
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, 2007

or

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

For the transition period from _____ to _____

Commission File Number: 000-26658



PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3148201

(IRS Employer Identification Number)

995 E. Arques Avenue

Sunnyvale, California 94085-4521

(Address of principal executive offices including zip code)

(408) 774-0330

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

As of April 30, 2007, there were 25,968,189 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 23.

PHARMACYCLICS, INC.
Form 10-Q
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Pharmacyclics

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

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

	<u>March 31,</u> <u>2007</u>	<u>June 30,</u> <u>2006</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,748	\$ 22,283
Marketable securities	26,793	18,194
Prepaid expenses and other current assets	1,105	961
Total current assets	<u>45,646</u>	<u>41,438</u>
Property and equipment, net	868	764
Other assets	523	527
	<u>\$ 47,037</u>	<u>\$ 42,729</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,000	\$ 1,908
Accrued liabilities	1,387	1,431
Total current liabilities	<u>2,387</u>	<u>3,339</u>
Deferred rent	75	70
Total liabilities	<u>2,462</u>	<u>3,409</u>
Stockholders' equity:		
Common stock	3	2
Additional paid-in capital	352,713	328,386
Accumulated other comprehensive income (loss)	22	(132)
Deficit accumulated during development stage.....	<u>(308,163)</u>	<u>(288,936)</u>
Total stockholders' equity	<u>44,575</u>	<u>39,320</u>
	<u>\$ 47,037</u>	<u>\$ 42,729</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		Nine Months Ended		Period From
	March 31,		March 31,		Inception
	2007	2006	2007	2006	(April 19, 1991)
					through
					March 31,
					2007
Revenues:					
License and milestone revenues	\$ --	\$ --	\$ --	\$ --	\$ 7,855
Contract and grant revenues	--	156	19	156	6,047
Total revenues	<u>--</u>	<u>156</u>	<u>19</u>	<u>156</u>	<u>13,902</u>
Operating expenses:					
Research and development*	5,669	5,313	15,557	19,315	288,184
General and administrative*	1,705	2,685	5,315	9,756	66,721
Purchased in-process research and development	--	--	--	--	6,647
Total operating expenses	<u>7,374</u>	<u>7,998</u>	<u>20,872</u>	<u>29,071</u>	<u>361,552</u>
Loss from operations	(7,374)	(7,842)	(20,853)	(28,915)	(347,650)
Interest and other income, net	615	467	1,626	1,449	39,487
Net loss	<u>\$ (6,759)</u>	<u>\$ (7,375)</u>	<u>\$ (19,227)</u>	<u>\$ (27,466)</u>	<u>\$ (308,163)</u>
Basic and diluted net loss per share	<u>\$ (0.26)</u>	<u>\$ (0.37)</u>	<u>\$ (0.82)</u>	<u>\$ (1.38)</u>	
Shares used to compute basic and diluted net loss per share	<u>25,938</u>	<u>19,904</u>	<u>23,581</u>	<u>19,871</u>	

* Includes non-cash share-based compensation of the following:

Research and development	\$ 561	\$ 559	\$ 1,379	\$ 2,306	\$ 4,612
General and administrative	360	814	940	2,575	4,888

