

BIOCRYST PHARMACEUTICALS INC

Form 10-Q

August 08, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2012

Commission File Number 000-23186

**BIOCRYST PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

DELAWARE  
(State of other jurisdiction of

62-1413174  
(I.R.S. Employer

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

incorporation or organization)

Identification No.)

4505 Emperor Blvd., Suite 200

Durham, North Carolina  
(Address of principal executive offices)

27003  
(Zip Code)

(919) 859-1302

(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  No

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  No

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  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

The number of shares of Common Stock, par value \$.01, of the Registrant outstanding as of July 31, 2012 was 50,493,786

**Table of Contents**

**BIOCRYST PHARMACEUTICALS, INC.**

**INDEX**

	<b>Page No.</b>
<u>Part I. Financial Information</u>	
<u>Item 1. Financial Statements:</u>	3
<u>Consolidated Balance Sheets June 30, 2012 and December 31, 2011</u>	3
<u>Consolidated Statements of Comprehensive Loss Three Months and Six Months Ended June 30, 2012 and 2011</u>	4
<u>Consolidated Statements of Cash Flows Six Months Ended June 30, 2012 and 2011</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>Item 4. Controls and Procedures</u>	30
<u>Part II. Other Information</u>	
<u>Item 1A. Risk Factors</u>	30
<u>Item 6. Exhibits</u>	43
<u>Signatures</u>	44
EX-10.1	
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****BIOCRYST PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****June 30, 2012 and December 31, 2011****(In thousands, except per share data)**

	<b>2012</b>	<b>2011</b>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Cash and cash equivalents	\$ 21,924	\$ 16,444
Restricted cash	2,230	625
Investments	12,958	25,274
Receivables from collaborations	5,084	5,831
Interest reserve	1,742	1,742
Inventories	263	263
Prepaid expenses and other current assets	344	378
Deferred collaboration expense	519	2,301
Total current assets	45,064	52,858
Investments	16,351	15,382
Furniture and equipment, net	882	1,098
Deferred collaboration expense	5,235	5,437
Other assets	8,704	7,433
Total assets	\$ 76,236	\$ 82,208
<b>Liabilities and Stockholders Equity</b>		
Accounts payable	\$ 3,328	\$ 2,497
Accrued expenses	8,206	12,616
Interest payable	3,500	1,400
Deferred collaboration revenue	4,072	9,786
Total current liabilities	19,106	26,299
Deferred collaboration revenue	6,512	7,103
Foreign currency derivative	4,959	4,000
Non-recourse notes payable	30,000	30,000
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.001 par value; shares authorized 5,000; no shares issued and outstanding		
Common stock, \$.01 par value: shares authorized 95,000; shares issued and outstanding 50,134 in 2012 and 45,662 in 2011	501	457
Additional paid-in capital	386,966	367,829
Accumulated other comprehensive income	40	40
Accumulated deficit	(371,848)	(353,520)

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

Total stockholders' equity	15,659	14,806
Total liabilities and stockholders' equity	\$ 76,236	\$ 82,208

See accompanying notes to consolidated financial statements.

**Table of Contents****BIOCRYST PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

Periods Ended June 30, 2012 and 2011

(In thousands, except per share data-Unaudited)

	Three Months		Six Months	
	2012	2011	2012	2011
<b>Revenues</b>				
Collaborative and other research and development	\$ 4,210	\$ 3,735	\$ 16,431	\$ 9,170
<b>Total revenues</b>	<b>4,210</b>	<b>3,735</b>	<b>16,431</b>	<b>9,170</b>
<b>Expenses</b>				
Research and development	12,777	14,442	28,302	27,941
General and administrative	1,609	3,536	3,306	6,971
<b>Total expenses</b>	<b>14,386</b>	<b>17,978</b>	<b>31,608</b>	<b>34,912</b>
Loss from operations	(10,176)	(14,243)	(15,177)	(25,742)
Interest and other income	57	136	128	239
Interest expense	(1,160)	(1,166)	(2,320)	(1,455)
Loss on foreign currency derivative	(997)	(998)	(959)	(2,340)
<b>Net loss</b>	<b>(12,276)</b>	<b>(16,271)</b>	<b>(18,328)</b>	<b>(29,298)</b>
Basic and diluted net loss per common share	\$ (0.25)	\$ (0.36)	\$ (0.38)	\$ (0.65)
Weighted average shares outstanding	49,218	45,111	48,161	45,063
Unrealized gain (loss) on investments	(9)	9		(14)
<b>Comprehensive loss</b>	<b>\$ (12,285)</b>	<b>\$ (16,262)</b>	<b>\$ (18,328)</b>	<b>\$ (29,312)</b>

See accompanying notes to consolidated financial statements.

**Table of Contents****BIOCRYST PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

Six Months Ended June 30, 2012 and 2011

(In thousands-Unaudited)

	2012	2011
<b>Operating activities</b>		
Net loss	\$ (18,328)	\$ (29,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	325	445
Stock-based compensation expense	2,178	2,728
Amortization of debt issuance costs	220	137
Change in fair value of foreign currency derivative	959	2,340
Changes in operating assets and liabilities:		
Receivables from collaborations	747	14,266
Prepaid expenses and other current assets	105	745
Deferred collaboration expense	1,984	977
Accounts payable and accrued expenses	(2,575)	(8,031)
Interest payable	2,100	1,318
Interest reserve		(3,000)
Deferred collaboration revenue	(6,305)	(425)
<b>Net cash used in operating activities</b>	<b>(18,590)</b>	<b>(17,798)</b>
<b>Investing activities</b>		
Acquisitions of furniture and equipment	(109)	(53)
Change in restricted cash	(1,605)	(791)
Purchases of investments	(14,534)	(27,676)
Sales and maturities of investments	25,811	26,189
<b>Net cash provided by (used in) investing activities</b>	<b>9,563</b>	<b>(2,331)</b>
<b>Financing activities</b>		
Exercise of stock options	510	238
Employee stock purchase plan sales	148	170
Purchases of treasury stock		(61)
Sale of common stock, net	15,339	(73)
Issuance of non-recourse notes payable		25,691
Payment of foreign currency derivative collateral	(1,490)	(2,450)
<b>Net cash provided by financing activities</b>	<b>14,507</b>	<b>23,515</b>
Increase in cash and cash equivalents	5,480	3,386
Cash and cash equivalents at beginning of period	16,444	13,622
<b>Cash and cash equivalents at end of period</b>	<b>\$ 21,924</b>	<b>\$ 17,008</b>

See accompanying notes to consolidated financial statements.

**Table of Contents**

**BIOCRYST PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**(In thousands, except per share amounts)**

**Note 1 Significant Accounting Policies**

***The Company***

BioCryst Pharmaceuticals, Inc. (the Company) is a biotechnology company that designs, optimizes and develops novel drugs that block key enzymes involved in the pathogenesis of disease related to therapeutic areas with unmet medical needs aligned with its capabilities and expertise. The Company was incorporated in Delaware in 1986 and its headquarters is located in Durham, North Carolina. Areas of interest for the Company are determined primarily by the scientific discoveries and the potential advantages that its experienced drug discovery group identifies, as well as by the associated potential commercial opportunity of those discoveries. The Company integrates the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design.

***Basis of Presentation***

Beginning in March 2011, the consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, JPR Royalty Sub LLC (Royalty Sub). Royalty Sub was formed in connection with a \$30,000 financing transaction the Company completed on March 9, 2011. See Note 4, Royalty Monetization, for a further description of this transaction. All intercompany transactions and balances have been eliminated.

The Company's financial statements became consolidated beginning in March 2011 with the creation of Royalty Sub, and have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. 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, 2011 and the notes thereto included in the Company's 2011 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, 2011 has been derived from the audited consolidated financial statements included in the Company's most recent Annual Report on Form 10-K.

***Reclassifications***

In the fourth quarter of 2011, the Company changed its classification of patent costs. This change resulted in \$387 and \$858 of patent expenses reclassified from general and administrative expense to research and development expense for the three months and six months ended June 30, 2011, respectively. Additionally, during the second quarter of 2012, the Company changed its classification of facilities costs and other costs directly related to its laboratory facility in Birmingham, Alabama from general and administrative expense to research and development expense. This change resulted in \$80 and \$176 of expenses being reclassified from general and administrative expense to research and development expense for the three months and six months ended June 30, 2011, respectively. These reclassifications had no effect on previously reported operating expenses or net loss amounts. Certain other balance sheet amounts as of December 31, 2011 have been reclassified to conform to the 2012 presentation.

***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. The carrying value of cash and cash equivalents approximates

fair value due to the short-term nature of these items.

***Restricted Cash***

Restricted cash as of June 30, 2012 includes \$300 (\$625 as of December 31, 2011) the Company is required to maintain in an interest bearing money market account to serve as collateral for a corporate credit card program and \$1,930 in royalty receipts paid by Shionogi & Co., Ltd. ( Shionogi ) designated for interest on the PhARMA Notes (defined in Note 4).

