PHARMACYCLICS INC Form 10-Q April 29, 2008

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

## FORM 10-O

TORNI IV 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, 2008
or [ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period fromto
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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer " Accelerated filer " Non-accelerated filer "   Small reporting Company x
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). (Check one): YES "NO x
As of Amil 20, 2008 there were 25,004,400 shows of the majetrant's Common Steel, non-value \$0,0001 non-

As of April 29, 2008 there were 25,994,490 shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding.

This quarterly report on Form 10-Q consists of 23 pages of which this is page 1. The Exhibits Index page immediately follows page 22.

Note: PDF provided as a courtesy

PART II. Other Information

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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, 2008		June 30, 2007
ASSETS				
Current assets:  Cash and cash equivalents  Marketable securities  Prepaid expenses and other current assets		16,279 4,993 611		11,941 26,821 961
Total current assets		21,883 633 523		39,723 849 523
	\$			41 <b>,</b> 095
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable				
Accrued liabilities		754 	_	1,189 
Total current liabilities  Deferred rent		2,348 74		2,615 79
Total liabilities		2,422		2,694
Stockholders' equity: Common stock		27 (334,823)	_	(9) (315,153)
			-	41,095
	==		=	========

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)

	March 31	onths Ended	March 31,	P (A	
	2008	2007		2007	
Revenues: License and milestone revenues				\$	\$
Contract and grant revenues				19	
Total revenues				19	
Operating expenses:  Research and development*	5,120	5,669	14,822	15,557	
General and administrative*	2,100	1,705	5,923	5,315	
Purchased in-process research and development					
Total operating expenses	7 <b>,</b> 220	7,374			
Loss from operations					
Interest and other income, net	240	615	1,075	1,626	
Net loss		\$ (6,759)			\$ ==
Basic and diluted net loss per share		\$ (0.26)			
Shares used to compute basic and diluted net loss per share	25 <b>,</b> 994		25 <b>,</b> 983	23581	
* Includes non-cash share-based compensation of the following:					
Research and development	\$ 196 330	\$ 561 360	\$ 751 1051	\$ 1,379 940	\$

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,		(
	2008		
Cash flows from operating activities:  Net loss	\$(19,670)		\$
Depreciation and amortization	263	343 (78) 	
Share-based compensation expense	1,802 (7)	2,319 	
Write-down of fixed assets  Changes in assets and liabilities:  Prepaid expenses and other assets	350	(140)	
Accounts payable	168 (435) (5)		
Net cash used in operating activities	(17,657)	(17,730)	-
Cash flows from investing activities:  Purchase of property and equipment	(47) 	(447)	
Purchases of marketable securities  Proceeds from maturities and sales of marketable securities		6,500	
Net cash provided by (used in) investing activities	21,947	(8,814)	-
Cash flows from financing activities:  Issuance of common stock, net of issuance costs  Exercise of stock options	48  	21,426 583 	
Issuance of convertible preferred stock, net of issuance costs Payments under capital lease obligations	 	 	
Net cash provided by financing activities		22,009	_
Increase (decrease) in cash and cash equivalents	11,941		_
Cash and cash equivalents at end of period		\$ 17,748 S	

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 - The Company and Summary of Significant Accounting Policies

#### The Company

Pharmacyclics is a pharmaceutical company leveraging our small-molecule drug development expertise to build a pipeline in oncology and immune mediated diseases based on novel targets, pathways, and mechanisms. To date, substantially all of our resources have been dedicated to the research and development of our products, and we have not generated any commercial revenues from the sale of our products. We do not expect to generate any product revenues until we receive the necessary regulatory and marketing approvals and launch one of our products, if at all.

We have incurred significant operating losses since our inception in 1991, and as of March 31, 2008, had an accumulated deficit of approximately \$334.8 million. Based upon our recent reduction in headcount and related expenses and the current status of our product development and plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We expect research and development expenses, as a result of on-going and future clinical trials, to consume a large portion of our existing cash resources. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will need to raise substantial additional capital to fund our operations in the future. Currently, we are actively seeking partnership collaborations for our product candidates. If we are unsuccessful in obtaining a partnership for one or more of our product candidates, providing sufficient funding for our product development, we will be required to raise additional funds through the public or private sale of securities or bank debt or otherwise. If we are unable to raise additional capital sufficient to fund our current operations, we may be required to reduce operating expenses. Our actual capital requirements will depend on many factors, including the following:

- our ability to establish and the scope of any new partnership collaborations;
- the progress and success of preclinical studies and clinical trials of our product candidates; and
- the costs and timing of obtaining regulatory approvals.

