BIOCRYST PHARMACEUTICALS INC
Form 10-Q
August 06, 2010

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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 June 30, 2010
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 (Do not check if a smaller reporting company)	Smaller reporting company o

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 July 30, 2010 was 44,915,435.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
BALANCE SHEETS
June 30, 2010 and December 31, 2009
(In thousands, except per share data)

	2010 (Unaudited)	2009 (Note 1)
Assets		
Cash and cash equivalents	$ 14,021	$ 41,125
Restricted cash	625	625
Marketable securities	41,531	27,839
Receivables from collaborations	20,531	33,722
Inventories	907	6,281
Prepaid expenses and other current assets	1,421	1,056
Deferred collaboration expense	719	374
Total current assets	79,755	111,022
Marketable securities	24,981	24,670
Furniture and equipment, net	3,330	3,872
Deferred collaboration expense	8,037	2,626
Total assets	$ 116,103	$ 142,190
Liabilities and Stockholders Equity		
Accounts payable	$ 1,438	$ 18,070
Accrued expenses	10,250	15,795
Accrued vacation	861	839
Deferred rent	52	52
Deferred collaboration revenue	2,497	2,497
Total current liabilities	15,098	37,253
Deferred rent	204	230
Deferred collaboration revenue	17,193	18,441
Stockholders equity:		
Preferred stock: shares authorized 5,000 Series B Junior Participating Preferred Stock, $.001 par value; shares authorized 95; shares issued and outstanding none		
Common stock, $.01 par value: shares authorized 95,000; shares issued and outstanding 44,894 in 2010 and 43,907 in 2009	449	439
Additional paid-in capital	358,604	348,572
Accumulated other comprehensive income (loss)	63	(25)
Accumulated deficit	(275,508)	(262,720)
Total stockholders equity	83,608	86,266
Total liabilities and stockholders equity	$ 116,103	$ 142,190

See accompanying notes to financial statements.

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BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
Periods Ended June 30, 2010 and 2009
(In thousands, except per share data)
(Unaudited)

	Three Months		Six Months	
	2010	**2009**	**2010**	**2009**
Revenues				
Product sales	$	$	$ 325	$
Royalties			711	
Collaborative and other research and development	7,616	4,787	32,651	9,146
Total revenues	7,616	4,787	33,687	9,146
Expenses				
Cost of products sold			86	
Research and development	14,737	11,213	39,654	22,502
General and administrative	3,209	2,313	7,006	4,770
Total expenses	17,946	13,526	46,746	27,272
Loss from operations	(10,330)	(8,739)	(13,059)	(18,126)
Interest and other income	137	55	271	150
Net loss	$ (10,193)	$ (8,684)	$ (12,788)	$ (17,976)
Basic and diluted net loss per common share	$ (0.23)	$ (0.23)	$ (0.29)	$ (0.47)
Weighted average shares outstanding	44,517	38,232	44,222	38,218

See accompanying notes to financial statements.

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BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
Six Months Ended June 30, 2010 and 2009
(In thousands)
(Unaudited)

	2010	2009
Operating activities		
Net loss	$ (12,788)	$ (17,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	789	823
Stock-based compensation expense	3,566	2,794
Changes in operating assets and liabilities:		
Receivables from collaborations	13,191	3,907
Inventories	5,374	
Prepaid expenses and other current assets	(365)	(5,607)
Deferred collaboration expense	155	188
Accounts payable and accrued expenses	(22,155)	(3,620)
Deferred rent	(26)	49
Deferred collaboration revenue	(1,248)	(1,286)
Net cash used in operating activities	**(13,507)**	**(20,728)**
Investing activities		
Acquisitions of furniture and equipment	(247)	(371)
Purchases of marketable securities	(29,476)	(500)
Sales and maturities of marketable securities	15,561	12,963
Net cash (used in) provided by investing activities	**(14,162)**	**12,092**
Financing activities		
Exercise of stock options	480	13
Employee stock purchase plan sales	173	91
Common stock issuance costs	(84)	
Purchases of treasury stock	(4)	
Net cash provided by financing activities	**565**	**104**
Decrease in cash and cash equivalents	(27,104)	(8,532)
Cash and cash equivalents at beginning of period	41,125	22,342
Cash and cash equivalents at end of period	**$ 14,021**	**$ 13,810**

See accompanying notes to financial statements.

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

Note 1 Significant Accounting Policies

Basis of Presentation

The balance sheet as of June 30, 2010, the statements of operations for the three and six months ended June 30, 2010 and 2009, and the statements of cash flows for the six months ended June 30, 2010 and 2009 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 Company s financial position, results of operations, and cash flows. 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, 2009 and the notes thereto included in the Company s 2009 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, 2009 has been derived from the audited financial statements included in the Company s most recent Annual Report on Form 10-K.

Cash and Cash Equivalents

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

Restricted Cash

During 2009, the Company initiated a new corporate card program. As a result, the Company was required to place $625,000 into an interest bearing money market account to serve as collateral for the program.

Marketable Securities

The objective of the Company s investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities the Company invests 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, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe that it has a material exposure to interest rate risk arising from its investments. Generally, the Company s investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its marketable securities as available-for-sale. 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. The Company periodically reviews its securities available-for-sale for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. At June 30, 2010, the Company believes that the costs of its securities are recoverable in all material respects.