**Table of Contents****Investments**

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. 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 its credit exposure. Per its policy, the Company is able to invest in marketable debt securities that may consist of U.S. government and government agency securities, money market and mutual fund investments, municipal and corporate notes and bonds, commercial paper and asset or mortgage-backed securities, among others. The Company's investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of three years and requires an average portfolio maturity of no more than two years. 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 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 investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), 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 investments 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. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At June 30, 2012, the Company believes that the costs of its investments are recoverable in all material respects.

The following tables summarize the fair value of the Company's investments by type. The estimated fair value of the Company's fixed income investments are classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These valuations are based on observable direct and indirect inputs, primarily quoted prices of similar, but not identical, instruments in active markets or quoted prices for identical or similar instruments in markets that are not active. These fair values are obtained from independent pricing services which utilize Level 2 inputs.

			<b>June 30, 2012</b>		
	<b>Amortized Cost</b>	<b>Accrued Interest</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
U.S. Treasury securities	\$ 1,999	\$ 2	\$ 7	\$	\$ 2,008
Obligations of U.S. government and its agencies	10,213	12		(3)	10,222
Corporate debt securities	6,872	34	15		6,921
Commercial paper	1,399				1,399
Certificate of deposit	800				800
Municipal obligations	7,895	43	21		7,959
<b>Total investments</b>	<b>\$ 29,178</b>	<b>\$ 91</b>	<b>\$ 43</b>	<b>\$ (3)</b>	<b>\$ 29,309</b>

**Table of Contents**

	December 31, 2011				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	\$ 1,998	\$ 2	\$ 14	\$	\$ 2,014
Obligations of U.S. government and its agencies	5,000	10			5,010
Corporate debt securities	10,924	80	15	(9)	11,010
Commercial paper	10,939		2	(1)	10,940
Asset-backed securities	611				611
Certificate of deposit	801	1			802
Municipal obligations	10,182	68	21	(2)	10,269
<b>Total investments</b>	<b>\$ 40,455</b>	<b>\$ 161</b>	<b>\$ 52</b>	<b>\$ (12)</b>	<b>\$ 40,656</b>

The following table summarizes the scheduled maturity for the Company's investments at June 30, 2012.

Maturing in one year or less	\$ 12,958
Maturing after one year through two years	16,351
<b>Total investments</b>	<b>\$ 29,309</b>

**Receivables from Collaborations**

Receivables are recorded for amounts due to the Company, primarily 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, 2012, the Company had the following receivables from collaborations.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	\$ 681	\$ 4,403	\$ 5,084
<b>Total receivables from collaborations</b>	<b>\$ 681</b>	<b>\$ 4,403</b>	<b>\$ 5,084</b>

Monthly invoices are submitted to the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority ( BARDA/HHS ) related to reimbursable research and development costs. The Company is also entitled to monthly reimbursement of indirect costs based on rates stipulated in the underlying contract. The Company's calculations of its indirect cost rates are subject to audit by the federal government.

**Inventory**

At June 30, 2012 and December 31, 2011, the Company's inventory consisted of peramivir finished goods inventory and supplies for the manufacture of peramivir. Inventory is stated at the lower of cost, determined under the first-in, first-out ( FIFO ) method, or market. The Company expenses costs related to the production of inventories as research and development expenses in the period incurred until such time it is believed that future economic benefit is expected to be recognized, which generally is reliant upon receipt of regulatory approval. Upon regulatory approval, the Company capitalizes subsequent costs related to the production of inventories.



**Table of Contents**

During 2011, based on the annual variability of influenza, which impacts potential clinical and commercial demand and timing for peramivir administration as well as the costs to store and maintain supplies, the Company decided for economic reasons to reduce its supplies inventory, resulting in a \$635 charge in 2011. Upon disposal of this inventory in early January 2012, the supplies inventory and related reserve were reduced by \$635.

The Company's inventory consisted of the following as of June 30, 2012 and December 31, 2011:

	2012	2011
Supplies	\$ 263	\$ 898
Finished goods	3,980	3,980
Reserve for finished goods	(3,980)	(4,615)
Net inventories	\$ 263	\$ 263

***Patents and Licenses***

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

***Accrued Expenses***

The Company generally enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include:

fees paid to Clinical Research Organization ( CROs ) in connection with preclinical and toxicology studies and clinical trials;

fees paid to investigative sites in connection with clinical trials;

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

professional fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which



## **Table of Contents**

services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Accrued expenses as of June 30, 2012 and December 31, 2011 included \$5,459 and \$8,622, respectively, of research and development costs.

### ***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 (Loss) Income***

Accumulated other comprehensive (loss) income is comprised of unrealized gains and losses on investments available-for-sale and is disclosed as a separate component of stockholders' equity.

### ***Revenue Recognition***

The Company recognizes revenues from collaborative and other research and development arrangements and product sales.

### ***Collaborative and Other Research and Development Arrangements and Royalties***

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. In the event a license agreement contains multiple deliverables, the Company evaluates whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of our license agreements, the Company receives royalty payments based upon our licensees' net sales of covered products. Generally, under these agreements, the Company receives royalty reports from our licensees approximately one quarter in arrears, that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured.

Royalty revenue paid by Shionogi on their product sales is subject to returns. RAPIACTA<sup>®</sup> is a newly introduced product and there is not sufficient historical experience that can be used to reasonably estimate product returns. Therefore, the Company defers recognition of RAPIACTA<sup>®</sup> royalty revenue from Shionogi until the earlier of (1) a right of return no longer exists or (2) the Company has developed sufficient historical experience to estimate product returns. RAPIACTA<sup>®</sup> royalty payments received from Shionogi sales in 2011 were \$1,216 and during the six months ended June 30, 2012 were \$1,666.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss 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 BARDA/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

*Product Sales*

Sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates.

**Table of Contents**

The Company recorded the following revenues for the three and six months ended June 30, 2012 and 2011:

	Three Months		Six Months	
	2012	2011	2012	2011
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	\$ 3,914	\$ 3,111	\$ 8,073	\$ 7,772
Shionogi (Japan)	296	296	592	592
Mundipharma (United Kingdom)		328	7,766	720
Grants (United States)				86
Total revenues	\$ 4,210	\$ 3,735	\$ 16,431	\$ 9,170

**Research and Development Expenses**

The Company's research and development costs are charged to expense when incurred. Research and development expenses include all direct and indirect development costs related to the development of the Company's portfolio of drug candidates. 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 fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. The Company expenses maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners, and other consideration paid to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

**Stock-Based Compensation**

All share-based payments, including grants of stock option awards and restricted stock awards, are recognized in the Company's Consolidated Statement of Comprehensive Loss based on their fair values. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock awards is based on the grant date closing price of the common stock. Stock-based compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award.

**Interest Expense and Deferred Financing Costs**

Interest expense for the three months ended June 30, 2012 and 2011 was \$1,160 and \$1,166, respectively, and \$2,320 and \$1,455 for the six months ended June 30, 2012 and 2011, respectively, and relates to the issuance of the PhaRMA Notes (defined in Note 4). Costs directly

associated with the issuance of the PhaRMA Notes have been capitalized and are included in other non-current assets on the consolidated balance sheet. These costs are being amortized to interest expense over the term of the PhaRMA Notes using the effective interest rate method. Amortization of deferred financing costs included in interest expense was \$110 and \$105 for the three months ended June 30, 2012 and 2011, respectively, and \$220 and \$136 for the six months ended June 30, 2012 and 2011, respectively.

***Currency Hedge Agreement***

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement (defined in Note 4) to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market

## **Table of Contents**

adjustments resulted in a loss of \$997 and \$998 for the three months ended June 30, 2012 and 2011, respectively, and a loss of \$959 and \$2,340 for the six months ended June 30, 2012 and 2011, respectively. Mark-to-market adjustments are determined by a third party pricing model which uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on thresholds defined in the Currency Hedge Agreement. As of June 30, 2012, \$4,970 of hedge collateral was posted under the agreement and is recorded in other assets.

### ***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. The calculation of diluted earnings per share for the six months ended June 30, 2012 and 2011 does not include 9,172 and 8,128, respectively, of such potential common shares, as their impact would be anti-dilutive.

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

### ***Concentration of Market Risk***

The Company's primary source of revenue is reimbursement of peramivir development expenses, which was earned under the cost-plus-fixed-fee contract with BARDA/HHS. The Company relies on BARDA/HHS to reimburse predominantly all of the development costs for its peramivir program. Accordingly, reimbursement of these expenses represents a significant portion of the Company's collaborative and other research and development revenues. The completion or termination of this program/collaboration could negatively impact the Company's future Consolidated Statements of Comprehensive Loss and Cash Flows. The Company's drug development activities are performed by a limited group of third party vendors. If any of these vendors were unable to perform their services, this could significantly impact the Company's ability to complete its drug development activities.

### ***Credit Risk***

Cash equivalents and investments are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the Consolidated Balance Sheet. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 24 months or less.

### ***Recent Accounting Pronouncements***

In May 2011, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurements and Disclosure Requirement in U.S. GAAP and IFRS. This ASU modifies the existing standards to include disclosure of all transfers between Level 1 and Level 2 asset and liability fair value categories. In addition, the ASU provides guidance on measuring the fair value of financial instruments managed within a portfolio and the

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

application of premiums and discounts on fair value measurements. The ASU requires additional disclosure for Level 3 measurements regarding the sensitivity of fair value to changes in unobservable inputs and any interrelationships between those inputs. The Company adopted this guidance effective January 2012. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. This ASU eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. Under this new ASU, an entity can elect to present items of net income, other comprehensive income and total comprehensive income in one continuous statement or in two separate, but consecutive statements. The Company adopted this guidance effective January 1, 2012.

