

BIOCRYST PHARMACEUTICALS INC

Form 10-Q

October 31, 2008

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**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 September 30, 2008  
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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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 October 24, 2008 was 38,257,681.

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**BIOCRYST PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
**September 30, 2008 and December 31, 2007**  
**(In thousands, except per share data)**

|   | <b>2008</b>        | <b>2007</b>       |
|---|--------------------|-------------------|
|   | <b>(Unaudited)</b> | <b>(Note 1)</b>   |
| <b>Assets</b>   |                    |                   |
| Cash and cash equivalents   | \$ 15,952          | \$ 31,155         |
| Marketable securities   | 48,726             | 19,542            |
| Receivables from collaborations   | 13,102             | 39,128            |
| Prepaid expenses and other current assets   | 2,331              | 1,880             |
| <b>Total current assets</b>   | <b>80,111</b>      | <b>91,705</b>     |
| Marketable securities   | 3,250              | 34,311            |
| Furniture and equipment, net  | 5,271              | 5,294             |
| Deferred collaboration expense  | 10,719             | 11,407            |
| <b>Total assets</b>   | <b>\$ 99,351</b>   | <b>\$ 142,717</b> |
| <b>Liabilities and Stockholders Equity</b>  |                    |                   |
| Accounts payable  | \$ 3,239           | \$ 19,772         |
| Accrued expenses  | 9,107              | 2,864             |
| Accrued vacation  | 828                | 824               |
| Deferred rent   | 40                 |                   |
| Deferred revenue  | 4,345              | 4,658             |
| <b>Total current liabilities</b>  | <b>17,559</b>      | <b>28,118</b>     |
| Deferred rent   | 230                |                   |
| Deferred revenue  | 46,554             | 49,694            |
| 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 38,248 in 2008 and 37,967 in 2007  | 382                | 380               |
| Additional paid-in capital  | 293,831            | 288,683           |
| Accumulated other comprehensive income  | 133                | 378               |
| Accumulated deficit   | (259,338)          | (224,536)         |
| <b>Total stockholders equity</b>  | <b>35,008</b>      | <b>64,905</b>     |

|  |           |            |
|--|-----------|------------|
| Total liabilities and stockholders' equity | \$ 99,351 | \$ 142,717 |
|--|-----------|------------|

See accompanying notes to financial statements.

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**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**Periods Ended September 30, 2008 and 2007**  
**(In thousands, except per share data)**  
**(Unaudited)**

|  | <b>Three Months</b> |             | <b>Nine Months</b> |             |
|--|---------------------|-------------|--------------------|-------------|
|  | <b>2008</b>         | <b>2007</b> | <b>2008</b>        | <b>2007</b> |
| <b>Revenues</b>                                  |                     |             |                    |             |
| Collaborative and other research and development | \$ 8,894            | \$ 20,463   | \$ 22,321          | \$ 43,066   |
| <b>Expenses</b>                                  |                     |             |                    |             |
| Research and development                         | 15,996              | 29,730      | 51,267             | 64,938      |
| General and administrative                       | 2,471               | 2,595       | 8,023              | 6,980       |
| Total expenses                                   | 18,467              | 32,325      | 59,290             | 71,918      |
| Loss from operations                             | (9,573)             | (11,862)    | (36,969)           | (28,852)    |
| Interest and other income                        | 578                 | 878         | 2,167              | 2,080       |
| Net loss   | \$ (8,995)          | \$ (10,984) | \$ (34,802)        | \$ (26,772) |
| Basic and diluted net loss per common share      | \$ (.24)            | \$ (.32)    | \$ (.91)           | \$ (.86)    |
| Weighted average shares outstanding              | 38,095              | 34,277      | 38,040             | 31,024      |
| See accompanying notes to financial statements.  |                     |             |                    |             |

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**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**Nine Months Ended September 30, 2008 and 2007**  
(In thousands)  
(Unaudited)

|   | <b>2008</b>      | <b>2007</b>      |
|---|------------------|------------------|
| <b>Operating activities</b>   |                  |                  |
| Net loss  | \$ (34,802)      | \$ (26,772)      |
| Adjustments to reconcile net loss to net cash used in operating activities: |                  |                  |
| Depreciation and amortization   | 1,163            | 752              |
| Stock-based compensation expense  | 4,509            | 4,371            |
| Changes in operating assets and liabilities:                                |                  |                  |
| Receivables from collaborations   | 26,026           | (16,192)         |
| Prepaid expenses and other current assets                                   | (451)            | 1,675            |
| Deferred collaboration expense  | 688              | (1,042)          |
| Accounts payable and accrued expenses                                       | (10,286)         | 12,020           |
| Deferred rent   | 270              |                  |
| Deferred revenue  | (3,453)          | 16,195           |
| <b>Net cash used in operating activities</b>                                | <b>(16,336)</b>  | <b>(8,993)</b>   |
| <b>Investing activities</b>   |                  |                  |
| Acquisitions of furniture and equipment                                     | (1,140)          | (1,834)          |
| Purchases of patents and licenses   |                  | (16)             |
| Purchases of marketable securities  | (84,309)         | (49,236)         |
| Maturities of marketable securities   | 85,941           | 33,017           |
| <b>Net cash provided by (used in) investing activities</b>                  | <b>492</b>       | <b>(18,069)</b>  |
| <b>Financing activities</b>   |                  |                  |
| Employee stock purchase plan sales  | 266              | 270              |
| Exercise of stock options   | 375              | 1,348            |
| Sale of common stock, net of issuance costs                                 |                  | 65,118           |
| <b>Net cash provided by financing activities</b>                            | <b>641</b>       | <b>66,736</b>    |
| (Decrease) increase in cash and cash equivalents                            | (15,203)         | 39,674           |
| Cash and cash equivalents at beginning of period                            | 31,155           | 4,418            |
| <b>Cash and cash equivalents at end of period</b>                           | <b>\$ 15,952</b> | <b>\$ 44,092</b> |

See accompanying notes to financial statements.