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		Period From
	March 31,		Inception
	2007	2006	(April 19, 1991)
			through
			March 31,
			2007
Cash flows from operating activities:			
Net loss	\$ (19,227)	\$ (27,466)	\$ (308,163)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	343	461	14,541
Purchased in-process research and development	--	--	4,500
Share-based compensation expense	2,319	4,881	9,500
Gain on sale of marketable securities	--	--	58
Write-down of fixed assets	--	--	381
Changes in assets and liabilities:			
Prepaid expenses and other assets	(140)	(118)	(1,628)
Accounts payable	(908)	(909)	1,000
Accrued liabilities	(44)	289	1,387
Deferred rent	5	(15)	75
Net cash used in operating activities	(17,652)	(22,877)	(278,349)
Cash flows from investing activities:			
Purchase of property and equipment	(447)	(377)	(12,021)
Proceeds from sale of property and equipment	--	--	112
Purchases of marketable securities	(14,945)	(3,435)	(524,178)
Proceeds from maturities and sales of marketable securities	6,500	19,448	497,349
Net cash provided by (used in) investing activities	(8,892)	15,636	(38,738)
Cash flows from financing activities:			
Issuance of common stock, net of issuance costs	21,426	380	308,771
Exercise of stock options	583	--	6,431
Proceeds from notes payable	--	--	3,000
Issuance of convertible preferred stock, net of issuance costs	--	--	20,514
Payments under capital lease obligations	--	--	(3,881)
Net cash provided by financing activities	22,009	380	334,835
Increase (decrease) in cash and cash equivalents	(4,535)	(6,861)	17,748
Cash and cash equivalents at beginning of period	22,283	27,666	--
Cash and cash equivalents at end of period	\$ 17,748	\$ 20,805	\$ 17,748

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 Policies

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, 2006 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, 2006. 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.

Share-Based Compensation

The company 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 has not been rendered that are outstanding as of July 1, 2005 shall be recognized as the requisite service is rendered.

The fair value of each stock option is estimated on the date of grant using the Black-Scholes valuation model using the assumptions noted in the following table. 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 rate of the stock options is based on a zero-coupon United States Treasury bond whose maturity period equals the expected term of the company's options.

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2007	2006	2007	2006
Stock Option Plans:				
Expected dividend yield	0 %	0 %	0 %	0 %
Expected stock price volatility	72 %	83 %	73 %	71 %
Risk free interest rate	4.42 %	4.30 %	4.46 %	4.17 %
Expected life (years)	4.51	4.98	4.52	4.98
Employee Stock Purchase Plan:				
Expected dividend yield	0 %	0 %	0 %	0 %
Expected stock price volatility	54 %	54 %	54 %	54 %
Risk free interest rate	4.42 %	4.42 %	4.42 %	4.42 %
Expected life (years)	2.00	2.00	2.00	2.00

The weighted average estimated grant date fair value, as defined by SFAS 123, for options granted under the company's stock option plans during the nine months ended March 31, 2007 and 2006 were \$1.82 and \$5.07 per share, respectively. The weighted average estimated grant date fair value of purchase awards under the company's employee stock purchase plan during the nine months ended March 31, 2007 and 2006 were \$3.30 and \$3.30 per share, respectively.

As of March 31, 2007, \$7,228,000 of total unrecognized compensation costs related to non-vested options are scheduled to be recognized over a weighted average period of 2.73 years. There were no capitalized share-based compensation costs at March 31, 2007.

The company accounts for equity instruments issued to non-employees for goods or services in accordance with the provisions of SFAS No. 123 and Emerging Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). Accordingly, as these instruments vest, the company is required to remeasure the fair value of the equity instruments at each reporting period prior to vesting and then finally at the vesting date of the equity instruments.

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 5,613,864 and 4,582,118 shares of common stock were outstanding at March 31, 2007 and 2006, 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 Plan:

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

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

1995 Non-Employee Directors Stock Option Plan. The company's Directors Plan was adopted by the Board of Directors on August 2, 1995 and provides for issuance of common stock to non-employee Directors pursuant to a predetermined formula. The exercise price of options granted under the Directors Plan must be at least equal to the fair value of Pharmacyclics' common stock on the date of grant. Each individual first elected or appointed as a non-employee Board member will automatically be granted, on the date of such election or appointment, a non-statutory option to purchase 10,000 shares of common stock vesting over five years. In addition, on the date of each annual stockholders' meeting each individual who is to continue to serve as a non-employee Board member after that annual meeting and has been a member of the Board for at least six months will automatically be granted a non-statutory option to purchase 5,000 shares of common stock. A total of 271,667 shares of common stock have been reserved for issuance under the Directors Plan. In December 2004, the remaining shares available for future

grant under the Directors Plan were transferred to the 2004 Plan. Additionally, if options granted under the Directors Plan expire or otherwise terminate without being exercised, the shares of common stock reserved for such options again become available for future grant under the 2004 Plan.

