BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 06, 2009

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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, 2009
Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**62-1413174**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2190 Parkway Lake Drive; Birmingham, Alabama	**35244**
(Address of principal executive offices)	(Zip Code)

(205) 444-4600
(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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.

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

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

The number of shares of Common Stock, par value $.01, of the Registrant outstanding as of October 23, 2009 was 38,823,355.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
BALANCE SHEETS
September 30, 2009 and December 31, 2008
(In thousands, except per share data)

	2009 (Unaudited)	2008 (Note 1)
Assets		
Cash and cash equivalents	$ 18,226	$ 22,342
Marketable securities	17,259	39,186
Receivables from collaborations	11,626	11,982
Prepaid expenses and other current assets	3,201	1,137
Deferred collaboration expense	374	377
Total current assets	50,686	75,024
Marketable securities	3,007	1,786
Furniture and equipment, net	4,175	4,881
Deferred collaboration expense	2,720	3,001
Total assets	$ 60,588	$ 84,692
Liabilities and Stockholders Equity		
Accounts payable	$ 3,200	$ 5,266
Accrued expenses	11,145	8,443
Accrued vacation	828	794
Deferred rent	53	40
Deferred revenue	2,509	2,565
Total current liabilities	17,735	17,108
Deferred rent	243	220
Deferred revenue	19,065	20,938
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 38,735 in 2009 and 38,275 in 2008	387	383
Additional paid-in capital	300,989	295,208
Accumulated other comprehensive income	40	103
Accumulated deficit	(277,871)	(249,268)

Total stockholders equity	23,545	46,426
Total liabilities and stockholders equity	$ 60,588	$ 84,692

See accompanying notes to financial statements.

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BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
Periods Ended September 30, 2009 and 2008
(In thousands, except per share data)
(Unaudited)

	Three Months		Nine Months	
	2009	**2008**	**2009**	**2008**
Revenues				
Collaborative and other research and development	$ 10,548	$ 8,894	$ 19,694	$ 22,321
Expenses				
Research and development	18,181	15,996	40,683	51,267
General and administrative	3,064	2,471	7,834	8,023
Total expenses	21,245	18,467	48,517	59,290
Loss from operations	(10,697)	(9,573)	(28,823)	(36,969)
Interest and other income	70	578	220	2,167
Net loss	$ (10,627)	$ (8,995)	$ (28,603)	$ (34,802)
Basic and diluted net loss per common share	$ (0.28)	$ (0.24)	$ (0.75)	$ (0.91)
Weighted average shares outstanding	38,460	38,095	38,300	38,040

See accompanying notes to financial statements.

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BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2009 and 2008
(In thousands)
(Unaudited)

	2009	2008
Operating activities		
Net loss	$ (28,603)	$ (34,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,217	1,163
Stock-based compensation expense	4,179	4,509
Changes in operating assets and liabilities:		
Receivables from collaborations	356	26,026
Prepaid expenses and other current assets	(2,064)	(451)
Deferred collaboration expense	284	688
Accounts payable and accrued expenses	670	(10,286)
Deferred rent	36	270
Deferred revenue	(1,929)	(3,453)
Net cash used in operating activities	**(25,854)**	**(16,336)**
Investing activities		
Acquisitions of furniture and equipment	(511)	(1,140)
Purchases of marketable securities	(18,466)	(84,309)
Sales and maturities of marketable securities	39,109	85,941
Net cash provided by investing activities	**20,132**	**492**
Financing activities		
Exercise of stock options	1,412	266
Employee stock purchase plan sales	194	375
Net cash provided by financing activities	**1,606**	**641**
Decrease in cash and cash equivalents	(4,116)	(15,203)
Cash and cash equivalents at beginning of period	22,342	31,155
Cash and cash equivalents at end of period	**$ 18,226**	**$ 15,952**

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, 2009, the statements of operations for the three and nine months ended September 30, 2009 and 2008, and the statements of cash flows for the nine months ended September 30, 2009 and 2008 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, 2009, the results of operations for the three and nine months ended September 30, 2009 and 2008, and cash flows for the nine months ended September 30, 2009 and 2008. 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, 2008 and the notes thereto included in the Company s 2008 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, 2008 has been derived from the audited financial statements included in the Company s most recent Annual Report on Form 10-K.

The Company has evaluated subsequent events for disclosure through November 5, 2009, the date of issuance of the accompanying interim financial statements.

Cash and Cash Equivalents

The Company generally considers cash equivalents to be all cash held in commercial checking accounts, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase.

Marketable 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. Unrealized gains and losses on securities available-for-sale are recognized in other comprehensive income, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations.

At September 30, 2009, the Company had approximately $20,266,000 of marketable securities, all of which were classified as available-for-sale. These securities consisted of U.S. Treasury and Agency securities and corporate bonds 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 generally accepted accounting principles. The following table summarizes by year the scheduled maturity for the securities available-for-sale at September 30, 2009 and includes accrued interest of approximately $14,000. Note that amounts are in thousands.

2010	$ 17,259
2011	3,007
	$ 20,266

At September 30, 2009, the amortized cost of securities available-for-sale, including accrued interest, was approximately $20,226,000. At September 30, 2009, gross unrealized gains on securities available-for-sale were approximately $42,000 and gross unrealized losses on securities available-for-sale were approximately $2,000.

