

BIOCRYST PHARMACEUTICALS INC

Form 10-Q

August 09, 2007

**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 June 30, 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 July 31, 2007 was 29,535,580.

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****BIOCRYST PHARMACEUTICALS, INC.****BALANCE SHEETS****June 30, 2007 and December 31, 2006****(In thousands, except per share data)**

	<b>2007</b> <b>(Unaudited)</b>	<b>2006</b> <b>(Note 1)</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 7,178	\$ 4,418
Marketable securities	23,690	33,040
Receivables from collaborations billed	3,460	249
Receivables from collaborations unbilled	14,813	4,307
Prepaid expenses and other current assets	2,287	3,776
Total current assets	51,428	45,790
Marketable securities	11,643	8,778
Furniture and equipment, net	3,169	3,029
Patents and licenses, net	314	290
Deferred collaboration expense	11,872	10,598
Total assets	\$ 78,426	\$ 68,485
<b>Liabilities and Stockholders Equity</b>		
Accounts payable	\$ 10,578	\$ 5,887
Accrued expenses	1,249	1,507
Accrued vacation	710	641
Deferred revenue	4,620	2,699
Total current liabilities	17,157	10,734
Deferred revenue	51,926	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 95,000; shares issued and outstanding 29,526 in 2007 and 29,249 in 2006	295	292
Additional paid-in capital	220,321	216,311
Accumulated other comprehensive (loss) income	(4)	33
Accumulated deficit	(211,269)	(195,481)
Total stockholders equity	9,343	21,155

Total liabilities and stockholders' equity	\$ 78,426	\$ 68,485
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See accompanying notes to financial statements.

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**Periods Ended June 30, 2007 and 2006**  
**(In thousands, except per share data)**  
**(Unaudited)**

	<b>Three Months</b>		<b>Six Months</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Revenues:</b>				
Collaborative and other research and development	\$ 13,444	\$ 1,558	\$ 22,603	\$ 2,330
<b>Expenses:</b>				
Research and development	19,013	11,190	35,208	19,234
General and administrative	2,013	1,384	4,385	2,879
Total expenses	21,026	12,574	39,593	22,113
Loss from operations	(7,582)	(11,016)	(16,990)	(19,783)
Interest and other income	619	933	1,202	1,818
Net loss	\$ (6,963)	\$ (10,083)	\$ (15,788)	\$ (17,965)
Basic and diluted net loss per common share	\$ (.24)	\$ (.35)	\$ (.54)	\$ (.62)
Weighted average shares outstanding	29,420	29,184	29,371	29,061
See accompanying notes to financial statements.				

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**Six Months Ended June 30, 2007 and 2006**  
(In thousands)  
(Unaudited)

	<b>2007</b>	<b>2006</b>
<b>Operating activities:</b>		
Net loss	\$ (15,788)	\$ (17,965)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	475	424
Stock-based compensation expense	2,810	1,177
Changes in operating assets and liabilities:		
Receivables from collaborations	(13,717)	28,025
Prepaid expenses and other current assets	1,489	(3,664)
Deferred collaboration expense	(1,274)	(1,999)
Accounts payable and accrued expenses	4,502	(3,218)
Deferred revenue	17,251	9,896
<b>Net cash (used in) provided by operating activities</b>	<b>(4,252)</b>	<b>12,676</b>
<b>Investing activities:</b>		
Acquisitions of furniture and equipment	(609)	(684)
Purchases of patents and licenses	(30)	(64)
Purchases of marketable securities	(13,584)	(29,958)
Maturities of marketable securities	20,032	11,196
<b>Net cash provided by (used in) investing activities</b>	<b>5,809</b>	<b>(19,510)</b>
<b>Financing activities:</b>		
Employee stock purchase plan sales	129	100
Exercise of stock options	1,074	2,632
<b>Net cash provided by financing activities</b>	<b>1,203</b>	<b>2,732</b>
Increase (decrease) in cash and cash equivalents	2,760	(4,102)
Cash and cash equivalents at beginning of period	4,418	29,157
<b>Cash and cash equivalents at end of period</b>	<b>\$ 7,178</b>	<b>\$ 25,055</b>

See accompanying notes to financial statements.

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

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

The balance sheet as of June 30, 2007, the statements of operations for the three and six months ended June 30, 2007 and 2006, and the statements of cash flows for the six months ended June 30, 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 June 30, 2007, the results of operations for the three and six months ended June 30, 2007 and 2006, and cash flows for the six months ended June 30, 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 June 30, 2007, the Company had approximately \$35.3 million of marketable securities of which \$19.7 million is classified as available-for-sale and \$15.6 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 June 30, 2007, the amortized cost of securities available-for-sale approximated fair value. 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 carried at amortized cost. The estimated fair value of these securities, both individually and in the aggregate, approximated amortized cost at June 30, 2007. Fair value was based on independent quoted market prices.

***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. At June 30, 2007, the Company had the following receivables from collaborations. Note that amounts are in thousands.

	<b>Billed</b>	<b>Unbilled</b>
U.S. Department of Health and Human Services	\$ 3,094	\$ 14,234
Mundipharma International Holdings Limited	212	579
Shionogi & Co., Ltd.	154	
Total	\$ 3,460	\$ 14,813





**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.

**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 June 30, 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 (Loss) Income**

Accumulated other comprehensive (loss) 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 \$4,391 of unrealized losses on its securities that are included in accumulated other comprehensive (loss) income at June 30, 2007. Other comprehensive loss for the periods ended June 30, 2007 and 2006 appear in the following table. Note that amounts are in thousands.