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

The following table summarizes the company's stock option activity for the nine months ended March 31, 2007:

	<u>Options Outstanding</u>		
	Shares	Number	Weighted
	Available for Grant		Average Exercise Price
Balance at June 30, 2006	1,088,095	5,266,802	\$ 13.26
Options granted	(1,060,909)	1,060,909	3.01
Options exercised	--	(133,164)	4.38
Options forfeited	84,746	(84,746)	5.29
Options expired	495,937	(495,937)	17.93
Balance at March 31, 2007	<u>607,869</u>	<u>5,613,864</u>	11.24

The total intrinsic value of stock options exercised during the nine month periods ended March 31, 2007 and 2006 was approximately \$64,099 and \$372,000, respectively. No income tax benefits were realized by the company in the nine month periods ended March 31, 2007 and 2006.

A summary of outstanding and vested stock options as of March 31, 2007 is as follows:

Range of Exercise Prices	<u>Options Outstanding</u>			<u>Options Exercisable</u>		
	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$2.76 - \$ 2.76	908,700	\$ 2.76	\$ --	--	\$ --	\$ --
\$3.22 - \$ 4.13	149,059	3.75	--	95,788	3.54	--
\$4.16 - \$ 4.16	1,154,850	4.16	--	211,180	4.16	--
\$4.25 - \$ 4.47	641,987	4.38	--	617,915	4.38	--
\$4.50 - \$ 7.39	634,892	6.73	--	585,159	6.82	--
\$7.43 - \$ 9.99	581,187	8.08	--	313,229	8.30	--
\$10.00 - \$ 19.75	593,874	14.79	--	516,212	15.30	--
\$20.25 - \$ 27.51	562,070	26.24	--	562,070	26.24	--
\$28.13 - \$ 66.13	360,945	49.45	--	360,945	49.45	--
\$78.13 - \$ 78.13	26,300	78.13	--	26,300	78.13	--
	<u>5,613,864</u>	\$ 11.24	<u>\$ --</u>	<u>3,288,798</u>	\$ 16.13	<u>\$ --</u>

As of March 31, 2007, the weighted average remaining contractual term of options outstanding and options vested was 6.85 and 5.16 years, respectively.

Employee Stock Purchase Plan. The company adopted an Employee Stock Purchase Plan (the "Purchase Plan") in August 1995. Qualified employees may elect to have a certain percentage of their salary withheld to purchase shares of the company's common stock under the Purchase Plan. The purchase price per share is equal to 85% of the fair market value of the stock on specified dates. Sales under the Purchase Plan in the nine month periods ended March 31, 2007 and 2006 were 28,233 and

43,656 shares of common stock at an average price of \$4.58 and \$5.26, respectively. Shares available for future purchase under the Purchase Plan are 290,905 at March 31, 2007.

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:

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2007	2006	2007	2006
Net loss	\$ (6,759,000)	\$ (7,375,000)	\$ (19,227,000)	\$ (27,466,000)
Change in net unrealized losses on available-for-sale securities	30,000	95,000	154,000	179,000
Comprehensive loss	\$ <u>(6,729,000)</u>	\$ <u>(7,280,000)</u>	\$ <u>(19,073,000)</u>	\$ <u>(27,287,000)</u>

Note 5 – Recent Accounting Pronouncements

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 108 (SAB 108). Due to diversity in practice among registrants, SAB 108 expresses SEC staff views regarding the process by which misstatements in financial statements are evaluated for purposes of determining whether financial statement restatement is necessary. SAB 108 is effective for fiscal years ending after November 15, 2006, and early application is encouraged. The adoption of SAB 108 did not have a material impact on our results from operations or financial position.

