
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2006

or

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

For the transition period from _____ to _____

Commission File Number: 000-26658

PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3148201

(IRS Employer Identification Number)

995 E. Arques Avenue

Sunnyvale, California 94085-4521

(Address of principal executive offices including zip code)

(408) 774-0330

(Registrant's telephone number, including area code)

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 reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

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

As of May 5, 2006, there were 19,938,013 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

This quarterly report on Form 10-Q consists of 30 pages of which this is page 1. The Exhibits Index page immediately follows page 30.

PHARMACYCLICS, INC.
Form 10-Q
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

PHARMACYCLICS, INC.
(a development stage enterprise)
CONDENSED BALANCE SHEETS
(unaudited; in thousands)

	March 31,		June 30,
	2006		2005
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 20,805	\$	27,666
Marketable securities	28,399		44,233
Prepaid expenses and other current assets	1,372		1,254
Total current assets	50,576		73,153
Property and equipment, net	800		884
Other assets	527		527
	<u>\$ 51,903</u>	<u>\$</u>	<u>74,564</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 2,206	\$	3,115
Accrued liabilities	1,647		1,358
Total current liabilities	3,853		4,473
Deferred rent	82		97
Total liabilities	3,935		4,570
Stockholders' equity:			
Common stock	2		2
Additional paid-in capital	322,324		317,063
Accumulated other comprehensive loss	(114)		(293)
Deficit accumulated during development stage.....	(274,244)		(246,778)
Total stockholders' equity	47,968		69,994
	<u>\$ 51,903</u>	<u>\$</u>	<u>74,564</u>

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

PHARMACYCLICS, INC.
(a development stage enterprise)
CONDENSED STATEMENTS OF OPERATIONS
(unaudited; in thousands, except per share data)

	Three Months Ended March 31,		Nine Months Ended March 31,		Period From Inception (April 19, 1991) through March 31, 2006
	2006	2005	2006	2005	
Revenues:					
License and milestone revenues	\$ --	\$ --	\$ --	\$ --	\$ 7,855
Contract and grant revenues	156	--	156	--	6,003
Total revenues	<u>156</u>	<u>--</u>	<u>156</u>	<u>--</u>	<u>13,858</u>
Operating expenses:					
Research and development*	5,313	6,513	19,315	18,899	266,205
General and administrative*	<u>2,685</u>	<u>1,912</u>	<u>9,756</u>	<u>5,492</u>	<u>59,243</u>
Total operating expenses	<u>7,998</u>	<u>8,425</u>	<u>29,071</u>	<u>24,391</u>	<u>325,448</u>
Loss from operations	(7,842)	(8,425)	(28,915)	(24,391)	(311,590)
Interest and other income, net	<u>467</u>	<u>469</u>	<u>1,449</u>	<u>1,345</u>	<u>37,346</u>
Net loss	\$ <u>(7,375)</u>	\$ <u>(7,956)</u>	\$ <u>(27,466)</u>	\$ <u>(23,046)</u>	\$ <u>(274,244)</u>
Basic and diluted net loss per share	\$ <u>(0.37)</u>	\$ <u>(0.40)</u>	\$ <u>(1.38)</u>	\$ <u>(1.17)</u>	
Shares used to compute basic and diluted net loss per share	<u>19,904</u>	<u>19,743</u>	<u>19,871</u>	<u>19,700</u>	
* Includes non-cash share-based compensation of the following:					
Research and development	\$ 559	\$ 9	\$ 2,306	\$ 19	\$ 2,607
General and administrative	814	--	2,575	--	3,191
Total non-cash share-based compensation	<u>\$ 1,373</u>	<u>\$ 9</u>	<u>\$ 4,881</u>	<u>\$ 19</u>	<u>\$ 5,798</u>

The accompanying notes are an integral part of these condensed financial statements

PHARMACYCLICS, INC.
(a development stage enterprise)
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited; in thousands)

	Nine Months Ended March 31,		Period From Inception (April 19, 1991) through March 31,
	2006	2005	2006
Cash flows from operating activities:			
Net loss	\$ (27,466)	\$ (23,046)	\$ (274,244)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	461	552	14,071
Non-cash share-based compensation expense	4,881	20	5,798
Gain on sale of marketable securities	--	--	58
Write-down of fixed assets	--	--	381
Changes in assets and liabilities:			
Prepaid expenses and other assets	(118)	(39)	(1,899)
Accounts payable	(909)	(154)	2,206
Accrued liabilities	289	142	1,647
Deferred rent	(15)	14	82
Net cash used in operating activities	<u>(22,877)</u>	<u>(22,511)</u>	<u>(251,900)</u>
Cash flows from investing activities:			
Purchase of property and equipment	(377)	(128)	(11,483)
Proceeds from sale of property and equipment	--	--	112
Purchases of marketable securities	(3,435)	(11,185)	(500,436)
Proceeds from maturities and sales of marketable securities	<u>19,448</u>	<u>49,666</u>	<u>471,865</u>
Net cash provided by (used in) investing activities	<u>15,636</u>	<u>38,353</u>	<u>(39,942)</u>
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs	380	469	293,014
Proceeds from notes payable	--	--	3,000
Issuance of convertible preferred stock, net of issuance costs	--	--	20,514
Payments under capital lease obligations	<u>--</u>	<u>--</u>	<u>(3,881)</u>
Net cash provided by financing activities	<u>380</u>	<u>469</u>	<u>312,647</u>
Increase (decrease) in cash and cash equivalents	(6,861)	16,311	20,805
Cash and cash equivalents at beginning of period	<u>27,666</u>	<u>14,007</u>	<u>--</u>
Cash and cash equivalents at end of period	<u>\$ 20,805</u>	<u>\$ 30,318</u>	<u>\$ 20,805</u>

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

PHARMACYCLICS, INC.
(a development stage enterprise)
NOTES TO CONDENSED FINANCIAL STATEMENTS

Note 1 - Summary of Significant Accounting Principles

Basis of Presentation

The accompanying interim condensed financial statements have been prepared by Pharmacyclics, Inc. (the company or Pharmacyclics), without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair presentation of its financial position, results of operations and cash flows in accordance with accounting principles generally accepted in the United States. The consolidated balance sheet at June 30, 2005 is derived from the audited consolidated balance sheet at that date which is not presented herein.

In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of results of operations, financial position and cash flows. These condensed financial statements should be read in conjunction with the financial statements included in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2005. Operating results for interim periods are not necessarily indicative of operating results for an entire fiscal year.

The preparation of 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 the disclosure of contingent amounts in the company's financial statements and the accompanying notes. Actual results could differ from those estimates.

Reclassifications

Certain auction rate securities have been reclassified from cash equivalents to marketable securities. Auction rate securities are variable rate bonds tied to short-term interest rates with maturities on the face of the securities in excess of ninety days. Auction rate securities have interest rate resets through a modified Dutch auction, at predetermined short-term intervals, usually every seven, twenty-eight or thirty-five days. They trade at par and are callable at par on any interest payment date at the option of the issuer. Interest paid during a given period is based upon the interest rate determined during the prior auction.

Although these securities are issued and rated as long-term bonds, they are priced and traded as marketable securities because of the liquidity provided through the interest rate reset. The company had classified these instruments as cash equivalents if the period between interest rate resets was ninety days or less, which was based on the company's ability to either liquidate our holdings or roll their investment over to the next reset period.

Based upon the company's re-evaluation of these securities, the company reclassified its auction rate securities in fiscal 2005, previously classified as cash equivalents, to marketable securities. The accompanying statements of cash flows have been revised to reflect the purchase and sale of auction rate securities during the periods presented. This revision resulted in an increase in purchases of marketable securities and sales of marketable securities of \$5,000,000 and \$33,425,000, respectively, in the nine months ended March 31, 2005.