	Three Months		Six Months	
	2007	2006	2007	2006
Net loss	\$ (6,963)	\$ (10,083)	\$ (15,788)	\$ (17,965)
Unrealized loss (gain) on securities available-for-sale	(30)	9	(37)	9
Other comprehensive loss	\$ (6,993)	\$ (10,074)	\$ (15,825)	\$ (17,956)

**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, 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.



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.

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.

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 June 30, 2007, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ( Incentive Plan ) and the Employee Stock Purchase Plan ( ESPP ). In addition, the Company made an inducement grant outside of the Incentive Plan and ESPP to recruit a new employee to a key position within the Company. Prior to January 1, 2006, the Company accounted for all share-based payments under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB Opinion No. 25 ), and other related interpretations, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* ( Statement No. 123 ). 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 \$2,809,692 (\$2,703,879 of expense related to the Incentive Plan, \$68,387 of expense related to the ESPP, and \$37,426 of expense related to the inducement grant) was recognized during the first six months of 2007, while \$1,176,673 (\$1,131,138 of expense related to the Plan and \$45,535 of expense related to the ESPP) was recognized during the first six months of 2006.

As of June 30, 2007, there was approximately \$15,305,154 of total unrecognized compensation cost related to non-vested employee stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: \$2,900,435 in the remainder of 2007, \$4,933,536 in 2008, \$4,210,206 in 2009, \$2,941,687 in

2010, and \$319,290 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.

***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 ( Incentive Plan ), as amended and restated in March 2007. The Incentive Plan was approved by the Company's stockholders on May 16, 2007 and permits the Company to issue awards for approximately 5.9 million shares of common stock over the term of the Incentive Plan as amended and restated. Under the Incentive 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 Incentive 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 Incentive Plan.

For each stock option award granted under the Incentive Plan during the first six 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 Incentive Plan during the first six months of 2007 and 2006 was \$6.08 and \$8.88, respectively. The fair value of the 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 Incentive Plan**

	<b>2007</b>	<b>2006</b>
Expected Life in Years	5.7	5.9
Expected Volatility	74.7%	82.5%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	4.7%	5.0%

Related activity under the Incentive Plan is as follows:

	Awards	Awards	Weighted Average Exercise Price
	Available	Outstanding	
Balance December 31, 2006	820,754	3,952,568	\$ 8.94
Incentive Plan amended	1,200,000		
Stock option awards granted	(1,380,706)	1,380,706	9.36
Restricted stock awards granted	(50,000)	50,000	
Stock option awards exercised		(201,774)	5.33
Stock option awards canceled	197,156	(197,156)	13.84
Balance June 30, 2007	787,204	4,984,344	8.92

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

#### ***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 June 30, 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 six 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.

#### ***Stock Inducement Grant***

In March 2007, the Company's Board of Directors approved a stock inducement grant of 110,000 stock option awards and 10,000 restricted stock awards to recruit a new employee to a key position within the Company. These awards were granted in April 2007 with an exercise price equal to the market price of the Company's stock at the date of grant. The awards vest 25% after one year and monthly thereafter on a pro rata basis over the next three years until fully vested after four years. The stock option awards have contractual terms of 10 years. The vesting exercise provisions of both the stock option awards and the restricted stock awards granted under the inducement grant 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 respective agreements.

For the stock option awards granted under the inducement grant, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the following assumptions: expected life of 5.7 years, expected volatility of 72.9%, expected dividend yield of 0.0%, and risk-free interest rate of 4.7%. The weighted average grant date fair value of these stock option awards was \$5.25. The fair value of the 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.

The exercise price of the stock option awards and the grant date fair value of the restricted stock granted under the inducement grant was \$8.20.



**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 deferred 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 payments made by Green Cross and Shionogi and the sublicense fees 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 recognition of the revenue and the expense from the Shionogi agreement began 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.

Upon adoption, the Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements. As of June 30, 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 June 30, 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.

In June 2007, the Emerging Issues Task Force ( EITF ) reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF Issue 07-3 ). The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If a company's expectations change, such that it does not expect the goods will be delivered or the services rendered, the capitalized nonrefundable advance payments should be charged to expense. EITF Issue 07-3 is effective for new contracts entered into during the fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. This consensus may not be applied to earlier periods and early adoption is not permitted. Currently, the Company charges nonrefundable advance payments for future research and development activities to expense as payments are made. Therefore, the adoption of this standard will have an impact on the Company's financial statements when adopted.

**Note 6 Subsequent Event**

On August 6, 2007, the Company entered into a Stock and Warrant Purchase Agreement with a group of existing stockholders for the private placement of 8,315,513 shares of the Company's common stock at a purchase price of \$7.80 per share and warrants to purchase 3,159,895 shares of the Company's common stock at a purchase price of \$0.125 per warrant. The aggregate purchase price of the transaction was approximately \$65.3 million. The exercise price of the warrants is \$10.25 per share. The participants in the transaction include funds managed by Baker Brothers Investments, Kleiner Perkins Caufield & Byers, EHS Holdings, OrbiMed Advisors, Texas Pacific Group Ventures, and Stephens Investment Management, all of whom are current shareholders in the Company.

The shares and warrants included in the private placement have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. The Company has agreed to register the shares, the warrants, and the shares of common stock issuable upon exercise of the warrants for resale. If registration is not completed within the period specified in the Stock and Warrant Purchase Agreement, the Company will be subject to pay liquidated damages to the group of institutional investors up to a maximum of 12% of the transaction value related to the common stock only. The Company expects the transaction to be closed on or about August 9, 2007.