The following table summarizes the fair value of the Company s securities by type at June 30, 2010. The estimated fair value of the Company s 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. Amounts are in thousands.

	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 18,512	$ 29	$ 36	$	$ 18,577
Obligations of U.S. government agencies	17,751	87	21	(7)	17,852
Corporate debt securities	13,562	129	29	(27)	13,693
Commercial paper	13,873	1		(7)	13,867
Municipal obligations	2,502	3	18		2,523
Total marketable securities	$ 66,200	$ 249	$ 104	$ (41)	$ 66,512

The following table summarizes the scheduled maturity for the Company s securities available-for-sale at June 30, 2010. Amounts are in thousands.

	2010
Maturing in one year or less	$ 41,531
Maturing after one year through two years	23,756
Maturing after two years	1,225
Total marketable securities	$ 66,512

Receivables from Collaborations

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At June 30, 2010, the Company had the following receivables from collaborations. Amounts are in thousands.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 4,953	$ 15,488	$ 20,441
Other	32	58	90
Total	$ 4,985	$ 15,546	$ 20,531

Included in receivables from the U.S. Department of Health and Human Services (HHS) is $8,354,000 related to indirect cost rate adjustments for calendar years 2007, 2008, 2009, and 2010. These adjustments are calculated as the difference between the actual indirect costs incurred against the contract during a calendar year and the indirect costs that are invoiced at a provisional billing rate during the calendar year. Because these adjustment amounts represent actual costs incurred in performance of the contract and the costs are allowable, reasonable, and allocable to the contract, the Company has recorded revenue accordingly. The Company s calculations of its indirect cost rates are subject to an audit by the federal government. The Company does not anticipate receiving payment for these indirect cost rate adjustments until those audits have been completed.

Inventories

Inventories on hand as of June 30, 2010 are related to peramivir manufacturing supplies (vials, stoppers, and seals) that are unused and have an alternative future use.

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, 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.

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In accordance with generally accepted accounting principles, the Company periodically reviews its furniture and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Furniture and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Patents and Licenses

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

Accrued Expenses

The Company records all expenses in the period incurred. In addition to recording expenses for invoices received, the Company estimates the cost of services provided by third parties or materials purchased for which no invoices have been received as of the balance sheet dates. Accrued expenses as of June 30, 2010 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 the Company s accounting for 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 (Loss)

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 $63,000 of unrealized gains on its securities available-for-sale that are included in accumulated other comprehensive income at June 30, 2010.

Other comprehensive loss for the periods ended June 30, 2010 and 2009 appear in the following table. Amounts are in thousands.

	Three Months		**Six Months**	
	2010	**2009**	**2010**	**2009**
Net loss	$ (10,193)	$ (8,684)	$ (12,788)	$ (17,976)
Unrealized (loss) gain on securities available-for-sale	(14)	(28)	88	(63)
Other comprehensive loss	$ (10,207)	$ (8,712)	$ (12,700)	$ (18,039)

Revenue Recognition

Prior to the fourth quarter of 2009, 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 is recognized 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. Under the Company s contract with HHS, revenue is recognized as reimbursable when direct and indirect costs are incurred.

During 2010, the Company recognized revenues related to product sales of peramivir. Sales are recognized when products are shipped, title and risk of loss have passed, and collectability is reasonably assured. The Company did not provide a right of product return in conjunction with these sales.

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.

The Company recorded the following revenues from collaborations for the periods ended June 30, 2010 and 2009. Amounts are in thousands.

	Three Months		Six Months	
	2010	**2009**	**2010**	**2009**
Product sales:				
NT Pharma, Co., Ltd.	$	$	$ 250	$
moksha8 Pharmaceuticals, Inc.			75	
Total product sales			325	
Royalties:				
Shionogi			711	
Total royalties			711	
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	6,924	4,148	17,613	7,806
Shionogi	296	296	13,375	605
Mundipharma	396	324	1,038	697
Green Cross		19	625	38
Total collaborative and other research and development revenues	7,616	4,787	32,651	9,146
Total revenues	$ 7,616	$ 4,787	$ 33,687	$ 9,146

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.

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 the Company to pay fees related to sublicense agreements or maintenance fees. Generally, 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 June 30, 2010, the Company had deferred collaboration expenses of approximately $8,756,000. Approximately $2,813,000 of 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.

The remaining $5,943,000 of the deferred expenses relates to consideration provided to AECOM and IRL (collectively, the Licensors) in May 2010 for modifications made to the existing licensing agreement. Under the terms of the amendment, the Company issued consideration in the form of common stock and cash to the Licensors in exchange for a reduction in the percentage of certain future payments the Company receives from third-party sub-licensees that must be paid to the Licensors (see Note 3 for further information). Amortization of this deferred expense began in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. The Company believes that this accounting treatment is reasonable and consistent with its collaboration accounting policies.

Stock-Based Compensation

All 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.