In December 2011, the FASB issued ASU 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05. This ASU defers the requirement in ASU 2011-05 to present reclassification adjustments for each component of accumulated other comprehensive income in both net income and other comprehensive income on the face of the financial statements. This ASU does not affect the requirement to present items of net income, other comprehensive income and total comprehensive income in one continuous statement or in two separate, but consecutive statements.

**Table of Contents****Note 2 Stock-Based Compensation**

As of June 30, 2012, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ( Incentive Plan ), which was amended and restated in March 2012 and approved by the Company's stockholders in May 2012, and the Employee Stock Purchase Plan ( ESPP ), which was amended and restated in March 2012 and approved by the Company's stockholders in May 2012. 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 \$2,178 (\$2,108 of expense related to the Incentive Plan and \$70 of expense related to the ESPP) was recognized during the first six months of 2012, while \$2,728 (\$2,603 of expense related to the Incentive Plan, \$88 of expense related to the ESPP, and \$37 of expense related to the inducement grant) was recognized during the first six months of 2011.

There was approximately \$9,912 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of June 30, 2012. That cost is expected to be recognized as follows: \$2,041 during the remainder of 2012, \$3,709 in 2013, \$2,538 in 2014, \$1,428 in 2015, and \$196 in 2016.

**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 closing market price of the Company's stock at the date of grant. Prior to March 1, 2011, 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. Commencing March 1, 2011, stock option awards granted to employees generally vest 25% each year until fully vested after four years. Stock option awards granted to non-employee directors of the Company generally vest monthly 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, 2011	2,010	7,858	\$ 6.21
Plan amendment	1,700		
Restricted stock awards granted	(415)		
Restricted stock awards cancelled	13		
Stock option awards granted	(1,563)	1,563	4.66
Stock option awards exercised		(303)	1.66
Stock option awards cancelled	419	(419)	8.32
Balance June 30, 2012	2,164	8,699	\$ 5.99

For stock option awards granted under the Incentive Plan during the first six months of 2012 and 2011, 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 per share of the awards granted during the first six months of 2012 and 2011 was \$3.04 and \$2.75, 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 table summarizes the key assumptions used by the Company to value the stock option awards granted during the first six months of 2012 and 2011. 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 the historical volatility on the Company's publicly traded common stock. 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.



**Table of Contents**

**Weighted Average Assumptions for Stock Option Awards Granted to  
Employees and Directors under the Incentive Plan**

	2012	2011
Expected Life in Years	5.5	5.5
Expected Volatility	87%	80%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	0.88%	2.20%

**Employee Stock Purchase Plan**

The Company has reserved a total of 975 shares of common stock to be purchased under the ESPP, of which 234 shares remain available for purchase at June 30, 2012. 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 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 or more in any one calendar year. The Company issued 52 shares during the first six months of 2012 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.

**Note 3 Collaborative and Other Research and Development Contracts**

*U.S. Department of Health and Human Services ( BARDA/HHS )*. In January 2007, BARDA/HHS awarded the Company a \$102,661, four-year contract for the advanced development of peramivir for the treatment of influenza. During 2009, peramivir clinical development shifted to focus on intravenous delivery and the treatment of hospitalized patients. To support this focus, a September 2009 contract modification was awarded to extend the intravenous ( i.v. ) peramivir program by 12 months and to increase funding by \$77,191. On February 24, 2011, the Company announced that BARDA/HHS had awarded it a \$55,000 contract modification, intended to fund completion of the Phase 3 development of i.v. peramivir for the treatment of patients hospitalized with influenza. This contract modification brings the total award from BARDA/HHS to \$234,852 and extends the contract term by 24 months through December 31, 2013, providing funding through completion of Phase 3 and to support the filing of a new drug application ( NDA ) to seek regulatory approval for i.v. peramivir in the U.S.

The contract with BARDA/HHS is 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. BARDA/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 BARDA/HHS at any time for breach or without cause.

*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 (the Shionogi Agreement ). Under the terms of the Shionogi Agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. The Company developed peramivir under a license from UAB and will owe sublicense payments to UAB on any future milestone 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. Shionogi has commercially launched peramivir under the commercial name RAPIACTA® 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. 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.

*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 forodesine, a Purine Nucleoside Phosphorylase ( PNP ) inhibitor, for use in oncology (the Original Agreement ). Under the terms of the Original Agreement, Mundipharma obtained rights to forodesine in markets across Europe, Asia, and Australasia in exchange for a \$10,000 up-front payment.

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

The Company deferred revenue recognition of the \$10,000 up-front payment that was received from Mundipharma in February 2006 because the Company was involved in the continued development of forodesine. Amortization of this revenue commenced in February 2006 and was initially scheduled to end in October 2017, which is the date of expiration for the last-to-expire patent covered by the agreement. The Company also deferred revenue recognition of a \$5,000 payment received

---

**Table of Contents**

from Mundipharma in connection with the initiation of a clinical trial in 2007. Amortization of this deferred revenue commenced in 2007 and was initially scheduled to end in October 2017. Under its agreement with AECOM/IRL, the Company paid sublicense payments related to these upfront cash payments received from Mundipharma. Expense recognition of these sublicense payments was deferred and recognized under the same term as the related deferred revenue.

On November 11, 2011, the Company entered into the Amended and Restated License and Development Agreement (the Amended and Restated Agreement) with Mundipharma, amending and restating the Original Agreement. Under the terms of the Amended and Restated Agreement, Mundipharma obtained worldwide rights to forodesine. Commencing on November 11, 2011, Mundipharma controls the development and commercialization of forodesine and assumes all future development and commercialization costs. Since the Company is no longer associated with the development of forodesine, amortization of the deferred revenue and expense associated with the Original Agreement ceased immediately. Mundipharma also purchased from the Company certain drug substance for forodesine at a cost of approximately \$901. The Amended and Restated Agreement provides for the possibility of future event payments totaling \$15,000 for achieving specified regulatory events for certain indications and tiered royalties ranging from mid to high single-digit percentages of net product sales in each country where forodesine is sold by Mundipharma. These royalties are subject to downward adjustments based on the then-existing patent coverage and/or the availability of generic compounds in each country.

The Amended and Restated Agreement is a multiple element arrangement for accounting purposes, in which the Company is required to deliver to Mundipharma both the worldwide rights to forodesine in the field of oncology and the transfer of product data and know-how to permit Mundipharma to develop and commercialize forodesine (the Knowledge Transfer). Without completion of the Knowledge Transfer, Mundipharma would not be able to develop and commercialize forodesine in the U.S. The Company accounted for these elements as a combined unit of accounting as they do not have stand-alone value to Mundipharma. The worldwide license rights were granted to Mundipharma on November 11, 2011. The Knowledge Transfer commenced in 2011 and was completed during the first quarter of 2012. Completion of the Knowledge Transfer concludes the Company's obligations under the Amended and Restated Agreement and resulted in the recognition of the unamortized deferred revenue and expense of \$7,766 and \$1,864, respectively, in the Consolidated Statements of Comprehensive Loss for the six months ended June 30, 2012. Recognition of these deferred amounts resulted in a \$2,337 decrease in the Company's deferred tax assets, with an equal reduction to the valuation allowance, resulting in no impact to net deferred tax assets.

*Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. (AECOM and IRL respectively).* In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL (collectively, the Licensors). The lead drug candidates from this collaboration are forodesine and ulodesine (formerly referred to as 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 inhibitors. The Company has since granted the worldwide license rights to develop forodesine to Mundipharma. 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 agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from \$1,400 to almost \$4,000 per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from \$150 to \$500, that are creditable against actual royalties and other payments due to the Licensors. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In May 2010, the Company amended the license agreement through which the Company obtained worldwide exclusive rights to develop and ultimately distribute any drug candidates that might arise from research on a series of PNP inhibitors, including forodesine and ulodesine. 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 its 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 the Company remains unchanged.

In consideration for these modifications in 2010, the Company issued to the Licensors shares of its common stock with an aggregate value of \$5,911 and paid the Licensors \$90 in cash. Additionally, at the Company's sole option and subject to certain agreed-upon conditions, any future non-royalty payments due to be paid by it to the Licensors under the license agreement may be made either in cash, in shares of its common stock, or in a combination of cash and shares.

On November 17, 2011, the Company further amended its agreements with the Licensors whereby the Licensors agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined in the license agreement) received by the Company under its Amended and Restated Agreement with Mundipharma that will be paid to AECOM/IRL.



## **Table of Contents**

On June 19, 2012, the Company further amended its agreement with the Licensors to include a compound for use in the field of antivirals and to clarify the exclusion of certain compounds for use as antibacterials.

*The University of Alabama at Birmingham ( 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, both parties shall cease using the other parties' proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi and Green Cross agreements, or commercializes products related to these programs, 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 will cease using the licensed technology.

