BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 08, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2013

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**62-1413174**
(State of other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4505 Emperor Blvd., Suite 200	
Durham, North Carolina	**27703**
(Address of principal executive offices)	**(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 x 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 x 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 x
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 x

The number of shares of Common Stock, par value $0.01, of the Registrant outstanding as of October 31, 2013 was 59,091,393.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

September 30, 2013 and December 31, 2012

(In thousands, except per share data)

	2013 (Unaudited)	2012 (Note 1)
Assets		
Cash and cash equivalents	$ 26,050	$ 20,891
Restricted cash	150	308
Investments	16,541	14,708
Receivables	2,369	4,562
Prepaid expenses and other current assets	1,656	1,097
Deferred collaboration expense	73	412
Total current assets	46,839	41,978
Investments	680	1,151
Furniture and equipment, net	359	583
Deferred collaboration expense	252	5,033
Other assets	5,075	8,694
Total assets	$ 53,205	$ 57,439
Liabilities and Stockholders Equity		
Accounts payable	$ 1,241	$ 3,974
Accrued expenses	7,668	9,860
Interest payable	2,734	1,998
Deferred collaboration revenue	1,539	1,392
Total current liabilities	13,182	17,224
Deferred collaboration revenue	5,032	5,920
Foreign currency derivative	1,581	4,749
Non-recourse notes payable	30,000	30,000
Stockholders equity:		
Preferred stock, $0.001 par value; shares authorized 5,000; no shares issued and outstanding		
Common stock, $0.01 par value: shares authorized 95,000; shares issued and outstanding 59,091 in 2013 and 50,893 in 2012	591	509
Additional paid-in capital	420,097	391,611
Accumulated other comprehensive income	2	27
Accumulated deficit	(417,280)	(392,601)
Total stockholders equity (deficit)	3,410	(454)

Total liabilities and stockholders equity	$ 53,205	$ 57,439

See accompanying notes to consolidated financial statements.

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BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Periods Ended September 30, 2013 and 2012

(In thousands, except per share data-Unaudited)

	Three Months		Nine Months	
	2013	2012	2013	2012
Revenues				
Royalty revenue	$ 8	$ 2,848	$ 2,042	$ 2,848
Collaborative and other research and development	2,381	2,913	4,722	19,344
Total revenues	2,389	5,761	6,764	22,192
Expenses				
Research and development	7,977	12,072	27,116	40,374
General and administrative	1,337	1,591	3,950	4,897
Royalty		114	81	114
Total operating expenses	9,314	13,777	31,147	45,385
Loss from operations	(6,925)	(8,016)	(24,383)	(23,193)
Interest and other income	18	54	72	182
Interest expense	(1,191)	(1,166)	(3,536)	(3,486)
Gain (loss) on foreign currency derivative	97	(572)	3,168	(1,531)
Net loss	$ (8,001)	$ (9,700)	$ (24,679)	$ (28,028)
Basic and diluted net loss per common share	$ (0.14)	$ (0.19)	$ (0.46)	$ (0.57)
Weighted average shares outstanding	57,124	50,661	53,910	49,001
Unrealized loss on investments	(4)		(25)	
Comprehensive loss	$ (8,005)	$ (9,700)	$ (24,704)	$ (28,028)

See accompanying notes to consolidated financial statements.

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BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2013 and 2012

(In thousands-Unaudited)

	2013	2012
Operating activities		
Net loss	$ (24,679)	$ (28,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	247	461
Gain on disposal of furniture and equipment	(47)	
Stock-based compensation expense	3,479	3,345
Amortization of debt issuance costs	329	329
Change in fair value of foreign currency derivative	(3,168)	1,531
Changes in operating assets and liabilities:		
Receivables	2,193	2,063
Prepaid expenses and other assets	(559)	(393)
Deferred collaboration expense	5,120	2,200
Accounts payable and accrued expenses	(4,925)	(3,779)
Interest payable	736	(472)
Interest reserve		1,742
Deferred collaboration revenue	(741)	(9,366)
Net cash used in operating activities	**(22,015)**	**(30,367)**
Investing activities		
Acquisitions of furniture and equipment	(26)	(115)
Proceeds from sale of furniture and equipment	50	
Change in restricted cash	158	325
Purchases of investments	(15,232)	(14,487)
Sales and maturities of investments	13,845	35,515
Net cash (used in) provided by investing activities	**(1,205)**	**21,238**
Financing activities		
Sale of common stock, net	23,648	17,811
Exercise of stock options	1,317	522
Employee stock purchase plan sales	124	321
Receipt (payment) of foreign currency derivative collateral	3,290	(2,010)
Net cash provided by financing activities	**28,379**	**16,644**
Increase in cash and cash equivalents	5,159	7,515
Cash and cash equivalents at beginning of period	20,891	16,444
Cash and cash equivalents at end of period	**$ 26,050**	**$ 23,959**

See accompanying notes to consolidated financial statements.