Our estimate 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. If we are required to raise additional funds, we cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to respond to competitive pressures or unanticipated requirements, to develop our product candidates, and to continue operations, any of which would have a material adverse effect on our business, financial condition and results of operations.

#### **Basis of Presentation**

The accompanying interim condensed financial statements have been prepared by Pharmacyclics, Inc. (the company or Pharmacyclics), without audit, in accordance with the instructions to Form 10-Q and, therefore, do not necessarily include all information and footnotes necessary for a fair statement of its financial position, results of operations and cash flows in accordance with accounting principles generally accepted in the United States. The balance sheet at June 30, 2007 is derived from the audited balance sheet at that date which is not

presented herein.

In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of results of operations, financial position and cash flows. These condensed financial statements should be read in conjunction with the financial statements included in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007. Operating results for interim periods are not necessarily indicative of operating results for an entire fiscal year.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and the disclosure of contingent amounts in the company's financial statements and the accompanying notes. Actual results could differ from those estimates.

#### Note 2 - Basic and Diluted Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common and potential common shares outstanding during the period. Potential common shares consist of shares issuable upon the exercise of stock options (using the treasury stock method). Options to purchase 5,660,942 and 5,613,864 shares of common stock were outstanding at March 31, 2008 and 2007, respectively, but have been excluded from the computation of diluted net loss per share because their effect was anti-dilutive.

#### Note 3 - Share-Based Compensation

The components of share-based compensation recognized in the company's statements of operations for the three and nine months ended March 31, 2008 and 2007, and since inception are as follows:

	Three Mon Marc	 		oths Ended ech 31,	A	Incep pril 1 thro
	 2008	 2007	 2008	2007	ע	ecembe 200
Research and development General and administrative	\$ 196,000 330,000	\$ 561,000 360,000	\$ 751,000 1,051,000	\$ 1,379,000 940,000	\$	5,76 6,29
Total share-based compensation	\$ 526,000	\$ 921,000	\$ 1,802,000	\$ 2,319,000	\$	12,06

The following table summarizes the company's stock option activity for the nine months ended March 31, 2008:

		Options (	Outst	anding
	Shares Available for Grant	Number		Weighted Average Exercise Price
Balance at June 30, 2007 Options granted Options forfeited or expired	532,619 (1,461,017) 1,389,189	5,589,114 1,461,017 (1,389,189)	\$	10.98 1.07 10.54
Balance at March 31, 2008	460,791 =======	5,660,942 =======		8.53

#### Employee Stock Purchase Plan

. The company adopted an Employee Stock Purchase Plan (the "Purchase Plan") in August 1995. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of the company's common stock under the Purchase Plan. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. Sales under the Purchase Plan in the nine month periods ended March 31, 2008 and 2007 were 26,301 and 28,233 shares of common stock at an average price of \$1.84 and \$4.58, respectively. Shares available for future purchase under the Purchase Plan are 234,506 at March 31, 2008.

#### Note 4 - Comprehensive Loss

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

The company's comprehensive losses were as follows:

			ths Ended ch 31,	Nine Months Ended March 31,			
	_	2008	 2007	2008	2007		
Net loss	\$	(6,980,000)	\$ (6,759,000)	\$(19,670,000)	\$(19,227,000		
on available-for-sale securities	_	9,000	30,000	36,000	154 <b>,</b> 000		
Comprehensive loss	\$	(6,971,000)	\$ (6,729,000)	\$(19,634,000)	\$(19,073,000 ======		

Note 5 - Income Taxes

We adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* ("FIN 48"), on July 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *Accounting for Income Taxes*, and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Based on our evaluation, we have concluded that there are no significant uncertain tax positions requiring recognition in our financial statements. We may from time to time be assessed interest or penalties by major tax jurisdictions, although there have been no such assessments historically, with no material impact to our financial results. In the event we receive an assessment for interest and/or penalties, it would be classified in the financial statements as income tax expense. As of July 1, 2007 open tax years in major jurisdictions date back to 1991 due to the taxing authorities' ability to adjust operating loss carry forwards. The Company does not anticipate a material change to its total amount of unrecognized tax benefits within the next 12 months.

