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

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2004

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	**94-3148201**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification Number)*

995 E. Arques Avenue
Sunnyvale, California 94085-4521
(408) 774-0330
(Address of principal executive offices including zip code and 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 [X] NO [ ].

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES [X] NO [ ].

As of April 15, 2004, there were 19,609,976 shares of the registrant's Common Stock outstanding, par value $0.0001 per share.

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

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, 2004	June 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,058	$ 50,371
Marketable securities	39,491	37,364
Prepaid expenses and other current assets	1,288	1,339
Total current assets	69,837	89,074
Property and equipment, net	1,391	2,206
Other assets	527	573
	$ 71,755	$ 91,853
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,035	$ 1,445
Accrued liabilities	1,307	963
Total current liabilities	3,342	2,408
Deferred rent	78	35
Total liabilities	3,420	2,443
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	276,611	275,829
Accumulated other comprehensive income	180	144
Deficit accumulated during development stage	(208,458)	(186,565)
Total stockholders' equity	68,335	89,410
	$ 71,755	$ 91,853

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,
	2004	2003	2004	2003	2004
Revenues:					
License and milestone revenues	$ --	$ --	$ --	$ --	$ 7,855
Contract revenues	--	--	--	--	5,847
Total revenues	--	--	--	--	13,702
Operating expenses:					
Research and development	6,096	5,963	18,213	17,666	215,692
General and administrative	1,418	1,573	4,442	4,557	40,181
Total operating expenses	7,514	7,536	22,655	22,223	255,873
Loss from operations	(7,514)	(7,536)	(22,655)	(22,223)	(242,171)
Interest and other income, net	233	339	762	1,451	33,713
Net loss	$ (7,281)	$ (7,197)	$ (21,893)	$ (20,772)	$ (208,458)
Basic and diluted net loss per share	$ (0.44)	$ (0.44)	$ (1.34)	$ (1.28)	
Shares used to compute basic and diluted net loss per share	16,365	16,208	16,289	16,200	

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,
	2004	**2003**	**2004**
Cash flows from operating activities:			
Net loss	$ (21,893)	$ (20,772)	$ (208,458)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,129	1,615	12,676
Stock compensation expense	14	9	864
Gain on sale of marketable securities	--	--	58
Write-down of fixed assets	--	--	381
Changes in assets and liabilities:			
Prepaid expenses and other assets	97	(49)	(1,815)
Accounts payable	590	(859)	2,035
Accrued liabilities	344	(118)	1,307
Deferred rent	43	(217)	78
Net cash used in operating activities	(19,676)	(20,391)	(192,874)
Cash flows from investing activities:			
Purchase of property and equipment	(314)	(120)	(10,679)
Proceeds from sale of property and equipment	--	--	112
Purchases of marketable securities	(29,948)	(25,745)	(418,399)
Proceeds from maturities and sales of marketable securities	27,857	23,004	379,030
Net cash used in investing activities	(2,405)	(2,861)	(49,936)
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs	768	39	252,235
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	768	39	271,868
Increase (decrease) in cash and cash equivalents	(21,313)	(23,213)	29,058
Cash and cash equivalents at beginning of period	50,371	89,324	--
Cash and cash equivalents at end of period	$ 29,058	$ 66,111	$ 29,058

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 presentation 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, 2003 filed with the Securities and Exchange Commission on September 25, 2003.

