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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2003

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
(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 ☒ 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 April 30, 2003, there were 16,229,538 shares of the registrant's Common Stock outstanding, par value \$0.0001 per share.

This quarterly report on Form 10-Q consists of 22 pages of which this is page 1. The Exhibit Index is located at page 19.

PHARMACYCLICS, INC.
Form 10-Q
Table of Contents

PART I. Financial Information	Page No.
Item 1. Financial Statements (unaudited):	
Condensed Balance Sheets as of March 31, 2003 and June 30, 2002	<u>3</u>
Condensed Statements of Operations for the three and nine months ended March 31, 2003 and 2002	<u>4</u>
Condensed Statements of Cash Flows for the nine months ended March 31, 2003 and 2002	<u>5</u>
Notes to Condensed Financial Statements	<u>6</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>8</u>
Item 3. Quantitative and Qualitative Disclosures About Market Risk	<u>18</u>
Item 4. Controls and Procedures	<u>18</u>
PART II. Other Information	
Item 1. Legal Proceedings	<u>19</u>
Item 2. Changes in Securities	<u>19</u>
Item 3. Defaults Upon Senior Securities	<u>19</u>
Item 4. Submission of Matters to a Vote of Security Holders	<u>19</u>
Item 5. Other Information	<u>19</u>
Item 6. Exhibits and Reports on Form 8-K	<u>19</u>
Signatures	<u>20</u>



Pharmacyclics®, the "pentadentate" logo®, Xcytrin® and Antrin®, are registered U.S. trademarks. Other trademarks, trade names or service marks used herein are the property of their respective owners.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2003	June 30, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 66,111	\$ 89,324
Marketable securities	28,337	25,594
Prepaid expenses and other current assets	1,381	1,182
Total current assets	95,829	116,100
Property and equipment, net	2,661	4,156
Other assets	606	756
	<u>\$ 99,096</u>	<u>\$ 121,012</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 925	\$ 1,784
Accrued liabilities	1,268	1,386
Total current liabilities	2,193	3,170
Deferred rent	17	234
Total liabilities	2,210	3,404
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	275,758	275,710
Accumulated other comprehensive income	165	163
Deficit accumulated during development stage	(179,039)	(158,267)
Total stockholders' equity	96,886	117,608
	<u>\$ 99,096</u>	<u>\$ 121,012</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,	
	2003	2002	2003	2002
Operating expenses:				
Research and development	\$ 5,963	\$ 7,411	\$ 17,666	\$ 27,536
Marketing, general and administrative	1,573	1,541	4,557	6,178
Total operating expenses	<u>7,536</u>	<u>8,952</u>	<u>22,223</u>	<u>33,714</u>
Loss from operations	(7,536)	(8,952)	(22,223)	(33,714)
Interest and other income, net	339	1,056	1,451	4,392
Net loss	<u>\$ (7,197)</u>	<u>\$ (7,896)</u>	<u>\$ (20,772)</u>	<u>\$ (29,322)</u>
Basic and diluted net loss per share	<u>\$ (0.44)</u>	<u>\$ (0.49)</u>	<u>\$ (1.28)</u>	<u>\$ (1.82)</u>
Weighted average shares used to compute basic and diluted net loss per share	<u>16,208</u>	<u>16,141</u>	<u>16,200</u>	<u>16,133</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,	
	2003	2002
Cash flows from operating activities:		
Net loss	\$ (20,772)	\$ (29,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,615	1,740
Stock compensation expense	9	87
Changes in assets and liabilities:		
Prepaid expenses and other assets	(49)	510
Accounts payable	(859)	(1,954)
Accrued liabilities	(118)	102
Deferred rent	(217)	56
Net cash used in operating activities	<u>(20,391)</u>	<u>(28,781)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(120)	(1,235)
Purchases of marketable securities	(25,745)	(44,059)
Proceeds from sales of marketable securities	4,000	--
Proceeds from maturities of marketable securities	19,004	96,880
Net cash provided by (used in) investing activities	<u>(2,861)</u>	<u>51,586</u>
Cash flows from financing activities:		
Proceeds from sale of common stock	39	434
Net cash provided by financing activities	<u>39</u>	<u>434</u>
Net increase (decrease) in cash and cash equivalents	(23,213)	23,239
Cash and cash equivalents at beginning of the period	89,324	51,391
Cash and cash equivalents at end of the period	<u>\$ 66,111</u>	<u>\$ 74,630</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 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, 2002 filed with the Securities and Exchange Commission on September 27, 2002.

