

BIOCRYST PHARMACEUTICALS INC

Form 10-Q

May 10, 2007

Table of Contents

**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  
Commission File Number 000-23186  
BIOCRYST PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

**DELAWARE**

(State of other jurisdiction of  
incorporation or organization)

**62-1413174**

(I.R.S. employer identification no.)

**2190 Parkway Lake Drive; Birmingham, Alabama 35244**

(Address of principal executive offices)

**(205) 444-4600**

(Registrant's telephone number, including area code)

Indicate by a 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 such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by a 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 a check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes  No

The number of shares of Common Stock, par value \$.01, of the Registrant outstanding as of April 30, 2007 was 29,360,050.

**BIOCRYST PHARMACEUTICALS, INC.  
INDEX**

	<b>Page No.</b>
<u>Part I. Financial Information</u>	
<u>Item 1. Financial Statements:</u>	
<u>Balance Sheets March 31, 2007 and December 31, 2006</u>	2
<u>Statements of Operations Three Months Ended March 31, 2007 and 2006</u>	3
<u>Statements of Cash Flows Three Months Ended March 31, 2007 and 2006</u>	4
<u>Notes to Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	20
<u>Part II. Other Information</u>	
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3. Defaults Upon Senior Securities</u>	21
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	21
<u>Item 5. Other Information</u>	21
<u>Item 6. Exhibits</u>	21
<u>Signatures</u>	22
<u>Exhibit 10.2</u>	
<u>Exhibit 10.4</u>	
<u>Exhibit 10.5</u>	
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	
<u>Exhibit 32.2</u>	



**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****BIOCRYST PHARMACEUTICALS, INC.****BALANCE SHEETS****March 31, 2007 and December 31, 2006****(In thousands, except per share data)**

	<b>2007</b>	<b>2006</b>
	<b>(Unaudited)</b>	<b>(Note 1)</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 9,207	\$ 4,418
Marketable securities	27,849	33,040
Receivables from collaborations billed	3,871	249
Receivables from collaborations unbilled	4,496	4,307
Prepaid expenses and other current assets	1,865	3,776
<b>Total current assets</b>	<b>47,288</b>	<b>45,790</b>
Marketable securities	5,793	8,778
Furniture and equipment, net	3,062	3,029
Patents and licenses, net	303	290
Deferred collaboration expense	11,470	10,598
<b>Total assets</b>	<b>\$ 67,916</b>	<b>\$ 68,485</b>
<b>Liabilities and Stockholders Equity</b>		
Accounts payable	\$ 8,209	\$ 5,887
Accrued expenses	1,537	1,507
Accrued vacation	672	641
Deferred revenue	3,161	2,699
<b>Total current liabilities</b>	<b>13,579</b>	<b>10,734</b>
Deferred revenue	40,344	36,596
Stockholders equity:		
Preferred stock: shares authorized 5,000		
Series B Junior Participating Preferred Stock, \$.001 par value; shares authorized 45; shares issued and outstanding none		
Common stock, \$.01 par value: shares authorized 45,000; shares issued and outstanding 29,350 in 2007 and 29,249 in 2006	294	292
Additional paid-in capital	217,979	216,311
Accumulated other comprehensive income	26	33
Accumulated deficit	(204,306)	(195,481)
<b>Total stockholders equity</b>	<b>13,993</b>	<b>21,155</b>

Total liabilities and stockholders' equity	\$ 67,916	\$ 68,485
--	-----------	-----------

See accompanying notes to financial statements.

Table of Contents

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**Three Months Ended March 31, 2007 and 2006**  
(In thousands, except per share data)  
(Unaudited)

	2007	2006
<b>Revenues:</b>		
Collaborative and other research and development	\$ 9,159	\$ 771
<b>Expenses:</b>		
Research and development	16,195	8,043
General and administrative	2,372	1,495
Total expenses	18,567	9,538
Loss from operations	(9,408)	(8,767)
Interest and other income	583	885
Net loss	\$ (8,825)	\$ (7,882)
Basic and diluted net loss per common share	\$ (.30)	\$ (.27)
Weighted average shares outstanding	29,274	28,938
See accompanying notes to financial statements.		

Table of Contents

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**Three Months Ended March 31, 2007 and 2006**  
(In thousands)  
(Unaudited)

	2007	2006
<b>Operating activities:</b>		
Net loss	\$ (8,825)	\$ (7,882)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	231	205
Stock-based compensation expense	1,376	420
Changes in operating assets and liabilities:		
Receivables from collaborations	(3,811)	29,370
Prepaid expenses and other current assets	1,911	(1,887)
Deferred collaboration expense	(872)	(2,075)
Accounts payable and accrued expenses	2,383	(1,663)
Deferred revenue	4,210	9,859
<b>Net cash (used in) provided by operating activities</b>	<b>(3,397)</b>	<b>26,347</b>
<b>Investing activities:</b>		
Acquisitions of furniture and equipment	(261)	(556)
Purchases of patents and licenses	(16)	(36)
Purchases of marketable securities		(17,639)
Maturities of marketable securities	8,169	3,500
<b>Net cash provided by (used in) investing activities</b>	<b>7,892</b>	<b>(14,731)</b>
<b>Financing activities:</b>		
Employee stock purchase plan sales	129	100
Exercise of stock options	165	2,142
<b>Net cash provided by financing activities</b>	<b>294</b>	<b>2,242</b>
Increase in cash and cash equivalents	4,789	13,858
Cash and cash equivalents at beginning of period	4,418	29,157
<b>Cash and cash equivalents at end of period</b>	<b>\$ 9,207</b>	<b>\$ 43,015</b>

See accompanying notes to financial statements.