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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, 2009, the Company had the following receivables from collaborations. Amounts are in thousands.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 2,333	$ 8,072	$ 10,405
Shionogi & Co., Ltd.	1,125		1,125
Green Cross Corporation	37		37
Mundipharma International Holdings Limited	34		34
Other	25		25
Total	$ 3,554	$ 8,072	$ 11,626

Unbilled receivables from the U.S. Department of Health and Human Services (HHS) are net of a reserve for costs and fees of $4,919,000 at September 30, 2009 that are uncertain of recovery and related to the voluntarily terminated Phase 3 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. 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 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, 2009 consisted primarily of development and clinical trial expenses payable to contract research organizations (CROs) in connection with the Company s research and development programs.

Income Taxes

The liability method is used in accounting for the Company s income taxes. 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.

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 approximately $40,000 of unrealized gains on its securities available-for-sale that are included in accumulated other comprehensive income at

September 30, 2009.

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Other comprehensive loss for the periods ended September 30, 2009 and 2008 appear in the following table. Amounts are in thousands.

	Three Months		Nine Months	
	2009	2008	2009	2008
Net loss	$ (10,627)	$ (8,995)	$ (28,603)	$ (34,802)
Unrealized loss on securities available-for-sale		(119)	(63)	(245)
Other comprehensive loss	$ (10,627)	$ (9,114)	$ (28,666)	$ (35,047)

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 from 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. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

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 cannot 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.

The Company recorded the following revenues from collaborations for the periods ended September 30, 2009 and 2008. Amounts are in thousands.

	Three Months		Nine Months	
	2009	2008	2009	2008
U.S. Department of Health and Human Services	$ 8,544	$ 6,142	$ 16,350	$ 16,217
Shionogi and Co., Ltd.	1,565	914	2,170	1,712
Green Cross Corporation	55	18	93	56
Mundipharma International Holdings Limited	359	1,377	1,056	3,007
Roche		443		1,329
Other	25		25	
Total	$ 10,548	$ 8,894	$ 19,694	$ 22,321

Research and Development Expenses

The Company s research and development costs are charged to expense when incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, 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 CROs. Costs for studies performed by CROs 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.

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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.

At September 30, 2009, the Company had deferred collaboration expenses of approximately $3,094,000. 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.

Stock-Based Compensation

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. 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, 2009, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan), which was amended and restated in February 2009 and approved by the Company s stockholders in April 2009, and the Employee Stock Purchase Plan (ESPP), which was amended and restated in February 2008 and approved by the Company s stockholders in May 2008. 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. Stock-based compensation expense of approximately $4,179,000 ($3,886,000 of expense related to the Incentive Plan, $181,000 of expense related to the ESPP, and $112,000 of expense related to the inducement grant) was recognized during the first nine months of 2009, while approximately $4,509,000 ($4,277,000 of expense related to the Incentive Plan, $120,000 of expense related to the ESPP, and $112,000 of expense related to the inducement grant) was recognized during the first nine months of 2008.

As of September 30, 2009, there was approximately $6,985,000 of total unrecognized compensation cost related to non-vested stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: $1,335,000 in the remainder of 2009, $3,813,000 in 2010, $1,273,000 in 2011, $441,000 in 2012, and $123,000 in 2013.

Net Loss 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.

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Note 2 Stock-Based Compensation

Stock Incentive Plan

The Company grants stock option awards and restricted stock awards to its employees, directors, and consultants of the Company under the Incentive Plan. 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.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2008	1,114,630	5,477,649	$ 8.30
Plan Amendment	1,540,000		
Stock option awards granted	(1,550,900)	1,550,900	1.99
Stock option awards exercised		(336,191)	4.20
Stock option awards canceled	486,728	(486,728)	8.15
Balance September 30, 2009	1,590,458	6,205,630	6.96

For stock option awards granted under the Incentive Plan during the first nine months of 2009 and 2008, 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 2009 and 2008 was $1.50 and $2.15, 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 following summarizes the key assumptions used by the Company to value the stock option awards granted during the first nine months of 2009 and 2008. 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 current date (if already vested) or at full vesting (if not yet vested) 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

	2009	2008
Expected Life in Years	5.6	5.5
Expected Volatility	104.3%	78.3%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	2.1%	2.8%

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 first quarter of 2009, 25,000 of these restricted stock awards vested. The remainder of these restricted stock awards will vest during the first quarter of 2011.

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. All of these restricted stock awards will vest on December 31, 2009.

Employee Stock Purchase Plan

The Company has reserved a total of 600,000 shares of common stock to be purchased under the ESPP, of which 56,494 shares remain available for purchase at September 30, 2009. 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 123,357 shares during the first nine months of 2009 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the look-back option were determined using a Black-Scholes option pricing model.

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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, 2009, 6,042 shares granted under the restricted stock awards have vested.

Note 3 Collaborative Agreements

U.S. Department of Health and Human Services. In January 2007, the Company was awarded a four-year contract from HHS to develop its influenza neuraminidase inhibitor, peramivir, for the treatment of seasonal and life-threatening influenza. The contract commits $102.6 million to support manufacturing, process validation, clinical studies, and other product approval requirements for 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. HHS makes periodic assessments of progress and the continuation of the contract is based on the Company s performance, timeliness and quality of deliverables, and other factors. The government has rights under certain contract clauses to terminate this contract. The contract is terminable by the government at any time for breach or without cause.