**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;

- 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, 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, Mundipharma and Shionogi license agreements, we deferred the upfront payments over the remaining life of the patents which are through 2023, 2017 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.

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.

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.

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 June 30, 2007 was \$211.3 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;

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 six months 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 up to a maximum of \$10 million. Mundipharma s portion of these reimbursable costs from the inception of the contract through June 30, 2007 has been approximately \$5.6 million, of which approximately \$0.8 million has not been paid and is reflected on our balance sheet in accounts receivable.

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.

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 primarily 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 our other agreements for 2007 is the continuing amortization of the upfront payment received.

In March 2007 we submitted a proposed pivotal trial of oral Fodosine in CTCL to the FDA and requested a special protocol assessment ( SPA ) which is a request for feedback from the FDA that allows a company to receive official evaluation and guidance on the design of pivotal trial protocols. In July 2007, we announced the Company had received an SPA for a pivotal trial of Fodosine in CTCL patients. The trial is planned to be a multicenter, multinational, open-label, single-arm, repeat dose pivotal trial which is expected to begin enrollment during the third quarter of 2007. 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.

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 and cash flows 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 June 30, 2007 compared to the three months ended June 30, 2006)**

Collaborative and other research and development revenues increased to \$13,444,000 for the three months ended June 30, 2007 as compared to \$1,558,000 for the three months ended June 30, 2006, primarily due to revenue from HHS related to our contract for the development of peramivir and the amortization of deferred revenue from our collaborations.

Research and development ( R&D ) expenses increased 69.9% to \$19,013,000 for the second quarter of 2007 from \$11,190,000 for the second quarter of 2006, while general and administrative ( G&A ) expenses increased 45.4% to \$2,013,000 for the second quarter of 2007 from \$1,384,000 for the second quarter of 2006. The variance in R&D expenses is mainly attributable to an increase in expenses related to manufacturing costs for our lead drug candidates, Fodosine and peramivir, animal studies related to our preclinical compounds and costs related to our increase in personnel required to support the advanced development of our drug candidates. The increase in G&A expenses is primarily due to an increase in personnel related costs as a result of increased headcount, and an increase of \$379,000 in share-based compensation expense.

Interest income for the three months ended June 30, 2007 was \$619,000 as compared to \$933,000 for the three months ended June 30, 2006. This decrease was due to a lower average balance of interest-bearing assets for the second quarter of 2007 versus the second quarter of 2006.

**Results of Operations (six months ended June 30, 2007 compared to the six months ended June 30, 2006)**

Collaborative and other research and development revenues increased to \$22,603,000 for the six months ended June 30, 2007 compared to \$2,330,000 for the six months ended June 30, 2006, primarily due to revenue 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. In addition, the



amortization of deferred revenue from our collaborations was \$1.5 million greater for the six months in 2007 primarily due to the amortization of the deferred revenue from the Roche and Shionogi collaborations.

R&D expenses increased 83.1% to \$35,208,000 for the six months ended June 30, 2007 from \$19,234,000 for the six months ended June 30, 2006. The increase is primarily attributable to an increase in expenses related to manufacturing costs for our lead drug candidates, Fodosine and peramivir, costs related to advanced clinical trials for these drug candidates, an increase in personnel related costs supporting the personnel required for the advanced development of our drug candidates and an increase in animal studies related to our preclinical compounds. Also recognized in R&D expenses during 2007 was approximately \$2 million of pre-contract 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 reimbursement under a contract award from HHS.

General and administrative expenses for the six months ended June 30, 2007 increased 52.3% to \$4,385,000 as compared to \$2,879,000 for the same period in 2006, primarily due to \$940,000 of additional share-based compensation expense compared to 2006, additional compensation expense related to an increase in personnel, and an increase in professional fees.

Interest income for the six months ended June 30, 2007 was \$1,202,000, a 33.9% decrease as compared to the same period in 2006. This increase was due to a lower average cash balance during the second quarter of 2007.

### **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, including government contracts, and to a lesser extent interest. For example, during the first six months of 2007, we received cash from collaborative and other research and development agreements and government contracts (primarily Shionogi, Mundipharma and HHS) of approximately \$24.8 million net of sublicense fees and on August 6, 2007 we announced a \$65.3 million private placement of common stock to certain existing stockholders, which we expect to close on or about August 9, 2007. Assuming the private placement closes, our outstanding common stock will increase by approximately 8.3 million shares and our fully-diluted outstanding shares will increase by an additional approximately 3.2 million shares pursuant to warrants exercisable at \$10.25 per share. 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.

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.



On August 7, 2007, we amended our lease for our current Birmingham facilities through June 30, 2015. We have an option to renew the lease for an additional five years at the current market rate in effect on June 30, 2015. The lease requires us to pay monthly rent currently at \$39,100 per month in July 2007 and escalating annually to a minimum of \$48,072 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 addition, the lease amendment provides an allowance of \$300,000 for our use in making certain improvements to the premises.

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, which will be partially funded by the \$300,000 tenant allowance in our lease amendment.

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.

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.

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 we expect will continue to have a significant positive impact on our financial position and cash flow. We 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 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, 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 special protocol assessment ( SPA ) which is a request for feedback from the FDA that allows a company to receive official evaluation and guidance on the design of pivotal trial protocols. In July 2007, we announced the Company had received an SPA for a pivotal trial of Fodosine in CTCL patients. The trial is planned to be a multicenter, multinational, open-label, single-arm, repeat dose pivotal trial which is expected to begin enrollment during the third quarter of 2007.



The collaboration with Roche for the worldwide development and commercialization of BCX-4208 in November 2005 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.