Share-Based Compensation

In December 2004, the FASB issued Statement of Financial Accounting Standards 123R ("SFAS 123R"), *Share-Based Payment - An Amendment of FASB Statements No. 123 and 95*. This revised standard addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. Under the new standard, companies are no longer able to account for share-based compensation transactions using the intrinsic-value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). Instead, companies are required to account for such transactions using a fair-value method and recognize the expense in the statement of operations.

The company adopted SFAS 123R effective beginning July 1, 2005 using the modified prospective application transition method. The modified prospective application transition method requires that companies recognize compensation expense on new share-based payment awards and existing share-based payment awards that are modified, repurchased, or cancelled after the effective date. Additionally, compensation cost of the portion of awards of which the requisite service has not been rendered that are outstanding as of the July 1, 2005 shall be recognized as the requisite service is rendered. The effect of recording share-based compensation was as follows:

	Three Months Ended March 31, 2006	Nine Months Ended March 31, 2006
Net effect on net loss	\$ (1,373,000)	\$ (4,881,000)
Net effect on basic and diluted net loss per share	\$ (0.07)	\$ (0.25)

The weighted average estimated grant date fair value, as defined by SFAS 123, for options granted under the company's stock option plans was \$5.07 per share during the first nine months of fiscal 2006 and the weighted average estimated grant date fair value of purchase awards under the company's employee stock purchase plan was \$3.30 per share during the first nine months of fiscal 2006.

If the company had applied the fair value recognition provision of SFAS No. 123R in the three and nine month periods ended March 31, 2005, the weighted average estimated grant date fair value for options granted under the company's stock option plans would have been \$6.87 per share and the weighted average estimated grant date fair value of purchase awards under the company's employee stock purchase plan would have been \$3.32 per share. The following table illustrates the effect on net loss per common share if the company had applied the fair value recognition provisions of SFAS No. 123R in three and nine months ended March 31, 2005 to share-based employee compensation:

	Three Months Ended March 31, 2005	Nine Months Ended March 31, 2005
Net loss, as reported	\$ (7,956,000)	\$ (23,046,000)
Employee share-based compensation using the fair value based method	\$ (2,023,000)	\$ (6,280,000)
Pro forma net loss	<u>\$ (9,979,000)</u>	<u>\$ (29,326,000)</u>
Basic and diluted net loss per share, as reported	<u>\$ (0.40)</u>	<u>\$ (1.17)</u>
Pro forma basic and diluted net loss per share	<u>\$ (0.51)</u>	<u>\$ (1.49)</u>

The estimated grant date fair values were calculated using the Black-Scholes valuation model and the following assumptions:

	Nine Months Ended March 31, 2006	2005
Stock option plans:		
Expected dividend yield	0 %	0 %
Expected stock price volatility	71 %	83 %
Risk free interest rate	4.17 %	3.69 %
Expected life (years)	4.98	5.06
Employee stock purchase plan:		
Expected dividend yield	0 %	0 %
Expected stock price volatility	54 %	77 %
Risk free interest rate	4.42 %	1.90 %
Expected life (years)	2.00	2.00

As of March 31, 2006, \$6,130,000 of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of 1.18 years.

There were no capitalized share-based compensation costs at March 31, 2006.

Note 2 - Basic and Diluted Net Loss Per Share

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential common stock if their effect is antidilutive. Potential common shares consist of the incremental common shares issuable upon the exercise of stock options (using the treasury stock method). Options to purchase 4,582,118 and 4,145,148 shares of common stock were outstanding at March 31, 2006 and 2005, respectively, and were excluded from the calculation of loss per share as they were antidilutive.

Note 3 — Share-Based Compensation Plans:

2004 Equity Incentive Award Plan. In December 2004, stockholders approved the 2004 Equity Incentive Award Plan (the “2004 Plan”) as a replacement for both the company’s 1995 Stock Option Plan (the “1995 Plan”) and the 1995 Non-Employee Directors Stock Option Plan (the “Directors Plan”). The adoption of the 2004 Plan included an increase of 600,000 in the number of shares available for issuance over the remaining shares available for issuance under the 1995 Plan and Directors Plan. In December 2005, the stockholders approved an increase in the total number of shares of common stock authorized for issuance under the 2004 Plan by an additional 1,000,000 shares. The 2004 Plan provides for the issuance of various types of equity awards, such as incentive stock options, nonstatutory stock options stock, restricted stock, stock appreciation rights and performance shares. The exercise price of all stock options granted under the 2004 Plan may not be less than the fair market value of the company’s common stock on the date of grant and no stock option will be exercisable more than ten years after the date it is granted. Stock options for employees and consultants typically vest over four years. Non-employee Directors receive annual, automatic, non-discretionary grants of nonqualified stock options. Each new non-employee Director receives an option to purchase 10,000 shares as of the date he or she first becomes a Director. This option grant vests in equal annual installments over five years. In addition, on the date of each annual meeting, each individual re-elected as a non-employee Director will receive an automatic option grant to purchase an additional 7,500 shares of common stock, provided such individual has served as a Director for at least six months prior to the date of grant. This option grant vests in equal monthly installments over twelve months following the date of grant.

1995 Stock Option Plan. The company's 1995 Plan was adopted by the Board of Directors in August 1995. Options issued under the 1995 Plan can, at the discretion of the plan administrator, be either incentive stock options or nonqualified stock options. In December 2003, the stockholders approved amendments to the 1995 Plan (i) such that the exercise price of all stock options must be at least equal to the fair value of Pharmacyclics’ common stock on the date of grant and (ii) that increased the total number of authorized shares under the plan to 5,345,724 shares of common stock. Generally, shares subject to options under the 1995 Plan vest over a four or five year period and are exercisable for a period of ten years. In December 2004, the remaining shares available for future grant under the 1995 Plan were transferred to the 2004 Plan. Additionally, if options granted under the 1995 Plan expire or otherwise terminate without being exercised, the shares of common stock reserved for such options again become available for future grant under the 2004 Plan.

1995 Non-Employee Directors Stock Option Plan. The company's Directors Plan was adopted by the Board of Directors on August 2, 1995 and provides for issuance of common stock to non-employee Directors pursuant to a predetermined formula. The exercise price of options granted under the Directors Plan must be at least equal to the fair value of Pharmacyclics’ common stock on the date of grant. Each individual first elected or appointed as a non-employee Board member will automatically be granted, on the date of such election or appointment, a non-statutory option to purchase 10,000 shares of common stock vesting over five years. In addition, on the date of each annual stockholders’ meeting each individual who is to continue to serve as a non-employee Board member after that annual meeting and has been a member of the Board for at least six months will automatically be granted a non-statutory option to purchase 5,000 shares of common stock. A total of 271,667 shares of common stock have been reserved for issuance under the Directors Plan. In December 2004, the remaining shares available for future grant under the Directors Plan were transferred to the 2004 Plan. Additionally, if options granted under the Directors Plan expire or otherwise terminate without being exercised, the shares of common stock reserved for such options again become available for future grant under the 2004 Plan.

The company settles stock option exercises with newly issued common shares.

The following table summarizes the company's stock option activity for the nine months ended March 31, 2006:

	Shares Available for Grant	Options Outstanding	
		Number	Weighted Average Exercise Price
Balance at June 30, 2005	760,296	4,785,838	\$ 15.40
Additional Authorized	1,000,000		
Options Granted	(134,383)	134,383	8.33
Options Exercised	--	(187,446)	7.07
Options Forfeited	60,404	(60,404)	8.70
Options Cancelled	90,253	(90,253)	21.19
Balance at March 31, 2006	<u>1,776,570</u>	<u>4,582,118</u>	15.51

The total intrinsic value of stock options exercised during the nine month periods ended March 31, 2006 and 2005 was \$372,000 and \$350,000, respectively. No income tax benefits were realized by the company in the three and nine month periods ended March 31, 2006 and 2005.