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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. 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. BioCryst has incurred losses and negative cash flows from operations since inception.

In the fourth quarter of 2012, the Company implemented a restructuring plan to significantly reduce its cost structure. Based on its current operating plans, the Company expects that it has sufficient liquidity, with its existing cash and investments of $43,421, to continue its planned operations through 2014. The Company s liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events in the future. In order to continue its operations substantially beyond 2014 it will need to: (1) successfully secure or increase U.S. Government funding of its programs; (2) out-license rights to certain of its product candidates, pursuant to which the Company would receive cash milestone payments; (3) raise additional capital through equity or debt financings or from other sources; (4) obtain product candidate regulatory approvals, which would generate revenue and cash flow; (5) reduce spending on one or more research and development programs; and/or (6) restructure operations. The Company will continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations.

Basis of Presentation

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 consolidated financial statements 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 consolidated financial position, results of operations, and cash flows.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2012 and the notes thereto included in the Company s 2012 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, 2012 has been derived from the audited consolidated financial statements included in the Company s most recent Annual Report on Form 10-K.

Cash and Cash Equivalents

The Company generally considers cash equivalents to be all cash held in commercial checking accounts, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase. 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 September 30, 2013 includes $150 the Company is required to maintain in an interest bearing money market account to serve as collateral for a corporate credit card program.

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

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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 18 months. 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 September 30, 2013, 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 fair values are obtained from independent pricing services which utilize Level 2 inputs.

	September 30, 2013				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 9,075	$ 62	$ 2	$ (2)	$ 9,137
Commercial paper	7,330		1		7,331
Municipal obligations	750	3			753
Total investments	$ 17,155	$ 65	$ 3	$ (2)	$ 17,221

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	December 31, 2012				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 999	$ 2	$ 2	$	$ 1,003
Obligations of U.S. Government and its agencies	3,505	6	2		3,513
Corporate debt securities	4,035	22	6		4,063
Commercial paper	1,695		1		1,696
Municipal obligations	5,541	27	16		5,584
Total investments	$ 15,775	$ 57	$ 27	$	$ 15,859

The following table summarizes the scheduled maturity for the Company s investments at September 30, 2013.

Maturing in one year or less	$ 16,541
Maturing after one year through two years	680
Total investments	$ 17,221

Receivables from Collaborations

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs from the U.S. Department of Health and Human Services and the National Institute of Allergy and Infectious Diseases (NIAID) or royalty receivables from Shionogi & Co., Ltd. (Shionogi). These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At September 30, 2013 and December 31, 2012, the Company had the following receivables.

	September 30, 2013		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 544	$ 1,803	$ 2,347
National Institute of Allergy and Infectious Diseases		22	22
Total receivables	$ 544	$ 1,825	$ 2,369

	December 31, 2012		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 150	$ 3,888	$ 4,038
Shionogi & Co. Ltd.	524		524
Total receivables	$ 674	$ 3,888	$ 4,562

Monthly invoices are submitted to the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA/HHS) and NIAID 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 contracts. The Company s calculations of its indirect cost rates are subject to audit by the federal government.

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 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

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these contractual commitments when the Company determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with its applicable 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 has 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 services will be performed and the level of effort 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 September 30, 2013 and December 31, 2012 included $2,846 and $6,573, 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. No reclassifications out of accumulated other comprehensive (loss) income were recorded during the three months and nine months ended September 30, 2013 and 2012.

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 is 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. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured.

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Royalty revenue paid by Shionogi on their product sales is subject to returns. Prior to the third quarter of 2012, the Company did not have sufficient historical experience to reasonably estimate product returns and therefore could not reasonably record the underlying revenue. During the third quarter of 2012, and after the completion of the 2011/2012 flu season in Japan, the Company obtained sufficient historical information to reasonably estimate product returns and recognized royalty revenue of $2,848, net of an allowance for estimated returns. During the nine months of 2013, the Company recognized royalty revenue of $2,042.

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 contracts with BARDA/HHS and NIAID, 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.