For the year, our cash, cash equivalents and marketable securities balance has decreased from \$46.2 million as of December 31, 2006 to \$42.5 million as of June 30, 2007, primarily due to the monthly cash burn from operations less the cash received from collaborations. Our gross cash burn for the first six months of 2007 was significantly offset by the reimbursement from Mundipharma for the clinical expenses incurred in 2006 and 2007, plus the event payment and upfront payment received from Mundipharma and Shionogi, respectively which totaled approximately \$24 million. We are continuing to project our net cash burn rate to average approximately \$3.0 million per month in 2007. We caution that our revenues, 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. Given that our average monthly burn rate in the first six months of this year was much lower than \$3 million, we expect the average monthly burn rate for the remaining six months will be correspondingly higher.

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing 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 June 30, 2007, we had \$42.5 million in cash, cash equivalents and marketable securities. On August 6, 2007, we announced a \$65.3 million private placement of unregistered common stock and warrants to certain existing stockholders, which we expect to close on or about August 9, 2007. With our currently available funds, the amounts to be received from HHS, Shionogi and our other collaborators, and assuming we receive the funds from the private placement, 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. For example, our recently announced private placement has registration provisions that would cause the Company to pay 1.5% per month up to a maximum of 12.0% of the stock proceeds if the shares are not registered in the time designated by the stock purchase agreement.

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 certain drug candidates; or a decision to build or expand internal development and commercial capabilities;



Successful commercialization of marketed products by either us or a partner;

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

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 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; and

the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

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 June 30, 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.

***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, 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.

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.

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.

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.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2007	2006	2007	2006
Direct external R&D expenses by program:				
PNP Inhibitor (Fodosine )	\$ 3,155	\$ 4,272	\$ 6,522	\$ 7,650
Neuraminidase Inhibitor (peramivir)	9,633	2,819	14,987	4,441
Hepatitis C Polymerase Inhibitor	150	426	595	669
Other	1,092	237	1,301	300
All other R&D expenses:				
Compensation and fringe benefits	2,664	1,498	5,117	2,716
Supplies and services	400	535	2,981	707
Maintenance, depreciation, and amortization	318	283	624	521
Overhead allocation and other	1,601	1,120	3,081	2,230
Total R&D expenses	\$ 19,013	\$ 11,190	\$ 35,208	\$ 19,234

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.

#### ***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.

As of June 30, 2007, we had two stock-based employee compensation plans, the Incentive Plan and the ESPP. In addition, we made an inducement grant outside of the Incentive Plan and ESPP to recruit a new employee to a key position within the Company. Prior to January 1, 2006, we accounted for all share-based payments under the recognition and measurement provisions of APB Opinion No. 25 and other related interpretations, as permitted by Statement No. 123. No stock-based compensation cost related to our employees was recognized in the Statements of Operations for any period ending prior to January 1, 2006. Stock-based compensation expense of \$2,809,692 (\$2,703,879 of expense related to the Incentive Plan, \$68,387 of expense related to the ESPP, and \$37,426 of expense related to the inducement grant) was recognized during the first six months of 2007, while \$1,176,673 (\$1,131,138 of expense related to the Plan and \$45,535 of expense related to the ESPP) was recognized during the first six months of 2006.

As of June 30, 2007, there was approximately \$15,305,154 of total unrecognized compensation cost related to non-vested employee stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: \$2,900,435 in the remainder of 2007, \$4,933,536 in 2008, \$4,210,206 in 2009, \$2,941,687 in 2010, and \$319,290 in 2011.

#### **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, or 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 funding from HHS for the development of peramivir our contract;

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;

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 June 30, 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 June 30, 2007 that have materially affected, or are reasonably likely to materially affect, BioCryst's internal control over financial reporting.

## **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. The information below updates our risk factors as of June 30, 2007. These risk factors should be read in conjunction with all risk factors and information disclosed in that Form 10-K.

#### **Risks Relating to Our Business**

*We have incurred substantial losses since our inception in 1986, expect to continue to incur such losses, and may never be profitable.*

Since our inception in 1986, we have not been profitable. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. As of June 30, 2007, our accumulated deficit was approximately \$211.3 million. To become profitable, we must successfully manufacture and develop drug product candidates, receive regulatory approval, and successfully commercialize or enter into profitable agreements with other parties. It could be several years, if ever, before we receive royalties from any current or future license agreements or revenues directly from product sales.

Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

*Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process.*

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability.

Our ability to successfully complete clinical trials is dependent upon many factors beyond our control, including but not limited to:

- our ability to find suitable clinical sites and investigators to enroll patients;
- the availability of and willingness of patients to participate in our clinical trials;
- difficulty in maintaining contact with patients to provide complete data after treatment;
- our product candidates may not prove to be either safe or effective;
- manufacturing or quality problems could affect the supply of drug product for our trials; and
- delays or changes in requirements by governmental agencies.

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Delays in patient enrollment can result in increased costs and longer development times. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidate.

***If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates or continue our research and development programs.***

To date, we have financed our operations primarily from sale of our equity securities and cash from collaborative and other research and development agreements including government contracts, and, to a lesser extent, interest. For the year, our cash, cash equivalents and marketable securities balance has decreased from \$46.2 million as of December 31, 2006 to \$42.5 million as of June 30, 2007, primarily due to the monthly cash burn from operations less the cash received from collaborations. Our gross cash burn for the first six months of 2007 was significantly offset by the reimbursement from Mundipharma for the clinical expenses incurred in 2006 and 2007, plus the event payment and upfront payment received from Mundipharma and Shionogi, respectively. We are continuing to project our net cash burn rate to average approximately \$3.0 million per month in 2007. We caution that our revenues, 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. Given that our average monthly burn rate in the first six months of 2007 was much lower than \$3 million, we expect the average monthly burn rate for the remaining six months of 2007 will be correspondingly higher.