#### Note 6 - Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS No. 157), "Fair Value Measurements" which clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective the first quarter of our 2009 fiscal year.

In June 2007, the FASB ratified EITF Issue No. 07-3 ("EITF 07-3"), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities. The scope of EITF 07-3 is limited to nonrefundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. This issue provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. Earlier application is not permitted. Companies should report the effects of applying this issue prospectively for new contracts entered into on or after the effective date of

this issue. We are currently evaluating the impact of this standard on our results of operations and our financial position.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our interim financial statements and the related notes appearing at the beginning of this report. The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended June 30, 2007 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 13, 2007.

The following discussion contains forward-looking statements that involve risks and uncertainties. These statements relate to future events, such as our future clinical and product development, financial performance and regulatory review of our product candidates. Our actual results could differ materially from any future performance suggested in this report as a result of various factors, including those discussed in Part II, Item IA, "Risk Factors", and elsewhere in this report, in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2007 and in our other Securities and Exchange Commission reports and filings. All forward-looking statements are based on information currently available to Pharmacyclics; and we assume no obligation to update such forward-looking statements. Stockholders are cautioned not to place undue reliance on such statements.

#### Overview

Pharmacyclics is a pharmaceutical company leveraging our small-molecule drug development expertise to build a pipeline in oncology and immune mediated diseases based on novel targets, pathways, and mechanisms. To date, substantially all of our resources have been dedicated to the research and development of our products, and we have not generated any commercial revenues from the sale of our products. We do not expect to generate any product revenues until we receive the necessary regulatory and marketing approvals and launch one of our products, if at all.

We have incurred significant operating losses since our inception in 1991, and as of March 31, 2008, had an accumulated deficit of approximately \$334.8 million. The process of developing and commercializing our products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements as well as regulatory and marketing approvals. These activities, together with our general and administrative expenses, are expected to result in significant operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, obtain required regulatory approvals and successfully manufacture and market our products.

Motexafin gadolinium (MGd), is an anti-cancer drug being evaluated in various clinical trials. Based on the clinical activity seen in our initial Phase 3 trial in a subset of patients with brain metastases from non-small cell lung cancer (NSCLC), we conducted a pivotal Phase 3 clinical trial to confirm the potential clinical benefits observed in patients with brain metastases from non-small cell lung cancer. This trial, known as the **SMART** (Study of Neurologic Progression with Motexafin Gadolinium And Radiation Therapy) trial, enrolled 554 patients with brain metastases from non-small cell lung cancer. The SMART trial was designed to compare the safety and efficacy of whole brain radiation therapy (WBRT) alone to WBRT plus MGd. The primary endpoint for the study was time to neurologic progression (TNP) as determined by a blinded events review committee.

In the pivotal SMART trial, investigators found that patients given MGd in addition to WBRT had a median time to neurologic progression of 15.4 months, compared to 10.0 months for patients who received only WBRT (p=0.12, hazard ratio=0.78. Although not statistically significant, the trend was in favor of MGd. In April 2007, we announced that the FDA had filed our NDA over protest. In December 2007, we announced that the FDA determined that our NDA was non- approvable which will require us, among other things, to conduct additional studies and submit that data before the FDA will approve MGd for marketing. We are seeking corporate partners to aid in the future development of MGd. The FDA has also designated MGd as an orphan drug for the treatment of brain metastases arising from solid tumors.

We also are evaluating MGd for the treatment of a diverse range of cancer types and in various clinical situations including MGd as a single agent and in combination with chemotherapy for treatment of recurrent lung cancer. We own the worldwide rights to MGd.

We are also developing several other drugs to various molecular targets in oncology and autoimmune diseases. PCI-24781 is a novel compound that inhibits all isoforms of histone deacetylase (HDAC) enzymes. In the cell nucleus, DNA is present with proteins as part of a tightly compacted complex called chromatin. HDAC enzymes play a role in modifying the structure of chromatin, allowing DNA

transcription - a process by which DNA controls cellular activity - to occur. HDAC inhibitors appear to alter the transcription process. HDAC inhibitors target tumors through multiple mechanisms, and laboratory studies have shown that they can prompt cells to stop growing or die. This may happen through the expression of tumor suppressor genes, the prevention of angiogenesis, and the targeting of various critical proteins.