The Company recorded the following revenues for the three and nine months ended September 30, 2013 and 2012:

	Three Months		Nine Months	
	2013	2012	2013	2012
Royalty revenue	$ 8	$ 2,848	$ 2,042	$ 2,848
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	2,063	2,618	3,812	10,690
National Institute of Allergy and Infectious Diseases	22		22	
Shionogi (Japan)	296	295	888	888
Mundipharma (United Kingdom)				7,766
Total revenues	$ 2,389	$ 5,761	$ 6,764	$ 22,192

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 product 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.

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Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock awards, are recognized in the Company s Consolidated Statements 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 September 30, 2013 and 2012 was $1,191 and $1,166, respectively, and $3,536 and $3,486 for the nine months ended September 30, 2013 and 2012, 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 Sheets. 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 for each of the three months ended September 30, 2013 and 2012, and $329 for each of the nine months ended September 30, 2013 and 2012.

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 Statements of Comprehensive Loss. Cumulative mark-to-market adjustments resulted in a gain of $97 and a loss of $572 for the three months ended September 30, 2013 and 2012, respectively, and a gain of $3,168 and a loss of $1,531 for the nine months ended September 30, 2013 and 2012, 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 September 30, 2013 and December 31, 2012, $1,890 and $5,180 of hedge collateral was posted under the agreement, respectively.

Restructuring Activities

During the fourth quarter of 2012, the Company announced a corporate restructuring plan to significantly reduce its cost structure in response to setbacks in several of its development programs. In connection with this plan, the Company recognized restructuring costs of $1,759, consisting of one-time termination benefits and charges related to vacant office space.

The following table sets forth activity in the restructuring liability for the nine months ended September 30, 2013.

	Employee separation costs	Facilities related charges	Total
Balance at December 31, 2012	$ 1,604	$ 97	$ 1,701
Accruals		(34)	(34)
Payments	(1,509)		(1,509)
Balance at September 30, 2013	$ 95	$ 63	$ 158

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 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 three months ended September 30, 2013 and 2012 does not include 2,783 and 1,207, respectively, of such potential common shares, as their impact would be anti-dilutive. The calculation of diluted earnings per share for the nine months ended September 30, 2013 and

2012 does not include 1,731 and 1,158, respectively, of such potential common shares, as their impact would be anti-dilutive.

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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

A significant source of revenue for the Company is reimbursement of peramivir development expenses, which is earned under the cost-plus-fixed-fee contract with BARDA/HHS. The Company relies on BARDA/HHS to reimburse substantially 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; however, this revenue has been decreasing recently due to a reduction in development activity. The completion or termination of this program/collaboration could negatively impact the Company s future Consolidated Statements of Comprehensive Loss and Cash Flows. Another significant source of revenue is royalty revenue from the net sales of RAPIACTA®. The underlying cash flow from these royalty payments goes directly to pay the interest, and then the principal, on the Company s non-recourse notes payable. Payment of the interest and the ultimate repayment of principal of these notes will be entirely funded by future royalty payments derived from net sales of RAPIACTA®. 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 Sheets. 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 no more than 18 months. A significant amount of the Company s receivables are due from BARDA/HHS, for which there is no assumed credit risk, or from Shionogi, for which a single royalty payment is remitted within two months of quarterly sales underlying the royalty payment. Accordingly, credit risk for these receivables is considered minimal based upon the nature of the underlying receivable and their timely remittance.

Recent Accounting Pronouncements

On February 5, 2013, the Financial Accounting Standards Board issued an amendment to ASU 2013-02, Comprehensive Income (Topic 220) (ASU 2013-02) to the disclosure requirements for reporting reclassifications out of accumulated other comprehensive income. ASU 2013-02 was effective for the first interim or annual period beginning after December 15, 2012. The amendment requires companies to present information about reclassification adjustments from accumulated other comprehensive income to the income statement, including the income statement line items affected by the reclassification. The information must be presented in the financial statements in a single note or on the face of the financial statements. The new accounting guidance also requires the disclosure to be cross referenced to other financial statement disclosures for reclassification items that are not reclassified to net income in their entirety in the same reporting period. The Company adopted ASU 2013-02 in the first quarter of 2013. The adoption did not have a material impact on the Company s consolidated financial position, results of operations, or cash flows.