**Table of Contents**

**BIOCRYST PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Unaudited)**

**Note 1 Significant Accounting Policies*****Basis of Presentation***

The balance sheet as of March 31, 2007, the statements of operations for the three months ended March 31, 2007 and 2006, and the statements of cash flows for the three months ended March 31, 2007 and 2006 have been prepared by the Company in accordance with accounting principles generally accepted in the United States and have not been audited. Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the financial position at March 31, 2007, the results of operations for the three months ended March 31, 2007 and 2006, and cash flows for the three months ended March 31, 2007 and 2006. There were no adjustments other than normal recurring adjustments.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2006 and the notes thereto included in the Company's 2006 Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 2006 has been derived from the audited financial statements included in the Company's most recent Annual Report on Form 10-K.

***Cash and Cash Equivalents***

The Company generally considers cash equivalents to be all cash held in money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase in accordance with Statement of Financial Accounting Standards No. 95, *Statement of Cash Flows*.

***Marketable Securities***

In accordance with Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the Company is required to classify securities as trading, available-for-sale, or held-to-maturity. The appropriateness of each classification is assessed at the time of purchase and at each reporting date. At March 31, 2007, the Company had approximately \$33.6 million of marketable securities of which \$12.8 million is classified as available-for-sale and \$20.8 million is classified as held-to-maturity. Securities available-for-sale consisted of U.S. Agency securities carried at fair value based on independent quoted market prices. At March 31, 2007, the amortized cost of securities available-for-sale was \$12.8 million. Unrealized gains and losses on securities available-for-sale are recognized in other comprehensive income. Securities held-to-maturity consisted of U.S. Treasury and Agency securities and commercial paper carried at amortized cost. The estimated fair value of these securities, which was also based on independent quoted market prices, approximated amortized cost at March 31, 2007.

***Receivables from Collaborations***

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs and event payments. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. To date, the Company has not established a reserve and has never had any default of amounts due from third parties.

***Furniture and Equipment***

Furniture and equipment are recorded at cost. Depreciation is computed using the straight-line method with estimated useful lives of five and seven years. Laboratory equipment, office equipment, leased equipment, and software are depreciated over a life of five years. Furniture and fixtures are depreciated over a life of seven years. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is less. In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( Statement No. 144 ), the Company periodically reviews its furniture and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Furniture and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.



**Table of Contents*****Patents and Licenses***

Patents and licenses are recorded at cost and amortized on a straight-line basis over their estimated useful lives or 20 years, whichever is less. The Company periodically reviews its patents and licenses for impairment in accordance with Statement No. 144 to determine any impairment that needs to be recognized.

***Accrued Expenses***

The Company records all expenses in the period incurred. In addition to recording expenses for invoices received, the Company estimates the cost of services provided by third parties or materials purchased for which no invoices have been received as of each balance sheet date. Accrued expenses as of March 31, 2007 and 2006 consisted primarily of development and clinical trial expenses payable to contract research organizations in connection with the Company's research and development programs.

***Accumulated Other Comprehensive Income***

Accumulated other comprehensive income is comprised of unrealized gains and losses on securities available-for-sale and is disclosed as a separate component of stockholders' equity. The Company had \$26,313 of unrealized gains on its securities that are included in accumulated other comprehensive income at March 31, 2007. Other comprehensive income for the three months ended March 31, 2007 and 2006 appears in the following table. Note that amounts are in thousands.

	<b>Three Months Ended March 31, 2007</b>	<b>Three Months Ended March 31, 2006</b>
Net loss	\$ (8,825)	\$ (7,882)
Unrealized loss on securities available-for-sale	(7)	
Other comprehensive income (loss)	\$ (8,832)	\$ (7,882)

***Revenue Recognition***

The Company's revenues have generally been limited to license fees, event payments, research and development fees, government contracts, and interest income. Revenue is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* ( SAB No. 104 ), and Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF Issue 00-21 ). License fees, future event payments, and research and development fees are recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. In the event a license agreement contains multiple deliverables, the Company evaluates whether the deliverables are separate or combined units of accounting in accordance with EITF Issue 00-21. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Future event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue.

Significant direct costs incurred upon entering into a licensing arrangement are deferred and charged to expense in proportion to the revenue recognized. Under the guidance of Emerging Issues Task Force Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* ( EITF Issue 99-19 ), and Emerging Issues Task Force Issue 01-14, *Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses* ( EITF Issue 01-14 ), reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses.



**Table of Contents**

Royalty revenue is recognized based on estimates of royalties earned during the applicable period and adjusted for differences between the estimated and actual royalties in the following period. If royalties can not be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. The Company has not received any royalties from the sale of licensed pharmaceutical products.

***Research and Development Expenses***

In accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs* ( Statement No. 2 ), the Company expenses research and development costs as incurred. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by contract research organizations ( CRO s ), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company s manufacturing and clinical and preclinical studies are performed by third-party CRO s. Costs for studies performed by CRO s are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company s on-going review of the level of services actually performed.

Additionally, the Company has license agreements with third parties, such as Albert Einstein College of Medicine of Yeshiva University ( AECOM ), Industrial Research, Ltd. ( IRL ), and the University of Alabama at Birmingham ( UAB ), which require maintenance fees or fees related to sublicense agreements. These fees are generally expensed as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period.

***Stock-Based Compensation***

In accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* ( Statement No. 123R ), all share-based payments, including grants of stock option awards and restricted stock awards, are recognized in the Company s income statement based on their fair values. Statement No. 123R was adopted by the Company on January 1, 2006 using the modified prospective transition method. Under the fair value recognition provisions of Statement No. 123R, stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award.