A summary of outstanding and vested stock options as of March 31, 2006 is as follows:

Range of Exercise Prices	Options Outstanding			Options Vested		
	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$3.22 - \$ 4.25	404,107	\$ 4.10	\$ 201,864	376,490	\$ 4.10	\$ 187,572
\$4.47 - \$ 4.47	553,092	4.47	71,902	373,681	4.47	48,579
\$5.16 - \$ 7.43	634,299	7.03	--	571,012	7.14	--
\$7.76 - \$ 7.76	677,485	7.76	--	108,371	7.76	--
\$8.20 - \$ 11.21	499,870	10.48	--	218,690	10.62	--
\$12.23 - \$ 18.07	655,003	17.01	--	611,686	17.12	--
\$19.25 - \$ 27.51	717,417	25.00	--	702,743	24.96	--
\$28.13 - \$ 78.13	440,845	51.92	--	438,798	52.01	--
	<u>4,582,118</u>		<u>\$ 273,766</u>	<u>3,401,471</u>		<u>\$ 236,151</u>

As of March 31, 2006, the weighted average remaining contractual term of options outstanding and options vested was 6.03 and 5.19 years, respectively.

Employee Stock Purchase Plan. The company adopted an Employee Stock Purchase Plan (the "Purchase Plan") in August 1995. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of the company's common stock under the Purchase Plan. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. There were 43,656 and 44,598 shares issued from the plan in the nine month periods ended March 31, 2006 and 2005, respectively. Shares available for future purchase under the Purchase Plan are 158,333 at March 31, 2006.

Note 4 - Comprehensive Loss

Comprehensive loss includes unrealized gains (losses) on marketable securities that are excluded from the results of operations.

The company's comprehensive losses were as follows:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2006	2005	2006	2005
Net loss	\$ (7,375,000)	\$ (7,956,000)	\$ (27,466,000)	\$ (23,046,000)
Change in net unrealized losses on available-for-sale securities	95,000	(134,000)	179,000	(176,000)
Comprehensive loss	<u>\$ (7,280,000)</u>	<u>\$ (8,090,000)</u>	<u>\$ (27,287,000)</u>	<u>\$ (23,222,000)</u>

Note 5 – Recent Accounting Pronouncements

In June 2005, the FASB issued Statement of Financial Accounting Standard No. 154, *Accounting Changes and Error Corrections*, ("SFAS 154"). SFAS 154 replaces Accounting Principle Bulletin No. 20 ("APB 20"), and Statement of Financial Accounting Standard No. 3, *Reporting Accounting Changes in Interim Financial Statements* ("SFAS 3"), and applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of change a cumulative effect of changing to the new accounting principle, whereas SFAS 154 requires retrospective application to prior periods' financial statements of a voluntary change in accounting principle unless it is impracticable. SFAS 154 enhances the consistency of financial information between periods. SFAS 154 is effective for fiscal years beginning after December 15, 2005. Our adoption of SFAS 154 is not expected to have a material impact on our results of operations or financial position.

Note 6 – Subsequent Event

In April 2006, the company acquired multiple small molecule drug candidates for the treatment of cancer and other diseases from Celera Genomics, an Applera Corporation business. Pursuant to an Assignment Agreement, the company acquired Celera technology and intellectual property relating to drugs that target histone deacetylase (HDAC) enzymes, selective HDAC enzymes, angiogenesis molecules and B cell tyrosine kinases involved in immune function. Under the terms of the agreement, the company will make a cash payment of \$2,000,000 on or before May 8, 2006 and an equity payment of between five hundred thousand and one million shares of the company's common stock, depending on the company's stock price during a specified period. If these programs meet certain developmental stage milestone events and result in drugs that are approved and commercialized in key geographical markets, the company will make future milestone payments to Celera of up to \$144 million. In addition, Celera will be entitled to royalty payments in the mid- to high single digits based on annual sales of any drugs commercialized from the three programs.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our interim financial statements and the related notes appearing at the beginning of this report. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended June 30, 2005 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 12, 2005.

The following discussion contains forward-looking statements that involve risks and uncertainties. These statements relate to future events, such as our future clinical and product development, financial performance and regulatory review of our product candidates. Our actual results could differ materially from any future performance suggested in this report as a result of various factors, including those discussed in "Factors That May Affect Future Operating Results" and elsewhere in this report, in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2005 and in our other Securities and Exchange Commission reports and filings. All forward-looking statements are based on information currently available to Pharmacyclics; and we assume no obligation to update such forward-looking statements. Stockholders are cautioned not to place undue reliance on such statements.

Overview

Pharmacyclics is a pharmaceutical company focused on the development of products that improve existing therapeutic approaches to cancer, atherosclerosis and other diseases. To date, substantially all of our resources have been dedicated to the research and development of our products, and we have not generated any commercial revenues from the sale of our products. We do not expect to generate any product revenues until we receive the necessary regulatory and marketing approvals and launch one of our products, if at all. In oncology, we are developing Xcytrin[®] (motexafin gadolinium) Injection and several compounds we acquired from Celera Genomics in April 2006. Our cardiology compound under development is Antrin[®] (motexafin lutetium) Angiophototherapy.

Xcytrin, our lead product candidate, is an anti-cancer drug being evaluated in various clinical trials. In December 2005, we announced the top line results of our pivotal Phase 3 clinical study of Xcytrin for the potential treatment of non-small cell lung cancer (NSCLC) patients with brain metastases. Although patients receiving Xcytrin had a longer time to neurologic progression, the study's primary endpoint, the difference compared to patients in the control arm did not reach statistical significance. This randomized controlled study, known as the **SMART** (Study of Neurologic Progression with **M**otexafin **G**adolinium **A**nd **R**adiation **T**herapy) trial enrolled 554 patients and was designed to compare the safety and efficacy of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin. The primary endpoint for the study was time to neurologic progression (TNP) as determined by a blinded events review committee.

In the intent-to-treat analysis, the median TNP was 15.4 months for patients receiving WBRT plus Xcytrin compared to 10.0 months for patients treated with WBRT alone ($P=0.122$, hazard ratio=0.78). Substantial differences in patient characteristics and outcomes were observed for the 348 patients enrolled in North America (63 percent of all patients enrolled in the study) compared to the other regions. In North America, the median TNP for WBRT plus Xcytrin treatment was 24.2 months compared to 8.8 months for WBRT alone ($P=0.004$, hazard ratio=0.53). By contrast, for regions outside of North America, there was no significant difference in TNP between treatment arms. Xcytrin was well tolerated in the study. The most common drug related grade 3 and 4 adverse events were hypertension (4%), elevated liver enzymes (3%) and fatigue (3%), all of which were reversible. We believe the reasons for the regional differences in treatment benefit may be related to the time interval between diagnosis of brain metastases and initiation of WBRT. In North America, most patients (79%) received WBRT within three weeks of their diagnosis of brain metastases. In certain European centers, there was substantial delay in the initiation of WBRT either due to use of chemotherapy as the initial therapy for brain metastases, or clinical practice patterns resulting in delays in access to radiation therapy. We believe that the clinical data indicate Xcytrin benefited patients that had prompt treatment with WBRT, regardless of region, and this benefit was progressively diminished by delay in initiation of radiation. Based on our ongoing review of the data from the SMART trial, we plan to submit a New Drug Application (NDA) to the FDA for the potential treatment of NSCLC patients with brain metastases.

Our strategy is to continue to evaluate Xcytrin for the treatment of a diverse range of cancer types and in various clinical situations including Xcytrin as a single agent and in combination with chemotherapy and/or radiation therapy. We are conducting Phase 2 clinical trials with Xcytrin used alone to treat recurrent metastatic lung cancer and to treat hematologic cancers such as lymphomas and chronic lymphocytic leukemia. We also are conducting Phase 2 clinical trials with Xcytrin in combination with stereotactic radiosurgery for the treatment of brain metastases, and in combination with chemotherapy for recurrent metastatic lung cancer.