Note 2 Stock-Based Compensation

As of September 30, 2013, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan) and the Employee Stock Purchase Plan (ESPP), both of which were amended and restated in March 2012 and approved by the Company s stockholders in May 2012. Stock-based compensation expense of $3,479 ($3,404 of expense related to the Incentive Plan and $75 of expense related to the ESPP) was recognized during the first nine months of 2013, while $3,345 ($3,233 of expense related to the Incentive Plan and $112 of expense related to the ESPP) was recognized during the first nine months of 2012.

There was approximately $6,383 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of September 30, 2013. That cost is expected to be recognized as follows: $1,819 during the remainder of 2013, $2,561 in 2014, $1,398 in 2015, $533 in 2016 and $72 in 2017.

Stock Incentive Plan

The Company grants stock option awards and restricted stock awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company s stock at the date of grant. Prior to March 1, 2011, stock option awards granted to employees generally vest

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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. In January 2013, the Company made retention grants of stock option awards and restricted stock. These awards vest 50% each year until fully vested after two years. In August 2013, the Company issued 1,032 performance-based stock options. These awards vest upon successful completion of specific development milestones. As of September 30, 2013 and based on the information available at that time, it is not considered probable that any of the specific development milestones will be met and, accordingly, no compensation expense has been recognized for options under this performance based grant award. 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 5 to 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, 2012	2,815	8,073	$ 6.09
Restricted stock awards granted	(310)		
Restricted stock awards cancelled	53		
Stock option awards granted	(3,237)	3,237	3.02
Stock option awards exercised		(562)	2.37
Stock option awards cancelled	1,624	(1,624)	6.96
Balance September 30, 2013	945	9,124	$ 5.07

For stock option awards granted under the Incentive Plan during the first nine months of 2013 and 2012, 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 nine months of 2013 and 2012 was $2.10 and $3.24, 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 nine months of 2013 and 2012. 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.

Weighted Average Assumptions for Stock Option Awards Granted to

Employees and Directors under the Incentive Plan

	2013	2012
Expected Life in Years	5.0	5.4
Expected Volatility	85%	87%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	0.90%	0.86%

Employee Stock Purchase Plan

The Company has reserved a total of 975 shares of common stock to be purchased under the ESPP, of which 88 shares remain available for purchase at September 30, 2013. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of

the beginning price or 85% of the ending price during each six-month purchase interval. 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 89 shares during the first nine months of 2013 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

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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. BARDA/HHS has rights under certain contract clauses to terminate this contract. The contract is terminable by BARDA/HHS at any time for breach or without cause.

In March 2013, BioCryst received written notification from BARDA/HHS in the form of a Stop-Work Order directing the Company to cease work on peramivir under its U.S. Government contract, except for certain activities primarily related to BioCryst s U.S. Food & Drug Administration (FDA) Type C meeting that was completed in April 2013. The notification confirmed that BARDA/HHS would continue to support and fund certain activities necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests.

On July 11, 2013, BARDA/HHS released funding under the contract to enable completion of an NDA filing. The decision by BARDA/HHS was the result of an In-Process Review (IPR) meeting that occurred in the second quarter of 2013. Based on the results of the IPR, BARDA/HHS decided to modify the March 2013 stop-work order to support activities directly associated with the filing of an NDA and to allow no more than $12,800 of funding already obligated under the contract to be used for that purpose.

Shionogi & Co., Ltd. (Shionogi). In March 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. 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.

National Institute of Allergy and Infectious Diseases (NIAID). In September 2013, NIAID contracted with the Company for the development of BCX4430 as a treatment for Marburg virus disease. NIAID, part of the National Institutes of Health, made an initial award of $5,000 to BioCryst. The total funding under this contract could be up to $22,000, if all contract options are exercised by NIAID.

The goals of this contract are to file investigational new drug (IND) applications for intravenous (i.v.) and intramuscular (i.m.) BCX4430 for the treatment of Marburg virus disease, and to conduct an initial Phase 1 human clinical trial. The aggregate $22,000 contract and option funding supports the appropriate IND-enabling program and the initial clinical trial.

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.

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

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received 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. 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). 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 concluded 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 three months ended March 31, 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 product candidates from this collaboration are forodesine and BCX4208. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, product candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or employees of 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 product candidates that might arise from research on a series of PNP inhibitors, including forodesine and BCX4208. 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. At June 30, 2013, the Company, during its routine evaluation, assessed the carrying value of its deferred collaboration costs associated with this agreement and determined a $4,995 write-off of the underlying asset was necessary. The determination of the write-off was based upon management s estimate of the future cash flows associated with out-licensing the PNP technology as compared to the carrying value of the deferred collaboration costs.

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.