The results of operations for the three and nine months ended March 31, 2004 are not necessarily indicative of the operating results that may be reported for the fiscal year ending June 30, 2004 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 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):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2004	2003	2004	2003
Net loss, as reported	$ (7,281)	$ (7,197)	$ (21,893)	$ (20,772)
Employee stock-based compensation using the fair value based method	(1,970)	(2,285)	(5,772)	(7,846)
Proforma net loss	$ (9,251)	$ (9,482)	$ (27,665)	$ (28,618)
Basic and diluted net loss per share, as reported	$ (0.44)	$ (0.44)	$ (1.34)	$ (1.28)
Proforma basic and diluted net loss per share	$ (0.57)	$ (0.59)	$ (1.70)	$ (1.77)

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 3,949,919 and 3,702,159 shares of common stock were outstanding at March 31, 2004 and 2003, 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 which 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,	
	2004	2003	2004	2003
Net loss	$ (7,281)	$ (7,197)	$ (21,893)	$ (20,772)
Change in net unrealized gains and losses on available-for-sale securities	75	(31)	36	2
Comprehensive loss	$ (7,206)	$ (7,228)	$ (21,857)	$ (20,770)

Note 4 - Subsequent Event

In February 2004, the company 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. On April 7, 2004, the company sold 3.2 million shares of common stock at a price of $13.00 per share in an underwritten public offering pursuant to this registration statement. The company received approximately $39.6 million in proceeds (before offering expenses) from the issuance of 3.2 million shares, representing gross proceeds of $41.6 million, less underwriting discounts and commissions.

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

The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from any future performance suggested in this report as a result of factors, including those discussed in "Factors That May Affect Future Operating Results" and elsewhere in this report and in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2003. All forward-looking statements are based on information currently available to Pharmacyclics; and we assume no obligation to update such forward-looking statements.

Overview

Pharmacyclics is a pharmaceutical company focused on the development of products for the treatment of cancer and atherosclerosis. To date we have devoted substantially all of our resources to the research and development of our products and have not derived any commercial revenues from the sale of our products. We have two primary investigational drug products, or research and development programs, for which we are currently focusing our efforts: Xcytrin® and Antrin®.

We are enrolling patients in a pivotal Phase 3 trial of Xcytrin for the potential treatment of lung cancer patients with brain metastases. This randomized controlled study, known as the SMART (**S**tudy of Neurologic Progression with **M**otexafin Gadolinium **A**nd **R**adiation **T**herapy) trial, will enroll about 550 patients; and we plan to complete enrollment in this trial in the fourth quarter of calendar 2004. 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. The FDA has also granted us Fast-Track designation for the SMART trial. This designation will not impact the results of our trial, but may facilitate and expedite the development and review of the application for the approval of the drug.

The SMART trial is based on the results of our completed large randomized trial in patients with brain metastases from solid tumors. That trial enrolled 401 patients and compared WBRT alone to WBRT plus Xcytrin. The primary end points were survival and time to neurologic progression. The overall trial did not meet its end points, but a benefit was seen in lung cancer, the largest sub-group of patients (N=251). There was an improvement in time to neurologic progression as assessed by investigators and by a blinded events review committee for lung cancer patients receiving Xcytrin. Lung cancer patients treated with Xcytrin were also found to have a reduction in death due to brain tumor progression as assessed by investigators. The results of this study were published in July 2003 in the *Journal of Clinical Oncology*. Patients receiving Xcytrin were also found to have improved time to neurocognitive progression. Neurogognitive progression is a quantitative and blinded assessment of cognitive functions such as memory, verbal fluency, decision-making ability and fine motor control. These results were published in January 2004 in the *Journal of Clinical Oncology*.

We are conducting several Phase 1 and Phase 2 clinical trials evaluating Xcytrin as a single agent, in combination with radiation, and in combination with chemotherapy for various cancers. We have begun Phase 2 clinical trials with Xcytrin used alone in hematologic cancers, such as chronic lymphocytic leukemia, and in combination with monoclonal antibodies Rituxan® and Zevalin® for recurrent lymphoma. Phase 1 trials are underway evaluating Xcytrin given in combination with doxorubicin and with docetaxel (Taxotere®) for lung, prostate, ovarian and breast cancer and combined with radiation and chemotherapy for the treatment of newly diagnosed, advanced head and neck cancer patients. We have also begun a Phase 1 clinical trial evaluating Xcytrin in combination with Temodar® (temozolamide) for the treatment of patients with relapsed malignant gliomas. Through our Cooperative Research and Development Agreement, the National Cancer Institute is conducting Phase 1 trials of Xcytrin for treatment of both primary adult and pediatric brain tumors, pancreatic cancer and lung cancer.