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 2008 fiscal year with early adoption permitted. We have not yet determined the impact, if any, that the implementation of SFAS No. 157 will have on our financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), which, among other things, requires applying a “more likely than not” threshold to the recognition and derecognition of tax positions. The provisions of FIN 48 will be effective for us on July 1, 2007. We are currently evaluating the impact of adopting FIN 48 on the financial statements, but we do not expect its adoption to have a significant transition effect.

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, 2006 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 12, 2006.

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 1A, “Risk Factors”, and elsewhere in this report, in the company's Annual Report on Form 10-K for the fiscal year ended June 30, 2006 and in our other Securities and Exchange Commission reports and filings. All forward-looking statements are based on information currently available to Pharmacylics; and we

assume no obligation to update such forward-looking statements. Stockholders are cautioned not to place undue reliance on such statements.

Overview

Pharmacylics is a pharmaceutical company focused on the development of products that improve therapeutic approaches to cancer and other diseases. To date, substantially all of our resources have been dedicated to the research and development of our products, and we have not generated any commercial revenues from the sale of our products. We do not expect to generate any product revenues until we receive the necessary regulatory and marketing approvals and launch one of our products, if at all.

We have incurred significant operating losses since our inception in 1991, and as of March 31, 2007, had an accumulated deficit of approximately \$308.2 million. The process of developing and commercializing our products requires significant research and development, preclinical testing and clinical trials, manufacturing arrangements as well as regulatory and marketing approvals. These activities, together with our general and administrative expenses, are expected to result in significant operating losses until the commercialization of our products generates sufficient revenues to cover our expenses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products under development, obtain required regulatory approvals and successfully manufacture and market our products.

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

The results of the study were presented at the 2006 Annual Meeting of the American Society of Clinical Oncology (ASCO). In the intent-to-treat analysis, the median TNP was 15.4 months for patients receiving WBRT plus Xcytrin compared to 10.0 months for patients treated with WBRT alone ($P=0.122$, hazard ratio=0.78). Substantial differences in patient characteristics and outcomes were observed for the 348 patients enrolled in North America (63 percent of all patients enrolled in the study) compared to the other regions. In North America, the median TNP for WBRT plus Xcytrin treatment was 24.2 months compared to 8.8 months for WBRT alone ($P=0.004$, hazard ratio=0.53). By contrast, for regions outside of North America, there was no significant difference in TNP between treatment arms. Xcytrin was well tolerated in the study. The most common drug related grade 3 and 4 adverse events were hypertension (4%), elevated liver enzymes (3%) and fatigue (3%), all of which were reversible. We believe the reasons for the regional differences in treatment benefit may be related to the time interval between diagnosis of brain metastases and initiation of WBRT.

In North America, most patients (79%) received WBRT within three weeks of their diagnosis of brain metastases. In certain European centers, there was substantial delay in the initiation of WBRT either due to use of chemotherapy as the initial therapy for brain metastases, or clinical practice patterns resulting in delays in access to radiation therapy. Moreover, there was an imbalance in treatment delay favoring the control arm of the study. As presented at ASCO in June of 2006, adjusting for this imbalance resulted in a treatment benefit for the Xcytrin arm of the study ($P=0.05$). We believe that the clinical data indicate Xcytrin benefited patients that had prompt treatment with WBRT, regardless of region, and that this benefit was progressively diminished by delay in initiation of radiation.

As presented at the Society of Neuro-Oncology Annual Meeting in November 2006, pooled data from two randomized trials involving 805 patients with brain metastases from NSCLC comparing Xcytrin plus WBRT to WBRT alone have shown a benefit for Xcytrin. In the pooled results analysis, the median TNP determined by a blinded events review committee was 15.4 months for patients receiving WBRT plus Xcytrin compared to 9.0 months for patients treated with WBRT alone ($P = 0.016$, hazard ratio = 0.73). Certain secondary endpoints also showed significant benefit for Xcytrin plus WBRT compared to WBRT alone: TNP as determined by investigators, $P = 0.015$, hazard ratio = 0.76; time to neurocognitive progression, $P = 0.02$, hazard ratio = 0.78.