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On June 19, 2012, the Company further amended its agreement with the Licensors whereby the Licensors changed the definition of the term Field to exclude certain compounds from the definition and also to include within the definition of the term Field the antiviral use of BCX4430. As of September 30, 2013, the Company is in the process of renegotiating the terms of this agreement.

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, each party shall cease using the other party s proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on 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. In accordance with termination provision under the license agreement, the Company provided ninety (90) days written notice of termination in April, 2013 following the termination of its antiviral development program for treatment of hepatitis C as announced in January 2013. The license agreement was terminated on July 28, 2013.

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 its license agreement with Shionogi (the Shionogi Agreement), pursuant to which Shionogi licensed from the Company the rights to market peramivir 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 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 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% 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 1st 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 peramivir 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.

In September 2013, Royalty Sub paid $1,844 of interest on the PhaRMA Notes from royalty payments received from RAPIACTA® sales from the preceding four calendar quarters. This payment resulted in an obligation shortfall of approximately $2,356 associated with accrued interest

due September 3, 2013. As stipulated under the PhaRMA Notes Indenture, if the amount available for payment on any Payment Date is insufficient to pay all of the interest due on a Payment Date, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Accordingly, commencing in September 2013, the Company began accruing interest at 14% per annum on the interest shortfall of $2,356. Under the terms of the Indenture, Royalty Sub s inability to pay the full amount of interest payable in September 2013 did not constitute an event of default under the PhaRMA Notes unless the shortfall, plus interest thereon, is not satisfied on the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2014.

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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 September 30, 2013, 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:

Payment Dates (Between Indicated Dates)	Redemption Percentage
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. Cumulative mark-to-market adjustments resulted in a gain of $97 and a loss of $572 for the three months ended September 30, 2013 and 2012, respectively, and a gain of $3,168 and a loss of $1,531 for the nine months ended September 30, 2013 and 2012, respectively. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds. As of September 30, 2013, $1,890 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 payment of a $1,950 termination fee. If the Company terminates the hedge agreement with respect to currency hedges for 2016 through 2020, the maximum obligation under the currency hedge is $5,850, including the $1,950 termination fee.

Note 5 Stockholders Equity

In June 2011, the Company entered into an At Market Issuance Sales Agreement (the ATM) with McNicoll, Lewis & Valak (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, 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% of the gross proceeds of the sales price per share of any common stock sold under the ATM. 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 nine months ended September 30, 2013, the Company sold an aggregate of 2,883 shares of common stock at an average per share price of $1.85 pursuant to the Agreement for net proceeds of $5,218.

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On August 6, 2013, the Company completed a public offering of 4,600 shares of common stock at a price of $4.40 per share. Net proceeds available to the Company from the offering, after deducting costs, were approximately $18,500.

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 product candidates and retention of key employees. In order for any of our product candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the product 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, seasonality of influenza, ongoing discussions with government agencies regarding future peramivir and/or BCX4430 development, as well as entering into, or modifying, licensing agreements for our product candidates. 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, including research and development expenses (and whether these expenses are reimbursable under government contracts), drug manufacturing, and clinical research activities, the ongoing requirements of our development programs, and the 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.

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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. 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 product candidates whereby we out-license rights to product candidates in geographies or therapeutic areas where we do not intend to and/or do not have the ability to commercialize them. We currently have commercial partnerships with Shionogi and Green Cross and a development partnership with Mundipharma.

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

Peramivir is a potent, intravenously administered investigational antiviral agent that rapidly delivers high plasma concentrations to the sites of influenza infection. Discovered by BioCryst, peramivir inhibits the interactions of influenza neuraminidase, an enzyme that is critical to the spread of influenza within the host. In laboratory tests, peramivir has shown activity against multiple influenza strains, including H7N9, H5N1 and pandemic H1N1 swine flu viral strains. We are developing peramivir under a $234.8 million contract with BARDA/HHS. We are seeking an indication for the treatment of acute uncomplicated influenza and expect to submit the peramivir NDA by the end of 2013.

In March 2013, we received written notification from BARDA/HHS in the form of a Stop-Work Order directing us to cease work on peramivir under our U.S. Government contract, except for certain activities primarily related to our FDA Type C meeting. The notification confirmed that BARDA/HHS would continue to support and fund certain activities necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests.

On April 15, 2013, we announced that we had received final meeting minutes from our Type C meeting regarding i.v peramivir with the FDA. The meeting minutes confirmed that our proposed peramivir NDA content supports a reviewable NDA submission for the indication of acute uncomplicated influenza. In addition, we have completed a pre-NDA meeting with the FDA, and in this meeting, we reached agreement with the FDA regarding all requirements for a complete NDA submission.