As of March 31, 2007, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ( Plan ) and the Employee Stock Purchase Plan ( ESPP ). Prior to January 1, 2006, the Company accounted for those plans under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and other related interpretations, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*. No stock-based compensation cost related to the Company s employees was recognized in the Statements of Operations for any period ending prior to January 1, 2006. Stock-based compensation expense of \$1,375,622 (\$1,343,247 of expense related to the Plan and \$32,375 of expense related to the ESPP) was recognized during the first three months of 2007, while \$419,809 (\$412,473 of expense related to the Plan and \$7,336 of expense related to the ESPP) was recognized during the first three months of 2006.

As of March 31, 2007, there was approximately \$12,078,183 of total unrecognized compensation cost related to non-vested employee stock option awards and stock awards granted under the Plan and the ESPP. That cost is expected to be recognized as follows: \$3,257,868 in the remainder of 2007, \$3,714,522 in 2008, \$3,192,937 in 2009, \$1,910,215 in 2010, and \$2,641 in 2011.

***Net Loss Per Share***

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards No. 128, *Earnings Per Share*. Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options and common shares expected to be issued under the Company s employee stock purchase plan were anti-dilutive.

**Table of Contents****Use of Estimates**

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 amounts reported in the financial statements. Examples include accrued clinical and preclinical expenses. Actual results could differ from those estimates.

**Note 2 Stock-Based Compensation****Stock Incentive Plan**

The Company grants stock option awards and restricted stock awards to employees, directors, and consultants of the Company under the Stock Incentive Plan ( Plan ), as amended and restated on March 7, 2006. The Plan was approved by the Company's stockholders on May 17, 2006 and permits the Company to issue awards for approximately 5.0 million shares of common stock over the term of the Plan as amended and restated. Under the Plan, stock option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Stock option awards granted to employees and consultants generally vest 25% after one year and monthly thereafter on a pro rata basis over the next three years until fully vested after four years. Stock option awards granted to non-employee directors of the Company generally vest over one year. All stock option awards have contractual terms of 10 years. The vesting exercise provisions of all awards granted under the Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Plan.

For each stock option award granted under the Plan during the first three months of 2007 and 2006, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value of the stock option awards granted under the Plan during the first three months of 2007 and 2006 was \$7.71 and \$13.75, respectively. The fair value of those stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the valuation date and the full contractual term. The expected volatility represents an average of the implied volatility on the Company's publicly traded stock options, the volatility over the most recent period corresponding with the expected life, and the Company's long-term reversion volatility. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

**Weighted Average Assumptions for Stock Option Awards Granted  
under the Plan**

	2007	2006
Expected Life	5.7	5.9
Expected Volatility	77.6%	85.7%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	4.7%	4.4%

Related activity under the Plan is as follows:

	Awards Available	Awards Outstanding	Weighted Average Exercise Price
Balance December 31, 2006	820,754	3,952,568	\$ 8.94
Stock option awards granted	(492,833)	492,833	11.69
Restricted stock awards granted	(50,000)	50,000	
Stock option awards exercised		(36,244)	4.55

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

Stock option awards canceled	1,488	(1,488)	22.72
Balance March 31, 2007	279,409	4,457,669	9.17

The grant date fair value of the restricted stock awards granted under the Plan during the first three months of 2007 was \$11.81.

**Table of Contents*****Employee Stock Purchase Plan***

The ESPP was originally approved by the Company's stockholders on May 29, 1995 and most recently amended on May 12, 2002. The Company has reserved a total of 400,000 shares of common stock to be purchased under the ESPP, of which 84,656 shares remain available for purchase at March 31, 2007. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than 3,000 shares may be purchased by any one employee at the six-month purchase dates and no employee may purchase stock having a fair market value at the commencement date of \$25,000 or more in any one calendar year. The Company issued 14,957 shares during the first three months of 2007 under the ESPP. The fair value expense of options granted under the ESPP was determined using a Black-Scholes option pricing model.

**Note 3 Collaborative Agreements**

In November 2005, the Company announced a collaborative relationship with F.Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche) for the development and commercialization of BCX-4208. In February 2006, the Company announced a collaborative relationship with Mundipharma International Holdings Limited (Mundipharma) for the development and commercialization of Fodosine. For these license agreements, the Company decided to defer the upfront payments received in these collaborations over the remaining life of the patents of the compounds licensed, which is through August 2023 for the Roche agreement and through October 2017 for the Mundipharma agreement. These upfront payments have been classified as deferred revenue on the balance sheet and the significant direct costs incurred upon entering into these licensing agreements related to sublicense fees paid to AECOM and IRL have been recorded as deferred assets on the balance sheet. As the Company recognizes the revenue related to these agreements, which began in February 2006 for the Mundipharma agreement and October 2006 for the Roche agreement, the Company will also recognize the proportionate amount of expense related to the deferred assets.

In June 2006 and in February 2007, the Company entered into collaborative relationships with Green Cross Corporation (Green Cross) and Shionogi & Co., Ltd. (Shionogi), respectively, for the development and commercialization of peramivir. Consistent with the accounting treatment in the Roche and Mundipharma license arrangements, the Company has deferred the upfront payment made by Green Cross and the sublicense fee payable by the Company to UAB. The recognition of the revenue and the expense from the Green Cross agreement began in August 2006 and will continue through November 2009. The upfront payment from Shionogi, which was received by the Company in April 2007, has not been recorded as a receivable as of March 31, 2007 since neither party had completed their performance obligations prior to quarter end. The recognition of the revenue and the expense from the Shionogi agreement will begin in April 2007 and will continue through December 2017.

In January 2007, the Company announced that it had been awarded a four-year contract from the U.S. Department of Health and Human Services (HHS) for the development of peramivir. The contract commits \$102.6 million to support the development of both intravenous and intramuscular formulations of peramivir. In addition, the contract also funds the validation of U.S. based manufacturing facilities. The contract with HHS is defined as a cost-plus-fixed-fee contract. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit.

**Note 4 Income Taxes**

Effective January 1, 2007, the Company 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 No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement 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.