Based on our review of the data from the SMART trial, pooled data from both of our randomized trials, and discussions with the U.S. Food and Drug Administration (FDA), we submitted a New Drug Application (NDA) to the FDA in December 2006, for the use of Xcytrin in combination with radiation therapy for the treatment of patients with brain metastases from NSCLC. In February 2007, we received a refuse to file letter from the FDA citing failure to demonstrate statistically significant differences between treatment arms in the company's trials. In April 2007, we requested that the FDA file our NDA over protest. File over protest is a procedure permitted by FDA regulations, which allows sponsors to have their NDA filed and reviewed when there is disagreement over the acceptability of the NDA. On April 23, 2007, we announced that the FDA had filed our NDA. The Prescription Drug User Fee Act (PDUFA) date for completion of review by FDA is December 31, 2007. The FDA has also designated Xcytrin as an orphan drug for the treatment of brain metastases arising from solid tumors.

The FDA's Division of Drug Oncology Products often requests that an outside advisory panel review aspects of a sponsor's NDA. While we believe that our NDA qualifies for such a review, we cannot assure you that there will be an advisory panel meeting to review our NDA.

The FDA could also require that we conduct additional studies and submit that data before it will approve our application, which would require us to expend more resources than we planned or than are available to us, and could substantially delay any approval of our application. The FDA has indicated that it is not satisfied with data included in our NDA, and we may need to expend additional resources or conduct additional studies, including clinical trials, to obtain data that the FDA believes is sufficient to support approval. It is also possible that additional studies may not result in approval of our application. Even though the FDA has accepted our NDA for filing over protest, there can be no assurance that it will be approved in a timely manner or at all.

We continue to evaluate Xcytrin for the treatment of a diverse range of cancer types and in various clinical situations including Xcytrin as a single agent and in combination with chemotherapy and/or radiation therapy. We are enrolling patients in Phase 2 clinical trials with Xcytrin used alone to treat lung cancer and to treat hematologic cancers such as lymphomas and chronic lymphocytic leukemia. Phase 2 trials for recurrent lung cancer are underway evaluating Xcytrin given in combination with Taxotere[®] and in combination with Alimta[®]. We have completed enrollment in a Phase 2 clinical trial with Xcytrin used in combination with stereotactic radiosurgery for the treatment of brain metastases from solid tumors.

In April 2006, we acquired the following drug candidates from Celera Genomics:

- A novel compound, known as PCI-24781, that inhibits histone deacetylase enzymes (HDAC) and is in a Phase 1 study for the treatment of advanced solid tumors.
- A first-in-class HDAC-8 selective inhibitor in preclinical development for the potential treatment of cancer and inflammatory diseases.
- A first-in-class Factor VIIa inhibitor targeting a tumor signaling pathway involved in angiogenesis, tumor growth and metastases.
- B cell associated tyrosine kinase (Btk) inhibitors potentially useful for treatment of lymphomas and autoimmune diseases.

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 Months ended			Percent change	Nine Months ended		
	March 31,		2006		March 31,		2006
	2007	2006			2007	2006	
Contract and grant revenues	\$ --	\$ 156,000	--	\$ 19,000	\$ 156,000	-88%	

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

Research and Development

	Three Months ended			Percent change	Nine Months ended		
	March 31,		2006		March 31,		2006
	2007	2006			2007	2006	
Research and development expenses	\$ 5,669,000	\$ 5,313,000	7%	\$ 15,557,000	\$ 19,315,000	-19%	

The increase of 7% or \$356,000 in research and development expenses for the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 was primarily due to an increase of \$346,000 in preclinical study costs, \$318,000 in costs associated with a 22% reduction in headcount offset by a decrease of \$242,000 in patient costs associated with the timing of clinical trial enrollment.

The decrease of 19% or \$3,758,000 in research and development expenses for the nine months ended March 31, 2007 as compared to the nine months ended March 31, 2006 was primarily due to a decrease of \$2,059,000 in outside clinical trial costs due to completion of the SMART trial, a decrease of \$927,000 in share-based compensation expense, a decrease of \$376,000 in personnel and consulting expenses, and a decrease of \$202,000 in drug manufacturing costs.