Laboratory studies also demonstrate that PCI-24781 inhibits homologous recombination, a cellular mechanism of DNA repair. These data suggest that PCI- 24781 could be used successfully in combination with other cancer therapies that generate DNA damage repaired by homologous recombination, such as gamma- irradiation, cisplatin, and certain other chemotherapy drugs.

PCI-24781 is now in a Phase 1 trial in patients with advanced solid tumors. The objective of the trial is to determine the safety and tolerability of an oral formulation of the drug, determine the maximum tolerated dose, and also to assess absorption and plasma levels of the drug. Studies indicate that PCI-24781 achieves sustained plasma levels following oral administration. We believe PCI- 24781 has desirable potency and pharmacokinetic properties, which may provide clinical advantages.

An HDAC-8 selective inhibitor is now in preclinical testing. We believe that this compound may exhibit more selectivity for certain types of cancer and may be useful for treatment of inflammatory and autoimmune diseases.

PCI-27483 is a small molecule inhibitor of Factor VIIa. This molecule selectively inhibits Factor VIIa when it is complexed with a protein called tissue factor (TF). In cancer, the Factor VIIa:TF complex is found in abundance in lung, breast, pancreatic, gastric, and colon tumors, and triggers a host of physiologic processes that facilitate tumor angiogenesis, growth and invasion. Laboratory studies and animal models indicate that inhibitors of Factor VIIa may block tumor growth and metastasis. Factor VIIa is also involved in blood coagulation and plays an important role in the increased incidence of thromboses seen in patients with cancer. We believe that PCI-27483 may be used for the treatment of cancer or cancer related thromboses. We are conducting the required preclinical safety studies to support the potential submission of an Investigational New Drug (IND) application with the FDA which is anticipated in the second half of calendar 2008.

PCI-32765 is an oral, small molecule tyrosine kinase inhibitor. When immune cells called B-lymphocytes are overactive, the immune system produces inflammatory cells and antibodies that begin to attack the body's own tissue, leading to autoimmune diseases such as rheumatoid arthritis. We are developing compounds that can inhibit an enzyme, known as Btk, which is required for immature B-cells to mature into fully functioning cells. In published studies, these compounds have demonstrated a dose dependent ability to inhibit disease development in animal models of rheumatoid arthritis and other immune diseases. Laboratory studies also have shown that these compounds may inhibit the proliferation of lymphoma cells, or malignancies involving B-cells, indicating their potential for treatment of certain lymphomas and leukemias. We are conducting the required preclinical safety studies to support the potential submission of an IND application with the FDA which is anticipated in the second half of calendar 2008.

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

#### Results of Operations

#### Revenues

	Three Mont		Nine Mont Marc			
	2008	2007	Percent change	2008	200	
Contract and grant revenues	\$	\$		\$	\$	

The decrease in contract and grant revenues for the three and nine months ended March 31, 2008 is the result of the completion of work associated with a federal grant awarded by the National Institutes of Health (NIH) in fiscal 2007.

#### Research and Development

		nths Ended			nths Ende
	2008	2007	Percent change	2008	200
Research and development expenses	\$5,120,000	\$5,669,000	-10%	\$14,822,000	\$ 15 <b>,</b> 55

The decrease of 10% or \$549,000 in research and development expenses for the three months ended March 31, 2008 as compared to the three months ended March 31, 2007 was primarily due to a decrease of \$995,000 in personnel costs due to lower headcount and a decrease in share-based compensation of \$365,000 partially offset by an increase of \$498,000 in drug manufacturing costs and \$275,000 of outside pre-clinical costs associated with our HDAC, Factor VIIa and Btk programs.

The decrease of 5% or \$735,000 in research and development expenses for the nine months ended March 31, 2008 as compared to the nine months ended March 31, 2007 was primarily due to a decrease of \$2,719,000 in personnel costs due to lower headcount, a decrease in share-based compensation of \$628,000 and a reduction of \$574,000 in consulting costs partially offset by an increase of \$2,073,000 in drug manufacturing costs and \$1,107,000 in outside preclinical costs associated with our HDAC, Factor VIIa and Btk programs.

We expect research and development expenses in our fiscal fourth quarter to be lower than our fiscal third quarter.