We acquired the following drug candidates from Celera:

- A drug candidate that inhibits histone deacetylase (HDAC) enzymes that is in a Phase 1 clinical trial for the treatment of refractory solid tumors.
- A first-in-class HDAC-8 selective inhibitor in preclinical development for the potential treatment of cancer.
- A first-in-class Factor VIIa inhibitor targeting a tumor signaling pathway involved in angiogenesis, tumor cell growth and metastases.
- B-cell-associated tyrosine kinase inhibitors.

We also completed a Phase 1 clinical trial with Antrin Angiophototherapy for the treatment of coronary artery disease in patients receiving balloon angioplasty and stents. This study was primarily designed to evaluate the safety of various doses of drug and light. Results of this trial were published in the September 2003 issue of the journal *Circulation*. Seventy-nine patients were treated on this protocol, which demonstrated the safety and feasibility of Antrin Angiophototherapy and determined optimum doses of drug and light for future trials. No major treatment-related angiographic or biochemical adverse effects or abnormalities were observed and no dose-limiting toxicities were noted. The most frequently reported side effects were mild, transient rash and reversible mild tingling in the hands and feet, some of which lasted days to weeks, but did not require clinical intervention. Currently, we do not plan to conduct further clinical trials with Antrin unless we are able to enter into a corporate partnership arrangement for its continued commercial development.

We have incurred significant operating losses since our inception in 1991, and as of March 31, 2006, had an accumulated deficit of approximately \$274.2 million. The process of developing and commercializing our products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements as well as regulatory and marketing approvals. These activities, together with our general and administrative expenses, are expected to result in significant operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, and obtain required regulatory clearances and successfully manufacture and market our products.

We are subject to risks common to pharmaceutical companies developing products, including risks inherent in our research, development and commercialization efforts, preclinical testing, clinical trials, uncertainty of regulatory and marketing approvals, uncertainty of market acceptance of our products, history of and expectation of future operating losses, reliance on collaborative partners, enforcement of patent and proprietary rights, and the need for future capital. In order for a product to be commercialized, we must conduct preclinical tests and clinical trials, demonstrate efficacy and safety of our product candidates to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, obtain market acceptance and, in many cases, obtain adequate coverage of and reimbursement for our products from government and private insurers. We cannot provide assurance that we will generate revenues or achieve and sustain profitability in the future.

Results of Operations

Revenues

	Three Months ended			Percent change	Nine Months ended			Percent change
	March 31,		March 31,					
	2006	2005	2006		2005			
Contract and grant revenues	\$ 156,000	\$ --	--	\$ 156,000	\$ --	--		

The increase in contract and grant revenues for the three and nine months ended March 31, 2006 was the result of a federal grant awarded by the National Institutes of Health (NIH).

Research and Development

	Three Months ended			Nine Months ended		
	March 31,		Percent	March 31,		Percent
	2006	2005	change	2006	2005	change
Research and development expenses	\$ 5,313,000	\$ 6,513,000	(18)%	\$ 19,315,000	\$ 18,899,000	2%

The decrease of 18% or \$1,200,000 in research and development expenses for the three months ended March 31, 2006 as compared to the three months ended March 31, 2005 was primarily due to the decrease in third party clinical trial and enrollment costs (\$1,542,000) due to the completion of the company's SMART trial. This decrease was partially offset by an increase in share-based compensation expense (\$550,000) due to the company's adoption of SFAS 123R in fiscal 2006.

The increase of 2% or \$416K in research and development expenses for the nine months ended March 31, 2006 as compared to the nine months ended March 31, 2005 was primarily due an increase in share-based compensation expense (\$2,287,000) due to the adoption of SFAS 123R and an increase in salary and related expenses (\$475,000) as the company increased headcount, partially offset by decreases in third party clinical trial and enrollment expenses (\$2,303,000) due to the completion of the SMART trial.

We expect research and development expenses to increase in our fourth quarter of fiscal 2006 due to the purchase of a drug substance intermediate.

Research and development costs are identified as either directly attributed to one of our research and development programs or as an indirect cost, with only direct costs being tracked by specific program. Direct costs consist of personnel costs directly associated with a program, preclinical study costs, clinical trial costs, and related clinical drug and device development and manufacturing costs, drug formulation costs, contract services and other research expenditures. Indirect costs consist of personnel costs not directly associated with a program, overhead and facility costs and other support service expenses. The following table summarizes our principal product development initiatives, including the related stages of development for each product, the direct costs attributable to each product and total indirect costs for each respective period. The information in the column labeled "Estimated Completion of Phase" is only our estimate of the timing of completion of the current in-process development phase. The actual timing of completion of those phases could differ materially from the estimates provided in the table. For a discussion of the risks and uncertainties associated with the timing and cost of completing a product development phase, see our "Factors That May Affect Future Operating Results" section below.

Prior to fiscal 1999, we did not track our research and development expenses by specific program and for this reason we cannot accurately estimate our total historical costs on a specific program basis. Direct costs by program and indirect costs are as follows:

Product	Description	Phase of Development	Estimated Completion of Phase	Related R&D Expenses Three Months ended		Related R&D Expenses Nine Months ended	
				March 31,		March 31,	
				2006	2005	2006	2005
XCYTRIN	Cancer	Several Phase 1 trials	Unknown	\$ 3,195,000	\$ 4,310,000	\$ 12,429,000	\$ 12,298,000
		Several Phase 2 trials	Unknown				
		Phase 3	Fiscal 2006				
ANTRIN	Coronary artery disease	Phase 1	Completed	145,000	329,000	566,000	572,000
Total direct costs.....				3,340,000	4,639,000	12,995,000	12,870,000
Indirect costs.....				1,973,000	1,874,000	6,320,000	6,029,000
Total research and development expenses.....				\$ 5,313,000	\$ 6,513,000	\$ 19,315,000	\$ 18,899,000

General and Administrative

	Three Months ended			Nine Months ended		
	March 31,		Percent change	March 31,		Percent change
	2006	2005		2006	2005	
General and administrative expenses	\$ 2,685,000	\$ 1,912,000	40%	\$ 9,756,000	\$ 5,492,000	78%

The increase of 40% or \$773,000 in general and administrative expenses for the three months ended March 31, 2006 as compared to the three months ended March 31, 2005 was primarily due to an increase in share-based compensation expense (\$814,000).

The increase of 78% or \$4,264,000 in general and administrative expenses for the nine months ended March 31, 2006 as compared to the nine months ended March 31, 2005, was primarily due to the increase in share-based compensation (\$2,575,000), salary and related expenses (\$891,000) and commercialization expenses (\$534,000) in anticipation of the company's potential commercialization efforts for its Xcytrin product.

We expect our fourth quarter of fiscal 2006 general and administrative expenses to approximate the amount incurred in our fiscal third quarter.

Interest and Other, Net

	Three Months ended			Nine Months ended		
	March 31,		Percent change	March 31,		Percent change
	2006	2005		2006	2005	
Interest and other, net	\$ 467,000	\$ 469,000	<1%	\$ 1,449,000	\$ 1,345,000	8%

The change in both periods was due to decreases in our cash, cash equivalent and marketable security balances, offset by higher interest rates earned on such balances. Our cash and marketable securities consist primarily of fixed rate instruments.

Liquidity and Capital Resources

Our principal sources of working capital have been private and public equity financings and proceeds from collaborative research and development agreements, as well as interest income.

As of March 31, 2006, we had approximately \$49,204,000 in cash, cash equivalents and marketable securities. Net cash used in operating activities of \$22,877,000 during the nine months ended March 31, 2006, resulted primarily from our net loss, net of depreciation and amortization, stock compensation expense and a decrease in accounts payable. Net cash used in operating activities of \$22,511,000 during the nine months ended March 31, 2005, resulted primarily from our net loss, net of depreciation and amortization

Net cash provided by investing activities of \$15,636,000 and \$38,353,000 in the nine months ended March 31, 2006 and 2005, respectively, consisted primarily of maturities and sales of marketable securities, net of purchases of marketable securities.

Net cash provided by financing activities of \$380,000 and \$469,000 in the nine months ended March 31, 2006 and 2005, respectively, consisted primarily of proceeds the issuance of shares from the company's stock plans.

