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

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FORM 10-Q

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

For the quarterly period ended **March 31, 2005**

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)*

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file 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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES ☒ NO ☐.

As of March 31, 2005, there were 19,745,002 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

This quarterly report on Form 10-Q consists of 24 pages of which this is page 1.

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**Form 10-Q**  
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PHARMACYCLICS<sup>®</sup>, (the pentadentate logo), Xcytrin<sup>®</sup> and Antrin<sup>®</sup> are registered U.S. trademarks of Pharmacyclics, Inc. Other trademarks, trade names or service marks used herein are the property of their respective owners.

## PART I - FINANCIAL INFORMATION

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### Item 1. Financial Statements

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

	<b>March 31,</b>		<b>June 30,</b>
	<b>2005</b>		<b>2004</b>
	<u>          </u>		<u>          </u>
<b>ASSETS</b>			
Current assets:			
Cash and cash equivalents .....	\$ 30,318	\$	42,432
Marketable securities .....	48,754		58,986
Prepaid expenses and other current assets .....	1,468		1,429
	<u>          </u>		<u>          </u>
Total current assets .....	80,540		102,847
Property and equipment, net .....	869		1,293
Other assets .....	527		527
	<u>          </u>		<u>          </u>
	<u>\$ 81,936</u>	<u>\$</u>	<u>104,667</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
Current liabilities:			
Accounts payable .....	\$ 3,012	\$	3,166
Accrued liabilities .....	1,270		1,128
	<u>          </u>		<u>          </u>
Total current liabilities .....	4,282		4,294
Deferred rent .....	99		85
	<u>          </u>		<u>          </u>
Total liabilities .....	4,381		4,379
Stockholders' equity:			
Common stock .....	2		2
Additional paid-in capital .....	316,755		316,266
Accumulated other comprehensive loss .....	(426)		(250)
Deficit accumulated during development stage.....	(238,776)		(215,730)
	<u>          </u>		<u>          </u>
Total stockholders' equity .....	77,555		100,288
	<u>          </u>		<u>          </u>
	<u>\$ 81,936</u>	<u>\$</u>	<u>104,667</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 1991) through March 31, 2005
	2005	2004	2005	2004	
Revenues:					
License and milestone revenues .....	\$ --	\$ --	\$ --	\$ --	\$ 7,855
Contract revenues .....	--	--	--	--	5,847
Total revenues .....	<u>--</u>	<u>--</u>	<u>--</u>	<u>--</u>	<u>13,702</u>
Operating expenses:					
Research and development .....	6,513	6,096	18,899	18,213	240,825
Marketing, general and administrative .....	1,912	1,418	5,492	4,442	47,074
Total operating expenses .....	<u>8,425</u>	<u>7,514</u>	<u>24,391</u>	<u>22,655</u>	<u>287,899</u>
Loss from operations .....	(8,425)	(7,514)	(24,391)	(22,655)	(274,197)
Interest and other income, net .....	469	233	1,345	762	35,421
Net loss .....	<u>\$ (7,956)</u>	<u>\$ (7,281)</u>	<u>\$ (23,046)</u>	<u>\$ (21,893)</u>	<u>\$ (238,776)</u>
Basic and diluted net loss per share .....	<u>\$ (0.40)</u>	<u>\$ (0.44)</u>	<u>\$ (1.17)</u>	<u>\$ (1.34)</u>	
Shares used to compute basic and diluted net loss per share .....	<u>19,743</u>	<u>16,365</u>	<u>19,700</u>	<u>16,289</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 1991) through March 31,
	2005	2004	2005
Cash flows from operating activities:			
Net loss .....	\$ (23,046)	\$ (21,893)	\$ (238,776)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	552	1,129	13,459
Stock compensation expense .....	20	14	888
Gain on sale of marketable securities .....	--	--	58
Write-down of fixed assets .....	--	--	381
Changes in assets and liabilities:			
Prepaid expenses and other assets .....	(39)	97	(1,995)
Accounts payable .....	(154)	590	3,012
Accrued liabilities .....	142	344	1,270
Deferred rent .....	14	43	99
Net cash used in operating activities .....	<u>(22,511)</u>	<u>(19,676)</u>	<u>(221,604)</u>
Cash flows from investing activities:			
Purchase of property and equipment .....	(128)	(314)	(10,940)
Proceeds from sale of property and equipment .....	--	--	112
Purchases of marketable securities .....	(6,185)	(29,948)	(448,701)
Proceeds from maturities and sales of marketable securities .....	16,241	27,857	399,463
Net cash provided by (used in) investing activities .....	<u>9,928</u>	<u>(2,405)</u>	<u>(60,066)</u>
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs .....	469	768	292,355
Proceeds from notes payable .....	--	--	3,000
Issuance of convertible preferred stock, net of issuance costs .....	--	--	20,514
Payments under capital lease obligations .....	--	--	(3,881)
Net cash provided by financing activities .....	<u>469</u>	<u>768</u>	<u>311,988</u>
Increase (decrease) in cash and cash equivalents .....	(12,114)	(21,313)	30,318
Cash and cash equivalents at beginning of period .....	<u>42,432</u>	<u>50,371</u>	<u>--</u>
Cash and cash equivalents at end of period .....	<u>\$ 30,318</u>	<u>\$ 29,058</u>	<u>\$ 30,318</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 unaudited condensed financial statements of Pharmacyclics, Inc. (the “company” or “Pharmacyclics”) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required for complete financial statements. In the opinion of management, the accompanying unaudited, condensed financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair statement of the company’s interim financial information. These financial statements and notes should be read in conjunction with the audited financial statements of the company included in the company’s Annual Report on Form 10-K for the year ended June 30, 2004 filed with the Securities and Exchange Commission on August 30, 2004.