On July 11, 2013, we announced that BARDA/HHS released funding of up to $12.8 million under the current $234.8 million contract to fund predominantly all activities necessary to file a New Drug Application (NDA) for intravenous peramivir. The decision by BARDA/HHS was a result of an In-Process Review (IPR) meeting that occurred in the second quarter of 2013. Based on the results of the IPR, BARDA/HHS decided to modify the March 2013 stop-work order to support activities directly associated with the filing of an NDA. In light of this funding decision, substantially all activities to file the peramivir NDA will be covered by this funding; however, we do expect to incur some modest unreimbursed costs in 2013 for the peramivir program.

BCX4161 & 2nd generation HAE compound

Discovered by BioCryst, BCX4161 is a novel, selective inhibitor of plasma kallikrein in development as an orally administered treatment for the prevention of attacks in patients with hereditary angioedema (HAE). By inhibiting plasma kallikrein, BCX4161 suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients. HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation.

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In March 2013, we announced initialization of a BCX4161 Phase 1 clinical trial to support the product candidate s development as a treatment for HAE. The main objectives for the BCX4161 Phase 1 clinical trial were to demonstrate safety, adequate and consistent drug exposure, and pharmacodynamic effects after oral administration. On July 22, 2013, we announced that the Phase 1 clinical trial of orally-administered BCX4161 in healthy volunteers successfully met all of its objectives. The safety, tolerability, drug exposure and on-target kallikrein inhibition results of the Phase 1 trial strongly support advancing the development program into a Phase 2a study in HAE patients.

Overall, 87 healthy volunteers completed the study: 30 received a single dose of BCX4161 from 50 mg up to 1000 mg, 40 subjects were dosed with 100 mg, 200 mg, 400 mg, or 800 mg BCX4161 every eight hours for seven days and 17 received placebo. Oral administration of BCX4161 was generally safe and well tolerated. There were no serious adverse events and no dose limiting adverse events. Laboratory tests of coagulation remained normal. Drug exposure was dose proportional through 400 mg three times a day. Steady state (day seven) blood levels were 30% higher compared to the first day of dosing. At 400 mg three times a day, pre-dose geometric mean (coefficient of variance, CV) drug levels on day 7 were 28.6 ng/mL (CV 77%) and post-dose maximum drug levels were 152 ng/mL (CV 57%). Kallikrein inhibition was observed throughout the dosing interval, $p<0.0001$ compared to placebo.

In late October 2013, we initiated participant screening in a proof of concept Phase 2a clinical trial in patients with HAE (entitled OPuS-1). This trial will test 400 mg of BCX4161 administered three times daily for 28 days in a randomized, placebo-controlled, two-period cross-over design. Approximately 25 HAE patients who have a high frequency of attacks (more than one per week) will be enrolled. The main goals for this clinical trial are to evaluate the safety and tolerability of BCX4161 and to estimate the degree of efficacy in reducing the frequency of attacks. This study is designed to provide proof of concept for oral kallikrein inhibition as a treatment strategy for HAE. On July 31, 2013, we were notified by the FDA that it had removed the clinical hold placed on BCX4161. This notification provides us the ability to initiate BCX4161 clinical trials in the United States and/or include U.S. clinical sites in our BCX4161 clinical trials. To date, our BCX4161 clinical trials have not been conducted in the U.S.

In addition, we are finalizing our nonclinical evaluation of a number of potent and specific second generation oral kallikrein inhibitors with oral bioavailability between 20% and 60%. One or more compounds are expected to enter preclinical development before the end of 2013.

BCX4430

In September 2013, the National Institute of Allergy and Infectious Diseases (NIAID) contracted with BioCryst for the development of BCX4430 as a treatment for Marburg virus disease. NIAID, part of the National Institutes of Health, made an initial award of $5.0 million to BioCryst. The total funding under the contract could be up to $22.0 million, if all contract options are exercised by NIAID. The goals of this contract are to file investigational new drug (IND) applications for intravenous (i.v.) and intramuscular (i.m.) BCX4430 for the treatment of Marburg virus disease, and to conduct an initial Phase 1 human clinical trial. The aggregate $22.0 million contract and option funding supports the appropriate IND-enabling program and the initial clinical trial.