The results of operations for the three and nine months ended March 31, 2003 are not necessarily indicative of the operating results that may be reported for the fiscal year ending June 30, 2003 or for any other future period.

Employee Stock-Based Compensation

The company accounts for employee stock-based compensation using the intrinsic value method prescribed in Account Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. As the company has issued all employee stock options with an exercise price of fair market value at the grant date, no stock compensation expense related to employees has been incurred. The impact on the company's operations if employee stock options were accounted for using the fair value method prescribed in Statement of Financial Accounting Standard No. 123 "Accounting for Stock Based Compensation" is outlined in the following table (in thousands):

	Three Months Ended March 31, 2003		Nine Months Ended March 31, 2003	
	2003	2002	2003	2002
Net loss, as reported	\$ (7,197)	\$ (7,896)	\$ (20,772)	\$ (29,322)
Employee stock-based compensation using the fair value based method	\$ (2,285)	\$ (3,138)	\$ (7,846)	\$ (9,370)
Proforma net loss	\$ (9,482)	\$ (11,034)	\$ (28,618)	\$ (38,692)
Basic and diluted net loss per share, as reported	\$ (0.44)	\$ (0.49)	\$ (1.28)	\$ (1.82)
Proforma basic and diluted net loss per share	\$ (0.59)	\$ (0.68)	\$ (1.77)	\$ (2.40)

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 shares 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 3,702,159 and 4,080,393 shares of common stock were outstanding at March 31, 2003 and 2002, respectively, and were excluded from the calculation of diluted net 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,	
	2003	2002	2003	2002
Net loss	\$ (7,197)	\$ (7,896)	\$ (20,772)	\$ (29,322)
Change in net unrealized gains and losses on available-for-sale securities	(31)	(495)	2	(914)
Comprehensive loss	<u>\$ (7,228)</u>	<u>\$ (8,391)</u>	<u>\$ (20,770)</u>	<u>\$ (30,236)</u>

Note 4 - Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force ("EITF") reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The company believes that the adoption of this standard will have no material impact on its financial statements.

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The company believes that the adoption of this standard will have no material impact on its financial statements.

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

In addition to historical information, this report contains predictions, estimates and other forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements may be identified by the use of words such as "expect," "believe," "anticipate," "project," and similar expressions. 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, 2002.

Overview

Pharmacyclics is a pharmaceutical company focused on the development of products that improve existing therapeutic approaches to 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 drug products, or research and development programs, upon which we are currently focusing our efforts: Xcytrin® (motexafin gadolinium) Injection and Antrin® (motexafin lutetium) Injection.

We have begun enrollment in a pivotal Phase III 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 enroll about 550 patients. 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.

The SMART trial is based on the results of a 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 and had improved time to neurocognitive progression.

We have completed patient enrollment in a multicenter Phase II trial with Xcytrin for the treatment of glioblastoma multiforme, a malignant primary brain tumor. We also have begun enrollment in Phase I clinical trials for head and neck cancer and for the use of Xcytrin with chemotherapy. Through our Cooperative Research and Development Agreement, the National Cancer Institute is conducting Phase I trials of Xcytrin for treatment of both primary adult and pediatric brain tumors, pancreatic cancer and lung cancer.

We also completed a Phase I clinical trial with Antrin phototherapy 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. In September 2002, we reported final results of this trial at the Transcatheter Cardiovascular Therapeutics meeting. 79 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. No instances of emergency coronary artery bypass, death, stroke or myocardial infarction occurred in patients who received both Antrin infusion and endovascular illumination and activation of the drug. 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.