We expect research and development expenses in our fiscal fourth quarter to be approximately the same as in 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:

Program#	Description	Phase of Development	Estimated Completion of Phase	Related R&D Expenses Three Months ended March 31,		Related R&D Expenses Nine Months ended March 31,	
				2007	2006	2007	2006
				XCYTRIN	Cancer	Several Phase 1 trials Several Phase 2 trials Phase 3	Unknown Unknown Fiscal 2006
HDAC Inhibitors	Cancer	Phase 1	Unknown	893,000	--	1,738,000	--
Btk Inhibitors	Lymphomas and autoimmune diseases	Preclinical	Unknown	396,000	--	740,000	--
Factor VIIa Inhibitor	Cancer	Preclinical	Unknown	122,000	--	134,000	--
	Total direct costs.....			3,289,000	3,195,000	8,682,000	12,429,000
	Indirect costs.....			2,380,000	2,118,000	6,875,000	6,886,000
	Total research and development expenses.....			\$ 5,669,000	\$ 5,313,000	\$ 15,557,000	\$ 19,315,000

General and Administrative

	Three Months ended March 31,			Percent change	Nine Months ended March 31,			Percent change
	2007	2006			2007	2006		
	General and administrative expenses	\$ 1,705,000	\$ 2,685,000		-36%	\$ 5,315,000	\$ 9,756,000	

The decrease of 36% or \$980,000 in general and administrative expenses for the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 was primarily due to a \$488,000 decrease in personnel expenses due to a reduction in employee headcount and a \$454,000 decrease in share-based compensation expense.

The decrease of 46% or \$4,441,000 in general and administrative expenses for the nine months ended March 31, 2007 compared to the nine months ended March 31, 2006 was primarily due to a \$1,207,000 decrease in commercialization expenses, a \$1,635,000 decrease in share-based compensation expense and a \$1,295,000 decrease in personnel expenses due to a reduction in employee headcount.

We expect general and administrative expenses in our fiscal fourth quarter to be approximately the same as in our fiscal third quarter.

Interest and Other, Net

	Three Months ended March 31,			Percent change	Nine Months ended March 31,			Percent change
	2007	2006			2006	2005		
	Interest and other, net	\$ 615,000	\$ 467,000		32%	\$ 1,626,000	\$ 1,449,000	

Interest and other, net is higher in both periods due to higher average investment balances and higher average interest rates. Our cash and marketable securities consist primarily of fixed rate instruments.

Liquidity and Capital Resources

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

As of March 31, 2007, we had approximately \$44,541,000 in cash, cash equivalents and marketable securities. Net cash used in operating activities of \$17,652,000 during the nine months ended March 31, 2007, resulted primarily from our net loss, net of depreciation and amortization, share-based compensation expense and a decrease in accounts payable. Net cash used in operating activities of \$22,877,000 during the nine months ended March 31, 2006, resulted primarily from our net loss, net of depreciation and amortization, share-based compensation expense and a decrease in accounts payable.

Net cash used in investing activities of \$8,892,000 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 investing activities of \$15,636,000 in the nine months ended March 31, 2007, consisted primarily of maturities and sales of marketable securities, net of purchases of marketable securities.

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

In August 2006, we entered into a common stock purchase agreement with Azimuth Opportunity Ltd., which provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase, at our discretion, up to \$20.0 million of our common stock, or 4,189,337 shares, whichever occurs first, at a discount of 5 to 7%, to be determined based on our market capitalization at the start of each sale period. The term of the purchase agreement is 18 months. Upon each sale of our common stock to Azimuth under the purchase agreement, we have also agreed to pay Reedland Capital Partners a placement fee equal to one percent of the aggregate dollar amount of common stock purchased by Azimuth. Azimuth is not required to purchase our common stock if the price of our common stock falls below \$3.00 per share.