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

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

Related R& Three Mon Marc

Program	Description	Phase of Development	Estimated Completion of Phase	2008
MGd	Cancer	Several Phase 2 trials	Unknown	\$ 662,000
HDAC Inhibitors	Cancer	Phase 1	Fiscal 2009	1,122,000
Btk Inhibitors	Lymphomas and autoimmune diseases	Preclinical	Fiscal 2009	950 <b>,</b> 000
Factor VIIa Inhibitor	Cancer	Preclinical	Fiscal 2009	483,000
	Total direct costs Indirect costs			
	Total research and development expenses			\$5,120,000 ==========

#### General and Administrative

	Three Months ended March 31,			Nine Months ende March 31,			
	2008	2007	Percent change	2008	200		
General and administrative expenses	\$2,100,000	\$1,705,000	23%	\$ 5,923,000	\$ 5,31		

The increase of 23% or \$395,000 in general and administrative expenses for the three months ended March 31, 2008 as compared to the three months ended March 31, 2007, was primarily due to \$244,000 in involuntary employee severance costs and a \$102,000 increase in legal and patent expenses.

The increase of 11% or \$608,000 in general and administrative expenses for the nine months ended March 31, 2008 compared to the nine months ended March 31, 2007 was primarily due to an increase \$339,000 in personnel costs (including employee severance costs of \$244,000), and an increase of \$429,000 in corporate communication expenses partially offset by a decrease of \$128,000 in patent expenses.

We expect general and administrative expenses in our fiscal fourth quarter to be lower than our fiscal third quarter.

#### Interest and Other, Net

	Three Months Ended March 31,					Nine Months Ended March 31,		
		 2008 		2007	Percent change	2008		200
Interest and other, net	\$ 2	40,000	\$	615,000	-61%	\$ 1,075,000	\$	1,62

Interest and other, net declined in both periods of fiscal 2008 as compared to fiscal 2007 due primarily to lower average investment balances. Our cash equivalents and marketable securities consist primarily of fixed rate instruments.

#### Liquidity and Capital Resources

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

As of March 31, 2008, we had approximately \$21,272,000 in cash, cash equivalents and marketable securities. As of March 31, 2008, our portfolio of cash, cash equivalents and marketable securities had an average maturity of approximately 48 days and consisted of debt instruments of corporations and government entities with strong credit ratings.

Net cash used in operating activities of \$17,657,000 during the nine months ended March 31, 2008, resulted primarily from our net loss, net of depreciation and amortization and share-based compensation expense.

Net cash provided by investing activities of \$21,947,000 in the nine months ended March 31, 2008 consisted primarily of maturities and sales of marketable securities. Net cash used in investing activities of \$8,814,000 in the nine months ended March 31, 2007 consisted primarily of purchases of marketable securities, net of maturities and sales of marketable securities.

Net cash provided by financing activities of \$48,000 in the nine months ended March 31, 2008 was due to sales of stock under the Company's employee stock purchase plan. Net cash provided by financing activities of 22,009,000 in the nine months ended March 31, 2007, consisted primarily of proceeds from a public offering of common stock.

In November 2006, we completed a public offering of common stock and sold 4,830,000 shares of common stock at a price of \$4.75 per share for net proceeds of approximately \$21,300,000. In February 2007, 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. We may seek to raise funds through additional public offerings in the future but cannot guarantee that such efforts will be successful.

Our future contractual obligations at March 31, 2008 are as follows:

	(	Operating Lease Commitments
Remaining 3 months of fiscal 2008 Fiscal 2009	\$	233,000 946,000 487,000
Total	\$	1,666,000

In April 2006, we acquired multiple small molecule drug candidates for the treatment of cancer and other diseases from Celera Genomics, an Applera Corporation business. Future milestone payments under the agreement could total as much as \$144 million, although we currently cannot predict if or when any of the milestones will be achieved. In addition, Celera will also be entitled to royalty payments in the mid- to high single digits based on annual sales of any drugs commercialized from these programs.

Based upon our recent reduction in headcount and related expenses and the current status of our product development and plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We expect research and development expenses, as a result of on-going and future clinical trials, to consume a large portion of our existing cash resources. Changes in our research and development plans or other changes affecting our operating expenses may affect actual future consumption of existing cash resources as well. In any event, we will need to raise substantial additional capital to fund our operations in the future. Currently, we are actively

seeking partnership collaborations for our product candidates. If we are unsuccessful in obtaining a partnership for one or more of our product candidates, providing sufficient funding for our product development, we will be required to raise additional funds through the public or private sale of securities, bank debt or otherwise. If we are unable to raise additional capital sufficient to fund our current operations, we may be required to reduce operating expenses. Our actual capital requirements will depend on many factors, including the following:

- our ability to establish and the scope of any new partnership collaborations;
- the progress and success of preclinical studies and clinical trials of our product candidates; and
- the costs and timing of obtaining regulatory approvals.