**Table of Contents**

Upon adoption, the Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements. As of March 31, 2007, all of the Company's deferred tax assets were fully reserved by a valuation allowance equal to 100% of the net deferred tax assets. The company has never been profitable and has not paid any income taxes. Tax years 2003-2006 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2003 are also open to examination to the extent of loss and credit carryforwards from those years.

The company has significant net operating loss and business credit carryovers which are subject to a valuation allowance due to the uncertain nature of the realization of the losses. The Internal Revenue Code imposes certain limitations on the utilization of net operating loss carryovers and other tax attributes after a change in control. The Company has encountered ownership changes which could significantly limit the possible utilization of such carryovers. The Company has not performed a detailed analysis to determine the effect of such ownership changes on its ability to use these net operating loss and credit carryforwards. However, it is not anticipated that limitations, if any, would have a material impact on the balance sheet as a result of offsetting changes in the deferred tax valuation allowance.

The Company will recognize interest and penalties accrued related to unrecognized tax benefits as components of its income tax provision. The Company did not have any interest and penalties accrued upon the adoption of FIN No. 48 and as of March 31, 2007, the Company does not have any interest and penalties accrued related to unrecognized tax benefits.

**Note 5 Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (Statement No. 157). The standard provides enhanced guidance for using fair value to measure assets and liabilities and also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. While the standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, it does not expand the use of fair value in any new circumstances. Statement No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Management of the Company is evaluating the impact of this standard, but does not anticipate that it will have a significant impact on its financial statements.

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

*This Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding future results, performance, or achievements of the Company. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and current reports on Form 8-K.*

**Overview**

Since our inception in 1986, we have been engaged in research and development activities and organizational efforts, including:

- identifying and licensing enzyme targets;
- drug discovery;
- structure-based design of drug candidates;
- small-scale synthesis of compounds;
- conducting preclinical studies and clinical trials;

establishing collaborative relationships with third parties for contract research related to the development of our drug candidates to support manufacturing, clinical development and regulatory compliance;

**Table of Contents**

establishing collaborative relationships with biotechnology or pharmaceutical companies and governmental agencies or other third parties for the further development and potential commercialization of our compounds;

recruiting our scientific and management personnel;

establishing laboratory facilities; and

raising capital.

Our revenues have generally been limited to license fees, event payments, research and development fees, government contracts, and interest income. Revenue is recognized in accordance with SAB No. 104 and EITF Issue 00-21. License fees, future event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized as earned over an estimated period determined by management based on the terms of the agreement and the products licensed. For example, in the Roche and Mundipharma licenses agreements, we deferred the upfront payments over the remaining life of the patents which are through 2023 and 2017, respectively. In the event a license agreement contains multiple deliverables, we evaluate whether the deliverables are separate or combined units of accounting in accordance with EITF Issue 00-21. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Future event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue.

Significant direct costs incurred upon entering into a licensing arrangement, such as our sublicense fees to AECOM and IRL for the Roche and Mundipharma agreements and to UAB for the Shionogi and Green Cross agreements, are deferred and charged to expense in proportion to the revenue recognized. Under the guidance of EITF Issue 99-19 and EITF Issue 01-14, reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. For example, the amounts received from Mundipharma and HHS for the reimbursement of development costs will be recorded as revenue in the period the related costs are incurred.

Royalty revenue is recognized based on estimates of royalties earned during the applicable period and adjusted for differences between the estimated and actual royalties in the following period. If royalties can not be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. We have not received any royalties from the sale of licensed pharmaceutical products.

It could be several years, if ever, before we will recognize significant revenue from royalties received pursuant to our license agreements or revenue directly from product sales. Future revenues, if any, are likely to fluctuate substantially from quarter to quarter.

We have incurred operating losses since our inception. Our accumulated deficit at March 31, 2007 was \$204.3 million. We expect to incur substantial expenditures relating to the development of our current and future drug candidates. During the three years ended December 31, 2006, we spent 66.0% of our research and development expenses on contract research and development, including:

payments to consultants;

funding of research at academic institutions;

toxicology studies on existing and potential drugs;

manufacturing of our raw materials, drug substance and drug products;

large scale synthesis and formulation of compounds;

**Table of Contents**

preclinical studies;

payments of amounts to academic institutions and others as a result of our recent collaborations;

engaging investigators to conduct clinical trials;

hiring CRO s for regulatory and clinical functions; and

using statisticians to evaluate the results of clinical trials.

The above expenditures for contract research and development for our current and future drug candidates will vary from quarter-to-quarter depending on the status of our research and development projects. For example, during the first quarter of 2007, we incurred significant costs related to the Phase II trials with peramivir and the ongoing manufacturing of drug substance for both peramivir and Fodosine . As these trials progress and additional trials are started in other indications, our costs for clinical studies will increase significantly. In addition, the costs associated with the manufacturing of Fodosine and peramivir will increase as we continue scaling up to the larger production runs required for clinical development, manufacturing validation and additional toxicology studies for these programs. Changes in our existing and future research and development and collaborative relationships also will impact the status of our research and development projects. For example, in January 2007, we announced a \$102.6 million contract with HHS for the funding of the development, manufacturing and clinical trials required for licensure of peramivir with both the intravenous ( i.v. ) and intramuscular ( i.m. ) formulations. In March 2007, we announced a license agreement with Shionogi for the development and commercialization of peramivir in Japan for an upfront payment of \$14 million. In November 2005 we entered into a license agreement with Roche for the worldwide development and commercialization for our second PNP inhibitor, BCX-4208. In addition to an upfront payment plus an advance payment for manufacturing we performed, Roche has taken over the development and is paying all costs associated with this program. In February 2006, we licensed Fodosine to Mundipharma for the development and commercialization of this drug in Europe, Asia and Australasia. In addition to the upfront payment of \$10 million, Mundipharma is paying 50% of the clinical development costs we incur for Fodosine on existing and planned clinical trials, but their portion shall not exceed \$10 million.