In April 2004, we completed a public offering of common stock and sold 3,200,000 shares of common stock at a price of \$13.00 per share for net proceeds of approximately \$39,350,000. 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, 2007 are as follows:

	Operating Lease Commitments
Remaining 3 months of fiscal 2007	\$ 227,000
Fiscal 2008 and 2009	1,861,000
Fiscal 2010	487,000
After Fiscal 2010	--
Total	<u>\$ 2,575,000</u>

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

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

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. 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 could 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, 2007, all other investment securities are classified as available-for-sale and consequently are recorded on the balance sheet at fair value with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) within stockholders' equity. Management assesses whether declines in the fair value of investment securities are other than temporary. If the decline in fair value is judged to be other than temporary, the cost basis of the individual security is written down to fair value and the amount of the write down is included in earnings. In determining whether a decline is other than temporary, management considers the following factors:

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

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

Research and Development Expenses and Accruals

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

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

Share-Based Compensation

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

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

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 rate of the stock options is based on a zero-coupon United States Treasury bond whose maturity period equals the expected term of the company's stock 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, 2007 would have declined by approximately \$284,000.

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 2007, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are adequate and effective to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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

PART II. OTHER INFORMATION

- | | | |
|------|-----|-------------------|
| Item | 1. | Legal Proceedings |
| | | Not Applicable. |
| Item | 1A. | Risk Factors |

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, 2006, 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.

To generate revenue, we will depend on FDA approval of our lead product candidate, Xcytrin for the potential treatment of non-small cell lung cancer patients with brain metastases. If we are unable to obtain FDA approval, our ability to generate revenue will be significantly delayed.

Our ability to generate revenue will depend on the successful development, regulatory approval and commercialization of Xcytrin. In December 2005, we announced the top line results of our pivotal Phase 3 clinical study of Xcytrin for the potential treatment of non-small cell lung cancer (NSCLC) patients with brain metastases. Although patients receiving Xcytrin had a longer time to neurologic progression (TNP), the study's primary endpoint, the difference compared to patients in the control arm did not reach statistical significance.

Although we have received a Special Protocol Assessment (SPA) from the FDA for our Phase 3 SMART trial, the study did not meet its primary endpoint with statistical significance. Based on our review of the data from the SMART trial, in December 2006 we submitted a New Drug Application (NDA) to the FDA for the potential treatment of NSCLC patients with brain metastases. In meetings with FDA in early 2006, FDA noted that the applicable review Division has not approved drugs based on the results of non-pre-specified subgroup analyses when the trial has failed to meet its primary endpoint. FDA discouraged the submission of an NDA based on subset analyses from the SMART trial. However, in subsequent meetings with FDA and further review of the data, the Agency indicated a willingness to review an NDA based on analyses which include all of the data.

In February 2007, we received a refuse to file letter from the FDA citing failure to demonstrate statistically significant differences between treatment arms in the company's trials. In April 2007, we requested that the FDA file our NDA over protest. File over protest is a procedure permitted by FDA regulations, which allows sponsors to have their NDA filed and reviewed when there is disagreement over the acceptability of the NDA. On April 23, 2007, we announced that the FDA had filed our NDA. The Prescription Drug User Fee Act (PDUFA) date for completion of review by FDA is December 31, 2007.

The FDA's Division of Drug Oncology Products often requests that an outside advisory panel review aspects of a sponsor's NDA. While we believe that our NDA qualifies for such a review, we cannot assure you that there will be an advisory panel meeting to review our NDA.

The FDA could also require that we conduct additional studies and submit that data before it will approve our application, which would require us to expend more resources than we planned or than are available to us, and could substantially delay any approval of our application. The FDA has indicated that it is not satisfied with data included in our NDA, and we may need to expend additional resources or conduct additional studies, including clinical trials, to obtain data that the FDA believes is sufficient to support approval. It is also possible that additional studies may not result in approval our application. Even though the FDA has accepted our NDA for filing over protest, there can be no assurance that it will be approved in a timely manner or at all.