The results of operations for the three and nine months ended March 31, 2005 are not necessarily indicative of the operating results that may be reported for the fiscal year ending June 30, 2005 or for any other future period.

**Employee Stock-Based Compensation**

The company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB 25”), Financial Accounting Standards Board (“FASB”) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation – an Interpretation of APB No. 25* (“FIN 44”) and complies with the disclosure provisions of Statement of Financial Accounting Standard No. 123, *Accounting for Stock-Based Compensation* (“SFAS No. 123”) as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation Disclosure* (“SFAS No. 148”).

Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the company’s stock and the exercise price. SFAS No. 123 defines a “fair value” based method of accounting for an employee stock option or similar equity instruments.

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. 123 to stock-based employee compensation (in thousands, except per share amounts):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>March 31,</b>		<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
Net loss, as reported .....	\$ (7,956)	\$ (7,281)	\$ (23,046)	\$ (21,893)
Employee stock-based compensation using the fair value based method .....	\$ (2,023)	\$ (1,970)	\$ (6,280)	\$ (5,772)
Proforma net loss .....	<u>\$ (9,979)</u>	<u>\$ (9,251)</u>	<u>\$ (29,326)</u>	<u>\$ (27,665)</u>
Basic and diluted net loss per share, as reported .....	<u>\$ (0.40)</u>	<u>\$ (0.44)</u>	<u>\$ (1.17)</u>	<u>\$ (1.34)</u>
Proforma basic and diluted net loss per share .....	<u>\$ (0.51)</u>	<u>\$ (0.57)</u>	<u>\$ (1.49)</u>	<u>\$ (1.70)</u>

## 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 4,145,148 and 3,949,919 shares of common stock were outstanding at March 31, 2005 and 2004, respectively, and were excluded from the calculation of loss per share as they were antidilutive.

## Note 3 - 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 (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2005	2004	2005	2004
Net loss .....	\$ (7,956)	\$ (7,281)	\$ (23,046)	\$ (21,893)
Change in net unrealized losses on available-for-sale securities .....	(134)	75	(176)	36
Comprehensive loss .....	<u>\$ (8,090)</u>	<u>\$ (7,206)</u>	<u>\$ (23,222)</u>	<u>\$ (21,857)</u>

## Note 4 – Recent Accounting Pronouncements

At its March 2004 meeting, the FASB's Emerging Issues Task Force ("EITF") reached a consensus on recognition and measurement guidance previously discussed under EITF 03-01, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under FASB Statement No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached is to be applied to other-than-temporary impairment evaluations. In September 2004, the FASB issued a final FASB staff position, FSP EITF Issue 03-01-1 that delays the effective date for the measurement and recognition guidance of EITF 03-01. We do not believe that this consensus on the recognition and measurement guidance will have an impact on our results of operations.

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 will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25. Instead, companies will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of income. SFAS 123R will be effective for public companies for fiscal years beginning after June 15, 2005. We will be required to implement the standard in the quarter that begins July 1, 2005. The company has not yet determined which fair-value method and transitional provision it will follow.

## 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, 2004 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 August 30, 2004.*

*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, 2004 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 drugs that improve treatment of serious illnesses such as cancer and atherosclerosis. 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.