We have also completed a Phase 1 clinical trial with Antrin photothерapy 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 phototherapy 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, 2004, we had an accumulated deficit of approximately $208.5 million. We expect to continue to incur 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.

As of March 31, 2004, we had approximately $68,549,000 in cash, cash equivalents and marketable securities. On April 7, 2004, we sold 3.2 million 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 $39.6 million in proceeds (before offering expenses) from the issuance of 3.2 million shares, representing gross proceeds of $41.6 million, less underwriting discounts and commissions.

Results of Operations

Research and Development

Research and development expenses increased $133,000 (2%) to $6,096,000 for the three months ended March 31, 2004, compared to $5,963,000 for the three months ended March 31, 2003. This increase was primarily due to higher third party clinical trial costs ($648,000) as the company continued to enroll patients in its SMART Phase 3 trial, as well as other Phase 1 and 2 clinical trials using Xcytrin. This increase was partially offset by decreases in building rent expense ($228,000) as the company renegotiated its building lease as of January 1, 2003 and the expiration of one building lease on December 31, 2003 and by a decrease in depreciation expense of $198,000. For the nine months ended March 31, 2004, research and development expenses increased $547,000 (3%) to $18,213,000 compared to $17,666,000 for the nine months ended March 31, 2003. The increase was due primarily to higher third party clinical trial expenses ($2,354,000) partially offset by lower payroll and related expenses ($1,303,000) due to lower average headcount and by lower building rent expense ($817,000). The company expects research and development expenses to increase slightly throughout fiscal 2004 as the company continues enrollment in its ongoing clinical trials.

General and Administrative

General and administrative expenses decreased approximately $155,000 (10%) to $1,418,000 for the three months ended March 31, 2004, compared to $1,573,000 for the three months ended March 31, 2003. For the nine months ended March 31, 2004, general and administrative expenses decreased approximately $115,000 (3%) to $4,442,000 compared to $4,557,000 for the nine months ended March 31, 2003. The decreases were primarily due to decreases in the company's building rent expense. The company expects general and administrative expenses to remain relatively consistent for the remainder of fiscal 2004.

Interest and Other Income, Net

Interest and other income, net was $233,000 and $339,000 for the three months ended March 31, 2004 and 2003, respectively, a decrease of 31%. For the nine months ended March 31, 2004 and 2003, interest and other income, net was $762,000 and $1,451,000 respectively, a decrease of 47%. The decreases were

primarily due to lower cash, cash equivalents and marketable securities balances combined with lower interest rates being earned by these balances.

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 grant and contract revenues and interest income.

As of March 31, 2004, we had approximately $68,549,000 in cash, cash equivalents and marketable securities. 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. On April 7, 2004, we sold 3.2 million 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 $39.6 million in proceeds (before offering expenses) from the issuance of 3.2 million shares, representing gross proceeds of $41.6 million, less underwriting discounts and commissions.

Net cash used in operating activities of $19,676,000 during the nine months ended March 31, 2004 resulted primarily from the company's net loss for the period, net of depreciation and amortization. Net cash used in operating activities of $20,391,000 during the nine months ended March 31, 2003 resulted primarily from the company's net loss for the period, net of depreciation and amortization.

Net cash used in investing activities of $2,405,000 and $2,861,000 for the nine months ended March 31, 2004 and 2003, respectively, consisted primarily of purchases of marketable securities, net of maturities and sales.

Net cash provided by financing activities of $768,000 and $39,000 for the nine months ended March 31, 2004 and 2003, respectively, primarily consisted of proceeds from the sale of common stock upon the exercise of stock options and from purchases under the company’s Employee Stock Purchase Plan.