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 the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Note 2 Stock-Based Compensation

As of June 30, 2010, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan), which was amended and restated in March 2010 and approved by the Company s stockholders in May 2010, and the Employee Stock Purchase Plan (ESPP), which was also amended and restated in March 2010 and approved by the Company s stockholders in May 2010. 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 $3,566,000 ($3,414,000 of expense related to the Incentive Plan, $77,000 of expense related to the ESPP, and $75,000 of expense related to the inducement grant) was recognized during the first six months of 2010, while $2,794,000 ($2,614,000 of expense related to the Incentive Plan, $105,000 of expense related to the ESPP, and $75,000 of expense related to the inducement grant) was recognized during the first six months of 2009.

There was approximately $8,954,000 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of June 30, 2010. That cost is expected to be recognized as follows: $2,511,000 in 2010, $2,835,000 in 2011, $1,842,000 in 2012, $1,530,000 in 2013, and $236,000 in 2014.

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Stock Incentive Plan

The Company grants stock option awards and restricted stock awards to its employees, directors, and consultants 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, 2009	1,773,372	5,826,528	$ 6.58
Plan amendment	1,300,000		
Stock option awards granted	(1,483,820)	1,483,820	6.73
Stock option awards exercised		(196,421)	2.45
Stock option awards canceled	104,017	(104,017)	10.12
Balance June 30, 2010	1,693,569	7,009,910	6.67

For stock option awards granted under the Incentive Plan during the first six months of 2010 and 2009, 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 six months of 2010 and 2009 was $4.69 and $1.10, 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 six months of 2010 and 2009. 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 paid 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

	2010	2009
Expected Life in Years	5.5	5.6
Expected Volatility	89.1%	104.7%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	2.5%	2.1%

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 vested on December 31, 2009.

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Employee Stock Purchase Plan

The Company has reserved a total of 825,000 shares of common stock to be purchased under the ESPP, of which 251,766 shares remain available for purchase at June 30, 2010. 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 29,728 shares during the first six months of 2010 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.

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 June 30, 2010, 7,916 shares granted under the restricted stock awards have vested.

Note 3 Collaborative Agreements

U.S. Department of Health and Human Services (HHS). 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 costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit. HHS will make periodic assessments of progress and the continuation of the contract is based on the Company s performance, the timeliness and quality of deliverables, and other factors. The contract is terminable by the government at any time for breach or without cause.

In September 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.

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 UAB on the upfront payment and 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 initially 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 its initiation of a Phase 2 clinical trial with i.v. peramivir. In November 2009, the Company received a second $7.0 million milestone payment from Shionogi for its filing of a New Drug Application (NDA) in Japan to seek regulatory approval for i.v. peramivir. In January 2010, the Company received a third $7.0 million milestone payment from Shionogi related to its achievement in obtaining marketing and manufacturing approval of i.v. peramivir in Japan.

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 in August 2006 and continued through November 2009.

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 purine nucleoside phosphorylase (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 possibility of 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.

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 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 discussion to resolve this dispute. The maximum potential exposure to the Company is estimated to be approximately $2.0 million. No amounts have been accrued as of June 30, 2010.

AECOM and IRL. In June 2000, the Company licensed a series of potent PNP inhibitors from the Licensors. The license agreement was amended in July 2002, April 2005, December 2009 and May 2010. The lead drug candidates from this collaboration are forodesine and BCX4208. 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 PNP inhibitors. The Company has the option to expand the agreement to include other inventions in the field made by the investigators or employees of the Licensors. The Company has agreed to use commercially reasonable efforts to develop these drugs. This license 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 the Licensors.

In addition, the Company 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 third-party sublicensees of the licensed PNP inhibitors, if any. The Company also agreed to pay annual license fees ranging from $150,000 to $500,000, creditable against actual royalties and other payments due to the Licensors.

In May 2010, the Company and the Licensors agreed to further amend the terms of the license agreement. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sublicensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone payments the Company may receive in the future under its license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from sublicensees of the Company in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by the Company remains unchanged.

In consideration for the modifications to the license agreement, the Company issued to the Licensors shares of the Company s common stock with an aggregate value of approximately $5.9 million, based upon the volume weighted average price of the Company s common stock for the twenty trading days preceding the date of the amendment, resulting in 761,326 shares issued. These shares were issued pursuant to the Company s effective registration statement on Form S-3. The Company also paid the Licensors approximately $90,000 in order to correct a calculation error with respect to the number of shares that were issued. The consideration issued to the Licensors related to the modification began to be amortized to expense in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. The Licensors agreed that they would not, during any trading day, sell or otherwise transfer or dispose of more than an amount of shares equal to thirty percent of the average daily number of shares of the Company s common stock traded over the previous ten trading days. The Company also agreed to pay certain fees or commissions incurred by the Licensors in connection with subsequent sales of the shares issued pursuant to the amendment.

Additionally, at the Company s sole option and subject to certain agreed upon conditions, any future non-royalty payments due to be paid by the Company to the Licensors under the license agreement may be made either in cash, in shares of the Company s common stock, or in a combination of cash and shares.

UAB. 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 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 each party shall cease using the other party s 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

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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, the Company will owe sublicense fees or royalties on amounts it receives.

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

The Company has incurred net losses since inception and, consequently, has not recorded any U.S. federal and state income taxes. The majority of the Company s deferred tax assets relate to net operating loss and research and development 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 these carryforwards. Accordingly, the Company has provided a full 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 assets until it is more likely than not that the related tax benefits will be realized.