We have two primary drug products, or research and development programs, for which we are currently focusing our efforts: Xcytrin<sup>®</sup> (motexafin gadolinium) Injection and Antrin<sup>®</sup> (motexafin lutetium) Angiophototherapy. Xcytrin, our lead product candidate, is an anti-cancer drug being evaluated in various clinical trials. We have enrolled patients in a pivotal randomized Phase 3 trial of Xcytrin for the potential treatment of lung cancer patients with brain metastases. This randomized controlled study, known as the SMART (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial, will be completed when the protocol mandated six months of follow-up evaluation of surviving patients is obtained. The trial will compare the effects of whole brain radiation therapy (WBRT) alone to WBRT plus Xcytrin in lung cancer patients with brain metastases. The primary efficacy endpoint will be time to neurologic progression as determined by a blinded events review committee. Survival and neurocognitive function will also be assessed as secondary endpoints of the trial. We requested and received a Special Protocol Assessment from the FDA for the SMART trial. Special Protocol Assessment provides for sponsors of clinical trials to receive official FDA evaluation, guidance and agreement on pivotal trials that will form the basis for final approval.

Our strategy is 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 have completed a multicenter Phase 2 trial with Xcytrin and radiation for the treatment of glioblastoma multiforme, a malignant primary brain tumor. We have also begun Phase 2 clinical trials with Xcytrin used alone in hematologic cancers such as lymphomas and chronic lymphocytic leukemia and a Phase 2 clinical trial with Xcytrin used alone for kidney cancer. Phase 1 trials are underway evaluating Xcytrin given in combination with Taxotere<sup>®</sup> for recurrent lung, prostate, ovarian and breast cancer, and with Taxotere and Cisplatin for newly diagnosed lung cancer. We also have an ongoing Phase 1 trial with Xcytrin combined with Temodar<sup>®</sup> for primary brain tumors and an ongoing Phase 1 trial with Xcytrin in combination with cisplatin, 5-fluorouracil and radiation for the treatment of advanced head and neck cancer.

We have 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.



We have incurred significant operating losses since our inception in 1991, and as of March 31, 2005, had an accumulated deficit of approximately \$238.8 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.

## Results of Operations

### Research and Development

	Three Months ended			Nine Months ended		
	March 31,		Percent	March 31,		Percent
	2005	2004	change	2005	2004	change
Research and development expenses	\$ 6,513,000	\$ 6,096,000	7%	\$ 18,899,000	\$ 18,213,000	4%

The increase of 7% or \$417,000 in research and development expenses for the three months ended March 31, 2005 as compared to the three months ended March 31, 2004 was primarily due to an increase of \$404,000 in costs to support our clinical trials.

The increase of 4% or \$686,000 in research and development expenses for the nine months ended March 31, 2005 as compared to the nine months ended March 31, 2004 was primarily due to an increase in employee costs of \$605,000 in order to support the continued development of Xcytrin.

We expect research and development expenses to increase in the future as a result of increased clinical development and manufacturing costs primarily related to our clinical development programs. The timing and the amount of these expenditures will primarily depend on the costs and outcome of our ongoing and future clinical trials, regulatory requirements and product manufacturing costs.

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. 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 1999, we did not track our historical 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 March 31,		Related R&D Expenses Nine Months ended March 31,	
				2005	2004	2005	2004
XCYTRIN	Cancer	Several Phase 1 trials	Unknown	\$ 4,310,000	\$ 3,926,000	\$ 12,298,000	\$ 10,676,000
		Several Phase 2 trials	Unknown				
		Phase 3	Fiscal 2006				
ANTRIN	Coronary artery disease	Phase 1	Completed	329,000	107,000	572,000	545,000
Total direct costs.....				4,639,000	4,033,000	12,870,000	11,221,000
Indirect costs.....				1,874,000	2,063,000	6,029,000	6,992,000
Total research and development expenses.....				\$ 6,513,000	\$ 6,096,000	\$ 18,899,000	\$ 18,213,000

#### Marketing, General and Administrative

	Three Months ended March 31,		Percent change	Nine Months ended March 31,		Percent change
	2005	2004		2005	2004	
Marketing, general and administrative expenses \$	1,912,000	\$ 1,418,000	35%	\$ 5,492,000	\$ 4,442,000	24%

The increases were primarily due to increases in employee costs and third party costs associated with the company's commercialization strategy for Xcytrin. Employee costs increased \$184,000 and \$400,000 for the three and nine months ended March 31, 2005, respectively and third party costs increased \$82,000 and \$554,000 for the three and nine months ended March 31, 2005, respectively.