On September 18, 2009, HHS and the Company executed a contract modification that awarded an additional $77.2 million to the Company to complete Phase 3 development of intravenous (i.v.) peramivir, bringing the total award from HHS for the development of peramivir to $179.9 million. The modification also extended the contract term by 12 months to five years.

The Company has determined that there is an excess of approximately $5.0 million dollars of peramivir active pharmaceutical ingredient (API) beyond that necessary to support U.S. regulatory approval. As permitted under our contract, in June 2009, the Company tendered payment of $5.0 million dollars to HHS for the repurchase of the excess API at acquisition cost. HHS has returned payment pending its complete review of the API excess in light of the clinical development plan as well as the calculation for the acquisition cost for the purchase of the excess API. HHS acknowledges that at least half of the API is excess.

Mundipharma International Holdings Limited (Mundipharma). In February 2006, the Company entered into an exclusive, royalty bearing right and license agreement with Mundipharma for the development and commercialization of the Company s lead PNP inhibitor, forodesine, for use in oncology. Under the terms of the agreement, Mundipharma obtained rights to forodesine in markets across Europe, Asia, and Australasia in exchange for a $10.0 million up-front payment. In addition, Mundipharma contributed $10.0 million of the documented out of pocket development costs incurred by the Company in respect of the current and planned trials as of the effective date of the agreement and Mundipharma will conduct additional clinical trials at their own cost up to a maximum of $15.0 million. The license provides for possible future event payments totaling $155.0 million for achieving specified development, regulatory and commercial events (including certain sales level amounts following a product s launch) for certain indications. In addition, the agreement provides that the Company will receive royalties (ranging from single digits to mid teens) based on a percentage of net product sales, which varies depending upon when certain indications receive NDA approval in a major market country and can vary by country depending on the patent coverage or sales of generic compounds in a particular country. Generally, all payments under the agreement are nonrefundable and non-creditable, but they are subject to audit. The Company licensed forodesine and other PNP inhibitors from AECOM and IRL and will owe sublicense payments to these third parties on the upfront payment, event payments, and royalties received by the Company from Mundipharma.

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For five years, Mundipharma will have a right of first negotiation on existing backup PNP inhibitors the Company develops through Phase 2b in oncology, but any new PNP inhibitors will be exempt from this agreement and the Company will retain all rights to such compounds. The Company retained the rights to forodesine in the U.S. and Mundipharma is obligated by the terms of the agreement to use commercially reasonable efforts to develop the licensed product in the territory specified by the agreement. The agreement will continue for the commercial life of the licensed products, but may be terminated by either party following an uncured material breach by the other party or in the event the pre-existing third party license with AECOM and IRL expires. It may be terminated by Mundipharma upon 60 days written notice without cause or under certain other conditions as specified in the agreement and all rights, data, materials, products and other information would be transferred back to the Company at no cost. In the event the Company terminates the agreement for material default or insolvency, the Company could have to pay Mundipharma 50% of the costs of any independent data owned by Mundipharma in accordance with the terms of the agreement.

The Company deferred the $10.0 million up-front payment that was received from Mundipharma in February 2006. This deferred revenue began to be amortized to revenue in February 2006 and will end in October 2017, which is the date of expiration for the last-to-expire patent covered by the agreement. The costs reimbursed by Mundipharma for the current and planned trials of forodesine were recorded as revenue when the expense was incurred up to the $10.0 million limit stipulated in the agreement.

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. 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, 2009.

Shionogi & Co., Ltd. (Shionogi). In March 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan in exchange for a $14.0 million up-front payment. The license provides for potential future milestone event payments (up to $21.0 million) and commercial event milestone payments (up to $95.0 million) in addition to double digit (between 10 and 20% range) royalty payments on product sales of peramivir. Generally, all payments under the agreement are nonrefundable and non-creditable, but they are subject to audit. Shionogi will be responsible for all development, regulatory and marketing costs in Japan. The term of the agreement is from February 28, 2007 until terminated by either party in accordance with the license agreement. Either party may terminate in the event of an uncured breach. Shionogi has the right of without cause termination. In the event of termination all license and rights granted to Shionogi shall terminate and shall revert back to the Company. The Company developed peramivir under a license from UAB and will owe sublicense payments to them on any future event payments and/or royalties received by the Company from Shionogi. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan and to provide rights for Shionogi to perform a Phase 3 clinical trial in Hong Kong.

The Company deferred the $14.0 million up-front payment that was received from Shionogi. This deferred revenue began to be amortized to revenue in April 2007 and will continue through December 2018. In December 2007, the Company received a $7.0 million milestone payment from Shionogi for their initiation of a Phase 2 clinical trial with i.v. peramivir.

In October 2008, we and our partner, Shionogi & Co., Ltd. of Japan, amended the license agreement to expand the territory in the agreement to include Taiwan and to provide rights for Shionogi to perform a Phase 3 clinical trial in Hong Kong.

Green Cross Corporation (Green Cross). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The Company received a one-time license fee of $250,000. The agreement also provides for relatively insignificant future milestone payments. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of

peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea. Both parties have the right to terminate in the event of an uncured material breach. In the event of termination all rights, data, materials, products and other information would be transferred to the Company. The Company deferred the up-front payment that was received from Green Cross. This deferred revenue began to be amortized to revenue August 2006 and will continue through November 2009.