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

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

The balance sheet as of September 30, 2008, the statements of operations for the three and nine months ended September 30, 2008 and 2007, and the statements of cash flows for the nine months ended September 30, 2008 and 2007 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 September 30, 2008, the results of operations for the three and nine months ended September 30, 2008 and 2007, and cash flows for the nine months ended September 30, 2008 and 2007. 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, 2007 and the notes thereto included in the Company's 2007 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, 2007 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 September 30, 2008, the Company had \$51,975,889 of marketable securities.

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (Statement No. 157) for financial assets and liabilities and any other assets and liabilities carried at fair value. This pronouncement defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. While this 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. The adoption of Statement No. 157 did not have a significant impact on the Company's financial statements.

Effective January 1, 2008, the Company also adopted Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Liabilities* (Statement No. 159), but did not elect to apply fair value accounting to any financial instruments that were not already accounted for at fair value under existing guidance. As a result, the adoption of Statement No. 159 did not have a significant impact on the Company's financial statements.

In an effort to minimize investment risk in light of the current economic environment, the Company sold two securities previously classified as held-to-maturity during the third quarter of 2008. The carrying amount of these securities was \$3,469,506, which represents amortized cost. The proceeds from the sale of these securities was \$3,458,814.

All of the Company's marketable securities are classified as available-for-sale at September 30, 2008. These securities consisted primarily of U.S. Treasury and Agency securities carried at estimated fair values. The estimated fair value of these securities was based on independent quoted market prices and represents the highest priority of Level 1 in the fair value hierarchy as defined in Statement No. 157. The following table summarizes by year the scheduled maturity for the securities available-for-sale at September 30, 2008 and includes accrued interest of \$1,902.



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|      |               |
|------|---------------|
| 2008 | \$ 46,936,771 |
| 2009 | 1,789,034     |
| 2010 | 3,250,084     |
|      | \$ 51,975,889 |

Unrealized gains and losses on securities available-for-sale are recognized in other comprehensive income. At September 30, 2008, the amortized cost of securities available-for-sale approximated estimated fair value.

**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. At September 30, 2008, the Company had the following receivables from collaborations.

|  | <b>Billed</b> | <b>Unbilled</b> | <b>Total</b>  |
|--|---------------|-----------------|---------------|
| U.S. Department of Health and Human Services | \$ 2,864,172  | \$ 8,440,986    | \$ 11,305,158 |
| Mundipharma                                  | 292,927       | 1,254,171       | 1,547,098     |
| Shionogi                                     | 250,219       |                 | 250,219       |
| Total  | \$ 3,407,318  | \$ 9,695,157    | \$ 13,102,475 |

Unbilled receivables from the U.S. Department of Health and Human Services ( HHS ) are net of a reserve for costs and fees of \$4,918,849 at September 30, 2008 that are uncertain of recovery and related to the voluntarily terminated Phase III studies of the peramivir intramuscular ( i.m. ) program. The Company is in discussions with HHS regarding the reimbursement of these costs and fees. To the extent that any additional recoveries are realized or become probable of realization, the reserve will be adjusted in a future period(s). Any such adjustments could have a material impact on future operating results.

**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*, 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**

The Company seeks patent protection on all internally developed processes and products. All patent related costs are expensed to general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

**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 September 30, 2008 and December 31, 2007 consisted primarily of development and clinical trial expenses payable to contract research organizations in connection with the Company's research and development programs.



**Table of Contents*****Income Taxes***

The liability method is used in accounting for income taxes in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* ( Statement No. 109 ). Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board 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 Statement No. 109, 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.

***Accumulated Other Comprehensive Income***

Accumulated other comprehensive income is comprised of unrealized gains and losses on securities available-for-sale and is disclosed as a separate component of stockholders' equity. The Company had \$133,381 of unrealized gains on its securities that are included in accumulated other comprehensive income at September 30, 2008.

Other comprehensive loss for the periods ended September 30, 2008 and 2007 appear in the following table.

|   | <b>Three Months</b> |                 | <b>Nine Months</b> |                 |
|---|---------------------|-----------------|--------------------|-----------------|
|   | <b>2008</b>         | <b>2007</b>     | <b>2008</b>        | <b>2007</b>     |
| Net loss  | \$ (8,994,926)      | \$ (10,983,719) | \$ (34,802,390)    | \$ (26,772,478) |
| Unrealized (loss) gain on securities available-for-sale | (118,765)           | 156,639         | (244,676)          | 119,785         |
| Other comprehensive loss                                | \$ (9,113,691)      | \$ (10,827,080) | \$ (35,047,066)    | \$ (26,652,693) |

***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.

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The Company recorded the following revenues from collaborations for the periods ended September 30, 2008 and 2007.

|  | Three Months |               | Nine Months   |               |
|--|--------------|---------------|---------------|---------------|
|  | 2008         | 2007          | 2008          | 2007          |
| U.S. Department of Health and Human Services | \$ 6,142,068 | \$ 18,610,479 | \$ 16,216,608 | \$ 37,837,063 |
| Shionogi                                     | 913,771      | 421,273       | 1,711,941     | 931,332       |
| Mundipharma                                  | 1,376,559    | 843,102       | 3,006,427     | 2,784,665     |
| Roche  | 443,349      | 569,493       | 1,330,049     | 1,456,193     |
| Other  | 18,750       | 18,750        | 56,250        | 56,525        |
| Total  | \$ 8,894,497 | \$ 20,463,097 | \$ 22,321,275 | \$ 43,065,778 |

Revenues from the contract with HHS for the nine months ended September 30, 2008 are shown net of a provision for costs and fees of \$4,918,849 (or \$0.13 per share), of which \$4,567,604 relates to revenues recognized in the three months ended March 31, 2008 and \$351,245 relates to revenues recognized in 2007. These costs and fees are uncertain of recovery and related to the voluntarily terminated Phase III studies of the peramivir i.m. program.