### **Note 4 Royalty Monetization**

#### ***Overview***

On March 9, 2011, the Company completed a \$30,000 financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from the Company the rights to market RAPIACTA® in Japan and, if approved for commercial sale, Taiwan. The Company received net proceeds of \$22,691 from the transaction after transaction costs of \$4,309 and the establishment of a \$3,000 interest reserve account by Royalty Sub, which will be available to help cover interest shortfalls in the future. As of June 30, 2012, \$1,742 remains in the interest reserve account for future interest payments.

As part of the transaction, the Company entered into a purchase and sale agreement dated as of March 9, 2011 with Royalty Sub, whereby the Company transferred to Royalty Sub, among other things, (i) its rights to receive certain royalty and milestone payments from Shionogi arising under the Shionogi Agreement, and (ii) the right to receive payments under a Japanese yen/US dollar foreign currency hedge arrangement (as further described below, the Currency Hedge Agreement ) put into place by the Company in connection with the transaction. Royalty payments will be paid by Shionogi in Japanese yen and milestone payments will be paid in U.S. dollars. The Company's collaboration with Shionogi was not impacted as a result of this transaction.

#### ***Non-Recourse Notes Payable***

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of \$30,000 in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the PhaRMA Notes ). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the Indenture ), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes issued are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. The PhaRMA Notes bear interest at 14% per annum, payable annually in arrears on September 1<sup>st</sup> of each year, beginning on September 1, 2011 (the Payment Date ). The Company remains entitled to receive any royalties and milestone payments related to sales of RAPIACTA® by Shionogi following repayment of the PhaRMA Notes.

Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of the Company's pledge of its equity interests in Royalty Sub in support of the PhaRMA Notes. The Company may, but is not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhaRMA Notes.

On September 1, 2012, \$4,200 of interest will be due and payable on the PhaRMA Notes. Based on royalty payments received from RAPIACTA® sales of \$1,930 (from September 2, 2011 through June 30, 2012) and the \$1,742 remaining balance in the interest reserve account,

the Company currently estimates that there will be an interest shortfall of approximately \$528 on

**Table of Contents**

September 1, 2012 Payment Date. As stipulated under the PhaRMA Notes Indenture, if the amounts available for payment on any Payment Date are insufficient to pay all of the interest due on a Payment Date, unless sufficient capital is contributed to Royalty Sub by the Company as permitted under the Indenture or the interest reserve account is available to make such payment, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Under the terms of the Indenture, Royalty Sub's inability to pay the full amount of interest payable on September 1, 2012 will not constitute an event of default under the PhaRMA Notes unless Royalty Sub fails to pay such unpaid interest, plus interest thereon, on or prior to the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2013.

The Indenture does not contain any financial covenants. The Indenture includes customary representations and warranties of Royalty Sub, affirmative and negative covenants of Royalty Sub, Events of Default and related remedies, and provisions regarding the duties of the Trustee, indemnification of the Trustee, and other matters typical for indentures used in structured financings of this type.

As of June 30, 2012, the aggregate fair value of the PhaRMA Notes approximate the carrying value of \$30,000 since the stated rate and terms are representative of current rates and terms available to the Company. The fair value was determined by a quoted price in a not actively traded market representing Level 2 in the fair value hierarchy as defined by U. S. GAAP.

Beginning on March 9, 2012, the PhaRMA Notes became redeemable by Royalty Sub. Accordingly, the PhaRMA Notes are redeemable at the option of Royalty Sub at any time at a redemption price equal to the percentage of the outstanding principal balance of the PhaRMA Notes being redeemed specified below for the period in which the redemption occurs, plus accrued and unpaid interest through the redemption date on the PhaRMA Notes being redeemed:

<b>Payment Dates (Between Indicated Dates)</b>	<b>Redemption Percentage</b>
From and including March 9, 2012 to and including March 8, 2013	107.0%
From and including March 9, 2013 to and including March 8, 2014	103.5%
From and including March 9, 2014 and thereafter	100.0%

**Foreign Currency Hedge**

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, the Company has the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which the Company may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$1,950 will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement.

The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Mark-to-market adjustments for the three months ended June 30, 2012 and 2011 resulted in a loss of \$997 and \$998, respectively, a loss of \$959 and \$2,340 for the six months ended June 30, 2012 and 2011, respectively. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds. As of June 30, 2012, \$4,970 was posted under the Currency Hedge Agreement. The Company will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. Subject to certain obligations the Company has in connection with the PhaRMA Notes, the Company has the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and paying a \$1,950 termination fee.

**Note 5 Stockholders Equity**

In June 2011, the Company entered into an At Market Issuance Sales Agreement (the ATM Agreement) with McNicoll, Lewis & Vlak (MLV) pursuant to which the Company may issue and sell \$70,000 in shares of its common stock at current market prices under a Form S-3 registration statement with MLV acting as the sales agent. Subject to the terms and conditions of the ATM Agreement, MLV will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instruction, including any price, time or size limits or other customary parameters or conditions the Company may impose. The Company will pay MLV an aggregate commission rate of 2% or 3% of the gross proceeds of the sales price per share of any common stock sold under the ATM Agreement depending on the number of shares sold. On June 28, 2011, the Company filed a Registration Statement on Form S-3, which became effective on July 13, 2011, for the issuance and sale of up to \$70,000 of equity or other securities. During the six months ended June 30, 2012, the Company sold an aggregate of 3,879 shares of common stock at an average per share price of \$4.09 pursuant to the ATM Agreement for net proceeds of \$15,339.

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

On March 15, 2012, the Company issued 193 shares of restricted common stock in lieu of a cash payment to employees as payment for their annual incentive award earned in 2011. The number of shares issued was based on the total value of the annual incentive earned in 2011 of \$1,542, less \$535 in withholding taxes paid in cash on the employees' behalf, divided by the closing common stock price on March 15, 2012 of \$5.23 per share.

**Table of Contents****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 and elsewhere in this report, as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See Information Regarding Forward-Looking Statements.*

**Cautionary Statement**

The discussion herein 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. Forward-looking statements regarding our financial condition and our results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. GAAP, as well as projections for the future. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to biotechnology and biopharmaceutical companies, including risks inherent in our drug discovery, drug development and commercialization efforts, clinical trials, uncertainty of regulatory actions and marketing approvals, reliance on collaborative partners, enforcement of patent and proprietary rights, the need for future capital, competition associated with products, potential competition associated with our drug candidates and retention of key employees. In order for any of our drug candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the drug candidate to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, and obtain market acceptance and adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements. Statements contained in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report which are not historical facts are, or may constitute, forward-looking statements. Forward-looking statements involve known and unknown risks that could cause our actual results to differ materially from expected results. The most significant known risks are discussed in the section entitled "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on any forward-looking statements.

Our revenues are difficult to predict and depend on numerous factors, including the prevalence and severity of influenza in regions for which peramivir has received regulatory approval as well as in those geographies that impact enrollment in our ongoing peramivir clinical trial. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward and the achievement of developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend on several factors. Research and development expenses, drug manufacturing, and clinical research activities, depend on the ongoing requirements of our development programs, availability of capital and direction from regulatory agencies, which are difficult to predict. Management may be able to control the timing and level of research and development and general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

## **Table of Contents**

### **Overview**

We are a biotechnology company that designs, optimizes and develops novel drugs that block key enzymes involved in the pathogenesis of diseases. We focus on therapeutic areas with unmet medical needs that are of interest to us and aligned with our capabilities and expertise. Our areas of interest and related development of drug candidates are determined by the scientific discoveries and the potential advantages that our experienced drug discovery group identifies, as well as by the associated potential commercial opportunity of those discoveries. We integrate the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design. Our strategy is to create a sustainable portfolio of commercial products and drug candidates whereby we out-license rights to drug candidates in geographies or therapeutic areas where we do not intend to and/or do not have the ability commercialize them.

### ***Critical Accounting Policies and Estimates***

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change and regularly discuss financial events, policies, and issues with members of our audit committee and our independent registered public accounting firm. We routinely evaluate our estimates and policies regarding revenue recognition, administration, inventory and manufacturing, taxes, stock-based compensation, research and development, consulting and other expenses and any associated liabilities.

### **Recent Corporate Highlights**

#### ***Peramivir and RAPIACTA® Royalty Monetization***

We are currently enrolling patients in our final i.v. peramivir Phase 3 trial, clinical trial 301. If this clinical trial is successful, results may be used to support a New Drug Application ( NDA ) with the U.S. Food & Drug Administration ( FDA ). We intend to conduct a planned interim analysis, which will help guide us to a more informed target enrollment population and will include an assessment of futility. This analysis is expected to be completed following the Southern Hemisphere flu season during the fourth quarter of 2012. If the analysis shows an efficacy trend in favor of peramivir, it is expected the clinical trial would continue toward either the current enrollment target or a higher target of up to 320 patients, depending on the trend. If, however, the new enrollment target to reach statistical significance is predicted to exceed 320 patients, we would terminate the clinical trial and evaluate the data in hand. We plan to provide an update following the planned interim analysis.