In February 2004, we filed a registration statement on Form S-3 to offer and sell, from time to time, equity, debt securities and warrants in one or more offerings up to a total dollar amount of \$100 million. In April 2004, we sold 3,200,000 shares of common stock at a price of \$13.00 per share in an underwritten public offering pursuant to this registration statement. We received approximately \$39,350,000 in net proceeds from the issuance of the 3,200,000 shares. We may seek to raise funds through additional public offerings in the future but cannot guarantee that such efforts will be successful.

In April 2006, the company acquired multiple small molecule drug candidates for the treatment of cancer and other diseases from Celera Genomics, an Applera Corporation business. Pursuant to an Assignment Agreement, the company acquired Celera technology and intellectual property relating to drugs that target histone deacetylase (HDAC) enzymes, selective HDAC enzymes, angiogenesis molecules and B cell tyrosine kinases involved in immune function. Under the terms of the agreement, the company will make a cash payment of \$2,000,000 on or before May 8, 2006 and an equity payment of between five hundred thousand and one million shares of the company's common stock, depending on the company's stock price during a specified period. If these programs meet certain developmental stage milestone events and result in drugs that are approved and commercialized in key geographical markets, the company will make future milestone payments to Celera of up to \$144 million. In addition, Celera will be entitled to royalty payments in the mid- to high single digits based on annual sales of any drugs commercialized from the three programs.

We lease our facility under a non-cancelable operating lease that expires in fiscal 2008. Future commitments as of March 31, 2006 are as follows:

	Operating Lease Commitments	Purchase Commitments(1)
Remaining 3 months of fiscal 2006	\$ 309,000	\$ 2,164,000
Fiscal 2007	1,220,000	--
Fiscal 2008	610,000	--
Total	<u>\$ 2,139,000</u>	<u>\$ 2,164,000</u>

(1) Represents a purchase commitment for a drug substance intermediate.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We expect research and development expenses, as a result of on-going and future clinical trials, to consume a large portion of our existing cash resources. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will need to raise substantial additional capital to fund our operations in the future. We expect to finance our future cash needs through public or private financings, collaborative relationships (partnerships with other drug manufacturers) or other arrangements to complete commercialization. Our actual capital requirements will depend on many factors, including the following:

- the progress and success of clinical trials of our product candidates;
- the costs and timing of obtaining regulatory approvals;
- our ability to establish and the scope of any new collaborations; and
- the timing and scope of commercialization expenses for Xcytrin.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The factors described above will impact our future capital requirements and the adequacy of our available funds. We will be required to raise additional funds and we cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations. See "Factors That May Affect Future Operating Results — We will need additional financing and we may have difficulty raising needed capital in the future."

Other Financial Arrangements

As of March 31, 2006, we had no off-balance sheet arrangements that are reasonably likely to have a future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies, Estimates and Judgments

This discussion and analysis of financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results, however, may differ significantly from these estimates under different assumptions or conditions.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Revenue Recognition

Revenues are recognized when persuasive evidence of an arrangement exists, title has transferred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. License revenue is typically recognized over the term of the arrangement and milestone revenue is recognized when earned as evidenced by achievement of the specified milestone and the absence of any on-going obligation. Grant revenue is recorded when qualifying expenses are incurred for the research that is performed as set forth under the terms of a federal grant from the National Institutes of Health (NIH). License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenues.

Cash Equivalents and Marketable Securities

We maintain investment portfolio holdings of various issuers, types and maturities. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At March 31, 2006, all other investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) within stockholders' equity. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

- Length of the time and the extent to which the market value has been less than cost;
- The financial condition and near-term prospects of the issuer; and
- Our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

To date we have had no declines in fair value that have been identified as other than temporary.

Research and Development Expenses and Accruals

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for clinical trials, manufacturing and process development, research and other consulting activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Share-Based Compensation

We have previously accounted for options issued to employees and members of the board of directors using the intrinsic method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). Beginning on July 1, 2005, we began to account for employee share-based payments in accordance with Statement of Financial Accounting Standards 123R ("SFAS 123R"), *Share-Based Payment - An Amendment of FASB Statements no. 123 and 95*. Under this standard, companies are no longer able to account for share-based compensation transactions in accordance with APB 25. Instead, companies are required to account for such transactions using a fair-value method and recognize the expense in the statement of operations.

We used the modified prospective application transition method to adopt SFAS 123R. The modified prospective application transition method requires that companies recognize compensation expense on new share-based payment awards and existing share-based payment awards that are modified, repurchased, or cancelled after the effective date. Additionally, compensation cost of the portion of awards of which the requisite service has not been rendered that are outstanding as of the July 1, 2005 shall be recognized as the requisite service is rendered. We use the Black-Scholes valuation model to determine the fair value of stock options issued. Volatility is based on the historical volatility of our common stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities that have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than two years. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of March 31, 2006 would have declined by \$114,000.

Item 4. Controls and Procedures

(a) *Evaluation of disclosure controls and procedures:* As required by Rule 13a-15 under the Securities Exchange Act of 1934, as of the end of the third fiscal quarter of 2006, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

(b) *Changes in internal controls over financial reporting:* There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings
Not Applicable.

Item 1A. Risk Factors

Factors That May Affect Future Operating Results

Risks Related to Pharmacocycles

All of our product candidates are in development, and we cannot be certain that any of our products under development will be commercialized.

To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products under development. The time frame necessary to achieve these goals for any individual product is long and uncertain. Before we can sell any of our products under development, we must demonstrate to the satisfaction of the FDA and regulatory authorities in foreign markets through the submission of preclinical (animal) studies and clinical (human) trials that each product is safe and effective for human use for each targeted disease. We have conducted and plan to continue to conduct extensive and costly clinical trials to assess the safety and effectiveness of our potential products. We cannot be certain that we will be permitted to begin or continue our planned clinical trials for our potential products, or if permitted, that our potential products will prove to be safe and produce their intended effects.

The completion rate of our clinical trials depends upon, among other factors, the rate of patient enrollment, the adequacy of patient follow-up and the completion of required clinical evaluations. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs or procedures used for the conditions we are investigating. Other companies are conducting clinical trials and have announced plans for future trials that are seeking or are likely to seek patients with the same diseases that we are studying. We may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on us. Many factors can affect the adequacy of patient follow-up and completion of required clinical evaluations, including failure of patients to return for scheduled visits or failure of clinical sites to complete necessary documentation. Delays in or failure to obtain required clinical follow-up and completion of clinical evaluations could also have a material adverse effect on the timing and outcome of our clinical trials and product approvals.

Additionally, clinical trials require substantial administration and monitoring. We may fail to effectively oversee and monitor the various trials we have underway at any particular time which would result in increased costs or delays of our clinical trials.

In December 2005, we announced the top line results of our pivotal Phase 3 clinical study of Xcytrin for the potential treatment of non-small cell lung cancer (NSCLC) patients with brain metastases. Although patients receiving Xcytrin had a longer time to neurologic progression (TNP), the study's primary endpoint, the difference compared to patients in the control arm did not reach statistical significance. In the intent-to-treat analysis, the median TNP was 15.4 months for patients receiving WBRT plus Xcytrin compared to 10.0 months for patients treated with WBRT alone ($P=0.122$, hazard ratio=0.78). Substantial differences in patient characteristics were observed for the 348 patients enrolled in North America (63 percent of all patients enrolled in the study) compared to the other regions. In North America, the median TNP for WBRT plus Xcytrin treatment was 24.2 months compared to 8.8 months for WBRT alone ($P=0.004$, hazard ratio=0.53). By contrast, for regions outside of North America, there was no significant difference in TNP between treatment arms. Xcytrin was well tolerated in the study. The most common drug related grade 3 and 4 adverse events were hypertension (4%), elevated liver enzymes (3%) and fatigue (3%), all of which were reversible.