**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. Prior to January 1, 2008, the Company also expensed nonrefundable advance payments for goods and services received in connection with research and development activities. Effective January 1, 2008, the Company adopted the consensus in Emerging Issues Task Force Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods and Services Received for Use in Future Research and Development Activities* ( EITF Issue 07-3 ). EITF 07-3 requires that these payments be deferred and recognized as an expense as the related goods are delivered or the related services are performed. The Company applied the new guidance to all advance payments made in the first nine months of 2008 for contracts executed after the effective date of this consensus. As a result, approximately \$156,000 of advanced payments are capitalized at September 30, 2008 that would have been expensed under the Company's former accounting policy.

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 fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments 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. The Company expenses maintenance payments as incurred.

The Company's accounting for deferred sublicense payments related to revenues that have been deferred is based on the guidance in SAB No. 104, which states that the incremental direct costs incurred related to the acquisition or origination of a contract in a transaction that results in the deferral of revenue may either be expensed as incurred or accounted for in accordance with paragraph 4 of Financial Accounting Standards Board ( FASB ) Technical Bulletin 90-1, *Accounting for Separately Priced Extended Warranty and Product Maintenance Costs* ( FTB 90-1 ). At September 30, 2008, the Company had deferred collaboration expenses of approximately \$11,644,000. These deferred expenses were sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments

from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

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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 September 30, 2008, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ( Incentive Plan ) and the Employee Stock Purchase Plan ( ESPP ). In addition, during 2007, 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 \$4,508,909 (\$4,276,748 of expense related to the Incentive Plan, \$119,883 of expense related to the ESPP, and \$112,278 of expense related to the inducement grant) was recognized during the first nine months of 2008, while \$4,370,552 (\$4,187,367 of expense related to the Incentive Plan, \$108,333 of expense related to the ESPP, and \$74,852 of expense related to the inducement grant) was recognized during the first nine months of 2007.

As of September 30, 2008, there was \$10,468,096 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: \$1,334,641 in the remainder of 2008, \$4,661,443 in 2009, \$3,427,749 in 2010, \$956,221 in 2011, and \$88,042 in 2012.

Statement 123R also requires that the benefits from tax deductions in excess of recognized compensation cost should be reported as a financing cash flow rather than as an operating cash flow. The Company has never recognized any benefits from such tax deductions, as the Company has always maintained a loss position.

***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, outstanding warrants, 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 February 2008. The Incentive Plan was approved by the Company's stockholders in May 2008. 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 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.





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Related activity under the Incentive Plan is as follows:

|  | Awards    | Options     | Weighted<br>Average<br>Exercise<br>Price |
|--|-----------|-------------|--|
|  | Available | Outstanding |  |
| Balance December 31, 2007                              | 592,027   | 5,023,258   | \$ 9.20                                  |
| Incentive plan amended                                 | 1,200,000 |             |  |
| Stock option awards granted to employees and directors | (979,172) | 979,172     | 3.34                                     |
| Stock option awards granted to consultants             | (65,000)  | 65,000      | 4.33                                     |
| Restricted stock awards granted                        | (76,536)  |             |  |
| Stock option awards exercised                          |           | (119,243)   | 3.14                                     |
| Stock option awards canceled                           | 300,174   | (300,174)   | 9.29                                     |
| Balance September 30, 2008                             | 971,493   | 5,648,013   | 8.25                                     |

For stock option awards granted to employees and directors under the Incentive Plan during the first nine months of 2008 and 2007, 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 these awards granted during the first nine months of 2008 and 2007 was \$2.15 and \$6.17, 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 to  
Employees and Directors under the Incentive Plan**

|                         | 2008  | 2007  |
|-------------------------|-------|-------|
| Expected Life in Years  | 5.5   | 5.7   |
| Expected Volatility     | 78.3% | 74.4% |
| Expected Dividend Yield | 0.0%  | 0.0%  |
| Risk-Free Interest Rate | 2.8%  | 4.6%  |

During 2007, the Company granted 50,000 restricted stock awards under the Incentive Plan with a grant date fair value of \$11.81. During the second quarter of 2008, the Company also granted 76,536 restricted stock awards under the Incentive Plan with a grant date fair value of \$3.12. None of the restricted stock awards granted under the Incentive Plan have vested as of September 30, 2008.

**Employee Stock Purchase Plan**

The ESPP was originally approved by the Company's stockholders in May 1995 and the most recent amendment was approved in May 2008. The Company has reserved a total of 600,000 shares of common stock to be purchased under the ESPP, of which 179,851 shares remain available for purchase at September 30, 2008. 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 84,907 shares during the first

nine months of 2008 under the ESPP. The fair value expense of options granted under the ESPP was determined using a Black-Scholes option pricing model.

**Table of Contents*****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. The stock option 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. The weighted average grant date fair value of these stock option awards was \$5.25. The exercise price of the stock option awards and the grant date fair value of the restricted stock awards granted under the inducement grant was \$8.20. As of September 30, 2008, 3,541 of the restricted stock awards have vested.