On March 9, 2011, we completed a \$30.0 million non-recourse financing transaction designed to monetize certain future royalty and milestone payments under our license agreement with Shionogi, pursuant to which Shionogi licensed from us the rights to market peramivir (under the commercial name RAPIACTA®) in Japan and, if approved for commercial sale, in Taiwan. We formed JPR Royalty Sub LLC ( Royalty Sub ), a newly created wholly-owned subsidiary, which completed a private placement to institutional investors of \$30.0 million in aggregate principal amount of PhaRMA Senior Secured 14.0% Notes. This private placement was exempt from registration under the Securities Act of 1933. The PhaRMA Notes, which are obligations of Royalty Sub, are secured by (i) Royalty Sub's rights to receive royalty payments from Shionogi in respect of commercial sales of RAPIACTA® in Japan and, if approved for commercial sale, in Taiwan, as well as future milestone payments payable by Shionogi under the Shionogi Agreement and all of Royalty Sub's other assets, and (ii) a pledge by us of our equity interest in Royalty Sub. Principal and interest on the PhaRMA Notes issued by Royalty Sub are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement. Principal on the PhaRMA Notes is required to be paid in full by the final legal maturity date of December 1, 2020, unless the PhaRMA Notes are repaid, redeemed or repurchased earlier. The PhaRMA Notes are redeemable by Royalty Sub beginning March 9, 2012 and bear interest at the rate of 14% per annum, payable annually in arrears on September 1<sup>st</sup> of each year (the Payment Date ), beginning on September 1, 2011. Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including us, except to the extent of our pledge of our equity interests in Royalty Sub in support of the PhaRMA Notes.

We received net proceeds of approximately \$22.7 million after deducting transaction costs of \$4.3 million and the establishment of a \$3.0 million interest reserve account available to help cover future annual interest shortfalls. On September 1, 2012, \$4.2 million of interest will be due and payable on the PhaRMA Notes. Based on royalty payments received from RAPIACTA® sales of \$1.9 million (from September 2, 2011 through June 30, 2012) and the \$1.7 million remaining balance in the interest reserve account, we currently estimate that there will be an interest shortfall of approximately \$0.5 million on September 1, 2012. As stipulated under the PhaRMA Notes indenture, if the amounts available for payment are insufficient to



**Table of Contents**

pay all of the interest due on a Payment Date, unless sufficient capital is contributed to Royalty Sub by the Company as permitted under the indenture or the interest reserve account is available to make such payment, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Under the terms of the indenture relating to the PhaRMA Notes, Royalty Sub's inability to pay the full amount of interest payable on September 1, 2012 will not constitute an event of default under the PhaRMA Notes unless Royalty Sub fails to pay such unpaid interest, plus interest thereon, on or prior to the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2013. Based on sales forecasts of RAPIACTA<sup>®</sup> provided to us by Shionogi, we currently estimate sufficient royalties will be received to fund the September 1, 2012 interest shortfall prior to September 1, 2013, however, no assurances can be given that these royalties will be received and available for payment of the interest shortfall.

In association with the PhaRMA Notes, we entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under this agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$2.0 million will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement. In conjunction with establishing the Currency Hedge Agreement, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our financial results. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. Subject to certain obligations we have in connection with the PhaRMA Notes, we have the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and paying a \$2.0 million termination fee. In advance of the May 18, 2014 termination date, we have a limitation on the maximum hedge collateral of approximately \$5.9 million. The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark-to-market adjustments will be recognized in our Consolidated Statements of Comprehensive Loss. Cumulative mark-to-market adjustments for the six months ended June 30, 2012 resulted in a \$1.0 million hedge loss and we posted \$5.0 million in collateral based on defined thresholds in since the inception of the agreement. Our operating results will continue to be impacted by mark-to-market adjustments while the Currency Hedge Agreement remains in effect.

***Ulodesine***

On July 24, 2012, we reported favorable 52-week results from the extension phase of our randomized Phase 2b trial of ulodesine added to allopurinol in patients with gout who had failed to reach the serum uric acid (sUA) therapeutic goal of <6 mg/dL on allopurinol alone, as well as positive Phase 2 safety results in patients with mild- to moderate-renal impairment. The results of the safety extension confirm that ulodesine was generally safe and well-tolerated. No clinical adverse event signals were observed that distinguished ulodesine from placebo, either by type or by rate at the doses tested. No opportunistic or unusual infections were observed and no signal for possible liver toxicities was detected. No fatal or life-threatening adverse events were observed in any of the treatment groups. Patients responded favorably to a vaccine challenge at 16 or 20 weeks of ulodesine treatment, confirming that patients maintained their ability to generate a healthy immune response, similar to patients who received placebo. Patients demonstrated a durable response to ulodesine over one year of treatment, with response rates at the end of the trial similar to those reported from the primary efficacy analysis at 12 weeks. In addition, we have initiated the Scientific Advice Process with the European Medicines Agency (EMA) and expect feedback in the third quarter of 2012.

In April 2012, we held an End of Phase 2 meeting with the FDA regarding the ulodesine gout program, which included discussions around the proposed Phase 3 program for the drug candidate's continued development. It is anticipated that ulodesine will be evaluated in Phase 3 testing as add-on treatment to the approved xanthine oxidase (XO) inhibitors, allopurinol or febuxostat, in gout patients who are not adequately responding to a XO inhibitor alone. The primary efficacy end point is expected to be the portion of patients with a serum uric acid (sUA) level that is < 6.0 mg/dL following six months of study drug administration. The proposed Phase 3 clinical trial plan anticipates enrollment of approximately 1,800 patients and 12 months of study drug exposure. We are incorporating advice received during this meeting into our Phase 3 plan and future development of ulodesine.

In January 2012, we reported positive long-term results from the extension phase of our randomized Phase 2b clinical trial of ulodesine added to allopurinol in patients with gout who had failed to reach the sUA therapeutic goal of <6 mg/dL on allopurinol alone. The results of this 24-week, blinded safety extension confirmed that ulodesine was generally safe and well-tolerated, and sustained sUA control over time. This longer-term safety profile of ulodesine is consistent with the 12-week primary analysis results originally reported in October 2011.

**Table of Contents*****Forodesine***

On November 11, 2011, we entered into the Amended and Restated License and Development Agreement with Mundipharma, amending and restating the February 1, 2006 exclusive, royalty-bearing Development and License Agreement for the development and commercialization of forodesine for use in the field of oncology. Under the terms of the Amended and Restated Agreement, Mundipharma obtained worldwide rights to forodesine, so they now control the worldwide development and commercialization of forodesine and assume all future development and commercialization costs. Amortization of deferred revenue and expense items associated with the initial agreement with Mundipharma ceased on November 11, 2011, when we were no longer responsible for the development of forodesine. Mundipharma also purchased from us certain drug substance for forodesine at a cost of approximately \$0.9 million in December 2011. Additionally, on November 17, 2011, we further amended our agreements with AECOM/IRL whereby AECOM/IRL agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined in the license agreement) received by us under our Amended and Restated Agreement with Mundipharma.

The Amended and Restated Agreement is a multiple element arrangement for accounting purposes, in which we were required to deliver to Mundipharma both the worldwide rights to forodesine and the transfer of product data and know-how to permit Mundipharma to develop and commercialize forodesine (the Knowledge Transfer). Without completion of the Knowledge Transfer, Mundipharma would not be able to develop and commercialize forodesine in the U.S. We have accounted for these elements as a combined unit of accounting as neither one has stand-alone value to Mundipharma. The world-wide license rights were granted to Mundipharma on November 11, 2011. The Knowledge Transfer commenced in the fourth quarter of 2011 and was completed during the first quarter of 2012. Completion of the Knowledge Transfer concludes our obligations under the Amended and Restated Agreement and results in the recognition of the unamortized deferred revenue and expense of \$7.8 million and \$1.9 million, respectively, in our Consolidated Statement of Comprehensive Loss for the six months ended June 30, 2012. Recognition of these deferred amounts resulted in a \$2.3 million decrease in our deferred tax assets, with an equal reduction to the valuation allowance, resulting in no impact to net deferred tax assets.

***Preclinical Compounds***

Our leading pre-clinical compounds include BCX4161, a potential oral prophylactic drug for hereditary angioedema, and BCX5191, a novel adenine nucleoside analog targeting viral RNA polymerase for the potential treatment of hepatitis C. In August 2012, we announced the completion of IND-enabling nonclinical safety studies of BCX5191 for hepatitis C and BCX4161 for hereditary angioedema. We are completing Phase 1 planning for both programs. The main success factors for the BCX5191 Phase 1 trial will be to confirm that low doses can be administered safely and deliver activity against the hepatitis C virus. The main success factors for the BCX4161 Phase 1 trial will be to demonstrate safety, adequate drug exposure via oral administration and pharmacodynamic effect on kallikrein inhibition. Both programs remain on track for the initiation of first-in-human trials before the end of 2012.