Approximately 159 patients were enrolled in a Phase II clinical trial with Antrin for patients with peripheral arterial disease of the lower extremities. The study was designed to evaluate Antrin alone compared to Antrin activated with varying doses of light for prevention of restenosis following balloon angioplasty of the femoral artery. We do not plan to perform any further clinical studies for this indication as our development efforts are primarily focused on treatment of vulnerable plaque in the coronary arteries.

We have incurred significant operating losses since our inception in 1991, and as of March 31, 2003, had an accumulated deficit of approximately \$179.0 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, to obtain required regulatory clearances and successfully manufacture and market our products.

Results of Operations

Research and Development

Research and development expenses decreased \$1,448,000 (20%) to \$5,963,000 for the three months ended March 31, 2003 compared to \$7,411,000 for the three months ended March 31, 2002. This decrease was due primarily to reductions in personnel costs (\$1,226,000), as the company focuses on conducting a Phase III trial with Xcytrin. In addition, expenses for contract pre-clinical studies were lower (\$368,000) due to the completion of activities in this area. For the nine months ended March 31, 2003, research and development expenses decreased \$9,870,000 (36%) to \$17,666,000 compared to \$27,536,000 for the nine months ended March 31, 2002. The decrease was due primarily to decreased personnel costs (\$3,398,000), third party clinical trial expenses (\$1,331,000), consulting/outside services (\$1,098,000), drug substance/manufacturing costs (\$1,648,000) and third party research/pre-clinical studies (\$1,529,000). We expect research and development expenses to increase over the near future as the company incurs additional expenses from its Phase III clinical trial.

Marketing, General and Administrative

Marketing, general and administrative expenses remained consistent at \$1,573,000 for the three months ended March 31, 2003, compared to \$1,541,000 for the three months ended March 31, 2002. For the nine months ended March 31, 2003, marketing, general and administrative expenses decreased \$1,621,000 (26%) to \$4,557,000 compared to \$6,178,000 for the nine months ended March 31, 2002. The decrease was primarily due to reductions in public relations and third party marketing expenses (\$993,000) and personnel costs (\$324,000).

Interest and Other Income, Net

Interest and other income, net was \$339,000 and \$1,056,000 for the three months ended March 31, 2003 and 2002, respectively, a decrease of 66%. For the nine months ended March 31, 2003 and 2002, interest and other income, net was \$1,451,000 and \$4,392,000, respectively, a decrease of 67%. The decreases were primarily due to lower cash, cash equivalents and marketable securities balances combined with lower interest rates being earned on 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, 2003, we had approximately \$94,448,000 in cash, cash equivalents and marketable securities. 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 cash used in operating activities of \$28,781,000 during the nine months ended March 31, 2002 resulted primarily from the net loss for the period and a reduction in accounts payable, partially affected by depreciation and amortization.

Net cash used in investing activities of \$2,861,000 in the nine months ended March 31, 2003 and provided by investing activities of \$51,586,000 for the nine months ended March 31, 2002, consisted primarily of the net activities of the company's investments in marketable securities.

Net cash provided by financing activities of \$39,000 and \$434,000 for the nine months ended March 31, 2003 and 2002, respectively, primarily consisted of proceeds from the sale of common stock under the company's Employee Stock Purchase Plan and the exercise of stock options.

We lease our facilities under non-cancelable operating leases that expire in fiscal 2004 and 2008. Future minimum lease payments and sublease income under non-cancelable operating leases as of March 31, 2003 are as follows:

	Operating Lease Commitments	Operating Sublease Income
Remaining 3 months of fiscal 2003	\$ 423,000	\$ (34,000)
Fiscal 2004	1,419,000	(69,000)
Fiscal 2005	1,162,000	--
Fiscal 2006	1,201,000	--
Fiscal 2007	1,220,000	--
Fiscal 2008	610,000	--
Total minimum lease payments and operating sublease income	<u>\$ 6,035,000</u>	<u>\$ (103,000)</u>

Based on the current status of our product development and commercialization plans, we believe cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least calendar year 2004. However, 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; the time and cost associated with 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 restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations.