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F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (Roche). In November 2005, the Company entered into an exclusive license with Roche for the development and commercialization of the Company s second generation PNP inhibitor, BCX-4208, for the prevention of acute rejection in transplantation and for the treatment of autoimmune diseases. However, in May 2008, the Company received notice that Roche was exercising the no cause termination right under the license agreement for BCX-4208. The license agreement was terminated during the fourth quarter of 2008.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL. The lead drug candidates from this collaboration are forodesine and BCX-4208. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, drug candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or employees of AECOM and IRL. The Company has agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from $1.4 million to almost $4.0 million per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from $150,000 to $500,000, that are creditable against actual royalties and other payments due to AECOM and IRL. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by AECOM and IRL**.**

The University of Alabama at Birmingham. The Company currently has agreements with UAB for influenza neuraminidase and complement inhibitors. Under the terms of these agreements, UAB performed specific research for the Company in return for research payments and license fees. UAB has granted the Company certain rights to any discoveries in these areas resulting from research developed by UAB or jointly developed with the Company. The Company has agreed to pay single digit royalties on BioCryst s sales of any resulting product and to share in future payments received from other third-party partners. The Company has completed the research under the UAB agreements. These two agreements have initial 25-year terms, are automatically renewable for five-year terms throughout the life of the last patent and are terminable by the Company upon three months notice and by UAB under certain circumstances. Upon termination both parties shall cease using the other parties proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi and Green Cross agreements, or commercializes products related to these programs, we will owe sublicense fees or royalties on amounts we receive.

Emory University (Emory). In June 2000, the Company licensed intellectual property from Emory related to the hepatitis C polymerase target associated with hepatitis C viral infections. Under the original terms of the agreement, the research investigators from Emory provided the Company with materials and technical insight into the target. The Company has agreed to pay Emory single digit royalties on sales of any resulting product and to share in future payments received from other third party partners, if any. The Company can terminate this agreement at any time by giving 90 days advance notice. Upon termination, the Company would cease using the licensed technology.

Note 4 Income Taxes

As of September 30, 2009, 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.

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The Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements as of September 30, 2009. Tax years 2005-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2005 are also open to examination to the extent of loss and credit carryforwards from those years.

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 as of September 30, 2009.

Note 5 Subsequent Events

In November 2009, the Company announced that Shionogi filed a New Drug Application (NDA) in Japan to seek regulatory approval for i.v. peramivir to treat patients with influenza. As a consequence of this filing, the Company will receive a milestone payment of $7.0 million under its agreement with Shionogi.

Also in November 2009, the Company received and filled an initial order for 10,000 courses of i.v. peramivir with a value of $22.5 million under a newly issued contract with HHS.

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 in cutaneous T-cell lymphoma (CTCL)

Following the completion of a Phase 1/Phase 2 clinical trial of forodesine in patients with refractory CTCL, in October 2007 we initiated a planned pivotal trial with an oral formulation of forodesine for treatment of patients with CTCL. This trial is being conducted under an SPA agreement negotiated with the U.S. Food and Drug Administration (FDA) and will serve as a basis for a new drug application to the FDA using the oral formulations in patients with relapsed CTCL. In February 2007, we announced that the Committee for Orphan Medicinal Products of the European Medicines Agency had granted orphan drug designation to forodesine for the treatment of CTCL. The trial continues to enroll subjects with CTCL stages IIB through IVA who have failed three systemic therapies. Enrollment in the study has continued to progress, and is now approaching the targeted 130 to 140 subjects in this study. We expect to report preliminary data on this study in the first half of 2010. Long-term data from a prior Phase 2 study of forodesine in patients with CTCL was presented at the 45th Annual Meeting of the American Society of Clinical Oncology. This poster presentation reviewed the safety and efficacy of forodesine for CTCL patients of stage Ib to stage IV who have failed standard therapies and received forodesine treatment for greater than 12 months.

Forodesine trial initiated for chronic lymphocytic leukemia (CLL) patients

We have initiated a second clinical trial that will evaluate forodesine in patients with CLL. The trial is a single arm exploratory study of single agent forodesine with response rate as the primary endpoint. The first patient was dosed during the first quarter of 2008 and the trial is ongoing. We announced interim data from the ongoing forodesine Phase 2 program in patients with CLL and data from a healthy subject pharmacokinetic (PK) and pharmacodynamic (PD) study. The interim analysis was conducted on data from an exploratory Phase 2 single-arm, open-label program in patients with CLL who failed previous treatment. No partial or complete responses were observed, but five out of 13 patients who were administered 200 mg of forodesine once-daily had substantial reductions in malignant lymphocytes. Forodesine was generally safe and well-tolerated at the 200 mg once-daily dose. The PK and PD study evaluated the effect of seven days of 200 mg forodesine dosed either once-daily or twice-daily in healthy volunteers. The study demonstrated substantially increased drug exposure and PD effect in volunteers administered forodesine 200 mg twice-daily compared to volunteers administered forodesine 200 mg once-daily. Based on both the CLL interim analysis and the PK and PD study results, the dosing regimen in the ongoing Phase 2 CLL study was amended to evaluate 200 mg forodesine twice-daily. We expect to provide an update on this study by the end of 2009.

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Continued development of i.v. peramivir Phase 2 and Phase 3 clinical trials

In July 2007, we announced the initiation of a Phase 2 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 we announced results of this exploratory Phase 2 trial. In February 2009, we presented the full data set from the trial at the XI International Symposium on Respiratory Viral Infections in Bangkok, Thailand. 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.