#### Interest and Other, Net

	Three Months ended March 31,		Percent change	Nine Months ended March 31,		Percent change
	2005	2004		2005	2004	
Interest and other, net	\$ 469,000	\$ 233,000	101%	\$ 1,345,000	\$ 762,000	77%

The increase in both periods was primarily due to higher balances of cash, cash equivalents and marketable securities from our public stock offering in April 2004 and higher interest rates. Our cash equivalents 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, 2005, we had approximately \$79,072,000 in cash, cash equivalents and marketable securities. 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 used in operating activities of \$19,676,000 during the nine months ended March 31, 2004, resulted primarily from our net loss, net of depreciation and amortization, partially offset by an increase in accounts payable and accrued liabilities.

Net cash provided by investing activities of \$9,928,000 in the nine months ended March 31, 2005, consisted primarily of maturities and sales of marketable securities, net of purchases of marketable securities. Net cash used in investing activities of \$2,405,000 in the nine months ended March 31, 2004 consisted primarily of purchases of marketable securities, net of maturities and sales of marketable securities.

Net cash provided by financing activities of \$469,000 and \$768,000 in the nine months ended March 31, 2005 and 2004, 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.

We lease our facility under a non-cancelable operating lease that expires in fiscal 2008. Future minimum lease payments under this non-cancelable operating lease as of March 31, 2005 are as follows:

	Operating Lease Commitments
Remaining 3 months of fiscal 2005 .....	\$ 295,000
Fiscal 2006 .....	1,201,000
Fiscal 2007 .....	1,220,000
Fiscal 2008 .....	610,000
Total minimum lease payments .....	<u>\$ 3,326,000</u>

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 fiscal year 2006. Our existing capital resources are insufficient to satisfy our capital requirements through testing, regulatory clearance and commercialization of Xcytrin. We will need to raise additional funds 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 status of product development; the time and cost involved in conducting clinical trials and obtaining regulatory approvals; filing, prosecuting and enforcing patent claims; competing technological and market developments; and our ability to market and distribute our products and establish new collaborative and licensing arrangements.

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 through public or private financings, collaborative relationships or other arrangements. 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 restrictions on our business. 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.

### **Critical Accounting Policies and the Use of Estimates**

We believe the following critical accounting policies presently involve our more significant judgments, assumptions 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 and milestone fees are recognized as revenue when earned over the period of the arrangement, as evidenced by achievement of the specified milestones and the absence of any on-going obligation. License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenue.

#### *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, 2005, these 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 its 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 accrual 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.

## Factors That May Affect Future Operating Results

*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 through 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 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 effect 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, demands on our clinical staff have been increasing and we expect they will continue to increase due to our monitoring of additional clinical trials. We may fail to effectively oversee and monitor these many simultaneous clinical trials, which would result in increased costs or delays of our clinical trials and negatively impact our ability to collect complete and audited data from clinical sites participating in our SMART trial. Even if these clinical trials are completed, we may fail to complete and submit a new drug application for many reasons, including, as was the case with our first Phase 3 trial of Xcytrin, failure to meet our primary endpoints. Even if we are able to submit a new drug application, the U.S. Food and Drug Administration, or FDA, may refuse to file our application or may not approve our application 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 is 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 delay or prevent regulatory clearance 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. In this regard, our initial Phase 3 trial of Xcytrin failed to meet its co-primary endpoints even though our Phase 1b/2 trial showed a benefit for treated patients. The outcome of the current Phase 3 trial may delay or prevent the regulatory clearance 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, 2005, had an accumulated deficit of approximately \$238.8 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 clearances and to successfully manufacture and market our proposed products. Our lead product, Xcytrin, may receive regulatory clearance on a delayed basis or may not receive such clearance at all, which would have a material impact on our ability to become profitable. 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 clearance to market a product, we will have to demonstrate that the product is safe and effective on 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 clearances. Data from our completed initial Phase 3 clinical trial of Xcytrin were not sufficient to obtain regulatory clearance. Any approval of Xcytrin will require at least one additional clinical trial, including the Phase 3 trial we are currently conducting. Conducting additional trials will cause significant delays in approval and consume additional resources and may not be sufficient to obtain regulatory clearance.

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 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 clearance 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.

Manufacturers of drugs also must 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.

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 fiscal year 2006. 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 clearance;
- 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;
- 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
- pricing and reimbursement policies of government and 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. 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 could have a material adverse effect on our ability to complete clinical development of our products. 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 affect 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 affect 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.