In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Global Market. On April 17, 2008, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market indicating that the Company does not comply with the \$1.00 minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 4450(a)(5). The notice further stated that pursuant to Marketplace Rule 4450(e)(2), we will be provided 180 calendar days, or until October 14, 2008 to regain compliance. If, at any time before October 14, 2008, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, and if we remain in compliance with other listing requirements, NASDAQ will notify the Company that we have regained compliance with NASDAQ's Marketplace Rules. NASDAQ may, in its sole discretion, require the Company to maintain a closing bid price of at least \$1.00 per share for a longer period before determining that the Company has demonstrated the ability to maintain long-term compliance. There can be no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ Global Market.

The notice further indicates that if compliance with the minimum bid price rule is not regained by October 14, 2008, NASDAQ will provide written notification that our common stock will be delisted. At that time we may appeal the NASDAQ's determination to a Listing Qualifications Panel. Alternatively, we may apply to transfer the listing of our common stock to The NASDAQ Capital Market if we satisfy the requirements for initial inclusion set forth in Marketplace Rule 4310(c), other than the minimum bid price requirement of Marketplace Rule 4310(c)(4). If the application is approved, we will be afforded the remainder of a second additional 180-day compliance period to regain compliance with the minimum bid price rule while on the NASDAQ Capital Market.

We will continue to monitor the bid price for our common stock and consider various options available to us if our common stock does not trade at a level that is likely to regain compliance. To maintain our listing on the NASDAQ Global Market, we are also required, among other things, to either maintain stockholders' equity of at least \$10 million or a market value of at least \$50 million. While we currently satisfy the stockholders' equity requirement, we may not continue to do so.

Our estimate 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. If we are required to raise additional funds, we cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, any additional equity financing may be dilutive to existing stockholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to respond to competitive pressures or unanticipated requirements, to develop our product candidates, and to continue operations, any of which would have a material adverse effect on our business, financial condition and results of operations.

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies, Estimates and Judgments

This discussion and analysis of financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an on-going basis, we evaluate our estimates, including those related to revenue recognition and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about

the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results, however, may differ significantly from these estimates under different assumptions or conditions and may adversely affect the financial statements.

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

#### Revenue Recognition

Revenues are recognized when persuasive evidence of an arrangement exists, title has transferred or services have been rendered, the price is fixed and determinable and collectibility is reasonably assured. License revenue is typically recognized over the term of the arrangement and milestone revenue is recognized when earned as evidenced by achievement of the specified milestone and the absence of any on-going obligation. License, milestone, contract and grant revenues are not subject to repayment. Any amounts received in advance of performance are recorded as deferred revenues.

#### Cash Equivalents and Marketable Securities

We maintain investment portfolio holdings of various issuers, types and maturities. We consider all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At March 31, 2008, all other investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) within stockholders' equity. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

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

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

#### Research and Development Expenses and Accruals

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

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

accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

#### **Share-Based Compensation**

We adopted SFAS 123R, *Share-Based Payments*, effective beginning July 1, 2005 using the modified prospective application transition method. The modified prospective application transition method requires that companies recognize compensation expense on new share-based payment awards and existing share-based payment awards that are modified, repurchased, or cancelled after the effective date. Additionally, compensation cost of the portion of awards of which the requisite service had not been rendered that were outstanding as of July 1, 2005 has been expensed as the requisite service was rendered.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes valuation model. Expected volatility is based on historical volatility data of the company's stock. The expected term of stock options granted is based on historical data and represents the period of time that stock options are expected to be outstanding. The expected term is calculated for and applied to one group of stock options as the company does not expect substantially different exercise or post-vesting termination behavior amongst its employee population. The risk-free interest rate is based on a zero-coupon United States Treasury bond whose maturity period equals the expected term of the company's options.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to interest rate risk relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities that have declined in market value due to changes in interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in debt instruments of the U.S. Government and its agencies and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than two years. Assuming a hypothetical increase in interest rates of one percentage point, the fair value of our total investment portfolio as of March 31, 2008 would have declined by approximately \$27,000.