For the Roche and Mundipharma collaborations, we will owe sublicense payments to AECOM and IRL on all upfront, future event payments and royalties. For the Shionogi and Green Cross collaborations, we will owe sublicense payments to UAB. The revenue from these agreements has been recorded as deferred revenue on our balance sheet and will be recognized over the remaining patent life of the related drug candidate. The payments to AECOM, IRL and UAB have been recorded as deferred assets on our balance sheet and will be recognized over the period of the related revenue recognition. Due to the nature of the potential milestones in our collaborations, it is difficult to predict if and when particular milestones will be achieved by us or our partners. The revenues expected from the Mundipharma agreement in 2007 will consist of continuing reimbursement of R&D expenses in accordance with the contract and the amortization of the upfront and event payments. The primary revenue expected from the Roche agreement for 2007 is the continuing amortization of the upfront payment received.

During January 2007, we initiated a pivotal clinical trial with Fodosine in T-ALL, which triggered a \$5 million event payment from Mundipharma. Subsequently, in March 2007, the Company made a decision to put this trial on voluntary hold to investigate particulates that were found in some batches of i.v. formulation. We are working closely with Mundipharma to determine a mutually agreeable course of future action with regard to the clinical evaluation of Fodosine in T-ALL. In March 2007 we submitted a proposed pivotal trial of oral Fodosine in CTCL to the FDA and requested a SPA. At present we are in active discussions with the FDA to finalize the requirements to obtain the SPA so that this pivotal clinical trial with Fodosine in CTCL patients can begin later in 2007.

The contract with HHS is a standard cost-plus-fixed-fee contract which provides for the reimbursement of allowable costs plus an element of overhead and profit. This is expected to have a significant positive revenue impact on our financial statements. As the costs of our peramivir program increase for the clinical trials, manufacturing and other expenses we will submit invoices to HHS for reimbursement of expenses allowable under the contract. The expenses

are recorded as R&D expenses and reimbursements are recorded as revenue. In the same way, as we incur R&D costs for our Fodosine program that are reimbursable under the Mundipharma contract or R&D expenses for peramivir that are related to the Shionogi contract, we will invoice the respective company for those costs. The amounts reimbursable will be recorded as revenue in the same period the costs are incurred.

## **Table of Contents**

Although we may, in some cases, be able to control the timing of development expenses, in part by accelerating or decelerating certain costs, many of these costs will be incurred irrespective of whether we are able to discover drug candidates or obtain collaborative partners for commercialization. In addition, the achievement of milestones in our collaboration agreements is uncertain and unpredictable and would most likely have a significant impact on our operating results in the periods they are achieved. As a result, we believe that quarter-to-quarter comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance. If we fail to meet the research, clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the price of our common stock.

### **Results of Operations (three months ended March 31, 2007 compared to the three months ended March 31, 2006)**

Collaborative and other research and development revenues increased to \$9,159,000 for the three months ended March 31, 2007 as compared to \$771,000 for the three months ended March 31, 2006, primarily due to reimbursement expected from HHS related to our contract for the development of peramivir, which included approximately \$2 million of pre-contract costs from 2006 that had been deferred on the Company's balance sheet as of December 31, 2006.

Research and development ( R&D ) expenses increased 101.4% to \$16,195,000 for the first quarter of 2007 from \$8,043,000 for the first quarter of 2006, while general and administrative ( G&A ) expenses increased 58.7% to \$2,372,000 for the first quarter of 2007 from \$1,495,000 for the first quarter of 2006. The variance in R&D expenses is mainly attributable to an increase in expenses related to clinical trials, manufacturing, and animal studies related to the advanced development of our drug candidates, Fodosine and peramivir. Recognized in R&D expenses during the first quarter of 2007 was approximately \$2 million of costs that were actually incurred during 2006. These costs were directly related to the Phase 2 trials for peramivir and were deferred at December 31, 2006 in anticipation of a contract award from HHS. In addition, there has been an increase in personnel related costs due to an increase in personnel to support the advanced development of our drug candidates, plus an increase of \$395,000 in the share-based compensation expense over the first quarter of 2006.

The increase in G&A expenses is primarily due to an increase in personnel related costs, including an increase of \$561,000 in share-based compensation expense, and an increase in professional fees.

Interest income for the three months ended March 31, 2007 was \$583,000 as compared to \$885,000 for the three months ended March 31, 2006. This decrease was due to a lower average balance of interest-bearing assets for the first quarter of 2007 versus the first quarter of 2006.

### **Liquidity and Capital Resources**

Cash expenditures have exceeded revenues since our inception. Our operations have principally been funded through public offerings and private placements of equity and debt securities and cash from collaborative and other research and development agreements and to a lesser extent interest. For example, during December 2005, we raised \$30.0 million (approximately \$29.9 million net of expenses) through a sale of 2,228,829 shares of our common stock. During 2006, we received cash from collaborative and other research and development agreements (primarily Roche and Mundipharma) of approximately \$31.8 million net of sublicense fees. Based on anticipated cash receipts from the HHS contract and the collaborations with Shionogi, Mundipharma and Roche we expect such cash receipts to increase significantly. Other sources of funding have included the following:

- other collaborative and other research and development agreements;

- government grants and contracts;

- equipment lease financing;

- facility leases;

- research grants; and

interest income.



**Table of Contents**

In addition, we have attempted to contain costs and reduce cash flow requirements by renting scientific equipment and facilities, contracting with other parties to conduct certain research and development and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities, undertake additional preclinical studies and clinical trials of compounds which have been or may be discovered and as we increase the manufacturing of our compounds for clinical trials and for the continuation of the validation process. We also expect to incur substantial expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical products advance through later stages of development.