As of December 31, 2009, the Company had net federal operating loss carryforwards of $187,427,790, net state operating loss carryforwards of $224,656,598, and research and development credit carryforwards of $32,115,994, all of which expire at various dates from 2010 through 2029.

The Company recognizes the impact of a tax position in its financial statements if it is more likely than not that the position will be sustained on audit based on the technical merits of the position. The Company concluded at December 31, 2009 that it had one uncertain tax position pertaining to its research and development credit carryforwards. The Company has not yet conducted an in-depth study of its research and development credits. This study could result in an increase or decrease to the Company s research and development credits. Until studies are conducted of the Company s research and development credits, no amounts are being recorded as an unrecognized tax benefits, separate from the valuation allowance against deferred tax assets. Any future changes to the Company s unrecognized tax benefits would be offset by an adjustment to the valuation allowance and there would be no impact on the Company s financial statements.

Additionally, utilization of the Company s net operating loss carryforwards could be subject to a substantial annual limitation due to ownership change limitations described in Section 382 of the Internal Revenue Code and similar state provisions. The annual limitations could result in the expiration of net operating loss carryforwards before utilization. The Company has not performed a Section 382 change in control study since 2007 in order to determine if there is an annual limitation on the amount of net operating loss carryforward that can be deducted in any single year. However, it is not anticipated that any such analysis would have an impact on the Company s financial statements as a result of offsetting changes in the valuation allowance.

Tax years 2006-2008 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2006 are also open to examination to the extent of loss and credit carryforwards from those years. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as components of its income tax provision. However, there were no provisions or accruals for interest and penalties during the six months ended June 30, 2010 and 2009.

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

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Commission, including the Company s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See Information Regarding Forward-Looking Statements.

Recent Corporate Highlights

Peramivir

Collaborative Agreements. In January 2007, the U.S. Department of Health and Human Services (HHS) awarded us a $102.6 million, four-year contract for the advanced development of peramivir. In September 2009, we received an award of $77.2 million toward completion of the Phase 3 development of intravenous (i.v.) peramivir pursuant to a 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. Any funding above the $179.9 million may be our responsibility. Through June 30, 2010, we have recognized approximately $132.7 million of revenue against the contract with HHS.

We have determined that there is an excess of up to $5.0 million of peramivir active pharmaceutical ingredient (API) manufactured under the contract with HHS. This excess API is beyond the amount necessary to support U.S. regulatory approval. HHS has acknowledged that at least half of the Company s estimate is excess. We are evaluating whether additional quantities of peramivir API are needed by the Company, and if so, the acquisition process to obtain the API from HHS.

In January 2006, the Company received U.S. Food and Drug Administration (FDA) Fast Track designation for peramivir. In October 2009, the FDA granted an Emergency Use Authorization (EUA) for i.v. peramivir, which expired in June 2010 with the expiration of the declared emergency. As a result, peramivir is now only available in the U.S. through clinical trials. 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. On November 4, 2009 we received an initial order for 10,000 courses of i.v. peramivir (600 mg once-daily for five days) for an aggregate purchase price of $22.5 million. We shipped the entire order from existing i.v. peramivir inventory to HHS on November 4, 2009. Under the Indefinite Delivery Indefinite Quantity contract issued to us on November 3, 2009, HHS may place additional orders for peramivir up to a total of 40,000 courses at the same unit price as the first order. We are also required to maintain the ability to manufacture additional treatment courses dependent on the volume and size of anti-viral orders received from HHS. In addition, separate from the RFP process, we have donated and transferred to HHS an initial supply sufficient for 1,200 courses of i.v. peramivir 600 mg once-daily for five days.

The minimum and maximum quantities of i.v. peramivir that may be ordered by HHS under the RFP are 1,000 and 40,000 treatment courses. We also are required to maintain the ability to manufacture additional courses for treatment or prophylaxis, dependent on the volume and size of orders received from HHS. Based on the RFP, we initiated manufacture of approximately 130,000 courses of i.v. peramivir at a cost of approximately $10.0 million, so that we would have additional inventory available in advance of potential orders. In addition, we have sufficient quantities of API of i.v. peramivir available to produce up to 350,000 additional courses.

In addition to the contract with HHS, in February 2007, we established a collaborative relationship with Shionogi & Co., Ltd. (Shionogi) for the development and commercialization of peramivir in Japan. We received an upfront payment of $14.0 million and the agreement provided for additional future clinical event milestone payments of up to $21.0 million. In October 2008, we and Shionogi 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 clinical trials of i.v. peramivir. The studies were sponsored by Shionogi and conducted during the 2008-2009 influenza season. Shionogi and Green Cross Corporation (Green Cross), the license holder of peramivir in Korea pursuant to a June 2006 license agreement with us, co-conducted the portion of the studies in Korea. Doses of i.v. peramivir of 300 mg and 600 mg, administered in single and multiple doses, were found to be generally safe and well-tolerated in these trials. Shionogi presented the data at the 2009 ICAAC / IDSA annual meeting in San Francisco, California.