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. The primary efficacy population was defined as patients with confirmed influenza. There were no statistically significant differences in any of the efficacy endpoints between the three treatment arms, and peramivir was generally safe and well-tolerated at these dose levels. Evaluation of time to clinical stability, the primary endpoint, showed a median of 23.7 hours for peramivir 200 mg, 37.0 hours for peramivir 400 mg and 28.1 hours for oseltamivir (p-0.306). This exploratory endpoint was driven by resolution of fever. Viral shedding (time weighted change from baseline in viral titer) was reduced by a median of -2.0 logs for peramivir 200 mg, -2.1 logs for peramivir 400 mg and -1.9 logs for oseltamivir (p=0.908). There was no mortality in the primary efficacy population, and there were no clinical relapses. Patients were discharged from hospital after a median of 4.0 days for peramivir 200 mg, 3.8 days for peramivir 400 mg, and 4.0 days for oseltamivir (p=0.994). The median number of days required for resumption of usual activities was 8.8 days for peramivir 200 mg, 9.0 days for peramivir 400 mg, and 13.7 days for oseltamivir (p=0.276).

The multicenter, randomized, double-blind, double-dummy, active-controlled, Phase 2 study enrolled 137 patients, who tested positive by rapid antigen test for influenza and had one or more criteria for hospitalization, namely: age ≥ 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 testing and were included in the intent-to-treat infected 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.

In September 2009 we announced that we are initiating two Phase 3 studies of i.v. peramivir for the treatment of hospitalized patients with serious influenza. These studies are intended to support U.S. regulatory approval of peramivir as a treatment for influenza. One Phase 3 study is a multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of i.v. peramivir administered once-daily for five days in addition to standard of care, compared to standard of care alone, in adults and adolescents who are hospitalized due to serious influenza. The other Phase 3 study is an open-label, randomized study of the anti-viral activity, safety and tolerability of i.v. peramivir 600 mg administered once-daily compared with split doses twice-daily for five days in adult and adolescent hospitalized subjects with confirmed or suspected influenza infection. The combined enrollment target for these studies is approximately 700 patients. We are advancing the clinical development of i.v. peramivir under our contract with HHS. We received an award of $77.2 million to complete Phase 3 development of i.v. peramivir pursuant to a recent contract modification with HHS. This additional funding brings the total award from HHS for the development of peramivir to $179.9 million and extends the contract term by 12 months to five years.

We have determined that there is an excess of approximately $5.0 million of peramivir API beyond that necessary to support U.S. regulatory approval. As permitted under our contract, in June 2009 we tendered payment of $5 million to HHS for the repurchase of the excess API at acquisition cost. HHS has returned payment pending its complete review of the API excess in light of the clinical development plan as well as the calculation for the acquisition cost for the purchase of the excess API. HHS acknowledges that at least half of the API is excess.

Also in September 2009, we received a request for proposal (RFP) from HHS for the supply of i.v. peramivir for the treatment of critically ill influenza patients under an Emergency Use Authorization (EUA). The RFP indicates that the minimum and maximum order quantities to be ordered by the government are 1,000 and 40,000 courses of anti-viral treatment. The RFP specifies that we would also be required to maintain the ability to manufacture additional

treatment courses dependent on the volume and size of anti-viral orders received from HHS for additional needs for either treatment or prophylaxis. The Company decided to initiate manufacture of approximately 133,000 courses of peramivir at a cost of approximately $10 million in advance of potential orders, so that it could have additional product available. On November 4, 2009 the Company received an initial order for 10,000 courses of i.v. peramivir (600 mg once-daily for five days) with a value of $22.5 million. The Company shipped the entire order from existing i.v. peramivir inventory to HHS on November 4, 2009.

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In October, the Company announced that the FDA, in response to a request from the U.S. Centers for Disease Control and Prevention, has issued an EUA for the investigational antiviral drug intravenous (i.v.) peramivir in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. Specifically, i.v. peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an i.v. drug is clinically appropriate, based on specific reasons

In addition to the U.S. Government order that came from the request for proposal (RFP) negotiations, BioCryst has donated and transferred to HHS an initial supply sufficient for 1,200 courses of i.v. peramivir 600 mg once-daily for five days. This transfer was made under the development contract with HHS to allow doctors and patients near-term access to the drug, and is separate from the RFP process.

Development of intramuscular peramivir

In May 2009, we announced preliminary results from the Phase 2 study of i.m. peramivir for the treatment of seasonal influenza. While the study demonstrated a numerical trend in its primary endpoint of improvement in the median time to alleviation of symptoms (TTAS) in subjects with confirmed, acute, uncomplicated influenza infection versus placebo, the difference between the two study groups was not statistically significant.

The median TTAS was 91.1 hours for those receiving a single 600 mg injection of i.m. peramivir, compared to 106.9 hours observed in those patients receiving placebo (p=0.22). The trial indicated that peramivir was generally safe and well tolerated with a similar adverse event profile noted in the peramivir and placebo treatment groups.

This Phase 2 study was a randomized, double-blind, placebo-controlled trial conducted in influenza seasons in the Southern Hemisphere (Australia, New Zealand and South Africa) in 2008 and the Northern Hemisphere (United States) in 2008 to 2009. It enrolled 405 subjects 18 years of age or older with acute uncomplicated influenza confirmed by positive rapid antigen test, whose symptom duration was 36 hours or less. The primary analysis population consisted of patients with confirmed influenza A. Approximately 79 percent of subjects with influenza A demonstrated the H274Y mutation. As reported in the CDCFluView Weekly Influenza Report, this mutation has been associated with resistance to the anti-viral treatment oseltamivir.