**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 forodesine HCl. 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 May 2008, the Company received notice that Roche was exercising the no cause termination right under the license agreement for BCX-4208. Upon the effective date of termination, which is 180 days from the date of notice, the Company will regain worldwide rights to BCX-4208. Earlier this year, Roche and the Company reported results of the recently completed Phase IIa trial with BCX-4208, a randomized, double blind, placebo controlled, dose ranging trial conducted in 66 patients with moderate to severe plaque psoriasis. Upon termination, the Company will recognize the remaining deferred revenue and deferred expense related to the license agreement, which are \$26.5 million and \$8.2 million, respectively, as of September 30, 2008.

The Company is currently in dispute with Mundipharma regarding the contractual obligations of the parties with respect to certain costs related to the manufacturing and development of forodesine HCl. Notwithstanding, the Company does not believe that it is responsible for any of the disputed amounts. The Company is engaged in ongoing discussions to resolve this dispute. The maximum potential exposure to the Company is estimated to be approximately \$2.5 million. Because of the preliminary nature of the discussions, no amounts have been accrued as of September 30, 2008.

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 October 2008, Shionogi and the Company amended their agreement to expand Shionogi's exclusive license to include Taiwan. This amendment did not include any additional upfront payment to the Company but, consistent with the original agreement between the parties, will include potential future royalties on sales.

In January 2007, the Company was awarded a four-year contract from the U.S. Department of Health and Human Services (HHS) for the advanced development of peramivir. The contract with HHS is defined as a cost-plus-fixed-fee

contract. That is, the Company is entitled to receive reimbursement for all reasonable and allowable costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit.

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In January 2008, the Company announced that the development costs of its peramivir program to anticipated product approval would cost in excess of the \$102.6 million contract since the development plan for peramivir had changed from that outlined in the original proposal to HHS. HHS has indicated that they will fund certain elements of the revised program, including the recently completed Phase II i.v. study evaluating peramivir in hospitalized subjects, the planning and conduct of the planned Phase II study of i.m. peramivir and the manufacturing and toxicology components of the program. Each of these elements has specific HHS funding limits and any costs outside the amounts approved by HHS may be the responsibility of the Company. The original contract of \$102.6 million, which we have not exceeded, and the four year term remain unchanged.

In January 2008, the Company disclosed that it would not pursue the Phase III i.m. program in peramivir for the current influenza season, but would move forward in evaluating higher doses than used in previous studies. In July 2008, HHS indicated that it does not intend to reimburse the Company all of the costs incurred related to these terminated Phase III studies. The Company continues to pursue reimbursement of these costs. During the second quarter of 2008, the Company recorded a \$4.9 million reserve against revenue for amounts the Company previously expected to receive from HHS related to the costs incurred in this program. Approximately \$4.6 million of the reserve relates to revenues recognized in the first quarter of 2008, while approximately \$0.3 million of the reserve relates to revenues recognized in 2007.

**Note 4 Income Taxes**

Effective January 1, 2007, the Company adopted the provisions of FIN No. 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement No. 109 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. The Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements. Tax years 2004-2006 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2004 are also open to examination to the extent of loss and credit carryforwards from those years.

As of September 30, 2008, the majority of the Company's deferred tax assets relate to net operating loss ( NOL ) carryforwards that can only be realized if the Company is profitable in future periods. It is uncertain whether the Company will realize any tax benefit related to the NOL carryforwards. Accordingly, the Company has provided a valuation allowance against the net deferred tax assets due to uncertainties as to their ultimate realization. The valuation allowance will remain at the full amount of the deferred tax asset until it is more likely than not that the related tax benefits will be realized.

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 related to unrecognized tax benefits upon the adoption of FIN No. 48 or as of September 30, 2008.

**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****Recent Corporate Highlights*****Continued development of oral forodesine HCl in cutaneous T-cell lymphoma ( CTCL )***

In October 2007, we enrolled the first patient in a pivotal Phase II clinical trial of oral forodesine HCl in patients with CTCL. The forodesine HCl pivotal trial in cutaneous T-cell lymphoma (CTCL) continues to enroll subjects with CTCL stages IIB through IVA who have failed three systemic therapies. The multinational trial continues and is being conducted in accordance with a Special Protocol Assessment ( SPA ) agreement between the U.S. Food and Drug Administration ( FDA ) and us. Enrollment in the CTCL study slowed over the summer below our projections. We have taken action to acceleration enrollment and early indications are that these actions are having a positive effect.

We will continue to monitor enrollment going forward.

**Table of Contents*****Forodesine HCl trial initiated for chronic lymphocytic leukemia ( CLL ) patients***

We have initiated a second clinical trial that will evaluate forodesine HCl in patients with CLL. The trial is a single arm study of single agent forodesine HCl with response rate as the primary endpoint. The first patient was dosed during the first quarter of 2008 and the trial is ongoing.

***Continued development of intramuscular ( i.m. ) peramivir***

In July 2008, we announced the initiation of a Phase II study of i.m. peramivir in the outpatient setting for the treatment of seasonal influenza. This Phase II study is a double blind, placebo controlled, parallel-group study that compares the efficacy of a single 600mg injection of i.m. peramivir to placebo in the treatment of seasonal influenza in the outpatient setting. The dose was selected based upon an analysis of a Phase I study in healthy volunteers of a new, more concentrated 150 mg/ml formulation of i.m. peramivir, as well as prior studies of peramivir in patients with influenza. The Phase II study will utilize the new, more concentrated formulation and needle length guidelines established in recently conducted pharmacokinetic studies. The primary endpoint of the study is time to alleviation of symptoms. Secondary endpoints include reduction in viral titers and safety and tolerability. Enrollment will continue in the northern hemisphere during the upcoming flu season.