Shionogi previously completed a Phase 2 study of i.v. peramivir administered via a single dose infusion in the outpatient setting for treatment of seasonal influenza. Shionogi presented the data at the 2008 ICAAC / IDSA annual meeting in Washington, D.C.

In January 2010, Shionogi received marketing and manufacturing approval for i.v. peramivir in Japan, and we received a third and final regulatory milestone payment of $7.0 million in January 2010 as a result of this approval. We may receive future commercial event milestone payments of up to $95.0 million from Shionogi. Shionogi has commercially launched peramivir under the commercial name RAPIACTA® in Japan. Shionogi has received the indications of single dose administration of 300 mg i.v. peramivir for adult uncomplicated seasonal influenza infection, as well as single and multiple dose administration of 600 mg i.v. peramivir for the patients at high-risk for complications associated with influenza. Shionogi is authorized to supply peramivir as either a 300 mg i.v. bag or a 150 mg vial for i.v. drip infusion. Shionogi also announced that it has completed clinical studies for pediatric patients and has filed an additional application for pediatric use of RAPIACTA® in Japan.

Additionally, in January 2010, we announced that Green Cross Corporation (Green Cross) had informed us that it had filed a New Drug Application (NDA) in South Korea to seek regulatory approval for i.v. peramivir to treat patients with influenza.

In addition to Shionogi and Green Cross, we have entered into several agreements with companies outside the U.S. to represent us and peramivir primarily for stockpiling opportunities. For example, on December 23, 2009, we entered into an agreement with Merck Serono, S.A., through its affiliate, Ares Trading S.A., to exclusively represent us and peramivir for stockpiling opportunities in Europe, Russia, Canada and Singapore. Also in December 2009, we entered into an agreement with Hikma Pharmaceuticals, PLC to represent us and peramivir for stockpiling opportunities in the Middle East and North Africa, excluding Israel. In January 2010 we entered into an agreement with moksha8 Pharmaceuticals, Inc. to exclusively represent us and peramivir for influenza stockpiling opportunities in Brazil and Mexico.

<u>Clinical Trials</u>. In July 2007, we initiated 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. 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. We presented the results at the XI International Symposium on Respiratory Viral Infection being held in Bangkok, Thailand in February 2009.

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. The combined enrollment target for these studies is approximately 700 patients, and approximately 300 study locations are targeted to participate in these studies globally. These studies are intended to support U.S. regulatory approval of i.v. peramivir as a treatment for influenza. The Phase 3 development program of i.v. peramivir is ongoing, with investigator sites enrolling patients in the southern hemisphere.

Additional studies to provide further evidence of the efficacy of i.v. peramivir are under discussion with the FDA and HHS.

Forodesine

An oral formulation of forodesine is currently in a pivotal trial for patients with CTCL. This trial is being conducted under an SPA agreement negotiated with the FDA and, if successful, will serve as a basis for an NDA to the FDA using the oral formulation in patients with relapsed CTCL. In January 2010, we announced that we had achieved our protocol-specific objective of enrolling 100 late-stage patients (Stage IIB to IVA) in this pivotal study. We expect to report top-line data on this study in the second half of 2010.

Long-term data from our Phase 2 study of forodesine in patients with CTCL was presented at the 45th Annual Meeting of the American Society of Clinical Oncology in May 2009. 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.

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The Phase 2 single-arm, open-label study evaluating 200 mg of forodesine twice-daily in patients with chronic lymphocytic leukemia (CLL) has reached its enrollment target of 26 patients and is ongoing. The Company expects to report data from this study in the second half of 2010.

BCX4208

In September 2009, we announced the initiation of a clinical study of BCX4208 for the treatment of gout, which is caused by elevated levels of uric acid in blood. We believe that BCX4208 is a good candidate to control gout because data from a prior Phase 2 clinical trial of BCX4208 for psoriasis indicated a dose related reduction in uric acid that was sustained for the duration of drug exposure. Our gout clinical trial was a Phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered BCX4208 in subjects with gout. The trial contained two parts: part one, which was a parallel-group study of multiple doses of BCX4208 randomized against a placebo and part two, which was a sequential-group study of escalating doses of BCX-4208, randomized against placebo.

In April 2010 we announced positive top-line results from a planned interim analysis of part one of our gout clinical study. The study s primary endpoint was the change in serum uric acid (sUA) concentration after 21 days of treatment compared to baseline concentration prior to treatment. Part one of the study randomized 60 gout patients with sUA concentrations greater than or equal to 8 mg/dL to placebo or to one of three different doses of BCX4208, a PNP inhibitor, administered once-daily for 21 days. All three doses of BCX4208 demonstrated a statistically significant reduction in sUA levels compared to placebo at day 22. BCX4208 doses of 40 mg, 80 mg and 120 mg per day showed median reductions in sUA levels of 2.7, 3.3 and 3.4 mg/dL, respectively.

The median reductions of sUA concentrations for these three doses ranged from 32.2 to 34.6 percent of baseline level. BCX4208 also demonstrated a statistically significant difference in the proportion of subjects with sUA levels less than 6 mg/dL, compared to subjects treated with placebo, on day 22. Among patients with a baseline sUA concentration below 10 mg/dL, up to 63 percent showed sUA levels below 6 mg/dL on day 22.