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements, and additional personnel resources and testing required for supporting 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 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 June 30, 2007, we had \$42.5 million in cash, cash equivalents and marketable securities. On August 6, 2007, we announced a \$65.3 million private placement of unregistered common stock and warrants to certain institutional investors, which we expect to close on or about August 9, 2007. Assuming the private placement closes, our outstanding common stock will increase by approximately 8.3 million shares and our fully-diluted outstanding shares will increase by an additional approximately 3.2 million shares pursuant to warrants exercisable at \$10.25 per share. Upon this sale of stock the Company is required to register the shares within 90 days, or 120 if reviewed by the SEC.

Failure to have the shares registered in this timeframe would trigger liquidated damages of 1.5% per month on the stock cost, up to a maximum of 12%, which could have a significant impact on our cash. With our currently available funds, the amounts to be received from HHS, Shionogi and our other collaborators, and assuming we receive the funds from the private placement, 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, but not limited to:

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 certain drug candidates; or our ability to build or expand internal development and commercial capabilities;

our ability to achieve successful commercialization of marketed products by either us or a partner;

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

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; and

the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

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.

***If HHS were to eliminate or reduce funding from our contract or dispute some of our incurred costs, this would have a significant negative impact on our anticipated revenues and cash flows and the development of peramivir.***

Our projections of revenues and incoming cash flows for 2007 are substantially dependant upon HHS reimbursement for the costs related to our peramivir program. If HHS were to eliminate or reduce the funding for this program or

disallow some of our incurred costs, we would have to obtain additional funding for development of this drug candidate or significantly reduce or stop the development effort.

In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion. The U.S. government may terminate its contract with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms, which would have a significant negative impact on our cash flows and operations.

***Our contract with HHS has special contracting requirements, which create additional risks or reduction or loss of funding.***

We have entered into a contract with HHS for the advanced development of our neuraminidase inhibitor, peramivir. In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

terminate or reduce the scope of our contract; and

audit and object to our contract-related costs and fees, including allocated indirect costs.

The U.S. government may terminate its contract with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries.

As a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

***If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our drug product candidates or if any partner terminates or fails to perform its obligations under agreements with us, expected revenues from commercialization of our product candidates could be under realized, delayed, terminated.***

Our business strategy is to maximize asset value. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third party alliances could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our drug product candidates. Our general strategy is to focus development and commercialization capabilities in specialty markets.

Currently, we have established collaborative relationships with four pharmaceutical companies, Roche, Mundipharma, Shionogi and Green Cross for development and commercialization of BCX-4208, Fodosine and peramivir, respectively. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including but not limited to:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;

- our contracts for collaborative arrangements may expire;

- our partners may choose to pursue alternative technologies, including those of our competitors;

- we may have disputes with a partner that could lead to litigation or arbitration;

- we do not have day to day control over the activities of our partners and have limited control over their decisions;

- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;

- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

- our partners may not devote sufficient capital or resources towards our product candidates; and

- our partners may not comply with applicable government regulatory requirements.

If any partner fails to fulfill its responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be under realized, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our compounds would severely affect our business, because if our compounds do not progress through the development process or reach the market in a timely manner, or at all, we may not receive additional future event payments and may never receive product or royalty payments.

***We have not commercialized any products or technologies and our future revenue generation is uncertain.***

Since we have never commercialized a product, our ability to receive revenue from products we commercialize presents several risks, which include:

- we have not yet commercialized any products or technologies, and we may never be able to do so;

- many competitors are more experienced and have significantly more resources;

- we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our company and our products;

- we may fail to employ a comprehensive and effective regulatory strategy which could result in a delay or failure in commercialization of our products;

our ability to successfully commercialize our products are affected by the competitive landscape, which cannot be fully known at this time;

reimbursement is constantly changing which could greatly affect usage of our products; and

any future revenue directly from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, manufacture, market and commercialize any approved drugs.



***If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.***

We depend on contract research organizations, third-party vendors and investigators for preclinical testing and clinical trials related to our drug discovery and development efforts, including the HHS contract. We intend to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the approval of our products. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors it could harm our competitive position.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current Good Laboratory Practices ( cGLP ), current Good Manufacturing Practices ( cGMP ), or current Good Clinical Practices ( cGCP ), and similar foreign standards and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed.

***If our development collaborations with other parties fail, the development of our drug product candidates will be delayed or stopped.***

We rely heavily upon other parties for many important stages of our drug development programs, including but not limited to:

- discovery of proteins that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;

- licensing or design of enzyme inhibitors for development as drug product candidates;

- execution of some preclinical studies and late-stage development for our compounds and product candidates;

- management of our clinical trials, including medical monitoring and data management;

- execution of additional toxicology studies that may be required to obtain approval for our product candidates;

- manufacturing the starting materials and drug substance required to formulate our drug products and the drug products to be used in both our clinical trials and toxicology studies; and

- management of our regulatory function.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our product development efforts would suffer. Similarly, if the contract research organizations that conduct our initial or late-stage clinical trials, conduct our toxicology studies, manufacture our starting materials, drug substance and drug products or manage our regulatory function breached their obligations to us, this would delay or prevent the development of our product candidates.