#### 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 2008, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.
- (b) Changes in internal controls over financial reporting: There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

ItemI. Legal Proceedings

Not Applicable.

ItemIA. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended June 30, 2007, which have not materially changed other than as set forth below. Those risks, which could materially affect our business, financial condition or future results, are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

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

We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our products. We are unable to entirely fund these efforts with our current financial resources. Currently, we are actively seeking partnership collaborations to help fund the development of our product candidates. If we are unsuccessful in obtaining a partnership for one or more of our product candidates, we will be required to raise additional funds through the public or private sale of securities, bank debt or otherwise.

Based upon our recent reduction in headcount and related expenses and the current status of our product development plans, we believe that our cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. We may, however, choose to raise additional funds before then. Our actual capital requirements will depend on many factors, including:

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

In addition, our ability to raise additional capital may be dependent upon our stock being quoted on the NASDAQ Global Market. On April 17, 2008, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market indicating that the Company does not comply with the \$1.00 minimum bid price requirement for continued listing set forth in NASDAQ Marketplace Rule 4450(a)(5). The notice further stated that pursuant to Marketplace Rule 4450(e)(2), we will be provided 180 calendar days, or until October 14, 2008 to regain compliance. If, at any time before October 14, 2008, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, and if we remain in compliance with other listing requirements, NASDAQ will notify the Company that we have regained compliance with NASDAQ's Marketplace Rules. NASDAQ may, in its sole discretion, require the Company to maintain a closing bid price of at least \$1.00 per share for a longer period before determining that the Company has demonstrated the ability to maintain long-term compliance. There can be no assurance that we will be able to satisfy the criteria for continued listing on the NASDAQ Global Market.

The notice further indicates that if compliance with the minimum bid price rule is not regained by October 14, 2008, NASDAQ will provide written notification that our common stock will be delisted. At that time we may

appeal the NASDAQ's determination to a Listing Qualifications Panel. Alternatively, we may apply to transfer the listing of our common stock to The NASDAQ Capital Market if we satisfy the requirements for initial inclusion set forth in Marketplace Rule 4310(c), other than the minimum bid price requirement of Marketplace Rule 4310(c)(4). If the application is approved, we will be afforded the remainder of a second additional 180-day compliance period to regain compliance with the minimum bid price rule while on the NASDAQ Capital Market.

We will continue to monitor the bid price for our common stock and consider various options available to us if our common stock does not trade at a level that is likely to regain compliance. To maintain our listing on the NASDAQ Global Market, we are also required, among other things, to either maintain stockholders' equity of at least \$10 million or a market value of at least \$50 million. While we currently satisfy the stockholders' equity requirement, we may not continue to do so.

We will need to raise any necessary additional funds through the public or private sale or securities, bank debt financings, collaborative arrangements with corporate partners or other sources that may be dilutive to existing stockholders or subject us to restrictive covenants. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves. Additional funds may not be available on acceptable terms, if at all. Our failure to raise capital when needed and on acceptable terms would require us to reduce our operating expenses, delay or reduce the scope of or eliminate one or more of our research or development programs and would limit our ability to respond to competitive pressures or unanticipated requirements and to continue operations. Any one of the foregoing would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Data already obtained from preclinical studies and clinical trials of our products under development do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, data from clinical trials we are conducting are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately

demonstrate the safety and effectiveness of a product under development could limit or prevent regulatory approval of the potential product and would materially harm our business. Our clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approval or may not result in marketable products.

In December 2005, we announced the top line results of our pivotal Phase 3 clinical study of MGd for the potential treatment of non-small cell lung cancer (NSCLC) patients with brain metastases. Although patients receiving MGd had a longer time to neurologic progression (TNP), the study's primary endpoint, the difference compared to patients in the control arm did not reach statistical significance.

In April 2007, we announced that the FDA had filed our NDA over protest. In December 2007, we announced that the FDA determined that our NDA was non-approvable which will require us, among other things, to conduct additional studies and submit that data before the FDA will approve MGd for marketing. Performance and completion of additional clinical studies will require years of testing and, even if positive results are achieved, may not result in MGd's approval.

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, 2008, had an accumulated deficit of approximately \$334.8 million. We expect to continue to incur substantial additional operating losses until such time, if ever, as the commercialization of our products generates sufficient revenues to cover our expenses. All of our product candidates are in the early stages of development and the commercialization of those products will not occur, if at all, for at least the next several years. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our product candidates, and to obtain required regulatory approvals and to successfully manufacture and market our proposed product. To date, we have not generated revenue from the commercial sale of our products.