Although we have received a Special Protocol Assessment (SPA) from the FDA for our Phase 3 SMART trial, the study did not meet its primary endpoint with statistical significance. Based on our ongoing review of the data from the SMART trial, we plan to submit a New Drug Application (NDA) to the FDA for the potential treatment of NSCLC patients with brain metastases. There can be no assurance that we can prepare and submit an NDA in a timely manner or at all. If an NDA is submitted by the company, there can be no assurance that it will be accepted for filing by the FDA. The FDA has substantial discretion in the approval process. If the FDA determines after an initial review of the NDA that the data included in the application is insufficient and not ready for formal

consideration, we could receive a "refuse to file" notice. The FDA could also require that we conduct additional studies and submit that data before it will reconsider our application. If the FDA is not satisfied with data included in our NDA, we may need to expend additional resources or conduct additional studies to obtain data that the FDA believes is sufficient. Even if the NDA is accepted for filing by the FDA, there can be no assurance that it would be approved in a timely manner or at all.

Data already obtained from preclinical studies and clinical trials of our products under development do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, data from clinical trials we are conducting are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a product under development could limit or prevent regulatory approval of the potential product and would materially harm our business. Our clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approval or may not result in marketable products. The outcome of the Phase 3 SMART trial did not reach statistical significance for the primary endpoint, which may limit or prevent the regulatory approval of Xcytrin as a treatment for brain metastases in patients with lung cancer and may result in material harm to our business. The outcomes of our other ongoing Phase 1 and Phase 2 trials with Xcytrin for additional cancer indications may not provide sufficient data supporting advancement of the development of Xcytrin for these additional cancer indications and also may result in material harm to our business.

We have a history of operating losses and we expect to continue to have losses in the future.

We have incurred significant operating losses since our inception in 1991 and, as of March 31, 2006, had an accumulated deficit of approximately \$274.2 million. We expect to continue to incur substantial additional operating losses until such time, if ever, as the commercialization of our products generates sufficient revenues to cover our expenses. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products, and to obtain required regulatory approvals and to successfully manufacture and market our proposed products. If our lead product, Xcytrin, fails to receive regulatory approval, our ability to become profitable would be materially impacted. To date, we have not generated revenue from the commercial sale of our products.

Failure to obtain product approvals or comply with ongoing governmental regulations could adversely affect our business.

The manufacture and marketing of our products and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA approval to market a product, we will have to demonstrate to the satisfaction of the FDA that the product is safe and effective for the patient population and for the diseases that will be treated. Clinical trials, and the manufacturing and marketing of products, are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources.

Data obtained from clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. Data from our completed Phase 3 SMART trial may not be sufficient to obtain regulatory approval. Conducting additional trials will cause significant delays in approval and consume additional resources and may not be sufficient to obtain regulatory approval.

In addition, we may encounter delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. The fast-track designation that we have received for our Phase 3 SMART trial of Xcytrin may not actually lead to a faster development, regulatory review, or approval process. We may encounter similar delays in foreign countries. We may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities and even if obtained, such approvals may not be received on a timely basis, or they may not cover the clinical uses that we specify.

Furthermore, regulatory approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions, including withdrawal of the product from the market. Any of the following events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our products, which in turn would have a material adverse effect on our business, financial condition and results of operations:

- failure to obtain and thereafter maintain requisite governmental approvals;
- failure to obtain approvals for specific indications of our products under development; or
- identification of serious and unanticipated adverse side effects in our products under development.

Any regulatory approval that we receive for a product candidate may be subject to limitations on the indicated uses for which the product may be marketed. In addition, if the FDA and/or foreign regulatory agencies approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion of the product will be subject to extensive regulatory requirements. We and the manufacturers of our product candidates must also comply with the applicable FDA Good Manufacturing Practice (“GMP”) regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of our products. We or our present or future suppliers may be unable to comply with the applicable GMP regulations and other FDA regulatory requirements. Failure of our suppliers to follow current Good Manufacturing Practice or other regulatory requirements may lead to significant delays in the availability of products for commercial or clinical use and could subject us to fines, injunctions and civil penalties. We also may be subject to delays in commercializing our products for Antrin Angiophototherapy due to delays in approvals of the third-party light sources required for this product.

We will need substantial additional financing and we may have difficulty raising needed capital in the future.

We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our products. We will expend additional funds for these purposes, to establish additional clinical and commercial-scale manufacturing arrangements and to provide for the marketing and distribution of our products. Specifically, we will require additional funds to commercialize our product. Even if we are able to develop Xcytrin successfully in light of the recent results from our Phase 3 clinical study, we expect additional development efforts and clinical trials will extend the timeline for development and will result in substantial additional expenses. We may be unable to fund these efforts with our current financial resources.

Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially and adversely affect our business, financial condition and operations.

We believe that our cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We may, however, choose to raise additional funds before then. Our actual capital requirements will depend on many factors, including:

- continued progress of our research and development programs;
- our ability to establish collaborative arrangements and maintain existing ones;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approval;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the amount and timing of capital equipment purchases;
- competing technological and market developments; and
- our ability to market and distribute our products and establish new licensing arrangements.

We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources that may be dilutive to existing stockholders or subject us to restrictive covenants. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require

us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves.

Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will harm our business.

Even if approved for marketing, our products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory approvals for the indications that we are studying, and the acceptance by physicians and patients of the clinical benefits that our products may offer;
- the establishment and demonstration in the medical community of the safety, clinical efficacy and cost-effectiveness of our products and their potential advantages over existing therapeutic products;
- marketing and distribution support;
- the introduction, market penetration and pricing strategies of competing and future products; and
- coverage and reimbursement policies of governmental and other third-party payors such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, purchase, utilize or recommend any of our products.

We may fail to adequately protect or enforce our intellectual property rights or secure rights to third-party patents.

We face risks and uncertainties related to our intellectual property rights. For example:

- we may be unable to obtain or maintain patent or other intellectual property protection for any products or processes that we may develop;
- third parties may obtain patents covering the manufacture, use or sale of these products, which may prevent us from commercializing any of our products under development globally or in certain regions; and
- any future patents that we may obtain may not prevent other companies from competing with us by designing their products or conducting their activities so as to avoid the coverage of our patents.

A number of third-party patent applications have been published, and some have issued, relating to expanded porphyrin chemistries. It is likely that competitors and other third parties have and will continue to file applications for and receive patents relating to similar or even the same compositions, methods or designs as those of our products. If any third-party patent claims are asserted against our products and are upheld as valid and infringed by our products, we could be prevented from practicing the subject matter claimed in such patents and therefore from developing or commercializing our products, require license(s) or have to redesign our products or processes to avoid infringement. Such licenses may not be available or, if available, may not be on terms acceptable to us. Alternatively, we may be unsuccessful in any attempt to redesign our products or processes to avoid infringement. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to the company and diversion of our efforts.

We are aware of several U.S. patents owned or licensed by Schering AG that relate to pharmaceutical formulations and methods for enhancing magnetic resonance imaging. Even though we have obtained the opinion of outside patent counsel that our cancer treatment compounds do not infringe any valid, unexpired claims of such patents, Schering AG may still choose to assert one or more of those patents. If any of our products were legally determined to be infringing a valid and enforceable claim of any of Schering AG's patents, our business could be materially adversely affected. Further, any allegation by Schering AG that we infringed their patents would likely result in significant legal costs and require the diversion of substantial management resources. We are aware that Schering AG has asserted patent rights against at least one other company in the contrast agent imaging market and that a number of companies have entered into licensing arrangements with Schering AG with respect to one or more of such patents. We cannot be

certain that we would be successful in defending a lawsuit or able to obtain a license on commercially reasonable terms from Schering AG, if required.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. Although we take steps to protect our proprietary rights and information, including the use of confidentiality and other agreements with our employees and consultants, and in our academic and commercial relationships, these steps may be inadequate, these agreements may be violated, or there may be no adequate remedy available for a violation. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in unpatented proprietary technology.