***Shionogi & Co., Ltd. development of intravenous ( i.v. ) peramivir for the treatment of influenza in the outpatient setting***

In July 2008, the Company announced preliminary results of a Phase II study of intravenous (i.v.) peramivir administered via a single dose injection in the outpatient setting for the treatment of seasonal influenza. The trial, conducted by the Company's partner, Shionogi & Co., Ltd. in Japan, met its primary endpoint of improvement in the median time to alleviation of symptoms in subjects with confirmed, acute, uncomplicated influenza infection, compared to placebo alone. Time to alleviation of symptoms was 81.8 hours for placebo, 59.1 hours for 300mg peramivir, and 59.9 hours for 600mg peramivir. This result was highly statistically significant (p=0.0046) for both the 300mg dose (p=0.0046) and the 600 mg dose. Further, safety assessments confirmed that peramivir was generally well-tolerated. Shionogi presented the data at the recent Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)/ Infectious Diseases Society of America (IDSA) annual meeting in Washington, D.C. Based on the results from this Phase II study, Shionogi has commenced preparations for a Phase III program with i.v. peramivir in the outpatient setting.

The Phase II study was a randomized, double-blind, placebo-controlled trial, which enrolled 300 subjects who had a positive rapid antigen test indicating acute influenza illness. Subjects were randomized to receive an i.v. injection of placebo or one of two doses of peramivir (300mg and 600mg) as a single dose administered within 48 hours of symptom onset.

***Continued development of intravenous ( i.v. ) peramivir Phase II clinical trial***

In July 2007, we announced the initiation of a Phase II clinical trial of i.v. peramivir to compare the efficacy and safety of i.v. peramivir to orally administered oseltamivir in patients who require hospitalization due to acute influenza. On October 27, 2008 the Company announced results of this exploratory Phase II trial. The study compared the efficacy and safety of five days of therapy with either 200 mg i.v. peramivir per day, 400 mg i.v. peramivir per day or 75 mg oral oseltamivir twice a day, in patients who required hospitalization related to influenza. These results will be submitted to an upcoming medical meeting.

The primary objective of the study was to evaluate time to clinical stability, which is a composite endpoint comprised of normalization of temperature, oxygen saturation, respiratory rate, systolic blood pressure and heart rate. This type of endpoint has previously been used in pneumonia studies, but not in influenza. Secondary objectives of the study included evaluation of viral shedding, mortality, clinical relapse and time to resumption of usual activities.

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In the primary efficacy population, for all groups combined, the study demonstrated a median of 25.3 hours to clinical stability, a median of 2.0 log reduction in time weighted change from baseline in viral titer, zero mortality, no clinical relapse and a median of 10.8 days to resumption of usual activities. There were no statistically significant differences in any of the endpoints between the three treatment arms. Peramivir was generally safe and well-tolerated at these dose levels.

The multicenter, randomized, double-blind, double-dummy, active-controlled, Phase 2 Study enrolled 137 patients, who tested positive by rapid antigen test (RAT) for influenza and had one or more criteria for hospitalization, namely: age  $\geq$  60 years, chronic lung disease, congestive heart failure, diabetes mellitus, low oxygen saturation, low blood pressure, or severity of illness requiring supportive care. Of the 137 patients randomized, 122 age 19 to 101 years had influenza confirmed by polymerase chain reaction (PCR) testing and were included in the intent-to-treat infected (ITTI) patient population; 41 patients received oseltamivir 75mg orally twice-daily, 41 patients received 200 mg i.v. peramivir once-daily and 40 patients received 400 mg i.v. peramivir once-daily.

***Developments in oral BCX-4208 Phase IIa clinical trial***

In July 2007, the Company and Roche initiated the first Phase IIa, randomized, double blind, placebo controlled, dose ranging study with BCX-4208 in 66 patients with moderate to severe plaque psoriasis. In this study, BCX-4208 was administered once a day for 6 weeks, at a dose of either 20mg or 120mg. Patients were monitored for at least four weeks following treatment. The primary objectives of the study were safety and tolerability. Secondary objectives included pharmacodynamic and pharmacokinetic measures, and clinical response.

Consistent with interim findings reported by the Company in May 2008, this study of BCX-4208, a potent, rationally designed, orally available purine nucleoside phosphorylase (PNP) inhibitor, met its primary objectives of safety and tolerability. In addition, BCX-4208 displayed dose-dependent reductions in peripheral blood lymphocyte counts, including subsets measuring B cells (CD20), total T cells (CD3), T helper cells (CD4) and T suppressor/cytotoxic cells (CD8). Further, plasma levels of BCX-4208 increased with dose, and plasma uric acid levels showed dose-related reductions with BCX-4208. In addition, consistent with interim results previously reported by the Company, no evidence of clinical efficacy, a secondary objective, was observed in psoriasis patients with doses and duration of administration tested.

In the Phase IIa trial, BCX-4208 was generally safe and well-tolerated at doses up to 120 mg daily. Most adverse events reported were considered mild or moderate, and low in frequency. No opportunistic infections were observed. In addition, detailed laboratory and clinical monitoring did not indicate any patterns suggestive of off-target adverse findings.

In May 2008, following review of a planned interim analysis of the Phase IIa trial, Roche terminated its license agreement for the development of BCX-4208 for autoimmune diseases and transplant. As a result, BioCryst regained worldwide rights to BCX-4208. Roche and BioCryst agreed to complete the Phase IIa trial.

**Results of Operations (three months ended September 30, 2008 compared to the three months ended September 30, 2007)**

Collaborative and other research and development revenues decreased to \$8.9 million for the three months ended September 30, 2008 as compared to \$20.5 million for the three months ended September 30, 2007. This decrease is driven by a reduction in peramivir related activities leading to a reduction in costs and associated revenue from the contract with HHS for the development of peramivir. Currently, the majority of the Company's revenues are derived from the reimbursement of costs under the contract with HHS.