***Our operations may be impaired unless we can successfully manage our growth.***

We expect to continue to expand our research and development, product development, sales and marketing and administrative operations. This expansion may place a significant strain on our management, operational and financial resources. To manage growth, we will be required to improve existing, and implement additional, operational and financial systems, procedures and controls and hire, train and manage additional employees. We cannot assure you that (i) our current and planned personnel, systems, procedures and controls will be adequate to support our anticipated growth, (ii) management will be able to hire, train, retain, motivate and manage required personnel or (iii) management will be able to successfully identify, manage and exploit existing and potential market opportunities. Our failure to manage growth effectively could limit our ability to achieve our research and development and commercialization goals.

***Failure to complete our assessment of the effectiveness of our internal control over financial reporting may subject us to regulatory sanctions and could result in a loss of public confidence, which could harm our operating results and our stock price.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, beginning with our year ending June 30, 2005, we will be required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting and our audited financial statements. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of June 30, 2005. If we do not complete timely assessment, we could be subject to regulatory sanctions and a loss of public confidence in our internal control. In addition, any failure to implement required new or improved controls, or difficulties encountered in our implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations.

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

The development, manufacturing, pricing, sales, 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 assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these 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.

***Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.***

Our certificate of incorporation, bylaws and stockholder rights plan may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable. In addition, provisions of the Delaware General Corporation Law also restrict certain business combinations with interested stockholders. These provisions are intended to encourage potential acquirers to negotiate with us and allow our board of directors the opportunity to consider alternative proposals in the interest of maximizing stockholder value. However, these prohibitions may also discourage acquisition proposals or delay or prevent a change in control, which could harm our stock price.

*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 reimbursement policies;
- 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.

***We are subject to uncertainties regarding healthcare reimbursement and reform.***

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may 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. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, the impact of the Medicare Prescription Drug Improvement and Modernization Act of 2003 on the use and reimbursement of pharmaceuticals will result in a decrease in the reimbursement levels for certain oncology drugs. Given this and other recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. One example of proposed reform that could affect our business is the current discussion of drug reimportation into the United States. In 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United

States back into the United States from other countries where the drugs were sold at a lower price. Although the Secretary of Health and Human Services has refused to implement the directive, in July 2003, the U.S. House of Representatives passed a similar bill that does not require the U.S. Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we or any potential collaborators receive for our products, adversely affecting our profitability. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could have a material adverse effect on our business, financial condition and results of operations.

Our ability to commercialize our products successfully will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment 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. 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 health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially adversely affect 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.

***New and Potential New Accounting Pronouncements May Impact Our Future Financial Position and Results of Operations.***

There may be potential new accounting pronouncements or regulatory rulings, which may have an impact on our future financial position and results of operations. In particular, in December 2004, the Financial Accounting Standards Board, ("FASB"), issued Statement of Financial Accounting Standards 123R (SFAS123R), *Share-Based Payment—An Amendment of FASB Statements No. 123 and 95*, which eliminated the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). SFAS 123R will instead require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and employee stock purchase plans. SFAS 123R is effective for public companies for fiscal years beginning after June 15, 2005. We will be required to implement the standard in the quarter that begins July 1, 2005. The adoption of FAS 123R will materially impact our results of operations.

### **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, 2005 would have declined by \$374,000.

### **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 2005, 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 have been no changes (including corrective actions with regard to significant deficiencies or material weaknesses) in our internal controls over financial reporting that occurred during the third fiscal quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

- |      |      |  |
|------|------|--|
| Item | 1.   | Legal Proceedings  |
|      |      | Not Applicable.  |
| 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  |
|      |      | Not Applicable.  |
| Item | 6.   | Exhibits   |
|      | a.   | Exhibits   |
|      | 10.1 | First Amendment To Patent License Agreement entered into on or about July 1, 1991 by and between the Company and the University of Texas System, Austin. |
|      | 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.  |

### **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: April 29, 2005

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

Richard A. Miller, M.D.

*President and Chief Executive Officer*

Dated: April 29, 2005

By: /s/ LEIV LEA

Leiv Lea

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



## 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)) for the registrant and we 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 quarterly report is being prepared;
  - b. 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;
  - c. 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; and
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: April 29, 2005

/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)) for the registrant and we 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 quarterly report is being prepared;
  - b. 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;
  - c. 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; and
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: April 29, 2005

/s/ LEIV LEA

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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, 2005 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.

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Richard A. Miller, M.D.  
President and Chief Executive Officer  
April 29, 2005

**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, 2005 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

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Leiv Lea  
Vice President, Finance and Administration  
and Chief Financial Officer and Secretary  
April 29, 2005