We rely heavily on third parties for product and clinical development, manufacturing, marketing and distribution of our products.

We currently depend heavily and will depend heavily in the future on third parties for support in product development, clinical development, manufacturing, marketing and distribution of our products. The termination of a significant number of our existing collaborative arrangements, or our inability to establish and maintain collaborative arrangements could have a material adverse effect on our ability to complete clinical development of our products.

We rely on contract clinical research organizations, or CROs, for various aspects of our clinical development activities including clinical trial monitoring, data collection and data management. As a result, we have had and continue to have less control over the conduct of clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Although we rely on CROs to conduct some of our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with the investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements.

Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Any failure of such CROs to successfully accomplish clinical trial monitoring, data collection and data management and the other services they provide for us in a timely manner and in compliance with regulatory requirements could have a material adverse effect on our ability to complete clinical development of our products and obtain regulatory approval. Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternate service provider. However, making such changes may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

We have no expertise in the development of light sources and associated light delivery devices required for our Antrin Angiophototherapy product under development. Successful development, manufacturing, approval and distribution of this product will require third-party participation for the required light sources, associated light delivery devices and other equipment. Failure to develop such relationships may require us to develop additional supply sources that may require additional clinical trials and regulatory approvals and could materially delay commercialization of our Antrin product under development. We may be unable to establish or maintain relationships with other supply sources on a commercially reasonable basis, if at all, or alternatively, the enabling devices may not receive regulatory approval.

We lack the resources, capability and experience necessary to manufacture pharmaceuticals and thus rely heavily upon contract manufacturers.

We have no manufacturing facilities and we currently rely on third parties for manufacturing and storage activities related to all of our products in development. Our manufacturing strategy presents the following risks:

- delays in scale-up to quantities needed for multiple clinical trials, or failure to manufacture such quantities to our specifications, or deliver such quantities on the dates we require, could cause delay or suspension of clinical trials, regulatory submissions and commercialization of our products in development;

- there is no guarantee that the supply of clinical materials can be maintained during the clinical development of our product candidates;
- our current and future manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding regulatory agencies for compliance with strictly enforced current Good Manufacturing Practice and similar foreign standards. Failure to pass these inspections could have a material adverse effect on our ability to produce our products to support our operations;
- if we need to change to other commercial manufacturing contractors, there is no guarantee that we will be able to locate a suitable replacement contractor. The FDA and comparable foreign regulators must approve material manufactured by these contractors prior to our use. This would require new testing and compliance inspections. The new manufacturers would have to practice substantially equivalent processes for the production of our products;
- our current manufacturers might not be able to fulfill our commercial needs, which would require us to seek new manufacturing arrangements and may result in substantial delays in meeting market demand; and
- any disruption of the ability of our manufacturing contractors to supply necessary quantities of our products could have a material adverse effect on our ability to support our operations.

Any of these factors could delay clinical trials or commercialization of our products under development and entail higher costs.

We lack marketing and sales experience.

We currently have limited marketing, sales and distribution experience. We must develop a sales force with technical expertise. We have no experience in developing, training or managing a sales force. We will incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build such a sales force, the cost of establishing such a sales force may exceed any product revenues, or our direct marketing and sales efforts may be unsuccessful. In addition, we compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against those of such other companies. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. To the extent we enter into co-promotion or other licensing agreements, our product revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful.

If we lose or are unable to hire and retain qualified personnel, then we may not be able to develop our products or processes.

We are highly dependent on qualified scientific and management personnel, and we face intense competition from other companies and research and academic institutions for qualified personnel. If we lose an executive officer, a manager of one of our programs, or a significant number of any of our staff or are unable to hire and retain qualified personnel, then our ability to develop and commercialize our products and processes may be adversely affected or prevented.

Our business is subject to risks associated with international operations and collaborations.

The laws of foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. In countries where we do not have and/or have not applied for patents on our products, we will be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the United States where we acquire patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our patented technology.

Until we or our licensees obtain the required regulatory approvals for pharmaceuticals in any specific foreign country, we or our licensees will be unable to sell these products in that country. International regulatory authorities have imposed numerous and varying regulatory requirements and the approval procedures can involve additional testing. Approval by one regulatory authority does not ensure approval by any other regulatory authority.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential drugs, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may need to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002, including Section 404, and the related rules and regulations of the Securities and Exchange Commission, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 and other requirements will increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements. While we have been able to complete a favorable assessment as to the adequacy of our internal control over financial reporting for our fiscal year ending June 30, 2005, there is no assurance that future assessments of the adequacy of our internal control over financial reporting will be favorable. If we are unable to obtain future unqualified reports as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our internal controls over financial reporting, which could adversely affect our stock price.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, coverage and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, we cannot provide any assurance that governmental authorities will find that our business practices comply with current or future administrative or judicial interpretations of potentially applicable laws and regulations. If we fail to comply with any of these laws and regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Our facility in California is located near an earthquake fault, and an earthquake or other types of natural disasters or resource shortages could disrupt our operations and adversely affect results.

Important documents and records, such as hard copies of our laboratory books and records for our drug candidates and compounds, are located in our corporate headquarters at a single location in Sunnyvale, California, which is near active earthquake zones. We do not have a formal business continuity or disaster recovery plan, and could therefore experience a significant business interruption in the event of a natural disaster, such as an earthquake, drought or flood, or localized extended outages of critical utilities or transportation systems. In addition, California from time to time has experienced shortages of water, electric power and natural gas. Future shortages and conservation measures could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

Risks Related to Our Industry

We face rapid technological change and intense competition.

The pharmaceutical industry is subject to rapid and substantial technological change. Therapies designed by other companies to treat the conditions that are the focus of our products are currently in clinical trials. Developments by others may render our products under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, sales, manufacturing,

financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing and other resources. In addition, we may experience competition from companies that have acquired or may acquire technology from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions that compete with our products.

We are engaged in the development of novel therapeutic technologies. As a result, our resources are limited and we may experience technical challenges inherent in such novel technologies.

Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings. Our competitors may price their products below ours, may receive better reimbursement or may have products that are more cost effective than ours.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if commercialized. The diseases for which we are developing our therapeutic products can also be treated, in the case of cancer, by surgery, radiation, biologics and chemotherapy, and in the case of atherosclerosis, by surgery, angioplasty, drug therapy and the use of devices to maintain and open blood vessels. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our products to receive widespread acceptance if commercialized.

The price of our common stock may be volatile.

The market prices for securities of biotechnology companies, including ours, have historically been highly volatile. Our stock, like that of many other companies, has from time to time experienced significant price and volume fluctuations unrelated to operating performance. The market price of our common stock may fluctuate significantly due to a variety of factors, including:

- the progress and results of our preclinical testing and clinical trials;
- quarterly fluctuations in our financial results;
- the development of technological innovations or new therapeutic products by us, our competitors or others;
- changes in governmental regulation;
- developments in patent or other proprietary rights by us, our competitors or others;
- developments and/or announcements by us, our competitors or others;
- litigation;
- public concern as to the safety of products developed by us, our competitors or others;
- departure of key personnel;
- ability to manufacture our products to commercial standards;
- changes in the structure of healthcare payment systems and the coverage and reimbursement policies of governmental and other third-party payors;
- our ability to successfully commercialize our products if they are approved;
- comments by securities analysts; and
- general market conditions in our industry.

In addition, if any of the risks described in this section entitled “Factors That May Affect Future Operating Results” actually occur, there could be a dramatic and material adverse impact on the market price of our common stock.

Current health care laws and regulations and future legislative or regulatory changes to the healthcare system may affect our ability to sell our products profitably.