We are not planning additional development of i.m. peramivir at this time; instead, our current efforts are focused on development of the i.v. formulation.

Shionogi & Co., Ltd. development of intravenous peramivir for the treatment of influenza in the outpatient setting

In October 2008, we and our partner, Shionogi & Co., Ltd. of Japan, amended the license agreement to expand the territory in the agreement to include Taiwan and to provide rights for Shionogi to perform a Phase 3 clinical trial in Hong Kong. In July 2009, Shionogi announced positive results in two Phase 3 studies of i.v. peramivir. The studies were sponsored by Shionogi and conducted during the 2008-2009 influenza season. Shionogi and Green Cross Corporation, the license holder of peramivir in Korea, co-conducted the portion of the studies in Korea.

In patients with uncomplicated seasonal influenza, Shionogi conducted a multi-center, randomized, double-blind, multi-national Phase 3 study that compared the efficacy and safety of a single dose of peramivir (either 300 mg or 600 mg) and treatment with oral oseltamivir phosphate 75 mg (Tamiflu®) twice a day for five-days. A total of 1,099 patients were enrolled at 146 centers in Japan, Korea and Taiwan. Both the 300 mg and 600 mg single dose peramivir groups demonstrated non-inferiority for the primary endpoint, TTAS, compared to the oseltamivir group. The medians for TTAS for the peramivir 300 mg, peramivir 600 mg and oseltamivir groups were 78.0 hrs, 81.0 hrs and 81.8 hrs, respectively.

Additionally, Shionogi conducted a double-blind, multi-center Phase 3 study of i.v. peramivir with dosing over multiple days. The study enrolled 42 influenza patients at high-risk of serious complications due to one or more qualifying conditions: diagnosis with poorly controlled diabetes mellitus, a chronic respiratory disease requiring pharmacotherapy, or current treatment with any immunosuppressive drug. Peramivir was administered at 300 mg or 600 mg per day, and the duration was adjusted (up to five days) on a case-by-case basis, depending on the patient s temperature and clinical condition. In this study, the median time to alleviation of symptoms in all 37 evaluable patients treated with either 300 mg or 600 mg peramivir daily was 68.6 hours.

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I.V. peramivir 300 mg and 600 mg in both single and multiple doses were generally safe and well-tolerated in these trials. Further analyses of the study data, including secondary efficacy endpoints and detailed safety, is underway. Additional data will be submitted for presentation at an upcoming medical meeting.

Further, Shionogi recently filed its New Drug Application soon to seek regulatory approval for i.v. peramivir in Japan. This filing triggered a $7.0 million milestone payment to us under the current license agreement between the two companies.

Partnerships for peramivir for influenza outside the U.S.

We have signed binding letters of intent with three partners to exclusively represent us and our anti-viral peramivir for influenza stockpiling opportunities, as well as for marketing and distribution of peramivir for seasonal influenza upon local regulatory approval, within their territories outside the U.S. Each partner has initiated discussions with key government officials in their respective territories to discuss peramivir s availability during this global health emergency. Our new partners include moksha8 Pharmaceuticals, Inc. for Brazil and Mexico, NT Pharma (Group) Co., Ltd. for China and Neopharm Group for Israel. BioCryst is in discussions with each of the parties regarding definitive agreements.

Moksha8 Pharmaceuticals, Inc. (moksha8) has established broad commercial operations in Brazil and Mexico, the two key countries in Latin America that represent approximately 75% of the Latin America pharmaceutical market. Moksha8 indicates that it is currently selling over $200 million of products in the anti-infectives, central nervous system and inflammation indications under partnerships with Roche and Pfizer. Products in moksha8 s portfolio include key brands such as Rocephin, Bactrim, Lexotan and Rivotril.

NT Pharma (NT) was established in 1995 and has over 1,000 employees, corporate offices in Hong Kong and sales and marketing subsidiaries in Shanghai, Beijing, Guangzhou, Suzhou, Taizhou and Hainan for the distribution of pharmaceutical products including prescription medicine and vaccines. In 2009, NT states that they expect to achieve sales revenue of RMB 3 billion (U.S.$440 million), with a nationwide network that covers more than 100 cities, 1,500 hospitals and 12,000 points of vaccination, reaching over 90% of China s urban population.

The Neopharm Group (Neopharm) provides innovative integrated solutions across the health care spectrum. Throughout the years Neopharm has evolved into a diversified health care company. Building leadership and combining strengths in the areas of branded pharmaceuticals and biological products, vaccines (including H1N1 vaccine), hospital products, orphan drugs, medical devices and diagnostics has enabled Neopharm to become the second largest group in the Israeli healthcare market with annual sales of more than U.S.$300 million.

Study of BCX-4208

We have initiated a clinical study of BCX4208 for the treatment of gout. The study is a Phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of BCX4208 in subjects with gout. The study s primary objective is to determine the effect of different doses of orally administered BCX4208 on serum uric acid levels in patients with gout. The trial is expected to enroll up to 120 subjects.