***Our development of both intravenous and intramuscular dosing of peramivir for avian flu is subject to all disclosed drug development and potential commercialization risks and numerous additional risks. Any potential revenue benefits to us are highly speculative.***



Further development and potential commercialization of peramivir is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In addition, potential commercialization of peramivir is subject to further risks, including but not limited to the following:

the injectable versions of peramivir are at an early stage of development and have been tested in a limited number of humans, primarily healthy volunteers, and may not be safe or effective;

necessary government or other third party funding and clinical testing for further development of peramivir may not be available timely, at all, or in sufficient amounts;

the avian flu prevention or treatment concerns may not materialize at all, or in the near future;

advances in flu vaccines could substantially replace potential demand for an antiviral such as peramivir;

any substantial demand for avian flu treatments may occur before peramivir can be adequately developed and tested in clinical trials;

numerous large and well-established pharmaceutical and biotech companies will be competing to meet the market demand for avian flu drugs and vaccines;

regulatory authorities may not make needed accommodations to accelerate the drug testing and approval process for peramivir; and

in the next few years, it is expected that a limited number of governmental entities will be the primary potential customers for peramivir and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues.

If any or all of these and other risk factors occur, we will not attain significant revenues or gross margins from peramivir and our stock price will be adversely affected.

***Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our drug product candidates and the materials for our product candidates. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and potential delays in finding new third-party manufacturers.***

We have limited manufacturing experience and only a small scale manufacturing facility. We currently rely upon third-party manufacturers to manufacture the materials required for our drug product candidates and most of the preclinical and clinical quantities of our product candidates. We depend on these third-party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party manufacturers may encounter difficulties with meeting our requirements, including but not limited to problems involving:

inconsistent production yields;

difficulties in scaling production to commercial and validation sizes;

interruption of the delivery of materials required for the manufacturing process;

scheduling of plant time with other vendors or unexpected equipment failure;

potential catastrophes that could strike their facilities;

potential impurities in our drug substance or drug products that could affect availability of product for our clinical trials or future commercialization;

poor quality control and assurance or inadequate process controls; and

lack of compliance with regulations and specifications set forth by the FDA or other foreign regulatory agencies.

These contract manufacturers may not be able to manufacture the materials required or our drug product candidates at a cost or in quantities necessary to make them commercially viable. We also have no control over whether third-party manufacturers breach their agreements with us or whether they may terminate or decline to renew agreements with us. To date, our third party manufacturers have met our manufacturing requirements, but they may not continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA's cGMPs, and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

If we are unable to enter into agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance on the part of our third party manufacturers, we may not be able to complete development of, or market, our product candidates.

Our raw materials, drug substances, and drug products are manufactured by a limited group of suppliers and some at a single facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of drugs for further preclinical testing and clinical trials.

***If the clinical trials of our drug product candidates fail, our product candidates will not be marketed, and we will not realize product related revenue.***

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. If we or other third party partners are unable to demonstrate that our product candidates are safe and effective, our product candidates will not receive regulatory approval and will not be marketed, and we will not realize product related revenue. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. Positive results from preclinical studies and early clinical trials do not ensure positive results in clinical trials designed to permit application for regulatory approval, called pivotal clinical trials. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective.

We negotiated a special protocol assessment, or SPA, with the FDA for the recently initiated pivotal clinical trial of our lead anti-cancer compound, Fodosine . An SPA is an agreement between an applicant and the FDA on the design and the size of clinical trials that is intended to form the basis of a New Drug Application ( NDA ). Once the FDA and an applicant reach an agreement on an SPA, the SPA cannot be changed after the clinical trial begins, except in limited circumstances such as a change in the science or clinical knowledge about the conditions being studied. Any significant change to the protocols for a clinical trial subject to an SPA would require prior FDA approval, which could delay implementation of such a change and continuation and completion of the related clinical trial. Receipt of the SPA does not ensure that Fodosine will receive FDA approval or that the process will be accelerated.

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Delays in patient enrollment can result in increased costs and longer development times. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidate.



***If we or our partners do not obtain and maintain governmental approvals for our products under development, we or our partners will not be able to sell these potential products, which would significantly harm our business because we will receive no revenue.***

We or our partners must obtain regulatory approval before marketing or selling our future drug products. If we or our partners are unable to receive regulatory approval and do not market or sell our future drug products, we will never receive any revenue from such product sales. In the United States, we or our partners must obtain FDA approval for each drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation. Neither the FDA nor foreign regulatory agencies have approved any of our drug product candidates. We have several drug products in various stages of preclinical and clinical development; however, we are unable to determine when, if ever, any of these products will be commercially available. Because of the risks and uncertainties in biopharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our product candidates, our management's credibility, our company's value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a product candidate, the approval may limit the indicated uses for a product candidate and/or may require post-marketing studies.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage. If we get approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug experience reporting regulations;

- product promotion;

- product manufacturing, including good manufacturing practice requirements; and

- product changes or modifications.

Our failure to comply with existing or future regulatory requirements, or our loss of, or changes to, previously obtained approvals, could have a material adverse effect on our business because we will not receive product or royalty revenues if we or our partners do not receive approval of our products for marketing.

In June 1995, we notified the FDA that we submitted incorrect data for our Phase II studies of BCX-34 applied to the skin for CTCL and psoriasis. In November 1995, the FDA issued a List of Inspectional Observations, Form FDA 483, which cited our failure to follow good clinical practices. The FDA also inspected us in June 1996. The focus was on the two 1995 Phase II dose-ranging studies of topical BCX-34 for the treatment of CTCL and psoriasis. As a result of the investigation, the FDA issued us a Form FDA 483, which cited our failure to follow good clinical practices. We are no longer developing BCX-34; however, as a consequence of these two investigations, our ongoing and future clinical studies may receive increased scrutiny, which may delay the regulatory review process.