In the United States, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system and, in particular, that are intended to contain or reduce the costs of medical products and services. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, could significantly influence the manner in which pharmaceutical products are prescribed and purchased and will impact reimbursement for our products, which could result in a reduction in demand for our products. The MMA established a new reimbursement methodology for certain drugs furnished in hospital outpatient departments and physicians’ offices which is based on the average sales price, or ASP, of the product. Application of the ASP reimbursement methodology has resulted in a decrease in the reimbursement levels for certain oncology drugs furnished in hospital outpatient departments and physicians’ offices in 2005. As implemented in a recent rule establishing an MMA-mandated competitive bidding program, or CAP, physicians who administer drugs in their offices will be offered an option to acquire drugs covered under the Medicare Part B benefit from vendors who are selected in a competitive bidding process. Winning vendors would be selected based on criteria that include their bid price. The Department of Health and Human Services, Centers for Medicare and Medicaid Services recently delayed implementation of the CAP program until at least July 2006. These new reimbursement measures could negatively impact our ability to sell our products. The MMA also established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries will be able to obtain prescription drug coverage from private sector providers. These private sector providers will be permitted to limit the number of prescription drugs that will be covered in each therapeutic category and class on their formularies. We cannot predict whether our products will be placed on the formularies of the private sector providers participating in the Part D program in 2006 and beyond, and if our products are not placed on such formularies, this could negatively impact our ability to sell our products. It remains difficult to predict the impact that the prescription drug program, and the MMA generally, will have on us and our industry. The expanded access to prescription medications afforded by Medicare coverage of prescription drugs may increase the volume of pharmaceutical sales. However, this potential sales volume increase may be offset by increased downward pricing pressures resulting from the enhanced purchasing power of private sector providers who will negotiate drug pricing on behalf of Medicare beneficiaries under Part D.

In addition, we may face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. The MMA contains provisions that may change U.S. importation laws and expand consumers’ ability to import lower priced versions of our and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The Secretary of Health and Human Services has not yet announced any plans to make the required certification. As directed by Congress, a task force on drug importation conducted a comprehensive study regarding the circumstances under which drug importation could be safely conducted and the consequences of importation on the health, medical costs and development of new medicines for U.S. consumers. The task force report issued its report in December 2004, finding that there are significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. In addition, a number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification, and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the U.S. Customs Service, and other government agencies. For example, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our profitability.

There also have been and likely will continue to be legislative and regulatory proposals at the state and federal levels that could bring about significant changes to the Medicaid drug rebate program and other federal pharmaceutical pricing programs in which we plan to participate for our products. Given these and other recent federal and state government initiatives directed at lowering the total cost of health care, federal and state lawmakers will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid programs. We cannot predict the impact on our business of any

legislation or regulations that may be adopted in the future. Any cost containment measures and other healthcare system reforms that are adopted could have a material adverse effect on our ability to operate profitably.

If our products are not accepted by the market or if users of our products are unable to obtain adequate coverage of and reimbursement for our products from government and other third-party payors, our revenues and profitability will suffer.

Our ability to commercialize our products successfully will depend in significant part on the extent to which appropriate coverage of and reimbursement for our products and related treatments are obtained from governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot provide any assurances that third-party payors will consider our products cost-effective or provide coverage of and reimbursement for our products, in whole or in part.

Uncertainty exists as to the coverage and reimbursement status of newly approved medical products and services and newly approved indications for existing products. Third-party payors may conclude that our products are less safe, less effective, or less cost-effective than existing products, and third-party payors may not approve our products for coverage and reimbursement. If we are unable to obtain adequate coverage of and reimbursement for our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them. Such reduction or limitation in use of our products could cause our sales to suffer. Even if third-party payors make reimbursement available, payment levels may not be sufficient to make the sale of our products profitable to us.

Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of medical services and products may result in inadequate coverage of and reimbursement for our products. Many third-party payors, including in particular HMOs, are pursuing various ways to reduce pharmaceutical costs, including, for instance, the use of formularies. The market for our products depends on access to such formularies, which are lists of medications for which third-party payors provide reimbursement. These formularies are increasingly restricted, and pharmaceutical companies face significant competition in their efforts to place their products on formularies of HMOs and other third-party payors. This increased competition has led to a trend of downward pricing pressure in the industry. The cost containment measures that third-party payors are instituting could have a material adverse effect on our ability to operate profitably.

Our business exposes us to product liability claims.

The testing, manufacture, marketing and sale of our products involve an inherent risk that product liability claims will be asserted against us. We face the risk that the use of our products in human clinical trials will result in adverse effects. If we complete clinical testing for our products and receive regulatory approval to market our products, we will mark our products with warnings that identify the known potential adverse effects and the patients who should not receive our product. We cannot ensure that physicians and patients will comply with these warnings. In addition, unexpected adverse effects may occur even with use of our products that receive approval for commercial sale. Although we are insured against such risks in connection with clinical trials and commercial sales of our products, our present product liability insurance may be inadequate. A successful product liability claim in excess of our insurance coverage could have a material adverse effect on our business, financial condition and results of operations. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our pharmaceutical products. A product liability claim or recall would have a material adverse effect on our reputation, business, financial condition and results of operations.

Our business involves environmental risks.

In connection with our research and development activities and our manufacture of materials and products, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of

contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not Applicable.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Submission of Matters to a Vote of Security Holders

Not Applicable.

Item 5. Other Information

Effective May 1, 2006 and pursuant to an agreement with the company, Hugo Madden, Ph.D., resigned as the company's Vice President, Chemical Operations, and was appointed to the newly established position of Vice President, Technology Development. This agreement replaces the existing employment agreement between the parties dated as of May 28, 1998, which is filed as Exhibit 10.41 to the Annual Report on Form 10-K for the year ended June 30, 1998. Effective May 1, 2006, the company also appointed Gregory W. Hemmi, Ph.D. to the position of Vice President, Chemical Operations replacing Dr. Madden. Dr. Hemmi has been employed in various scientific and manufacturing positions with the company since 1992, most recently serving as Senior Director of Chemical Operations.

Item 6. Exhibits

a. Exhibits

4.3* Stock Purchase Agreement By and Between Pharmacyclics, Inc. and Applera Corporation dated April 7, 2006.

10.64* Assignment Agreement By and Between Pharmacyclics, Inc. and Applera Corporation dated April 7, 2006.

31.1 Rule 13a-14(a)/15d-14(a) Certification of CEO.

31.2 Rule 13a-14(a)/15d-14(a) Certification of CFO.

32.1 Section 1350 Certifications of CEO and CFO.

99.1 Letter Agreement, dated April 17, 2006, by and between the Company and Hugo Madden.

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

Signatures

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

Pharmacyclics, Inc.

(Registrant)

Dated: May 9, 2006

By: /s/ RICHARD A. MILLER, M.D.

Richard A. Miller, M.D.

President and Chief Executive Officer

Dated: May 9, 2006

By: /s/ LEIV LEA

Leiv Lea

*Vice President, Finance and Administration and
Chief Financial Officer and Secretary*

EXHIBITS INDEX

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

Rule 13a-14(a)/15d-14(a) Certification

I, Richard A. Miller, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pharmacyclics, Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2006

/s/ RICHARD A. MILLER, M.D.

Richard A. Miller, M.D.
President and Chief Executive Officer

Rule 13a-14(a)/15d-14(a) Certification

I, Leiv Lea, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pharmacyclics, Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2006

/s/ LEIV LEA

Leiv Lea
Vice President, Finance and Administration
and Chief Financial Officer and Secretary

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report of Pharmacyclics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ending March 31, 2006 as filed with the Securities and Exchange Commission (the "Report"), I, Richard A. Miller, M.D., President and Chief Executive Officer of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350), that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ RICHARD A. MILLER, M.D.

Richard A. Miller, M.D.
President and Chief Executive Officer
May 9, 2006

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report of Pharmacyclics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ending March 31, 2006 as filed with the Securities and Exchange Commission (the "Report"), I, Leiv Lea, Vice President, Finance and Administration and Chief Financial Officer and Secretary of the Company, certify, pursuant to § 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350), that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ LEIV LEA

Leiv Lea
Vice President, Finance and Administration
and Chief Financial Officer and Secretary
May 9, 2006