Critical Accounting Policies

Reference is made to "Critical Accounting Policies and Estimates" included on page 27 of our Annual Report on Form 10-K for the year ended June 30, 2002. As of the date of the filing of this Quarterly Report, we have not identified any critical accounting policies other than those discussed in our Annual Report for the year ended June 30, 2002 and have not otherwise concluded that any of these policies have become out of date or otherwise misleading.

Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force ("EITF") reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The company believes that the adoption of this standard will have no material impact on its financial statements.

In January 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The company believes that the adoption of this standard will have no material impact on its financial statements.

FACTORS THAT MAY AFFECT FUTURE OPERATING RESULTS

Risks Related to Pharmacyclics

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 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 to produce their intended effects.

The completion rate of our clinical trials depends upon, among other factors, the rate of patient enrollment. 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 as scheduled for many reasons, including, as was the case with our previous Phase III trial of Xcytrin, failure to meet our primary endpoints. Even if we are able to submit a new drug application, the Food and Drug Administration may refuse to file our application or may not clear our application in a timely manner or may deny the application entirely.

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 such as ours 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 obtaining promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of one of our products 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. For example, our previous Phase III trial of Xcytrin failed to meet its co-primary endpoints, survival or time to neurologic progression, even though our Phase Ib/II trial showed a benefit for treated patients. This outcome may delay or prevent the regulatory clearance of Xcytrin as a treatment for brain metastases and 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, 2003, had an accumulated deficit of approximately \$179.0 million. We expect to continue to incur substantial additional operating losses until 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 under development, to obtain required regulatory clearances and to successfully manufacture and market our proposed products. Our lead product, Xcytrin, currently being developed for the potential treatment of brain metastases originating from non-small cell lung cancer, 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. All revenues to date are primarily from license and milestone payments and, to a lesser extent, funding from one government research grant.

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 U.S. Food and Drug Administration (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 Phase III clinical trial of Xcytrin was not sufficient to obtain regulatory clearance and an additional trial, which is currently enrolling patients, will be necessary to do so. 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. 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 on a timely basis or 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 or maintain requisite governmental approvals;
- failure to obtain approvals of clinically intended uses of our products under development; or
- identification of serious and unanticipated adverse side effects of 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. We have not been subject to a Good Manufacturing Practice inspection by the FDA or any state agency. We may be subject to delays in commercializing our products for photodynamic therapies due to delays in approvals of the third-party light sources required for these products.

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 they achieve will depend upon a number of factors, including:

- the receipt of regulatory approvals for the uses that we are studying;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products and diagnostic and/or imaging techniques; 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, 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

A number of third-party patent applications have been published, and some have issued, relating to biometallic and 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 the third party's patents are upheld as valid and infringed by our products, we could be prevented from practicing the subject matter claimed in such patents, 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 to Schering AG that relate to pharmaceutical formulations and methods for enhancing magnetic resonance imaging. We have obtained the opinion of special patent counsel that our magnetic resonance imaging detectable compounds do not infringe the claims of such patents. Nevertheless, 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. Schering AG sent communications to us suggesting that our oral magnetic resonance imaging contrast agent, Citra Vu, may infringe certain of their patents. 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. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an adequate remedy available for breach of the agreements. 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

We currently depend heavily and will depend heavily in the future on third parties for support in product development, manufacturing, marketing and distribution. We depend upon the National Cancer Institute for the sponsoring and funding of certain of the clinical trials of our Xcytrin radiation enhancer product in development. We cannot be certain that the National Cancer Institute will enlist support for all such trials or that it will continue our funding. If the National Cancer Institute did not support such trials, we might have to fund the continuation of such trials ourselves or reduce the number of disease types in our clinical trials. We cannot be certain that any of the third parties upon which we depend will fulfill their obligations in a manner that maximizes our revenues. Any reduction or discontinuance of efforts by our partners or the termination of our alliances with them could have a material adverse effect on our business, financial condition and results of operations.