Results of Operations (three months ended September 30, 2009 compared to the three months ended September 30, 2008)

For the three months ended September 30, 2009, collaborative and other research and development revenues were $10.5 million compared to $8.9 million for the three months ended September 30, 2008. This increase was the result of higher revenues from our contract with HHS for the development of peramivir and from our collaboration with Shionogi. The increase in revenues was offset by a reduction in revenue from our collaboration with Mundipharma, as well as lower amortization of deferred revenue from our collaboration arrangements. Included in revenue from HHS for the three months ended September 30, 2009 was approximately $2.0 million, which represents the difference between the provisional indirect rates billed to HHS during 2008 and the actual indirect rates as determined in the Company s annual incurred cost submission. This additional revenue will be subject to an audit performed by the government and any adjustments that could have a material impact would be recorded in future period(s).

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Research and development (R&D) expenses increased to $18.2 million for the third quarter of 2009 from $16.0 million for the third quarter of 2008. The higher R&D expenses resulted from an increase in manufacturing costs and consulting fees associated with our peramivir program, offset by reductions in clinical development costs for our peramivir and forodesine programs. In addition, general operating costs as well as personnel related costs were lower in the current quarter of 2009 compared to the same quarter of the prior year.

General and administrative (G&A) expenses increased to $3.1 million for the third quarter of 2009 from $2.5 million for the third quarter of 2008, primarily due to increases in legal and consulting fees.

Interest income for the three months ended September 30, 2009 was $0.1 million as compared to $0.6 million for the three months ended September 30, 2008. The decrease was driven by a lower average cash and securities balance as well as a significantly lower yield earned on interest-bearing assets.

The net loss for the third quarter of 2009 was $10.6 million, or $0.28 per share, compared to a net loss of $9.0 million, or $0.24 per share for the third quarter of 2008.

Results of Operations (nine months ended September 30, 2009 compared to the nine months ended September 30, 2008)

Collaborative and other R&D revenues decreased to $19.7 million for the nine months ended September 30, 2009 as compared to $22.3 million for the nine months ended September 30, 2008. This change was driven by a reduction in revenue from our collaboration with Mundipharma and lower amortization of deferred revenue from our collaboration arrangements. Revenues related to our contract with HHS for the development of peramivir were higher during the first nine months of the current year compared to the same period of last year due to a $4.9 million reserve recorded against revenue in 2008 for amounts we had previously expected to receive from HHS. In addition, revenue from our collaboration with Shionogi was higher during the nine months ended September 30, 2009.

R&D expenses decreased to $40.7 million for the first nine months of 2009 from $51.3 million for the same period of the prior year. The decrease in R&D expenses was due to a decrease in clinical development costs and toxicology costs associated with our peramivir and forodesine programs, a reduction in manufacturing costs associated with our forodesine program, and lower costs incurred on the pre-clinical compounds. In addition, general operating costs as well as personnel related costs were lower in the first nine months of 2009 compared to the first nine months of 2008. These reductions in R&D expenses were partially offset by an increases in manufacturing costs and consulting fees associated with our peramivir program.

G&A expenses decreased to $7.8 million for the nine months ended September 30, 2009 from $8.0 million for the nine months ended September 30, 2008. The lower expenses were primarily due to decreases in personnel related costs and consulting fees, offset by an increase in legal fees.

Interest income for the nine months ended September 30, 2009 was $0.2 million as compared to $2.2 million for the nine months ended September 30, 2008, due to a lower average cash and securities balance as well as significantly lower yield earned on interest-bearing assets.

The net loss for the nine months ended September 30, 2009 was $28.6 million, or $0.75 per share, compared to a net loss of $34.8 million, or $0.91 per share for the nine months ended 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 grants and contracts.

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.

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The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. Our policy is to place our cash, cash equivalents and investments with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. We have not realized any significant losses from our investments.

At December 31, 2008, we had long-term operating lease obligations, which provide for aggregate minimum payments of $641,323 in 2009, $575,246 in 2010 and $551,744 in 2011. 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;
- payments under collaborative and licensing agreements with corporate partners; and
- lease or loan financing and future public or private financing.

Our cash, cash equivalents and investments balance has decreased from $63.3 million as of December 31, 2008 to $38.5 million as of September 30, 2009, primarily due to monthly cash burn from operations offset by cash received from collaborations. As a result, our net cash burn rate has been approximately $2.8 million per month in 2009. Given certain manufacturing activities in anticipation of government needs, and pending certain clinical activities, we now expect our cash use for 2009 to be near the top end of the previous guidance range of $30 to $38 million. Cash use during the remainder 2009 will depend on potential events such as the level of i.v. peramivir manufacturing and stockpiling activities. During the upcoming planning cycle, the Company will align its cash needs and clinical development activities to carry its clinical programs through 2010.

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.

With the funds available at September 30, 2009 and future amounts that are expected to be received from HHS, Shionogi, and our other collaborators, we believe that our resources are sufficient to fund our operations for at least the next twelve months. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time.

Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- our ability to perform under the contract with HHS and receive reimbursement;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;

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- 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 and we may seek to raise capital at any time we deem market conditions to be favorable. 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, 2009, we are not involved in any unconsolidated entities or off-balance sheet arrangements.

Contractual Obligations

Our contractual obligations as of December 31, 2008 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, 2008.

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.

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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, 2008, 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 from 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 Mundipharma license agreement, we deferred the upfront payment over the remaining life of the patent, which is 2017. In the event a license agreement contains multiple deliverables, we evaluate whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

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 our partners 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

Our research and development costs are charged to expense when incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Major components of R&D expenses consist of personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of our manufacturing and our clinical and preclinical studies are performed by third-party CROs. We accrue costs for studies performed by CROs 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.