On November 12, 2012, we announced proof-of-principle data at the 2nd Antivirals Congress in Cambridge demonstrating that BCX4430 is efficacious and well-tolerated in a preclinical disease model for evaluating efficacy against yellow fever virus infection.

The objective of our broad spectrum antiviral (BSAV) program is to develop a broad-spectrum therapeutic for viruses that pose a threat to national health and security. We are continuing our collaboration with U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) regarding filoviruses, while seeking additional U.S. Government funding for the further development of BCX4430. The primary focus of the program is treatment of hemorrhagic fever viruses, such as Marburg virus and Ebola virus. BCX4430 is the lead compound in our BSAV research program.

Ulodesine

Ulodesine is a purine nucleoside phosphorylase (PNP) inhibitor developed as a once-daily oral, chronic treatment for gout. It acts upstream of xanthine oxidase in the purine metabolism pathway to reduce the production of serum uric acid (sUA). Xanthine oxidase inhibitors, such as allopurinol and febuxostat, reduce uric acid production. In Phase 2 clinical trials, the combination of low doses of ulodesine and allopurinol resulted in a synergistic effect in reducing sUA.

In July 2012, we announced favorable 52-week safety results and sustained efficacy from the extension phase of the 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, as well as positive Phase 2 safety results in patients with mild to moderate

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renal impairment. The approximate doubling of sUA response rates with ulodesine seen at 12 weeks was sustained through 52 weeks of treatment. After 52 weeks of treatment, ulodesine doses of 5 mg, 10 mg, and 20 mg/day showed response rates of 45%, 47% and 64%, respectively, compared to 19% for placebo. With the results of the 203 clinical trial, we have now concluded Phase 2 testing and are ready for Phase 3 development. We intend to out-license ulodesine on a worldwide basis prior to initiating Phase 3 development. Due to the cost of Phase 3 development and commercialization, we do not plan to initiate Phase 3 development without a partner. We cannot predict if, or when, we will be successful with an outlicensing transaction.

Forodesine

Discovered by BioCryst, forodesine is a PNP inhibitor in development by Mundipharma as a treatment for cancer under a world-wide license agreement. In January 2013, Mundipharma s Japanese subsidiary, Mundipharma K.K., initiated enrollment in a phase 1/2 clinical trial of forodesine in recurrent/refractory peripheral t-cell lymphoma patients. The objective of the Phase 1 portion is to confirm safety and tolerability in recurrent/refractory peripheral T-cell lymphoma patients during repeated oral administration of forodesine 300 mg twice daily for 28 days, to evaluate pharmacokinetics, and to determine the recommended dose for Phase 2. The goal of the Phase 2 portion is to evaluate the efficacy, safety, and pharmacokinetics of the recommended dosage regimen determined in the Phase 1 portion. The primary efficacy endpoint shall be objective response rate (ORR) based on evaluation by an image assessment committee.

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. 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 Amended and Restated 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 are 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). The world-wide license rights were granted to Mundipharma upon execution of Amended and Restated Agreement and the Knowledge Transfer was completed in the first quarter of 2012. We have accounted for these elements as a combined unit of accounting as neither one has stand-alone value to Mundipharma. Upon completion of the Knowledge Transfer, the unamortized deferred revenue and deferred expense of $7.8 million and $1.9 million, respectively, was recognized in our Statements of Comprehensive Loss in the quarter ended March 31, 2012.

Results of Operations (three months ended September 30, 2013 compared to the three months ended September 30, 2012)

For the three months ended September 30, 2013, total revenues decreased to $2.4 million compared to $5.8 million for the three months ended September 30, 2012. This decrease resulted primarily from the recognition of $2.8 million of previously deferred RAPIACTA® royalty revenue in the third quarter of 2012 and approximately a $532,000 decline in reimbursable BARDA/HHS revenue associated with a decline in third quarter 2013 reimbursable peramivir development expenses, as compared to the third quarter of 2012. Revenues in the third quarter of 2013 included $2.1 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of i.v. peramivir and $0.3 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the third quarter of 2012 included $2.8 million of royalty revenue from Shionogi sales of RAPIACTA®, $2.7 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.

Research and development expenses for the third quarter of 2013 decreased to $8.0 million from $12.1 million in the same quarter of 2012. The 2013 R&D expenses, compared with 2012, reflect decreased spending on our ulodesine and BCX5191 programs, reduced R&D infrastructure costs and the conclusion of the clinical development program for peramivir and its transition to NDA preparation. This decrease was partially offset by higher development expenses for BCX4161 associated with advancing our hereditary angioedema program.