BCX4208 was generally safe and well-tolerated at the doses evaluated in part one of this study. Reductions in peripheral blood lymphocytes were observed in patients treated with BCX4208. The protocol included stopping rules for total lymphocyte counts and CD4+ cell counts below certain thresholds; no subjects were discontinued for these reasons, and all 60 subjects completed the first part of this study. Overall, the frequency of adverse events in each of the BCX4208 treatment groups was comparable to that observed in the placebo group. All patients received prophylactic medicine for gout flares; the incidence of gout flares observed was low.

We announced on August 5, 2010 that we achieved positive top-line results in part two of our gout clinical study, after completion of dose cohorts at 160 mg and 240 mg per day. The primary endpoint of part two of this study was the change in sUA concentration at day 22, following 21 days of once-daily treatment, compared to baseline sUA concentration prior to treatment. Data was evaluated using least square means (LSM) and an analysis of covariance (ANCOVA) model with factors for treatment and baseline sUA.

All doses of BCX4208 evaluated met the primary endpoint of the study, including both doses studied in part two. BCX4208 doses of 160 mg and 240 mg per day showed LSM reductions in sUA levels of 3.6 and 4.5 mg/dL at day 22 ($p<0.001$ for both doses), compared to placebo change of -0.02 mg/dL. The LSM reduction of sUA concentration percent change from baseline level was 35.7 percent for the 160 mg dose and 46.0 percent for the 240 mg dose ($p<0.001$ for both doses). BCX4208 also demonstrated a statistically significant difference in the proportion of subjects with sUA levels less than 6 mg/dL, compared to subjects treated with placebo, on day 22. The proportion of subjects achieving sUA levels less than 6 mg/dL was 47 percent for the 160 mg dose and 77 percent for the 240 mg dose, compared to zero percent in the placebo group.

Part two of the study was designed to sequentially evaluate the safety and efficacy of up to three higher doses (160 mg, 240 mg and 320 mg once-daily) of BCX4208, and included various stopping criteria related to both safety and efficacy. Enrollment in the study was closed after the 240 mg treatment group achieved two efficacy stopping criteria: greater than 4 mg/dL reduction in sUA from baseline, and greater than 60 percent of patients achieving sUA concentration below 6 mg/dL.

BCX4208 was generally safe and well-tolerated at all doses evaluated in this study. Reductions in peripheral blood lymphocytes were observed in patients treated with BCX4208. The protocol included individual subject stopping criteria for CD4+ cell counts below certain thresholds; no subjects were discontinued for this reason. Overall, the frequency of adverse events in each of the

BCX4208 treatment groups was comparable to that observed in the placebo group. Additional studies designed to evaluate longer-term exposure are needed to further define the safety and tolerability profile of BCX4208.

Detailed results from our gout clinical study will be submitted for presentation at an upcoming scientific meeting.

Additionally, on June 1, 2010, we announced that we were initiating a Phase 2 study of BCX4208 alone and in combination with allopurinol in patients with gout. This randomized, double-blind, multi-center, placebo-controlled study is designed to evaluate the urate-lowering activity and safety of several doses of BCX4208 alone and in combination with selected doses of allopurinol administered once-daily in patients with gout for 21 days. The enrollment target for this study is approximately 80 patients. The study utilizes a factorial design, evaluating BCX4208 at doses of 20 mg, 40 mg and 80 mg administered as monotherapy or in combination with allopurinol at doses of 100 mg, 200 mg and 300 mg. Allopurinol administered at 300 mg is the most common treatment dose for patients with gout. The doses of BCX4208 selected for this study have been found to be generally safe and well-tolerated in patients with psoriasis or gout. We expect to complete this study during 2010 and to provide top-line data by the end of 2010.

License Agreement with Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. (AECOM and IRL respectively).

In June 2000, we licensed a series of potent PNP inhibitors from AECOM and IRL (collectively, the Licensors). The license agreement was amended in July 2002, April 2005, December 2009 and May 2010. The lead drug candidates from this collaboration are forodesine and BCX4208. We have obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, drug candidates that might arise from research on these PNP inhibitors. We have the option to expand the agreement to include other inventions in the field made by the investigators or employees of the Licensors. We have agreed to use commercially reasonable efforts to develop these drugs. We may terminate the license agreement at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In addition, we 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 us, and to share approximately 25% of future payments received from third-party sublicensees of the licensed PNP inhibitors, if any. We also agreed to pay annual license fees ranging from $150,000 to $500,000, creditable against actual royalties and other payments due to the Licensors.

Effective May 5, 2010, we and the Licensors agreed to further amend the terms of the license agreement. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sublicensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone payments we may receive in the future under our license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from our sublicensees in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by us remains unchanged.

In consideration for the modifications to the license agreement, we issued to the Licensors shares of our common stock with an aggregate value of approximately $5.9 million, based upon the volume weighted average price of our common stock for the twenty trading days preceding the date of the amendment, resulting in 761,326 shares issued. These shares were issued pursuant to our effective registration statement on Form S-3. We also paid the Licensors approximately $90,000 in order to correct a calculation error with respect to the number of shares that were issued. The consideration issued to the Licensors related to the modification began to be amortized to expense in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. The Licensors agreed that they would not, during any trading day, sell or otherwise transfer or dispose of more than an amount of shares equal to thirty percent of the average daily number of shares of our common stock traded over the previous ten trading days. We also agreed to pay certain fees or commissions incurred by the Licensors in connection with subsequent sales of the shares issued pursuant to the amendment.