Research and development ( R&D ) expenses decreased 46.1% to \$16.0 million for the third quarter of 2008 from \$29.7 million for the third quarter of 2007. The decrease in R&D expenses is due to a reduction in manufacturing costs associated with both our peramivir and forodesine HCl programs and a reduction in our clinical development costs associated with our peramivir program. These reductions were offset by an increase in our clinical development costs in the forodesine HCl program.

General and administrative ( G&A ) expenses decreased 4.8% to \$2.5 million for the third quarter of 2008 from \$2.6 million for the third quarter of 2007.





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Interest income for the three months ended September 30, 2008 was \$0.6 million as compared to \$0.9 million for the three months ended September 30, 2007. This decrease was due to a lower average cash balance for the 2008 third quarter and more favorable interest rates in the 2007 third quarter.

The net loss for the third quarter of 2008 was \$9.0 million, or \$0.24 per share, compared to a net loss of \$11.0 million, or \$0.32 per share for the third quarter of 2007.

**Results of Operations (nine months ended September 30, 2008 compared to the nine months ended September 30, 2007)**

Collaborative and other research and development revenues decreased to \$22.3 million for the nine months ended September 30, 2008 as compared to \$43.1 million for the nine months ended September 30, 2007. The decrease is primarily due to a reduction in peramivir related activities leading to a reduction in costs and associated revenue from HHS, plus the \$4.9 million reserve on revenue and receivables due from HHS that was recorded in the second quarter of 2008.

R&D expenses decreased 21.1% to \$51.3 million for the nine months ended September 30, 2008 from \$64.9 million for the nine months ended September 30, 2007. The decrease in R&D expenses is due to a reduction in manufacturing costs associated with both our peramivir and forodesine HCl programs, a reduction in our clinical development costs associated with our peramivir program, and a reduction in toxicology costs within our peramivir program. These reductions were offset by an increase in our clinical development costs for forodesine HCl and increases in personnel related costs and professional services.

G&A expenses increased 14.9% to \$8.0 million for the nine months ended September 30, 2008 from \$7.0 million for the nine months ended September 30, 2007. The increase in G&A expenses is primarily due to an increase in professional fees and personnel related costs.

Interest income for the nine months ended September 30, 2008 was \$2.2 million as compared to \$2.1 million for the nine months ended September 30, 2007.

The net loss for the nine months ended September 30, 2008 was \$34.8 million, or \$0.91 per share, compared to a net loss of \$26.8 million, or \$0.86 per share for the nine months ended September 30, 2007.

**Changes in Financial Condition since December 31, 2007**

Since our most recent fiscal year end, there have been two primary factors that have had an impact on our financial condition. Our receivables from collaborations, primarily HHS, have decreased from \$39.1 million at December 31, 2007 to \$13.1 million at September 30, 2008. This positive impact on our cash position was offset by a decrease in our accounts payable and accrued expenses from \$23.5 million at December 31, 2007 to \$13.2 million at September 30, 2008.

**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 nine months of 2008, we received cash from collaborative and other research and development agreements and government contracts (primarily Shionogi, Mundipharma and HHS) of approximately \$44.9 million. Other sources of funding have included the following:

other collaborative and other research and development agreements;

government grants and contracts;

equipment lease financing;

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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 in general and specifically related to our clinical trial activity. 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 primarily 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 significant losses from such investments.

On August 7, 2007, we amended our lease for our current Birmingham facilities, consisting of 50,150 square feet, 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 provided 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 5,565 square feet under lease through February 28, 2010. This lease requires us to pay \$7,652 per month and escalates annually to \$8,118 per month in the final year.

At December 31, 2007, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$619,346 in 2008, \$623,894 in 2009 and \$554,287 in 2010. 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 2007 Shionogi began a phase II trial with peramivir in Japan which triggered a milestone payment to us for \$7 million which was received in December 2007.

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In January 2007, we announced that HHS had awarded the Company a \$102.6 million, four-year contract for the advanced development of 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, rejection of significant costs by HHS or cancellation of this contract by HHS would have a significant negative effect on our financial position. In January 2008, we announced that the development costs of our peramivir program to anticipated product approval would cost in excess of the \$102.6 million contract since the development plan for peramivir had changed from that outlined in the original proposal to HHS. HHS has indicated that they will fund certain elements of our revised program, including the ongoing Phase II i.v. study evaluating peramivir in hospitalized subjects, the planning and conduct of the planned Phase II study of i.m. peramivir and the manufacturing and toxicology components of the program. Each of these elements has specific HHS funding limits and any costs outside the approved amounts by HHS may be our responsibility. In January 2008, we disclosed that we would not pursue the Phase III i.m. program in peramivir for the current influenza season, but would move forward in evaluating higher doses than used in previous studies. In July 2008, HHS indicated that it does not intend to reimburse us all of the costs incurred related to these terminated Phase III studies. We continue to pursue reimbursement of these costs. During the second quarter of 2008, we recorded a \$4.9 million reserve against revenue for amounts we previously expected to receive from HHS related to the costs incurred in this program. Approximately \$4.6 million of the reserve relates to revenues recognized in the first quarter of 2008, while approximately \$0.3 million of the reserve relates to revenues recognized in 2007.

In February 2006, we licensed forodesine HCl 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 forodesine HCl 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 forodesine HCl 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, we made a decision to put this trial on voluntary hold to investigate particulates that were found in some batches of i.v. formulation. In December 2007, we announced the termination of our development in T-ALL with forodesine HCl. In July 2007, we announced that we had received an SPA for a pivotal trial of forodesine HCl in CTCL patients. The trial is a multicenter, multinational, open-label, single-arm, repeat dose pivotal trial which began enrollment during October 2007. In the first quarter of 2008, we initiated a second clinical trial for patients with CLL. For the year, our cash, cash equivalents and marketable securities balance has decreased from \$85.0 million as of December 31, 2007 to \$67.9 million as of September 30, 2008, primarily due to the monthly cash burn from operations offset by cash received from collaborations. As a result of these items and the reimbursement from our contract with HHS, our net cash burn rate has been approximately \$1.9 million per month in 2008. 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. We are projecting our 2008 net cash burn to be approximately \$25 million.