We invest our excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. These investments are generally not collateralized and mature within two years. We have not realized any losses from such investments.

We have financed some of our equipment purchases with lease lines of credit. Our lease for our current Birmingham facilities expires on June 30, 2010. We have an option to renew the lease for an additional five years at the current market rate in effect on June 30, 2010 and a one-time option to terminate the lease on June 30, 2008 for a termination fee of approximately \$124,000. The lease requires us to pay monthly rent currently at \$37,963 per month in December 2006 and escalating annually to a minimum of \$41,481 per month in the final year, plus our pro rata share of operating expenses and real estate taxes in excess of base year amounts.

In August 2006, we opened an office in Cary, North Carolina for the establishment of our clinical and regulatory operation. We currently have 5,375 square feet under lease through February 2010. This lease requires us to pay \$7,391 per month and escalates annually to \$7,841 per month in the final year.

We have not incurred any significant charges related to building renovations since 2001. Our capital costs during 2006 were approximately \$1.4 million and we anticipate capital costs of approximately \$2.0 million in 2007.

At December 31, 2006, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$549,758 in 2007, \$565,257 in 2008 and \$538,351 in 2009. These obligations include the future rental of our operating facilities.

We plan to finance our needs principally from the following:

payments under our contract with HHS;

our existing capital resources and interest earned on that capital;

payments under collaborative and licensing agreements with corporate partners; and

lease or loan financing and future public or private financing.

For the year, our cash, cash equivalents and marketable securities balance has decreased from \$46.2 million as of December 31, 2006 to \$42.8 million as of March 31, 2007, primarily due to the monthly cash burn from operations less the cash received from collaborations.

The collaboration with Roche for the worldwide development and commercialization of BCX-4208 provided an upfront payment of \$30 million, which was received in 2006. Roche has taken over the development and is paying all costs associated with this program. The agreement also provides for future event payments and royalties to be made by Roche upon the achievement of certain clinical, regulatory and sales events.

In February 2006, we licensed Fodosine to Mundipharma for the development and commercialization of this drug in Europe, Asia and Australasia. In addition to the upfront payment of \$10 million, which was received in February 2006, Mundipharma is paying 50% of the clinical development costs we are incurring for Fodosine on existing and planned clinical trials, but their portion shall not exceed \$10 million. In addition, Mundipharma will conduct additional clinical trials at their own cost up to a maximum of \$15 million. The agreement also provides for future event payments and royalties to be made by Mundipharma upon the achievement of certain clinical,



**Table of Contents**

regulatory and sales events. In January 2007, we initiated our pivotal study with Fodosine in T-cell leukemia patients under an SPA negotiated with the FDA, which triggered a \$5 million event payment from Mundipharma. Subsequently, in March 2007, the Company made a decision to put this trial on voluntary hold to investigate particulates that were found in some batches of i.v. formulation. We are working closely with Mundipharma to determine a mutually agreeable course of future action with regard to the clinical evaluation of Fodosine in T-ALL. In March 2007 we submitted a proposed pivotal trial of oral Fodosine in CTCL to the FDA and requested a SPA. At present we are in active discussions with the FDA to finalize the requirements to obtain the SPA so that this pivotal clinical trial with Fodosine in CTCL patients can begin later in 2007.

In January 2007, we announced that HHS had awarded the Company a \$102.6 million, four-year contract for the advanced development of peramivir. Funding from the contract will support manufacturing, process validation, clinical studies and other product approval requirements for peramivir. The contract is a standard cost plus fixed fee contract, which will have a significant positive impact on our financial position and cash flow. We will bill our incurred costs to HHS on a monthly basis. Any significant delays in payment or cancellation of this contract by HHS would have a significant negative effect on our financial position.

In March 2007, we announced a collaborative agreement with Shionogi for rights to peramivir in Japan. This agreement required an upfront payment of \$14 million that was received in April 2007.

With the award of the HHS contract to fund the development of peramivir and the current and planned trials for Fodosine, we expect an increase in our research and development expenses for 2007. However, with the expected reimbursement from the HHS contract and our other partners, we are projecting our net cash burn rate to average approximately \$3.0 million per month in 2007. We caution that both our expenses and our cash flows will vary significantly from quarter to quarter due to the nature of the trials in influenza and the reimbursement from HHS.

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related manufacturing, personnel resources and testing required to support the development of our drug candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and burn rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our drug candidates, the amount and timing of funding we receive from HHS for peramivir, the amount of funding or assistance, if any, we receive from other governmental agencies or other new partnerships with third parties for the development of our drug candidates, the progress and results of our current and proposed clinical trials for our most advanced drug products, the progress made in the manufacturing of our lead products and the progression of our other programs.

As of March 31, 2007, we had \$42.8 million in cash, cash equivalents and marketable securities. With our currently available funds and amounts to be received from HHS, Shionogi and our other collaborators, we believe these resources will be sufficient to fund our operations for at least the next twelve months. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time. Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- our ability to perform under the contract with HHS and receive reimbursement;
- the progress and magnitude of our research, drug discovery and development programs;

- changes in existing collaborative relationships or government contracts;

- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;

- the extent to which our partners, including governmental agencies will share in the costs associated with the development of our programs or run the development programs themselves;

- our ability to negotiate favorable development and marketing strategic alliances for our drug candidates;

the scope and results of preclinical studies and clinical trials to identify and evaluate drug candidates;

**Table of Contents**

our ability to enroll sites and patients in our clinical trials;

the scope of manufacturing of our drug candidates to support our preclinical research and clinical trials;

increases in personnel and related costs to support the development of our drug candidates;

the scope of validation for the manufacturing of our drug substance and drug products required for future NDA filings;

competitive and technological advances;

the time and costs involved in obtaining regulatory approvals;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

our dependence on others for development and commercialization of our product candidates; and

successful commercialization of our products consistent with our licensing strategy.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from the HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

**Off-Balance Sheet Arrangements**

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of March 31, 2007, we are not involved in any material unconsolidated entities or off-balance sheet arrangements.