We may be unsuccessful in entering into additional strategic alliances for the development or commercialization of other product candidates. Even if we did enter into any such alliances, they might not be on terms favorable to us or they might ultimately be unsuccessful.

We have no expertise in the development of light sources and associated light delivery devices required for our photoangioplasty and photodynamic therapy products under development. Successful development, manufacturing, approval and distribution of our photosensitization products will require third party participation for the required light sources, associated light delivery devices and other equipment. We currently obtain lasers from Diomed, Inc. and cylindrically diffusing light fibers from CardioFocus, Inc. on a purchase order basis, and such entities are under no obligation to continue to deliver light devices on an

ongoing basis. Failure to maintain 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 supplied by other sources may not receive regulatory approval for use in photoangioplasty.

We have limited manufacturing experience and thus rely heavily upon contract manufacturers

We must manufacture our products in commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. We do not own the manufacturing facilities necessary to provide clinical and commercial quantities of our products.

We utilize contract manufacturers to formulate, fill, package and label clinical quantities of Xcytrin and Antrin on a purchase order basis. Any failure by these third parties to supply our or the National Cancer Institute's requirements for clinical trial materials would jeopardize the completion of our clinical trials and could therefore have a material adverse effect on us.

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 intend to 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.

Our capital requirements are uncertain 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 require 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. We may require additional funds to complete our planned Phase III trial with Xcytrin for brain metastases. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable 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 calendar year 2004. As described above under "Liquidity and Capital Resources," however, this is a forward-looking statement and is subject to risks and uncertainties. Our actual capital requirements will depend on many factors, including:

- continued progress of our research and development programs;
- our ability to establish collaborative arrangements;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearances;
- the costs involved in preparing, filing, prosecuting, maintaining 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.

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.

Risks Related to Our Industry

We face rapid technological change and intense competition

The pharmaceutical industry is subject to rapid and substantial technological change. 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, 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.

We are a relatively new enterprise and 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, diagnostic and imaging effects than our products. We are aware that one of our competitors in the market for photodynamic therapy drugs has received marketing approval of a product for certain uses in the United States and other countries. 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.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if they are commercialized. The diseases for which we are developing our therapeutic products can also be treated, in the case of cancer, by surgery, radiation 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 of the securities of small capitalization biotechnology companies, including ours, have historically been highly volatile. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a variety of factors, including:

- the results of preclinical testing and clinical trials by us or our competitors;

- technological innovations or new therapeutic products;
- governmental regulation;
- developments in patent or other proprietary rights;
- litigation;
- public concern as to the safety of products developed by us or others;
- comments by securities analysts; and
- general market conditions in our industry.

In addition, if any of the negative consequences or risks described in these "Factors that May Affect Future Operating Results" actually occurred, the market price of our common stock may decrease.

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, as well as 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, given 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 the reform of the Medicare and Medicaid systems. 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 can 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. Although we are insured against such risks up to a \$10,000,000 annual aggregate limit 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 accidental 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 values 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, 2003 would have declined by \$293,000.

Item 4. *Controls and Procedures*

Within the 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of the company's management, including the company's president and chief executive officer along with the chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation, the company's president and chief executive officer along with the chief financial officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to the company that is required to be included in our periodic SEC filings.

There have been no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date we carried out this evaluation.

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 Third Amendment to New Lease dated February 5, 2003 by and between Registrant and Metropolitan Life Insurance Company.

99.1 Certification.

b. Reports on Form 8-K

None.

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: May 6, 2003

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

Dated: May 6, 2003

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

Sarbanes-Oxley Section 302(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-14 and 15d-14) for the registrant and we have:
 - a. designed such disclosure controls and procedures 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 as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

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

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

Sarbanes-Oxley Section 302(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-14 and 15d-14) for the registrant and we have:
 - a. designed such disclosure controls and procedures 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 as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 6, 2003

/s/ LEIV LEA

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