As our clinical programs continue to progress 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.

On September 30, 2008, we reduced our staff by 19 people as part of our cost containment strategy. The reduction is part of a strategic initiative to focus the Company's resources on the execution of our late-stage clinical trials and the development of our most promising pre-clinical compounds. The one-time cost of this reduction was approximately \$340,000.

As of September 30, 2008, we had \$67.9 million in cash, cash equivalents and marketable securities, which included the \$65.3 million from the private placement of unregistered common stock and warrants to certain existing stockholders, which closed on August 9, 2007. With our currently available funds and the amounts to be received from HHS, Shionogi and our other collaborators, we believe these resources will be sufficient to fund our operations for at least the next twelve months. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time.

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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 engage sites and enroll subjects 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 of September 30, 2008, we are not involved in any material unconsolidated entities or off-balance sheet arrangements.

**Contractual Obligations**

Our contractual obligations as of December 31, 2007 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, 2007.



**Table of Contents****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, 2007, 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. For example, upon termination of the license agreement with Roche, we will recognize the remaining deferred revenue and deferred expense, which are \$26.5 million and \$8.2 million, respectively, as of September 30, 2008.

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 and EITF Issue 07-3. 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.





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Additionally, we have license agreements with third parties, such as AECOM, IRL, and UAB, which require fees related to sublicense agreements or maintenance fees. We expense sublicense payments 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. We expense maintenance payments as incurred.

Our accounting for deferred sublicense payments related to revenues that have been deferred is based on the guidance in SAB No. 104, which states that the incremental direct costs incurred related to the acquisition or origination of a contract in a transaction that results in the deferral of revenue may either be expensed as incurred or accounted for in accordance with paragraph 4 of FTB 90-1. At September 30, 2008, we had deferred collaboration expenses of approximately \$11,644,000. These deferred expenses were sub-license payments, paid to our academic partners upon our receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

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.

|   | <b>Three Months Ended</b> |                  | <b>Nine Months Ended</b> |                  |
|---|---------------------------|------------------|--------------------------|------------------|
|   | <b>September 30,</b>      |                  | <b>September 30,</b>     |                  |
|   | <b>2008</b>               | <b>2007</b>      | <b>2008</b>              | <b>2007</b>      |
| Direct external R&D expenses by program:    |                           |                  |                          |                  |
| PNP Inhibitor (forodesine HCl)              | \$ 3,662                  | \$ 6,767         | \$ 11,497                | \$ 13,289        |
| Neuraminidase Inhibitor (peramivir)         | 4,984                     | 16,470           | 17,698                   | 33,542           |
| Other                                       | 429                       | 1,138            | 2,724                    | 3,034            |
| All other R&D expenses:                     |                           |                  |                          |                  |
| Compensation and fringe benefits            | 3,649                     | 3,113            | 10,185                   | 8,230            |
| Supplies and services                       | 858                       | 193              | 2,251                    | 1,089            |
| Maintenance, depreciation, and amortization | 979                       | 355              | 1,974                    | 979              |
| Overhead allocation and other               | 1,435                     | 1,694            | 4,938                    | 4,775            |
| <b>Total R&amp;D expenses</b>               | <b>\$ 15,996</b>          | <b>\$ 29,730</b> | <b>\$ 51,267</b>         | <b>\$ 64,938</b> |

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.

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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 may commence are unknown.

***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. During the quarter, the Company made improvements to accelerate its financial statement close process, thereby providing financial information in a more timely manner. As a result of accelerating the close process, the use of estimates in determining accrued expenses is more prevalent. The process of estimating accrued expenses 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 substances and drug products; and

professional service fees.

We base our expenses related to clinical trials on 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, adjustments are made to the accrual accordingly. If we incur costs that were previously not identified, or if we underestimate or overestimate the level of services performed or the costs of these services, actual expenses could differ from the 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 September 30, 2008, we had two stock-based employee compensation plans, the Incentive Plan and the ESPP. 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.

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**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, 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 testing, clinical trials, and other research and development efforts;

the potential funding from our contract with HHS for the development of peramivir;

the further preclinical or clinical development and commercialization of our product candidates, including peramivir, forodesine HCl and other PNP inhibitor and hepatitis C development programs;

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

our ability to establish and maintain collaborations;

plans, programs, progress and potential success of our collaborations, including Mundipharma for forodesine HCl and Shionogi and Green Cross for peramivir;

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 we have no obligation to update or revise the statements. We caution 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.



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**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 primarily 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. However, we do not believe that we have material exposure to interest rate risk arising from our investments.

**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 September 30, 2008, 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 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 September 30, 2008 that have materially affected, or are reasonably likely to materially affect, BioCryst's internal control over financial reporting.



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**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

None

**Item 1A. Risk Factors**

Our 2007 Annual Report on Form 10-K includes a detailed discussion of our risk factors. The information below updates our risk factors as of September 30, 2008. 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. 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. 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. Clinical trials may not be adequately designed or executed, which could affect the potential outcome and analysis of study 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, 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;

clinical protocols or study procedures may not be adequately designed or followed by the investigators;

manufacturing of quality problems could affect the supply of drug product for our trials; and

delays or changes in requirements by governmental agencies.



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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.