**Contractual Obligations**

Our contractual obligations as of December 31, 2006 are described in our Annual Report on Form 10-K. There have been no material changes in contractual obligations outside the ordinary course of business since December 31, 2006.

**Critical Accounting Policies**

We have established various accounting policies that govern the application of accounting principles generally accepted in the United States, which were utilized in the preparation of our financial statements. Certain accounting policies involve significant judgments and assumptions by management that have a material impact on the carrying value of certain assets and liabilities. Management considers such accounting policies to be critical accounting policies. The judgments and assumptions used by management are based on historical experience and other factors, which are believed to be reasonable under the circumstances. Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates, which could have a material impact on the carrying values of assets and liabilities and the results of operations.

While our significant accounting policies are more fully described in Note 1 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2006, and Note 1 to our financial statements included in Part I, Item I of this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and

estimates that we use in the preparation of our financial statements.

**Table of Contents*****Revenue Recognition***

Our revenues have generally been limited to license fees, event payments, research and development fees, government contracts, and interest income. Revenue is recognized in accordance with SAB No. 104 and EITF Issue 00-21. License fees, future event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized as earned over an estimated period determined by management based on the terms of the agreement and the products licensed. For example, in the Roche and Mundipharma license agreements, we deferred the upfront payments over the remaining life of the patents which are through 2023 and 2017, respectively. In the event a license agreement contains multiple deliverables, we evaluate whether the deliverables are separate or combined units of accounting in accordance with EITF Issue 00-21. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Future event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue.

Significant direct costs incurred upon entering into a licensing arrangement, such as our sublicense fees to AECOM and IRL for the Roche and Mundipharma agreements and to UAB for the Shionogi and Green Cross agreements, are deferred and charged to expense in proportion to the revenue recognized. Under the guidance of EITF Issue 99-19 and EITF Issue 01-14, reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. For example, the amounts received from Mundipharma and HHS for the reimbursement of development costs will be recorded as revenue in the period the related costs are incurred.

Royalty revenue is recognized based on estimates of royalties earned during the applicable period and adjusted for differences between the estimated and actual royalties in the following period. If royalties can not be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. We have not received any royalties from the sale of licensed pharmaceutical products.

***Research and Development Expenses***

Major components of R&D expenses consist of personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CRO s, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. We charge these costs to expense when incurred, consistent with Statement No. 2. These costs are a significant component of R&D expenses. Most of our manufacturing and our clinical and preclinical studies are performed by third-party CRO s. We accrue costs for studies performed by CRO s over the service periods specified in the contracts and adjust our estimates, if required, based upon our on-going review of the level of services actually performed. We expense both our internal and external research and development costs as incurred.

Additionally, we have license agreements with third parties, such as AECOM, IRL, and UAB that require maintenance fees or fees related to sublicense agreements. These fees are generally expensed as incurred unless they are related to revenues that have been deferred in which case the expenses will be deferred and recognized over the related revenue recognition period.

We group our R&D expenses into two major categories: direct external expenses and all other R&D expenses. Direct external expenses consist of costs of outside parties to conduct laboratory studies, to develop manufacturing processes and manufacture the product candidate, to conduct and manage clinical trials and similar costs related to our clinical and preclinical studies. These costs are accumulated and tracked by program. All other R&D expenses consist of costs to compensate personnel, to purchase lab supplies and services, to maintain our facility, equipment and overhead and similar costs of our research and development efforts. These costs apply to work on our clinical and preclinical candidates as well as our discovery research efforts. These costs have not been charged directly to each program historically because the number of product candidates and projects in research and development may vary from period to period and because we utilize internal resources across multiple projects at the same time.





**Table of Contents**

The following table summarizes our R&D expenses for the periods indicated. Note that amounts are in thousands.

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
Direct external R&D expenses by program:		
PNP Inhibitor (Fodosine )	\$ 3,367	\$ 3,378
PNP Inhibitor (BCX-4208)	54	37
Neuraminidase Inhibitor (peramivir)	5,354	1,622
Hepatitis C Polymerase Inhibitor	445	243
Other	155	26
All other R&D expenses:		
Compensation and fringe benefits	2,453	1,218
Supplies and services	2,581	172
Maintenance, depreciation, and amortization	306	238
Overhead allocation and other	1,480	1,109
Total R&D expenses	\$ 16,195	\$ 8,043

At this time, due to the risks inherent in the clinical trial process and given the stages of our various product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our drug candidates for potential commercialization. While we are currently focused on advancing each of our development programs, our future R&D expenses will depend on the determinations we make as to the scientific and clinical success of each drug candidate, as well as ongoing assessments as to each drug candidate's commercial potential. As such, we are unable to predict how we will allocate available resources among our product development programs in the future. In addition, we cannot forecast with any degree of certainty the development progress of our existing partnerships for our drug candidates, which drug candidates will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot be certain that any of our drug candidates will prove to be safe and effective or will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory clearance. We, the FDA or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our products under development. Delays or rejections may be encountered based on additional governmental regulation, legislation, administrative action or changes in FDA or other regulatory policy during development or the review process. Other risks associated with our product development programs are described in Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K, as updated by Part II, Item IA of this report and as updated from time to time in our subsequent periodic reports and current reports filed with the SEC. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of completion of any of our product development programs and the period in which material net cash inflows from any of our product development programs will commence are unavailable.