Additionally, at our sole option and subject to certain agreed upon conditions, any future non-royalty payments due to be paid by us to the Licensors under the license agreement may be made either in cash, in shares of our common stock, or in a combination of cash and shares.

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Results of Operations (three months ended June 30, 2010 compared to the three months ended June 30, 2009)

For the three months ended June 30, 2010, total revenues increased to $7.6 million compared to $4.8 million for the three months ended June 30, 2009. This $2.8 million increase was driven primarily by higher revenue from the contract with HHS for the continued development of i.v. peramivir.

Research and development (R&D) expenses increased to $14.7 million for the quarter from $11.2 million in the same quarter of last year. The $3.5 million increase resulted primarily from higher development costs associated with the BCX4208 program for the treatment of gout and the peramivir program for influenza. These increases in R&D expenses were partially offset by a decrease in development costs associated with the forodesine program.

General and administrative (G&A) expenses increased to $3.2 million for the second quarter of 2010 from $2.3 million in the same quarter as last year. This increase was primarily due to higher consulting fees and personnel related costs.

Our net loss for the three months ended June 30, 2010 was $10.2 million, or $0.23 per share, compared to a net loss of $8.7 million, or $0.23 per share for the three months ended June 30, 2009.

Results of Operations (six months ended June 30, 2010 compared to the six months ended June 30, 2009)

For the six months ended June 30, 2010, total revenues increased to $33.7 million compared to $9.1 million for the six months ended June 30, 2009. This $24.6 million increase was driven primarily by a $9.8 million increase in revenue from the contract with HHS, as well as the recognition of a $7.0 million milestone payment from the Company s partner, Shionogi, and the sale of $6.4 million of peramivir API to collaborators Shionogi and Green Cross during the first quarter of 2010.

R&D expenses increased to $39.7 million for the first half of 2010 from $22.5 million in same period as last year. This $17.2 million increase was primarily due to an increase of $7.4 million in development costs associated with the peramivir program, $6.3 million of manufacturing costs related to production of peramivir API for Shionogi and Green Cross, as well as higher development costs associated with the BCX4208 program. In addition, personnel related costs and general operating expenses were modestly higher during the first six months of 2010 as compared to the same period in 2009. These increases in R&D expenses were partially offset by lower development costs associated with the forodesine program.

G&A expenses increased to $7.0 million for the six months ended June 30, 2010 from $4.8 million for the six months ended June 30, 2009, primarily due to increases in consulting fees and personnel related costs.

The net loss for the six months ended June 30, 2010 was $12.8 million, or $0.29 per share, compared to a net loss of $18.0 million, or $0.47 per share for the six months ended June 30, 2009.

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 cash from collaborative and other research and development agreements, including government 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 projects 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.

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, 2009, we had long-term operating lease obligations, which provide for aggregate minimum payments of $565,000 in 2010, $854,000 in 2011 and $871,000 in 2012. 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.

As of June 30, 2010, we held cash, cash equivalents and securities of $81.2 million, a decrease of $13.1 million as compared to December 31, 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 $2.2 million per month for the first six months of 2010. We expect our 2010 cash use to be within, but at the high end of our previous guidance range of between $25.0 and $30.0 million. This is due in part to lower than expected royalty income as a result of the mild flu activity following approval of peramivir in Japan. In response, we have taken action to reduce costs, while maintaining momentum within our clinical programs. This outlook may change depending on the timing of payments from HHS related to our peramivir program.

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 June 30, 2010 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;
- 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;

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- 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 June 30, 2010, we are not involved in any unconsolidated entities or off-balance sheet arrangements.

Contractual Obligations

Our contractual obligations as of December 31, 2009 are described in our Annual Report on Form 10-K for the year ended December 31, 2009. There have been no material changes in contractual obligations outside the ordinary course of business since December 31, 2009.

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.

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Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates, which could have a material impact on the carrying values of assets and liabilities and the results of operations.

While our significant accounting policies are more fully described in Note 1 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009, 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

Prior to the fourth quarter of 2009, 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 is recognized 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. 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. 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. Under our contract with HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Royalty revenue is recognized based on estimates of royalties earned during the applicable period and adjusted for differences between the estimated and actual royalties in the following period.

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. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by contract research organizations (CROs), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of our manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by us over the service periods specified in the contracts and estimates are adjusted, 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 the University of Alabama at Birmingham (UAB), which require fees related to sublicense agreements or maintenance fees. Generally, 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.