***Our later stage clinical trials may not adequately show our drugs are safe or effective.***

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety profiles and show positive therapeutic effects in the patients being treated by achieving pre-determined endpoints according to the trial protocols. Failure to achieve either of these could result in delays in our trials or even require the performance of additional unplanned trials. This could result in delays in the development of our drug candidates and could result in significant unexpected costs.

***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.***

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. 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.

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

Our projections of revenues and incoming cash flows are substantially dependent upon HHS reimbursement for the costs related to our peramivir program. If HHS were to eliminate, reduce or delay 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. For example, in January 2008, we announced the development cost of our peramivir program to product approval would cost in excess of the \$102.6 million contract since the development plan for peramivir has changed from that outlined in the original proposal to HHS. HHS has indicated that they will fund certain elements of our revised program, including the ongoing Phase II i.v. study in hospitalized subjects, planning and conduct of the planned Phase II i.m. study, manufacturing and toxicology. Each of these elements has specific HHS funding limits and costs outside the approved amounts by HHS may be the responsibility of the Company. In January 2008, we disclosed that we would not pursue the Phase III i.m. program in peramivir for the current influenza season, but would move forward in evaluating higher doses than used in previous studies. In July 2008, HHS indicated that it does not intend to reimburse us all of the costs incurred related to these terminated Phase III studies. We continue to pursue reimbursement of these costs. During the second quarter of 2008, we recorded a \$4.9 million reserve against revenue for amounts we previously expected to receive from HHS related to the costs incurred in this program. Approximately \$4.6 million of the reserve relates to revenues recognized in the

first quarter of 2008, while approximately \$0.3 million of the reserve relates to revenues recognized in 2007.

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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 of 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 does 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, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.***

Our business strategy is to increase the asset value of our drug candidate portfolio. 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.

Currently, we have established collaborative relationships with certain pharmaceutical companies, Roche (recently terminated) Mundipharma, and both Shionogi and Green Cross for the development and commercialization of BCX-4208, forodesine HCl and peramivir, respectively. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

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;

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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 reduced, 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.

For example, in May 2008, we received notice that Roche was exercising the no cause termination right under the license agreement for BCX-4208. Upon the effective date of termination, we will regain worldwide rights to BCX-4208. We will determine the future development plans of BCX-4208 after receiving top line data from all subjects in the Phase IIa trial due later in 2008.

We are currently in dispute with Mundipharma regarding the contractual obligations of the parties with respect to certain costs related to the manufacturing and development of forodesine HCl. Notwithstanding, we do not believe that we are responsible for any of the disputed amounts. We are engaged in ongoing discussion to resolve this dispute. The maximum potential exposure to us is estimated to be approximately \$2.5 million. Because of the preliminary nature of the discussions, no amounts have been accrued as of September 30, 2008.

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

We have not commercialized any products or technologies, and we may never be able to do so. We currently have no marketing capability and no direct or third-party sales or distribution capabilities and may be unable to establish these capabilities for products we plan to commercialize. In addition, our revenue from collaborative agreements is dependent upon the status of our preclinical and clinical programs. If we fail to advance these programs to the point of being able to enter into successful collaborations, we will not receive any future event or other collaborative payments.

Our ability to receive revenue from products we commercialize presents several risks, including:

we or our collaborators may fail to successfully complete clinical trials sufficient to obtain FDA marketing approval;

many competitors are more experienced and have significantly more resources and their products could be more cost effective or have a better efficacy or tolerability profile than our product candidates;

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;



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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 development collaborations with third parties, such as our development partners and contract research organizations, 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 compounds 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; and

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.

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 or perform their services inconsistent with industry standards and not in accordance with the required regulations, this would delay or prevent the development of our product candidates.

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.

***Our development of both intravenous and intramuscular dosing of peramivir for avian and seasonal influenza 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 currently in Phase II clinical development and have been tested in a limited number of humans 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;

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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;

injectable forms of peramivir may not prove to be accepted by patients and physicians as a treatment for seasonal influenza compared to the other currently marketed antiviral drugs, which would limit revenue from non-governmental entities;

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 from stockpiling orders from these entities.

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;

product liability claims;

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.

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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 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 process of preparing for and obtaining FDA approval may be 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. 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.

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***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, transplant rejection, psoriasis and other autoimmune indications), oncology, influenza, and hepatitis C. 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 Glaxo Smith Kline 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.





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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 to produce 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 have 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.

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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 or commercialize our product candidates and any such events would significantly impair the value of such product candidates.

***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 \$11 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 facility incurs damage or power is lost for a significant length of time, our business will suffer.***

We currently 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.

In addition, 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.

***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.

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***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 September 30, 2008, the 52-week range of the market price of our stock was from \$2.40 to \$8.33 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;

announcements relating to the status of our programs;

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.

***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.

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

None

**Item 3. Defaults Upon Senior Securities**

None

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

None

**Item 5. Other Information**

None

**Item 6. Exhibits**

See the Exhibit Index attached to this quarterly report and incorporated herein by reference.

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**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 31<sup>st</sup> day of October 2008.

BIOCRYST PHARMACEUTICALS, INC.

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

/s/ Stuart Grant  
Stuart Grant  
*Chief Financial Officer*

/s/ Michael A. Darwin  
Michael A. Darwin  
*VP Finance (Principal Financial and  
Accounting Officer) and Treasurer*

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**INDEX TO 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 and restated effective November 6, 2007. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 13, 2007.  |
| 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 filed June 17, 2002. |
| 4.2           | Amendment to Rights Agreement, dated as of August 5, 2007. Incorporated by reference to Exhibit 4.2 of the Company's Form 10-Q filed August 9, 2007.  |
| 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.   |
| #             | Confidential treatment granted.   |
| &             | Management contracts.   |
| *             | Confidential treatment requested.   |