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, 2007, had an accumulated deficit of approximately \$308.2 million. We expect to continue to incur substantial additional operating losses until such time, if ever, as the commercialization of our products generates sufficient revenues to cover our expenses. Our achieving profitability depends upon our ability, alone or with others, to successfully complete the development of our products, and to obtain required regulatory approvals and to successfully manufacture and market our proposed products. If our lead product, Xcytrin, fails to receive regulatory approval on a timely basis, or at all, our ability to become profitable would be materially impacted. To date, we have not generated revenue from the commercial sale of our products.

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

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

Data obtained from clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. In the refusal to file letter we received from the FDA, the FDA indicated that data from our completed Phase 3 SMART trial was not sufficient to support regulatory approval of our NDA for the potential treatment of NSCLC patients with brain metastases. If the FDA requires us to conduct additional trials before approving our NDA, this would cause significant delays in approval and consume additional resources, and the data obtained from additional trials may not be sufficient to obtain regulatory approval.

In addition, we may encounter delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We may encounter similar delays in foreign countries. We may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities and even if obtained, such approvals may not be received on a timely basis, or they may not cover the clinical uses that we specify.

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

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

Any regulatory approval that we receive for a product candidate may be subject to limitations on the indicated uses for which the product may be marketed. In addition, if the FDA and/or foreign regulatory agencies approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion of the product will be subject to extensive regulatory requirements. We and the manufacturers of our product candidates must also comply with the applicable FDA Good Manufacturing Practice (“GMP”) regulations, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used in commercial manufacturing of our products. We or our present or future suppliers may be unable to comply with the applicable GMP regulations and other FDA regulatory requirements. Failure of our suppliers to follow current 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 will need substantial additional financing and we may have difficulty raising needed capital in the future.

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

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

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

- continued progress of our research and development programs;
- our ability to obtain approval of our NDA for the use of Xcytrin in combination with radiation therapy for the treatment of patients with brain metastases from NSCLC on a timely basis;
- our ability to establish collaborative arrangements and maintain existing ones;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approval;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the amount and timing of capital equipment purchases;
- competing technological and market developments; and
- our ability to market and distribute our products and establish new licensing arrangements.

In August 2006, we entered into a common stock purchase agreement with Azimuth Opportunity Ltd., which provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to \$20 million of our common stock, or 4,189,337 shares, whichever occurs first, at a discount of 5% to 7%, to be determined based on our market capitalization at the start of each sale period. The term of the purchase agreement is 18 months. Upon each sale of our common stock to Azimuth under the purchase agreement, we have also agreed to pay Reedland Capital Partners a placement fee equal to one percent of the aggregate dollar amount of common stock purchased by Azimuth. Even though we have entered into this purchase agreement with Azimuth, Azimuth would not be required to purchase our common stock if the price of our common stock falls below \$3.00 per share. In addition, the number of shares we are permitted to sell to Azimuth is limited by applicable NASDAQ rules. Furthermore, we may decide not to sell any shares of our common stock pursuant to this agreement.

We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources that may be dilutive to existing stockholders or subject us to restrictive covenants. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, such arrangements may require us to relinquish rights to some of our technologies, product candidates or products under development that we would otherwise seek to develop or commercialize ourselves.

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. The support of our NDA requires highly specialized skills. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. We will need to hire additional personnel as we continue to expand our research and development activities, pursue our NDA filing, and build a sales and marketing team in the United States.

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

- the progress and results of our preclinical testing and clinical trials;
- developments in the status of our NDA for the use of Xcytrin in combination with radiation therapy for the treatment of patients with brain metastases from NSCLC;
- 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.

Item	2.	Unregistered Sales of Equity Securities and Use of Proceeds
		Not Applicable.
Item	3.	Defaults Upon Senior Securities
		Not Applicable.
Item	4.	Submission of Matters to a Vote of Security Holders
		Not Applicable.

Item 5. Other Information
Not Applicable.

Item 6. Exhibits

- 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.

EXHIBITS INDEX

<u>Exhibit Number</u>	<u>Description</u>
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