At June 30, 2010, we had deferred collaboration expenses of approximately $8.8 million. Approximately $2.8 million of these deferred expenses were sub-license payments, paid to our academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

The remaining $6.0 million of the deferred expenses relates to consideration provided to Licensors in May 2010 for modifications made to the existing licensing agreement. Under the terms of the amendment, we issued consideration in the form of common stock and cash to the Licensors in exchange for a reduction in the percentage of certain future payments we receive from third-party sub-licensees that must be paid to the Licensors. Amortization of this deferred expense began in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. We believe that this accounting treatment is reasonable and consistent with our collaboration accounting policies.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Direct external R&D expenses by program:				
PNP Inhibitor (forodesine)	$ 1,174	$ 2,387	$ 3,675	$ 4,742
Neuraminidase Inhibitor (peramivir)	4,547	3,092	19,608	5,935
PNP Inhibitor (4208)	2,383	176	3,913	387
Other	488	28	564	
Indirect R&D expenses:				
Compensation and fringe benefits	3,744	3,024	6,988	6,208
Professional services	195	459	368	853
Travel	25	107	130	183
Overhead allocation and other	2,181	1,940	4,408	4,194
Total R&D expenses	$ 14,737	$ 11,213	$ 39,654	$ 22,502

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

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Factors in Part II, Item 1A of this Quarterly Report on Form 10-Q, 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.

Stock-Based Compensation

All 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 within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created in Section 21E. All statements other than statements of historical facts contained in this filing, are 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, predicts, potential, the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical 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);
- the ongoing and future preclinical or clinical development and commercialization of our product candidates, including peramivir, forodesine, BCX4208 and other PNP inhibitor and hepatitis C development programs;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our ability to establish and maintain collaborations;
- plans, programs, progress and potential success of our collaborations, including Mundipharma for forodesine 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 relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors. Any forward-looking statement reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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.

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 June 30, 2010, the Company s disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company 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 the Company in such reports is accumulated and communicated to the Company s management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2010 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

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.

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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.

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 that 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 product 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 product 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 product 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 product 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, we 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. We also have obligations with HHS under the Indefinite Delivery Indefinite Quantity contract issued in November 2009. 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 contracts 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 International Holdings Limited (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;

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 product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product 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 (cGLP), current Good Manufacturing Practices (cGMP) and current Good Clinical Practices (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 of 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 i.v. peramivir currently in clinical development may not prove to be safe and sufficiently effective for market approval in the United States or other major markets;
- 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 flu prevention or pandemic treatment concerns may not materialize at all, or in the near future;

advances in flu vaccines or other antivirals, including competitive i.v. antivirals, could substantially replace potential demand for peramivir;

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

government use of peramivir may compete with our clinical trials;

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 flu drugs and vaccines;

the only major markets in which patents relating to peramivir have issued or been allowed are the United States, Canada, Japan, Australia and many contracting and extension states of the European Union, while no patent applications or issued patents for peramivir exist in other potentially significant markets;

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. In January 2006, the Company received FDA Fast Track designation for peramivir. In October 2009, the FDA granted Emergency Use Authorization (EUA) for i.v. peramivir, which expired in June 2010 with the expiration of the declared emergency. As a result, peramivir is now only available in the U.S. through clinical trials.

Emergency use of peramivir may create certain liabilities for us. 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. There is no assurance that the FDA will grant another EUA for peramivir. Our competitors may develop products that could compete with or replace peramivir. We may face competition in markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

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 additional 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 us. The sale of peramivir, emergency use or other use of peramivir in any country may create certain liabilities for us.

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.

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.

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.

Recently enacted health care reform legislation in the United States may adversely affect our business and the potential return on future drug products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and approved the Health Care and Education Affordability Reconciliation Act (the Acts). These Acts will affect basic health care benefits, place limitations on health care spending, create large-scale health services and products purchasing organizations and, more specifically, impose an annual fee on the sale of branded prescription pharmaceuticals to federal health insurance programs such as Medicare and Medicaid. Our business strategy is dependent upon the commercial success of our future drug products, and the volume of sales of our future drug products will depend upon the availability of reimbursement from third-party payors, including government payors such as Medicare and Medicaid. The Acts may restrict the coverage and reimbursement of our future drug products by Medicare, Medicaid and other government programs and impose fees on our sales of future drug products. While we cannot predict how or to what extent these Acts or health care reform in general will affect us, restrictions on coverage, reimbursement of our future drug products, or the imposition of fees on future sales could have a material adverse affect on our business, financial condition and results of operations.

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

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

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

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

We and our partners are performing research on or developing products for the treatment of several disorders including T-cell mediated disorders (T-cell cancers and other autoimmune indications), gout, CTCL, CLL, 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.

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, we do not have worldwide patent protection for our product candidates and 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.

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.

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 unexpected 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 June 30, 2010, the 52-week range of the market price of our stock was from $3.65 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 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 6th day of August, 2010.

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

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	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed November 4, 2008.
3.4	Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company s Form 8-K filed November 4, 2008.
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*)	Fourth Amendment Agreement by and among Albert Einstein College of Medicine of Yeshiva University, Industrial Research Ltd. and BioCryst Pharmaceuticals, Inc., effective May 5, 2010. (Portions omitted pursuant to request for confidential treatment.)
10.2&	BioCryst Pharmaceuticals, Inc. Amended and Restated Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Company s Form 8-K filed on May 18, 2010.
10.3&	BioCryst Pharmaceuticals, Inc. Amended and Restated Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.2 to the Company s Form 8-K filed on May 18, 2010.
(31.1)	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(31.2)	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32.1)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(32.2)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Confidential treatment requested.

&

Management contracts.

( ) Filed herewith.

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