In March 2012, we reported that we filed a suggestion with the United States Patent & Trademark Office (USPTO) to declare an interference to remedy the apparent error made by the USPTO when it issued U.S. Patent 8,119,607 to Biota Holdings Limited containing a claim that covers the structure of BCX5191, a BioCryst-discovered nucleoside analog hepatitis C viral RNA polymerase (NS5B) inhibitor. BioCryst's patent application covering BCX5191 is PCT/US2008/050929, having an international filing date of January 11, 2008 and claiming priority to U.S. Provisional Application Number 60/880,278, dated January 12, 2007, and was filed approximately 18 months prior to Biota's application. At least with respect to the hepatitis C inhibitor BCX5191, discovered and being developed by BioCryst, the Company believes the Biota patent was improvidently granted by the USPTO. Before considering our suggestion for interference, the USPTO must deem our claim allowable under the standard patent prosecution process. In May 2012, the USPTO issued a non-final rejection with respect to our revised claims. Our response, which we expect will address the patent examiner's objections, is due no later than mid-November 2012.

**Results of Operations (three months ended June 30, 2012 compared to the three months ended June 30, 2011)**

For the three months ended June 30, 2012, total revenues increased to \$4.2 million compared to \$3.7 million for the three months ended June 30, 2011. Revenue in the second quarter of 2012 consisted of \$3.9 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and \$0.3 million associated with collaborative revenue amortization from other corporate partnerships. BARDA/HHS revenue increased during the second quarter of 2012 related to an increase in reimbursable peramivir expenses as adjusted by continued development and ongoing 301 clinical trial activity as compared to the second quarter of 2011. Revenues in the second quarter of 2011 consisted of \$3.1 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and \$0.6 million associated with collaborative revenue amortization from other corporate partnerships.

Research and development (R&D) expenses decreased to \$12.8 million for the second quarter of 2012 from \$14.4 million in the same quarter of the prior year. R&D expenses in the second quarter of 2012, compared with the prior year, reflect spending associated with our peramivir program described above, increased spending on our pre-clinical compounds (primarily BCX 4161, a potential oral prophylactic drug for hereditary angioedema and BCX5191, an adenine nucleoside for the potential



**Table of Contents**

treatment of hepatitis C), offset by lower development costs associated with our ulodesine program for the treatment of gout due to the completion of certain Phase 2 studies. In connection with the Amended and Restated License and Development Agreement with Mundipharma, and the Knowledge Transfer that occurred in the first quarter of 2012, we should not incur any significant forodesine costs in the future.

General and administrative expenses decreased to \$1.6 million for the second quarter of 2012 compared to \$3.5 million in the same quarter of the prior year. The decrease of \$1.9 million is primarily the result of costs incurred in 2011 relating to the transition of our headquarters to Durham, North Carolina, as well as reductions in other administrative expenses during 2012.

Interest expense related to the non-recourse notes issued in conjunction with the peramivir royalty monetization transaction in March 2011 was \$1.2 million in the second quarter of both 2012 and 2011. In addition, a mark-to-market loss of \$1.0 million was recognized in the second quarter of both 2012 and 2011 related to our foreign currency hedge, resulting from changes in the U.S. dollar/Japanese yen exchange rate.

**Results of Operations (six months ended June 30, 2012 compared to the six months ended June 30, 2011)**

For the six months ended June 30, 2012, total revenues increased to \$16.4 million compared to \$9.2 million for the six months ended June 30, 2011. Revenues in the first six months of 2012 included the recognition of \$7.8 million of previously deferred revenue associated with the Amended and Restated License and Development Agreement with Mundipharma. The recognition of this revenue and the related expense (noted below) did not impact the Company's cash balance. The remaining revenue consisted of \$8.1 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and \$592,000 associated with collaborative revenue amortization from other corporate partnerships. BARDA/HHS revenue increased in the six months ended June 30, 2012 compared to the prior year period due to an increase in reimbursable peramivir expenses reflecting continued development and ongoing 301 clinical trial activity. Revenues in the first six months of 2011 consisted of \$7.8 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and \$1.4 million associated with collaborative revenue amortization from other corporate partnerships.

R&D expenses increased to \$28.3 million for the first six months of 2012 from \$27.9 million in the same six months of the prior year. Approximately \$1.9 million of the 2012 R&D expense resulted from the recognition of previously deferred expenses associated with the Amended and Restated License and Development Agreement with Mundipharma. The remaining 2012 R&D expenses, compared with the prior year, reflect spending associated with our peramivir program described above, increased spending on our pre-clinical compounds (primarily BCX4161, a potential oral prophylactic drug for hereditary angioedema, and BCX5191, an adenine nucleoside for the potential treatment of hepatitis C), partially offset by lower development costs associated with our ulodesine program for the treatment of gout due to the completion of certain Phase 2 studies. In connection with the Amended and Restated License and Development Agreement with Mundipharma, and the Knowledge Transfer that occurred in the first quarter of 2012, we should not incur any significant forodesine costs in the future.

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,	
	2012	2011	2012	2011
R&D expenses by program:				
Ulodesine	\$ 2,942	\$ 6,052	\$ 5,477	\$ 10,475
Peramivir	3,489	3,603	7,628	7,517
Forodesine	60	422	2,460	1,094
BCX4161	2,029	1,564	4,287	2,961
BCX5191	2,375	358	4,267	360
Other research, preclinical and development costs	1,882	2,443	4,183	5,534
Total R&D expenses	\$ 12,777	\$ 14,442	\$ 28,302	\$ 27,941

General and administrative expenses decreased to \$3.3 million for the first six months of 2012 compared to \$7.0 million in the same period of the prior year. The decrease of \$3.7 million is primarily the result of costs incurred in 2011 relating to the transition of our headquarters to Durham, North Carolina, as well as reductions in other administrative expenses during 2012.

Interest expense related to the non-recourse notes issued in conjunction with the peramivir royalty monetization transaction in March 2011 increased to \$2.3 million in the first six months of 2012 compared to \$1.5 million in the first six months of 2011, due to recognizing a full six

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

month period of interest expense in 2012 compared to a partial six month period in 2011. In addition, a mark-to-market loss of \$1.0 million was recognized in the first six months of 2012 related to our foreign currency hedge, compared to a mark-to-market loss of \$2.3 million in the first six months in the prior year, resulting from changes in the U.S. dollar/Japanese yen exchange rate.

---

## **Table of Contents**

### ***Liquidity and Capital Resources***

Cash expenditures have exceeded revenues since our inception and we expect our 2012 operating expense to exceed our 2012 revenue. Our operations have principally been funded through public offerings and private placements of equity securities; cash from collaborative and other research and development agreements, including government contracts; and to a lesser extent, the Pharma Notes financing. On February 24, 2011, we announced that BARDA/HHS had awarded us a \$55.0 million contract modification intended to fund completion of the Phase 3 development of i.v. peramivir, bringing the total award from BARDA/HHS to \$234.8 million and extending the contract term by 24 months through December 2013. On March 9, 2011, we completed a \$30.0 million non-recourse debt financing transaction designed to monetize certain future royalty and milestone payments under our license agreement with Shionogi. We received net proceeds from this transaction of approximately \$22.7 million, excluding hedge collateral posted subsequent to the closing of the transaction. In June 2011, we entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with McNicoll, Lewis & Vlak ("MLV") pursuant to which we may issue and sell \$70.0 million in shares of our common stock at current market prices under a Form S-3 registration statement with MLV acting as the sales agent. As of June 30, 2012, we have sold an aggregate of 4.3 million shares of common stock at an average per share price of \$3.95 pursuant to the ATM Agreement for net proceeds of \$16.4 million.

Other sources of funding have included the following:

other collaborative and other research and development agreements;

government grants;

equipment lease financing;

facility leases;

research grants; and

interest income.

As of June 30, 2012, we had net working capital of \$26.0 million, a decrease of approximately \$0.6 million from \$26.6 million at December 31, 2011. The decrease in working capital was principally due to the funding of our normal operating expenses associated with the development of our drug candidates and \$1.5 million in cash collateral posted against foreign currency losses, partially offset by \$15.3 million in net proceeds derived from the sale of common stock through offerings under the ATM Agreement through our Form S-3 shelf registration. Our principal sources of liquidity at June 30, 2012 were approximately \$21.6 million in cash and cash equivalents; approximately \$29.3 million in investments considered available-for-sale; and approximately \$5.1 million in BARDA/HHS receivables.

We have attempted to contain costs and reduce cash flow requirements by closely managing our third party costs and headcount, 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. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

At December 31, 2011, we had long-term operating lease obligations, which provide for aggregate minimum payments of approximately \$0.9 million in 2012, \$1.0 million in 2013, \$1.0 million in 2014 and \$0.3 million in 2015. These obligations include the future rental of our operating facilities.



**Table of Contents**

We plan to finance our needs principally from the following:

payments under our contract with BARDA/HHS;

our existing capital resources and interest earned on that capital;

payments under collaborative and licensing agreements with corporate partners; and

lease or loan financing and future public or private equity financing.

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 BARDA/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 candidates, the progress made in the manufacturing of our lead drug candidates and the progression of our other programs.

With the funds available at June 30, 2012, future amounts that are expected to be received from BARDA/HHS, and our other financing sources, we believe these resources will be sufficient to fund our operations at least through 2013. 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 BARDA/HHS and receive reimbursement;

the progress and magnitude of our research, drug discovery and development programs;

changes in existing collaborative relationships or government contracts;

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

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

our ability to negotiate favorable development and marketing strategic alliances for certain drug candidates or a decision to build or expand internal development and commercial capabilities;

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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 drug 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 equity or debt securities or collaborative or other arrangements with corporate

---

**Table of Contents**

partners or from other sources, including governmental agencies in general and from the BARDA/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. Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates as well as rate of reimbursement by BARDA/HHS of our peramivir expenses. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our drug candidates; obtaining funding from collaborative partners; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our drug candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; and the level of required administrative support for our daily operations.