***If our drug product candidates do not achieve broad market acceptance, our business may never become profitable.***

Our drug product candidates may not gain the market acceptance required for us to be profitable even if they successfully complete initial and final clinical trials and receive approval for sale by the FDA or foreign regulatory agencies. The degree of market acceptance of any product candidates that we or our partners develop will depend on a number of factors, including but not limited to:

- our clinical evidence of safety and efficacy;

- cost-effectiveness, convenience and ease of use of our product candidates;





their safety, availability and effectiveness relative to alternative treatments;

the actual and potential side effects or other reactions;

reimbursement policies of government and third-party payers; and

the effectiveness of marketing and distribution support for our product candidates.

Physicians, patients, payers or the medical community in general may not accept or use our product candidates even after the FDA or foreign regulatory agencies approve the drug candidates. If our product candidates do not achieve significant market acceptance, we will not have enough revenues to become profitable.

***We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.***

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. We face, and will continue to face, competition in the licensing of desirable disease targets, licensing of desirable drug product candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

other drug development technologies;

methods of preventing or reducing the incidence of disease, including vaccines; and

new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We and our partners are performing research on or developing products for the treatment of several disorders including T-cell mediated disorders (T-cell cancers, psoriasis, transplant rejection, and rheumatoid arthritis), oncology, influenza, hepatitis C and cardiovascular disorders. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai's Targretin for CTCL and the current neuraminidase inhibitors marketed by GSK and Roche for influenza. In addition, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and in the fields of PNP, influenza, hepatitis C, and in other therapeutic areas where we have discovery efforts ongoing. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

capital resources;

research and development resources, including personnel and technology;

regulatory experience;

preclinical study and clinical testing experience;

manufacturing and marketing experience; and

production facilities.



Any of these competitive factors could reduce demand for our products.

***If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish.***

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including but not limited to trade name, trade mark and patent protection for our company and its products, methods, processes and other technologies we may license or develop, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office ( USPTO ), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. The validity, scope, enforceability and commercial value of these rights, therefore, is highly uncertain.

Our success depends in part on avoiding the infringement of other parties' patents and other intellectual property rights as well as avoiding the breach of any licenses relating to our technologies and products. In the U.S., patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, avoiding patent infringement may be difficult and we may inadvertently infringe third-party patents or proprietary rights. These third parties could bring claims against us, our partners or our licensors that even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

If we or our partners are unable or fail to adequately, initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of the drug product candidates that we license to derive revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including but not limited to any tradename, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions has issued to us a number of patents for our various inventions and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We have also filed certain trademark and tradename applications worldwide. We cannot assure you as to:

the degree and range of protection any patents will afford against competitors with similar products;

if and when patents will issue;

If patents do issue we can not be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or

whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

obtain licenses or redesign our products or processes to avoid infringement;

stop using the subject matter claimed in those patents; or

pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the USPTO or other foreign patent office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any such proceeding may be substantial whether or not we are successful.

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license our technology and any such events would significantly impair the value of such a license.

***If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our drug product candidates and the expansion of our business will be delayed or stopped.***

We are highly dependent upon our senior management and scientific team, the loss of whose services might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, operational and scientific personnel, will harm our business because we rely upon these personnel for many critical functions of our business. In addition, we rely on members of our scientific advisory board and consultants to assist us in formulating our research and development strategy. All of the members of the scientific advisory board and all of our consultants are otherwise employed and each such member or consultant may have commitments to other entities that may limit their availability to us.

***We may be unable to establish sales, marketing and distribution capabilities necessary to successfully commercialize products we may develop.***

We currently have no marketing capability and no direct or third-party sales or distribution capabilities. If we successfully develop a drug product candidate and decide to commercialize it ourselves rather than relying on third parties, as we are considering doing in the United States for Fodosine, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for that product.

***If users of our drug products are not reimbursed for use, future sales of our drug products will decline.***

The lack of reimbursement for the use of our product candidates by hospitals, clinics, patients or doctors will harm our business. Medicare, Medicaid, health maintenance organizations and other third-party payers may not authorize or otherwise budget for the reimbursement of our products. Governmental and third-party payers are increasingly challenging the prices charged for medical products and services. We cannot be sure that third-party payers would view our product candidates as cost-effective, that reimbursement will be available to consumers or that reimbursement will be sufficient to allow our product candidates to be marketed on a competitive basis. Changes in reimbursement policies, or attempts to contain costs in the health care industry could limit or restrict reimbursement for our product candidates and would materially and adversely affect our business, because future product sales would decline and we would receive less product or royalty revenue.

***The Medicare prescription drug coverage legislation and future legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In the United States, there have been a number of legislative and regulatory proposals, at both the federal and state government levels, to change the healthcare system in ways that could affect our ability to sell our products profitably, if approved. For example, the Medicare Prescription Drug and Modernization Act of 2003 (MMA), went into effect in 2006 and has changed the types of drugs covered by Medicare, and the methodology used to determine the price for such drugs. Further federal and state proposals and healthcare reforms are likely. Our business could be harmed by the MMA, by the possible effect of this legislation on amounts that private payors will pay and by other healthcare reforms that may be enacted or adopted in the future.



***There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our clinical trials in the amount of \$10 million. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;

an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;

withdrawal of clinical trial volunteers or patients;

damage to our reputation and the reputation of our products, resulting in lower sales;

regulatory investigations that could require costly recalls or product modifications;

litigation costs; and

the diversion of management's attention from managing our business.