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.

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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Direct external R&D expenses by program:				
PNP Inhibitor (forodesine HCl)	$ 2,444	$ 3,662	$ 7,186	$ 11,497
Neuraminidase Inhibitor (peramivir)	9,778	4,984	15,713	17,698
Other	349	429	736	2,724
All other R&D expenses:				
Compensation and fringe benefits	3,044	3,649	9,252	10,185
Professional services	70	858	923	2,251
Travel	126	78	309	295
Operating and overhead allocation	2,370	2,336	6,564	6,617
Total R&D expenses	$ 18,181	$ 15,996	$ 40,683	$ 51,267

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

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

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Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. 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. To date, there have been no material changes to our estimates. Examples of estimated accrued expenses include:

- fees paid to CROs 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

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. 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.

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 negat 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 potential for a stockpiling order or profit from any order for peramivir;
- the potential use of peramivir as a treatment for H1N1 flu (or other strains of flu);
- our ability or the ability of our manufacturers to fully meet the demand for peramivir in the event of emergency use authorization or stockpiling;

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

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

our ability to establish and maintain collaborations;

plans, programs, filings, progress and potential success of our collaborations, including Mundipharma for forodesine 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 disclaim any obligation to update or revise the statements except as required by law. 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. Our policy is to place our cash, cash equivalents and investments with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. We have not realized any significant losses from our investments.

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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 of 1934, as amended (the Exchange Act) is recorded, processed, summarized and reported in a timely manner under the Exchange Act. 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, 2009, 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 Exchange Act, 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, 2009 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 2008 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, 2009. 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 or quality control 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 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 amount or profitability of any orders for peramivir by any government agency or other party, 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 and we may seek to raise capital at any time we deem market conditions to be favorable. 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 any 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 or other actions taken under the contract, 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. Further, HHS may challenge actions that we have taken or may take under our contract, which could negatively impact our operating results and cash flows.

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 extraordinary provisions which would not typically be found in commercial contracts. For instance, government contracts permit unilateral modification by the government, interpretation of relevant regulations (i.e., federal acquisition regulation clauses), and the ability to terminate without cause. As such, the company may be at a disadvantage as compared to other commercial contracts. In addition, U.S. government contracts are subject to audit and modification by the

government at its sole discretion. If the government terminates its contract with us for its convenience or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

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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 Mundipharma for the development and commercialization of forodesine and with each of Shionogi and Green Cross for the development and commercialization of peramivir. 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;
- we may have disputes with a partner that could lead to litigation or arbitration;

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- 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.

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;
- 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.

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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 applicable FDA current Good Laboratory Practices, or cGLP, current Good Manufacturing Practices, or cGMP and current Good Clinical Practices, or cGCP, and comparable foreign standards. 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., and our business, financial condition and results of operations could be materially adversely affected.

Our development peramivir for 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 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 pandemic treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines could substantially replace potential demand for an antiviral such as peramivir;

any substantial demand for avian flu treatments or other pandemic flu treatment 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;

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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.

There are risks related to the potential emergency use or sale of peramivir.

To the extent that peramivir is used as a treatment for H1N1 flu (or other strains of flu), there can be no assurance that it will prove to be generally safe, well tolerated and effective. Emergency use of peramivir may create certain liabilities for the company. There is no assurance that we or our manufacturers will be able to fully meet the demand for peramivir in the event of additional orders. Further, we may not achieve a favorable price for additional orders of peramivir in the U.S. or in any other country. Our competitors may develop products that could compete with or replace peramivir.

There is no assurance that the non-U.S. partnerships that we have entered into for peramivir will result in any order for peramivir in those countries. There is no assurance that peramivir will be approved for emergency use or will achieve market approval in those countries. In the event that any emergency use is granted, there is no assurance that any order by any non-U.S. partnership will be substantial or will be profitable to the company. The sale of peramivir, emergency use or other use of peramivir in any country may create certain liabilities for the company.

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 and export laws of the U.S. 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.

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In June 1995, we notified the FDA that we submitted incorrect data for our Phase 2 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 2 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.

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. With respect to the neuraminidase inhibitors, these companies may develop i.v. formulations that could compete with peramivir. Further, 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.

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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. Further, our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. The validity, scope, enforceability and commercial value of these rights, therefore, is highly uncertain.

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

If we or our partners are unable or fail to adequately initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of the drug product candidates 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 trade name, 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 trade name 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.

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

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license 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 approximately $11.0 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.

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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.

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, 2009, the 52-week range of the market price of our stock was from $0.85 to $13.47 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.

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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.

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

On November 4, 2009, the Company received an initial order for 10,000 courses of i.v. peramivir with a value of $22.5 million under a newly issued contract with HHS. The Company shipped the entire order from existing i.v. peramivir inventory to HHS on November 4, 2009.

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 5th day of November 2009.

BIOCRYST PHARMACEUTICALS, INC.

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

/s/ Stuart Grant
Stuart Grant
Chief Financial Officer

/s/ J. Michael Mills
J. Michael Mills
Controller and Principal Accounting Officer

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INDEX TO EXHIBITS

Number	Description
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.
10.1	Amendment #9 to the Agreement between the Company and the U.S. Department of Health & Human Services, dated September 18, 2009.
10.2	Amendment #10 to the Agreement between the Company and the U.S. Department of Health & Human Services, dated October 15, 2009.
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.