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

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

Data obtained from clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals.

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 received on a timely basis, or they may not cover the clinical uses that we specify.

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

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

Any regulatory approval that we receive for a product candidate may be subject to limitations on the indicated uses for which the product may be marketed. In addition, if the FDA and/or foreign regulatory agencies approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion of the product will be subject to extensive regulatory requirements. We and the manufacturers of our product candidates must also comply with the applicable FDA Good Manufacturing Practice ("GMP") regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they

can be used to commercial manufacturing of our products. We or our present or future suppliers may be unable to comply with the applicable GMP regulations and other FDA regulatory requirements. Failure of our suppliers to follow current GMP Practice or other regulatory requirements may lead to significant delays in the availability of products for commercial or clinical use and could subject us to fines, injunctions and civil penalties.

We rely heavily on third parties for product and clinical development of our products.

We currently depend heavily and will depend heavily in the future on third parties for support in product development and clinical development of our products. The termination of a significant number of our existing collaborative arrangements, or our inability to establish and maintain collaborative arrangements could have a material adverse effect on our ability to complete clinical development of our products. Given our limited resources, it may be necessary to establish partnerships with other pharmaceutical companies that have greater financial and technical resources in order to successfully develop and commercialize our products. There is no assurance that such partnerships can be obtained, and if obtained, may require us to relinquish product rights that could affect the financial success of these products.

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

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

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

We are highly dependent on qualified scientific and management personnel. We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified management and personnel with pre-clinical and clinical experience. We will need to hire additional personnel as we continue to expand our research and development and partnering activities.

We face intense competition from other companies and research and academic institutions for qualified personnel. We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other

businesses, particularly in the San Francisco, California area. 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, raise additional capital or implement our business strategy may be adversely affected or prevented. In particular, if we lose additional members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

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 sometimes unrelated to operating performance. For example, during the period beginning July 1, 2004 and ending April 25, 2008, the sales price for one share of our common stock reached a high of \$12.86 per share and a low of \$0.55 per share. 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, clinical trials, product development and partnering activities:
- quarterly fluctuations in our financial results;
- the development of technological innovations or new therapeutic products by us, our competitors or others;
- changes in governmental regulation;
- developments in patent or other proprietary rights by us, our competitors or others;
- developments and/or announcements by us, our competitors or others;
- litigation;
- public concern as to the safety of products developed by us, our competitors or others;
- departure of key personnel;
- ability to manufacture our products to commercial standards;
- changes in the structure of healthcare payment systems and the coverage and reimbursement policies of governmental and other third-party payors;
- our ability to successfully commercialize our products if they are approved;
- comments by securities analysts; and
- general market conditions in our industry.

In addition, if any of the risks described in this section entitled "Risk Factors" actually occur, there could be a dramatic and material adverse impact on the market price of our common stock.

ItemJ. Unregistered Sales of Equity Securities and Use of Proceeds

Not Applicable.

ItemK. Defaults Upon Senior Securities

Not Applicable.

ItemL. Submission of Matters to a Vote of Security Holders

Not Applicable.

ItemM. Other Information

Not Applicable.

#### ItemN. Exhibits

- 31.1 Rule 13a-14(a)/15d-14(a) Certification of CEO.
- 31.2 Rule 13a-14(a)/15d-14(a) Certification of CFO.
- 32.1 Section 1350 Certifications of CEO and CFO.

#### **Signatures**

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

Pharmacyclics, Inc.

(Registrant)

Dated: April 29, 2008 By: /s/ RICHARD A. MILLER, M.D.

Richard A. Miller, M.D.

President and Chief Executive Officer

Dated: April 29, 2008 By: /s/ LEIV LEA

Leiv Lea

Vice President, Finance and Administration and

Chief Financial Officer and Secretary

# EXHIBITS INDEX

Exhibit <u>Number</u>	<u>Description</u>	
31.1	Rule 13a-14(a)/15d-14(a) Certification of CEO.	PDF provided as courtesy
31.2	Rule 13a-14(a)/15d-14(a) Certification of CFO.	PDF provided as courtesy
32.1	Section 1350 Certifications of CEO and CFO.	PDF provided as courtesy