**Table of Contents**

***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

fees paid to CRO s in connection with preclinical and toxicology studies and clinical trials;

fees paid to investigative sites in connection with clinical trials;

fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and drug products; and

professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we incur costs that we previously failed to identify, or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

***Stock-Based Compensation***

In accordance with Statement No. 123R, all share-based payments, including grants of stock option awards and restricted stock awards, are recognized in our income statement based on their fair values. We adopted Statement No. 123R on January 1, 2006 using the modified prospective transition method. Under the fair value recognition provisions of Statement No. 123R, stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the life of an award, the stock price volatility, and the expected term. Compensation cost is recognized on a straight-line basis over the requisite service period.

***Information Regarding Forward-Looking Statements***

This filing contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These forward-looking statements can generally be identified by the use of words such as may, will, intends, plans, believes, anticipates, expects, estimates, predicts, potential, the negative, and similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

the initiation, timing, progress and results of our preclinical and clinical trials, research and development programs;

the potential for funding from HHS for the development of peramivir from the RFP;

the further preclinical or clinical development and commercialization of our product candidates;

the implementation of our business model, strategic plans for our business, product candidates and technology;

**Table of Contents**

our ability to establish and maintain collaborations with biotechnology or pharmaceutical companies and governmental agencies or other third parties;

the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;

our ability to operate our business without infringing the intellectual property rights of others;

estimates of our expenses, future revenues, capital requirements and our needs for additional financing;

the timing or likelihood of regulatory filings and approvals;

our financial performance; and

competitive companies, technologies and our industry.

These statements reflect our current views with respect to future events and BioCryst has no obligation to update or revise the statements. BioCryst cautions that you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in **Risk Factors** in our Annual Report on Form 10-K, as updated by Part II, Item 1A of this report.

You should read this discussion completely and with the understanding that our actual future results may be materially different from what we expect. We may not update these forward-looking statements, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing our risk. We invest excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we believe we have no material exposure to interest rate risk arising from our investments. Therefore, no quantitative tabular disclosure is provided.

**Item 4. Controls and Procedures**

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Securities Exchange Act is recorded, processed, summarized and reported in a timely manner under the Securities Exchange Act of 1934. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2007, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by BioCryst in the reports filed or submitted by it under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by BioCryst in such reports is accumulated and communicated to the Company's management, including the Chairman and Chief Executive Officer and Chief Financial Officer of BioCryst, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2007 that have materially affected, or are reasonably likely to materially affect, BioCryst's internal control over financial reporting.



**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings:**

None

**Item 1A. Risk Factors:**

Our 2006 Annual Report on Form 10-K includes a detailed discussion of our risk factors. As of March 31, 2007, there have been no material changes in the risk factors disclosed in the Form 10-K.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds:**

None

**Item 3. Defaults Upon Senior Securities:**

None

**Item 4. Submission of Matters to a Vote of Security Holders:**

None

**Item 5. Other Information:**

None

**Item 6. Exhibits:**

a. Exhibits:

<b>Number</b>	<b>Description</b>
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Bylaws of Registrant as amended December 15, 2005. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 16, 2005.
4.1	Rights Agreement, dated as of June 17, 2002, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes the Certificate of Designation for the Series B Junior Participating Preferred Stock as Exhibit A and the form of Rights Certificate as Exhibit B. Incorporated by reference to Exhibit 4.1 to the Company's Form 8-A dated June 17, 2002.
10.1	Stock Incentive Plan, as amended and restated effective March 7, 2006. Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q dated August 9, 2006.
10.2	Employment Letter Agreement dated June 19, 2007, by and between the Company and W. James Alexander.
10.3	Amended and Restated Employment Letter Agreement dated February 14, 2007, by and between the Company and Jon P. Stonehouse. Incorporated by reference to Exhibit 10.12 to the Company's Form 10-K for the year ended December 31, 2006, dated March 14, 2007.
10.4	License, Development and Commercialization Agreement dated as of February 28, 2007, by and between the Company and Shionogi & Co., Ltd. (Portions omitted pursuant to request for confidential treatment and filed separately with the Commission.)
10.5	Employment Letter Agreement dated April 2, 2007, by and between the Company and David McCullough.
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 10th day of May 2007.

BIOCRYST PHARMACEUTICALS, INC.

/s/Jon P. Stonehouse  
Jon P. Stonehouse  
*Chief Executive Officer*

/s/Michael A. Darwin  
Michael A. Darwin  
*Chief Financial Officer (Principal  
Financial  
and Accounting Officer), Secretary and  
Treasurer*



**Table of Contents**

**EXHIBIT INDEX**

<b>Number</b>	<b>Description</b>
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Bylaws of Registrant as amended December 15, 2005. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 16, 2005.
4.1	Rights Agreement, dated as of June 17, 2002, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes the Certificate of Designation for the Series B Junior Participating Preferred Stock as Exhibit A and the form of Rights Certificate as Exhibit B. Incorporated by reference to Exhibit 4.1 to the Company's Form 8-A dated June 17, 2002.
10.1	Stock Incentive Plan, as amended and restated effective March 7, 2006. Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q dated August 9, 2006.
10.2	Employment Letter Agreement dated June 19, 2007, by and between the Company and W. James Alexander.
10.3	Amended and Restated Employment Letter Agreement dated February 14, 2007, by and between the Company and Jon P. Stonehouse. Incorporated by reference to Exhibit 10.12 to the Company's Form 10-K for the year ended December 31, 2006, dated March 14, 2007.
10.4	License, Development and Commercialization Agreement dated as of February 28, 2007, by and between the Company and Shionogi & Co., Ltd. (Portions omitted pursuant to request for confidential treatment and filed separately with the Commission.)
10.5	Employment Letter Agreement dated April 2, 2007, by and between the Company and David McCullough.
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.