We lease our facilities under non-cancelable operating leases that expire in fiscal 2008. Future minimum lease payments under non-cancelable operating leases as of March 31, 2004 are as follows:

	Operating Lease Commitments
Remaining 3 months of fiscal 2004	$ 286,000
Fiscal 2005	1,162,000
Fiscal 2006	1,201,000
Fiscal 2007	1,220,000
Fiscal 2008	610,000
Total minimum lease payments	$ 4,479,000

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. We expect to complete enrollment of our Phase 3 clinical trial of our first investigational drug Xcytrin in patients with brain metastases from non-small cell lung cancer in the fourth calendar quarter of 2004 (the second fiscal quarter of our fiscal 2005). We cannot assure you that our current capital resources will be sufficient to satisfy our capital needs through full enrollment of the Xcytrin trial or, if Xcytrin is ultimately approved for sale, through its production, marketing and commercialization. If our existing capital resources are insufficient to satisfy our capital requirements through testing,

regulatory clearance and commercialization of Xcytrin, we would be required 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 may be required to raise additional funds through public or private financings, collaborative relationships or other arrangements. We cannot be certain that such additional funding, if needed, 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

Critical accounting policies are defined by the SEC as those that are most important to the portrayal of a company's financial condition and results, and that require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. We have identified the following critical accounting policies used in the preparation of our financial statements and accompanying notes.

Revenue Recognition

Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred 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 June 30, 2003, 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 separate component of accumulated other comprehensive income. 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;
- 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; and
- To date we have had no declines in fair value that have been identified as other than temporary.

Factors That May Affect Future Operating Results

Risks Related to Pharmacyclics

We operate in an environment that involves a number of risks and uncertainties. The risks and uncertainties described below are the material risks and uncertainties of which we are currently aware. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition would suffer. The risks discussed below also include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements. All forward-looking statements are based on information currently available to Pharmacyclics and we assume no obligation to update any such forward-looking statements.

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. 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 approved 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.

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. 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 which 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, 2004, had an accumulated deficit of approximately $208.5 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 which could delay, limit or prevent regulatory clearances. Data from our completed initial Phase 3 clinical trial of Xcytrin was 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 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 Good Manufacturing Practice regulations and other FDA regulatory requirements. Failure of our suppliers to follow current Good Manufacturing Practices 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 phototherapy due to delays in approvals of the third-party light sources required for this product.

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 magnetic resonance imaging detectable compounds do not infringe the 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.

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 biopharmaceuticals 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 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 enter into other 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 phototherapy 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 which 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 biopharmaceuticals 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 Good Manufacturing Practices and similar foreign standards;

- 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; and

- 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.

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.

We may need 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 may require additional funds to complete our current Phase 3 trial with Xcytrin for the potential treatment of brain metastases in lung cancer patients.

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 investments, 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 which 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.

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 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.

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 facilities in California are 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 revenues and 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 the section entitled "Factors That May Affect Future Operating Results" actually occur, it could have a dramatic and material adverse impact on the market price of our common stock.

We are subject to uncertainties regarding health care 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 may result in a decrease in the reimbursement levels for 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.

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 which 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, 2004 would have declined by $386,000.

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 2004, 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 2004 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. Changes in Securities

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 and Reports on Form 8-K

a. Exhibits

10.1	The Company's 1995 Non-Employee Directors Stock Option Plan
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

b. Reports on Form 8-K

On January 29, 2004, we filed a Current Report on Form 8-K, under Item 12, announcing our financial results for the fiscal quarter ended December 31, 2003.

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Signatures

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

PHARMACYCLICS, INC.
(Registrant)

Dated: April 30, 2004

By: /s/ RICHARD A. MILLER, M.D.
Richard A. Miller, M.D.
President and Chief Executive Officer

Dated: April 30, 2004

By: /s/ LEIV LEA
Leiv Lea
Vice President, Finance and Administration and Chief Financial Officer

EXHIBITS INDEX

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