or both. Also, our products under development may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use. Institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. Additionally, the failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials.

Failure of clinical trials can occur at any stage of testing. Any of these events would adversely affect our ability to market a product candidate.

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

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

The process of obtaining FDA and other required regulatory approvals is expensive. The time required for FDA and other approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. The process of obtaining FDA and other required regulatory approvals for many of our products under development is further complicated because some of these products use

non-traditional or novel materials in non-traditional or novel ways, and the regulatory officials have little precedent to follow. With respect to internal programs to date, we have limited experience in filing and prosecuting applications to obtain marketing approval.

Table of Contents

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

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

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

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

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

If there is a failure to comply with applicable regulatory requirements, we or our collaborator may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

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

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

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

risk of accidental contamination or injury caused by these materials.

Table of Contents

RISKS RELATING TO PRODUCT MANUFACTURING AND SALES

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

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

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

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

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

- we and our collaborators may not be able to initiate or continue clinical trials of products that are under development;
- we and our collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and
- we and our collaborators may not be able to meet commercial demands for any approved products.

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

We have no sales, marketing or product distribution experience. If we receive required regulatory approvals, we plan to rely primarily on sales, marketing and distribution arrangements with third parties, including our collaborative partners. For example, as part of our agreements with Genentech, Wyeth, Procter & Gamble and Ortho Biotech Products, we have granted our collaborators exclusive rights to distribute certain products resulting from such collaborations, if any are ever successfully developed. We may have to enter into additional marketing arrangements in the future and we may not be able to enter into these additional arrangements on

Table of Contents

terms which are favorable to us, if at all. In addition, we may have limited or no control over the sales, marketing and distribution activities of these third parties and sales through these third parties could be less profitable to us than direct sales. These third parties could sell competing products and may devote insufficient sales efforts to our products. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

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

- we may not be able to attract and build a significant and skilled marketing staff or sales force;
- the cost of establishing a marketing staff or sales force may not be justifiable in light of the revenues generated by any particular product; and
- our direct sales and marketing efforts may not be successful.

RISKS RELATED TO OUR COMMON STOCK

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

The trading price of our common stock has been volatile and may continue to be volatile in the future. For example, our stock has traded as high as $6.59 and as low as $2.46 per share for the period January 1, 2004 through September 30, 2005. 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 market place 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;
- deviations in our operating results from the estimates of securities analysts;

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

any intellectual property lawsuits involving us;

sales of large blocks of our common stock;

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

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

FDA or international regulatory actions; and

general market conditions.

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

Table of Contents

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. As of September 30, 2005, we had outstanding approximately 48.3 million shares of common stock. Substantially all of these shares may also be resold in the public market at any time. In addition, we have a significant number of shares that are subject to outstanding options and warrants. The exercise of these options and warrants and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

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: March 31, 2006

By: /s/ MICHAEL P. GRAY

Michael P. Gray

Vice President of Finance and Chief Financial Officer

(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act.
32.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b)/15d-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)/15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.

Confidential treatment has been requested as to certain portions of this exhibit.