***If our computer systems fail or our facility incurs damage, our business will suffer.***

Our drug development activities depend on the security, integrity and performance of the computer systems supporting them, and the failure of our computer systems could delay our drug development efforts. We currently store most of our preclinical and clinical data at our facility. Duplicate copies of most critical data are stored off-site in a bank vault. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

In addition, we store numerous clinical and stability samples at our facility that could be damaged if our facility incurred physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to maintain power to all critical functions, but any loss of these samples could result in significant delays in our drug development process.

***If, because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.***

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result and any liabilities could exceed our resources. Compliance with environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

**Risks Relating to Our Common Stock**

***Our stock price is likely to be highly volatile and the value of your investment could decline significantly.***

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended June 30, 2007, the 52-week range of the market price of our stock was from \$6.57 to \$14.94 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

announcements of technological innovations or new products by us or our competitors;

developments or disputes concerning patents or proprietary rights;

additional dilution through sales of our common stock or other derivative securities;

status of new or existing licensing or collaborative agreements and government contracts;

we or our partners achieving or failing to achieve development milestones;

publicity regarding actual or potential medical results relating to products under development by us or our competitors;

publicity regarding certain public health concerns for which we are or may be developing treatments;

regulatory developments in both the United States and foreign countries;

public concern as to the safety of pharmaceutical products;

actual or anticipated fluctuations in our operating results;

changes in financial estimates or recommendations by securities analysts;

changes in the structure of healthcare payment systems, including developments in price control legislation;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

additions or departures of key personnel or members of our board of directors;

purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;

economic and other external factors or other disasters or crises; and

period-to-period fluctuations in our financial results.

***Because stock ownership is concentrated, you and other investors will have limited influence on stockholder decisions.***

As of July 31, 2007, our directors, executive officers and our stockholders who held 5% or greater of our outstanding common stock beneficially owned approximately 36.3% of our outstanding common stock and common stock equivalents. Assuming our private placement of common stock announced August 6, 2007 closes, that stock ownership concentration would increase to approximately 54.3%. As a result, these holders, if acting together, are able



to significantly influence matters requiring stockholder approval, including the election of directors. This concentration of ownership may delay, defer or prevent a change in our control.

***We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.***

Our board of directors has the authority to issue up to 4,955,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and supermajority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

In June 2002, our board of directors adopted a stockholder rights plan and, pursuant thereto, issued preferred stock purchase rights ( Rights ) to the holders of our common stock. The Rights have certain anti-takeover effects. If triggered, the Rights would cause substantial dilution to a person or group of persons who acquires more than 15% (19.9% for William W. Featheringill, a Director who owned approximately 9.64% as of August 6, 2007, but owned more than 15% at the time the Rights were put in place) of our common stock on terms not approved by the board of directors. In August 2007, this plan was amended for a transaction involving funds managed by or affiliated with Baker Bros. Advisors, LLC such that they could purchase up to 25% without triggering the Rights. Assuming closing of the private placement announced August 6, 2007, such group would own approximately 19.0% of our fully-diluted stock.

***We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.***

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

**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:**

- (a) The Company's annual meeting of stockholders was held on May 16, 2007.
- (b) Nominees Higgins and Seidenberg were elected as directors for three-year terms expiring in 2010. Messrs., Bennett, Biggar, Featheringill, Horovitz, Sherrill, Spencer, Stonehouse and Steer continue as directors.
- (c) Motion before stockholders:

1. Election of two directors as follows -

<b>Name</b>	<b>Votes For</b>	<b>Abstentions/ Withheld</b>
John L. Higgins	26,120,421	428,735
Beth C. Seidenberg, M.D.	25,527,035	1,022,121

2. Approval of the Stock Incentive Plan

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
16,422,029	1,247,175	53,724

3. Approval of Amendment of Certificate of Incorporation

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
25,455,349	1,037,284	56,522

4. Ratification of Ernst & Young, LLP

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
26,386,608	110,543	52,004

**Item 5. Other Information:**

On August 5, 2007, in connection with the private placement transaction announced by the Company on August 6, 2007, the Company amended the definition in clause (2) of **Acquiring Person** in the Rights Agreement dated June 17, 2002, by and between the Company and American Stock Transfer & Trust Company (the **Rights Agreement** ) to increase the ownership percentage that will trigger the rights from 15% to 25.0% for Baker Bros. Advisors, LLC or any of its affiliates or associates, or any entities that it manages. The beneficial ownership of the Company's common stock by Baker Bros. Advisors, LLC and its affiliates will exceed 15% as a result of the private placement transaction.

**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	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	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.
4.2	Amendment to Rights Agreement, dated as of August 5, 2007.
10.1	Stock Incentive Plan, as amended and restated effective March 2007.
10.2	Employment Letter Agreement dated April 2, 2007, by and between the Company and David McCullough. Incorporated by reference to Exhibit 10.5 to the Company's Form 10-Q dated May 10, 2007.
10.3	Agreement dated January 3, 2007, between BioCryst Pharmaceuticals, Inc. and the Dept. of Health and Human Services, as amended by Amendment number 1 dated January 3, 2007 and Amendment number 2 dated May 11, 2007. (Portions omitted pursuant to request for confidential treatment and filed separately with the Commission.)
10.4	Third Amendment to Lease Agreement dated August 7, 2007, by and between Riverchase Capital LLC, a Florida limited liability company, Stow Riverchase, LLC, a Florida limited liability company, as successor landlord to RBP, LLC and the Company.
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.

**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 9th day of August 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*

**Exhibit Index**

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