***Financial Outlook for 2012 Revised Guidance***

Based upon current trends and assumptions, as well as our planned operations, we expect 2012 net operating cash usage to be in the range of \$37 to \$43 million, reflecting an increase of \$5 million from previously provided financial guidance, and we expect our total operating expenses to be in the range of \$57 to \$69 million, unchanged from previously provided guidance. The projected \$5 million increase in our 2012 operating cash usage is due to a projected increase in R&D expenditures for the development of our preclinical hepatitis C compound, as well as a lower net margin contribution related to the advanced development of our i.v. peramivir program with BARDA/HHS. Our operating cash forecast excludes any potential cash inflows from out-licensing or other sources. Our ability to remain within our operating expense and operating cash target ranges is subject to multiple factors, including unanticipated or additional general development and administrative costs and other factors described under the Risk Factors located elsewhere in this report. Furthermore, these ranges are highly dependent on peramivir-related operating expenses, which are reimbursed by BARDA/HHS. Our peramivir expenses are hard to predict and are largely a function of the rate of enrollment in the our ongoing 301 Phase 3 clinical trial, which in turn is dependent on the prevalence and severity of influenza in those geographies where we have enrolling clinical trial sites.

***Off-Balance Sheet Arrangements***

As of June 30, 2012, we are not involved in any unconsolidated entities or off-balance sheet arrangements.

***Critical Accounting Policies***

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

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2011 Annual Report on Form 10-K, 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 consolidated financial statements.

***Inventory***

Our inventories consist of peramivir finished goods and supplies for the manufacture of peramivir, which are valued at the lower of cost or market using the first-in, first-out (i.e., FIFO) method. Cost includes materials, labor, overhead, shipping and handling costs. Our inventories are subject to expiration dating. We regularly evaluate the carrying value of our inventories and provide valuation reserves for any estimated obsolete, short-dated or unmarketable inventories. In addition, we may experience spoilage of our raw materials and supplies. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment.



---

## **Table of Contents**

### ***Accrued Expenses***

We generally enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing, and services are completed over an extended period of time. We record liabilities under these contractual commitments when we determine an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

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

fees paid to investigative sites in connection with clinical trials;

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

professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

### ***Revenue Recognition***

The Company recognizes revenues from collaborative and other research and development arrangements and product sales. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

#### ***Collaborative and Other Research and Development Arrangements and Royalties***

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized 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.

Under certain of our license agreements, we receive royalty payments based upon our licensees' net sales of covered products. Generally, under these agreements, we receive royalty reports from our licensees approximately one quarter in arrears, that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured.

Royalty revenue paid by Shionogi on their product sales is subject to returns. RAPIACTA® is a newly introduced product and there is not sufficient historical experience that can be used to reasonably estimate product returns. Accordingly, we defer recognition of royalty revenue

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

from Shionogi until the earlier of a right of return no longer exists or until we have developed sufficient historical experience to estimate product returns.

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 BARDA/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

## **Table of Contents**

### *Product Sales*

Sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates.

### *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 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 UAB, which require fees related to sublicense agreements or maintenance fees. We expense sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. We expense maintenance payments as incurred.

At June 30, 2012, we had deferred collaboration expenses of approximately \$5.8 million. These deferred expenses were sub-license payments, paid to our academic partners upon receipt of consideration from various commercial partners, and other consideration to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications 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.

### *Stock-Based Compensation*

All share-based payments, including grants of stock option awards and restricted stock awards, are recognized in our Consolidated Statements of Comprehensive Loss 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. 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. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock awards is based on the grant date closing price of the common stock. Compensation expense is recognized on a straight-line basis over the vesting periods. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. Significant management judgment is also required in determining estimates of future stock price volatility and forfeitures to be used in the valuation of the options. Actual results, and future changes in estimates, may differ substantially from our current estimates.

### *Foreign Currency Hedge*

In connection with our issuance of the PhaRMA Notes, we entered into a foreign Currency Hedge Agreement (the Currency Hedge Agreement) to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$2.0 million will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement. In conjunction with establishing the Currency Hedge Agreement, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our financial results. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreements. In establishing the hedge, we provided initial funds of approximately \$2.0 million to support our potential hedge obligations. Subject to certain obligations we have in connection with the PhaRMA Notes, we have the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and payment of a \$2.0 million termination fee. Prior to this termination date, the maximum amount of hedge collateral we may be required to post is \$5.9 million.



## **Table of Contents**

The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark-to-market adjustments will be recognized in our Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments for the six months ended June 30, 2012 resulted in a \$1.0 million loss. Mark-to-market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds and as of June 30, 2012, \$5.0 million was posted under the agreement.

### ***Tax***

We account for uncertain tax positions in accordance with U.S. GAAP. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income in each of the jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable.

### ***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, estimates, 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 Business, 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 BARDA/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 further preclinical or clinical development and commercialization of our drug candidates, including peramivir, forodesine and other PNP inhibitor and hepatitis C development programs;

the implementation of our business model, strategic plans for our business, drug 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;

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub;

the foreign currency hedge agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes;

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

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

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

---

**Table of Contents**

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**

***Interest Rate Risk***

We are subject to interest rate risk on our investment portfolio and borrowings under our non-recourse debt facility.

We invest in marketable securities in accordance with our investment policy. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintain liquidity sufficient to meet cash flow requirements. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our 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 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.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments. We generally have the ability to hold our fixed-income investments to maturity and therefore do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. 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. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

***Foreign Currency Risk***

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we are required to post collateral based on our potential obligations under the Currency Hedge Agreement as determined by periodic mark-to-market adjustments. Provided the Currency Hedge Agreement remains in effect, we may be required to pay a premium in the amount of \$2.0 million in each year beginning in May 2014 and continuing through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the Currency Hedge Agreement) is such that the U.S. dollar is worth 100 yen or less.



---

**Table of Contents**

**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 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, 2012, 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 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, 2012 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**

*An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the Securities and Exchange Commission, before deciding to buy our common stock.*

**Risks Relating to Our Business**

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

Since our inception in 1986, we have not achieved profitability. 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, or our collaborative partners, must successfully manufacture and develop drug product candidates, receive regulatory approval, and successfully commercialize and/or enter into profitable agreements with other parties. It could be several years, if ever, before we receive significant 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.

## **Table of Contents**

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 that 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 reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.***

If we fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, or development and commercial diligence obligations, fail to make milestone payments in accordance with applicable provisions, or fail to pay the minimum annual payments under our respective licenses, our licensors may terminate the applicable license. As a result, our development of the respective product candidate or commercialization of the product would cease.

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

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements, and additional personnel resources and testing required for supporting the development of our drug candidates, will consume significant capital resources. Our expenses, revenues and cash burn rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our drug candidates, the amount of funding we receive from BARDA/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, including ulodesine, the amount or profitability of any orders for peramivir by any government agency or other party, the progress and results of

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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 drug 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

---

**Table of Contents**

other sources, including governmental agencies in general and from any BARDA/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 or lack of an acceptable partnership may require us to delay, scale back or eliminate certain of our research and development programs.

We expect that we will be required to raise additional capital or enter into one or more acceptable partnership arrangements in order to complete the development of ulodesine. The inability to raise such capital or enter into sufficient acceptable partnership arrangements may require us to delay or eliminate the development of ulodesine for the treatment of gout.

***If BARDA/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 BARDA/HHS reimbursement for the costs related to our peramivir program. If BARDA/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, BARDA/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 BARDA/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. In addition, U.S. government contracts are subject to an in process review, where the U.S. government will review the project and will consider its options under the contract. As such, we may be at a disadvantage as compared to other commercial contracts. 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.

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

We have entered into a contract with BARDA/HHS for the advanced development of our neuraminidase inhibitor, peramivir. In contracting with BARDA/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. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event BARDA/HHS determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA/HHS would be entitled to recoup any overpayment as a result. 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

## Table of Contents

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 candidates or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our drug 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 candidates.

We have licensed worldwide rights to forodesine to Mundipharma. In addition, we have established collaborative relationships 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 drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;

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

our partners may not devote sufficient capital or resources towards our drug 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 drug candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our drug candidates would severely affect our business,

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

because if our drug candidates 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 milestone, product sales 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.

**Table of Contents**

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 drug 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.

***If our development collaborations with third parties, such as our development partners and contract research organizations, fail, the development of our drug candidates will be delayed or stopped.***

We rely heavily upon other parties for many important stages of our drug candidate development, 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 candidates;

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

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

manufacturing the starting materials and drug substance required to formulate our drug products and the drug candidates 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 drug 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 drug 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 drug candidates could be delayed, and our business, financial condition and results of operations could be materially adversely affected.

## **Table of Contents**

*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;

the i.v. peramivir interim analysis may result in early termination of the clinical study and subsequent evaluation of the clinical data may not show that peramivir is safe and effective, or the results may be insufficient for approval or any further stockpiling or other peramivir purchase;

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;

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.

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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

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

To the extent that peramivir is used as a treatment for H1N1 flu (or other strains of flu), there can be no assurance that it will prove to be generally safe, well tolerated and effective. Emergency use of peramivir may create certain liabilities for 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. 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.

## Table of Contents

*Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our drug candidates and the materials for our drug 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 candidates and most of the preclinical and clinical quantities of our drug 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, such as the April 2011 earthquake in Japan, that could strike their facilities or have an effect on infrastructure;

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 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 the 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 any of our third-party manufacturers, we may not be able to complete development of, or market, our drug candidates.

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

***Royalties and milestone payments from Shionogi under the Shionogi Agreement will be required to be used by Royalty Sub to service its obligations under its PhaRMA Notes, and generally will not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes.***

In March 2011, our wholly-owned subsidiary Royalty Sub issued \$30.0 million in aggregate principal amount of PhaRMA Notes. The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and, if approved for commercial sale, Taiwan, (ii) rights to certain payments under a Japanese yen/U.S. dollar foreign currency hedge arrangement put into place by us in connection with the issuance of the PhaRMA Notes and (iii) the pledge by us of our equity interest in Royalty Sub. Payments from Shionogi to us under the Shionogi Agreement will generally not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes. Accordingly, these funds will be required to be dedicated to Royalty Sub's debt service and not available to us for product development or other purposes.

**Table of Contents**

***If royalties from Shionogi are insufficient for Royalty Sub to make payments under the PhaRMA Notes or if an event of default occurs under the PhaRMA Notes, investors may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub, in which case we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes.***

Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub, is subject to numerous risks. Peramivir was first approved for marketing and manufacturing in Japan in October 2009 and has been offered for sale in Japan only since January 2010. As a result, there is very little sales history for peramivir in Japan, and there can be no assurance that peramivir will gain market acceptance in the Japanese market. In addition, Shionogi's sales of peramivir are expected to be highly seasonal and vary significantly from year to year, and the market for products to treat or prevent influenza is highly competitive. Under our license agreement with Shionogi, Shionogi has control over the commercial process for peramivir in Japan and Taiwan. Royalty Sub's ability to service the PhaRMA Notes may be adversely affected by, among other things, changes in or termination of our relationship with Shionogi, reimbursement, regulatory, manufacturing and/or intellectual property issues, product returns, product recalls, product liability claims and allegations of safety issues, as well as other factors.

On September 1, 2012, \$4.2 million of interest will be due and payable on the PhaRMA Notes. Based on royalty payments received from RAPIACTA® sales of \$1.9 million (from September 2, 2011 through June 30, 2012) and the \$1.7 million remaining balance in the interest reserve account, we currently estimate that there will be an interest shortfall of approximately \$0.5 million on September 1, 2012. Under the terms of the indenture relating to the PhaRMA Notes, Royalty Sub's inability to pay the full amount of interest payable on September 1, 2012 will not constitute an event of default under the PhaRMA Notes unless Royalty Sub fails to pay such unpaid interest, plus interest thereon, on or prior to the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2013. Based on sales forecasts of RAPIACTA® provided to us by Shionogi, we currently estimate sufficient royalties will be received to fund the September 1, 2012 interest shortfall prior to September 1, 2013, however, no assurances can be given that these royalties will be received and available for payment of the interest shortfall. In the event that for any reason Royalty Sub is unable to service its obligations under the PhaRMA Notes or an event of default were to occur under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and exercise other remedies available to them under the indenture in respect of the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes and we might otherwise be adversely affected.

***Shionogi's failure to successfully market and commercialize peramivir in Japan would have a material adverse effect on Royalty Sub's ability to service its obligations on the PhaRMA Notes.***

The successful commercialization of peramivir in Japan depends on the efforts of Shionogi and is beyond the control of us or Royalty Sub. As discussed above, peramivir has only recently been introduced into the Japanese market, and there can be no assurance that peramivir will gain market acceptance in Japan. Future sales by Shionogi will depend on many factors, including the incidence and severity of seasonal influenza in Japan each year (both of which can vary very significantly from year to year), the perceived and actual efficacy and safety of peramivir, experience of physicians and patients with peramivir, continued market acceptance, continued availability of supply, competition, sales and marketing efforts, governmental regulation and pricing and reimbursement in Japan. Shionogi is responsible for the marketing and sale of peramivir in Japan, including with respect to the pricing of peramivir in that market. There are no minimum royalties, sales levels or other performance measures required of Shionogi under the Shionogi Agreement and Shionogi could in its sole discretion reduce or cease its sale efforts of peramivir in Japan, subject to its covenant in the Shionogi Agreement to use diligent efforts to commercialize peramivir in Japan. If Shionogi is unable to or fails to successfully market and commercialize peramivir, it would have a material adverse effect on Royalty Sub's ability to service its obligations under the PhaRMA Notes and our ability to benefit from our equity interest in Royalty Sub.

***We may be required to pay significant premiums under the foreign currency hedge arrangement entered into by us in connection with the issuance of the PhaRMA Notes. In addition, because our potential obligations under the foreign currency hedge are marked to market, we may experience additional quarterly volatility in our operating results and cash flows attributable to the foreign currency hedge arrangement.***

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a foreign currency hedge arrangement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the currency hedge arrangement, we may be required to pay a premium in the amount of \$2.0 million in each year beginning in May 2014 and, provided the currency hedge arrangement remains in effect, continuing through May 2020. Such payment will

## **Table of Contents**

be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the currency hedge arrangement) is such that the U.S. dollar is worth 100 yen or less. We will be required to mark-to-market our potential obligations under the currency hedge and post cash collateral, which may cause us to experience additional quarterly volatility in our operating results and cash flows as a result. Additionally, we may be required to pay significant premiums or a termination fee under the foreign currency hedge agreement entered into by us in connection with the issuance of the PhaRMA Notes. As of June 30, 2012, we have realized a foreign currency hedge loss of approximately \$5.0 million and posted cash collateral of approximately \$5.0 million.

***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, or if our vendor data systems fail, suffer damage or are destroyed. If we receive 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.

***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 candidates, and development and marketing of our drug 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 drug candidates or technologies obsolete or noncompetitive.

---

## Table of Contents

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), CTCL, CLL, influenza, gout, hereditary angiodema, 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 GlaxoSmithKline plc and F. Hoffman-La Roche, Ltd. and Hoffman-La Roche, Inc. (collectively, 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 U.S. 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 drug 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

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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 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

## Table of Contents

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 cannot 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.

We may not be successful in our attempts to provoke the interference with respect to BCX5191, or the interference may take longer than expected, be more costly or may not be resolved in our favor.

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. 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

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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;

## **Table of Contents**

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.

***Insurance coverage is increasingly more costly and difficult to obtain or maintain.***

While we currently have insurance for our business, property, directors and officers, and our products, insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

***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 facilities. Duplicate copies of most critical data are secured off-site. 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 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 has been, and is likely to continue to be highly volatile, which could result in the value of an investment declining 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, 2012, the 52-week range of the market price of our stock was from \$5.95 to \$2.28 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;

**Table of Contents**

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 estimate 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.

***Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.***

As of June 30, 2012, our current 5% and greater stockholders and their affiliates beneficially owned approximately 34% of our outstanding common stock. These stockholders, if they act together, may be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions such as:

a merger or corporate combination with or into another company;

a sale of substantially all of our assets; and

## Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

amendments to our certificate of incorporation.

***Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.***

Future sales of our common stock by current stockholders into the public market could cause the market price of our stock to fall. As of June 30, 2012, there were approximately 50,134,000 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition.

In addition, on June 28, 2011, we filed with the SEC a shelf registration statement on Form S-3. This shelf registration statement has been declared effective and allows us to sell up to \$70 million of securities, including common stock, preferred stock, depository shares, stock purchase contracts and warrants, from time to time at prices and on terms to be determined at the time of sale.

As of June 30, 2012, there were 9,171,591 stock options and shares of restricted stock outstanding and 2,164,461 shares available for issuance under our Amended and Restated Stock Incentive Plan and equity compensation grants outside such plan. The shares underlying existing stock options and restricted stock and possible future stock options, stock appreciation rights and stock awards have been registered pursuant to registration statements on Form S-8.

**Table of Contents**

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market

may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

*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.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 8<sup>th</sup> day of August, 2012.

BIOCRYST PHARMACEUTICALS, INC.

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

/s/ Thomas R. Staab, II  
Thomas R. Staab, II  
*Chief Financial Officer*

/s/ Robert S. Lowrey  
Robert S. Lowrey  
*Controller and Principal Accounting Officer*

**Table of Contents****INDEX TO EXHIBITS**

<b>Number</b>	<b>Description</b>
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	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.
(10.1)	Sixth Amendment Agreement by and among Albert Einstein College of Medicine, Industrial Research, Ltd. and BioCryst Pharmaceuticals, Inc., dated as of June 19, 2012. (Portions omitted pursuant to request for confidential treatment.)
(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.
(101)*	Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three and six months ended June 30, 2012, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

( ) Filed herewith.

\* In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall not be deemed to be filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be part of any registration or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.  
Confidential treatment requested.