General and administrative expenses decreased to $1.3 million for the third quarter of 2013 compared to $1.6 million in the same quarter of 2012. The decrease of $0.3 million is due primarily to the December 2012 corporate restructuring that reduced BioCryst s cost structure and operations.

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Interest expense related to the non-recourse notes issued in conjunction with the non-dilutive peramivir royalty monetization transaction was $1.2 million for the third quarter of 2013 and 2012. In addition, a mark-to-market gain of $0.1 million was recognized in the third quarter of 2013 related to our foreign currency hedge, established in conjunction with the royalty monetization, as compared to a mark-to-market loss of $0.6 million in the same quarter in 2012. These gains/losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement.

Results of Operations (nine months ended September 30, 2013 compared to the nine months ended September 30, 2012)

For the nine months ended September 30, 2013, total revenues decreased to $6.8 million compared to $22.2 million for the nine months ended September 30, 2012. The decrease was primarily due to the recognition of $7.8 million of previously deferred forodesine-related revenue during the first quarter of 2012, as well as a $6.9 million decrease in BARDA/HHS revenue due to a decline in reimbursable peramivir expenses as compared to the first nine months of 2012. Revenues in the first nine months of 2013 included $2.0 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, $3.8 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of i.v. peramivir and $0.9 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the first nine 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, $2.8 million of royalty revenue from Shionogi sales of RAPIACTA®, $10.7 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and $0.9 million associated with collaborative revenue amortization from other corporate partnerships.

Research and development (R&D) expenses decreased to $27.1 million for the nine months of 2013 from $40.4 million in the same nine months of the prior year. Lower 2013 development expenses were associated with spending decreases in the BCX5191 and peramivir programs as well as reduced R&D infrastructure costs, which were partially offset by higher BCX4161 costs. In addition, approximately $1.9 million of this decrease resulted from the recognition in the 2012 period of previously deferred expenses associated with the Amended and Restated License and Development Agreement with Mundipharma which was not repeated in the 2013 period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
R&D expenses by program:				
BCX4161	$ 4,312	$ 2,306	$ 10,549	$ 6,593
Peramivir	2,187	2,373	4,479	10,001
BCX4430	623	286	3,173	946
Ulodesine	213	2,698	5,844	8,175
BCX5191		2,590	532	6,857
Forodesine			22	2,176
Other research, preclinical and development costs	642	1,819	2,517	5,626
Total R&D expenses	$ 7,977	$ 12,072	$ 27,116	$ 40,374

General and administrative expenses decreased to $4.0 million for the first nine months of 2013 compared to $4.9 million in the same period of the prior year. The decrease of $0.9 million is primarily due to the December 2012 restructuring that reduced BioCryst s cost structure and operations.

Interest expense related to the non-recourse notes issued in conjunction with the non-dilutive peramivir royalty monetization transaction was $3.5 million for the first nine months of both 2013 and 2012. In addition, a mark-to-market gain of $3.2 million was recognized in the first nine months of 2013 related to our foreign currency hedge, established in conjunction with the royalty monetization, compared to a mark-to-market loss of $1.5 million in the same quarter in 2012, resulting from changes in the U.S. dollar/Japanese yen exchange rate. These gains/losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception and we expect our 2013 operating expenses to exceed our 2013 revenue. Our operations have principally been funded through public offerings and private placements of equity

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securities; cash from collaborative and other research and development agreements, including government contracts; and to a lesser extent, the PhaRMA Notes financing. In addition, we have funded our operations and specific development programs through government contracts. Currently, we have $234.8 million of funding through December 2013 under a BARDA/HHS contract for the development of peramivir and $5.0 million of committed funding under a $22.0 million contract with NIAID for the development of BCX4430. Our BARDA/HHS contract is subject to a March 2013 stop-work order, which was modified in July 2013 to support activities directly associated with a peramivir NDA filing and to allow up to $12.8 million of funding under the contract to be used for that purpose. However, the level of activity on the peramivir program has decreased as compared to previous quarters and fiscal years, and as a result, revenue associated with reimbursement of peramivir development expenses has become a smaller component of our total revenue and therefore has contributed less to our operating cash flows. 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. 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 September 30, 2013, we had net working capital of $33.7 million, an increase of approximately $8.9 million from $24.8 million at December 31, 2012. The increase in working capital was principally due to our normal operating expenses associated with the development of our product candidates, which offset approximately $18.5 million in net proceeds derived from the sale of 4.6 million shares of common stock through our August 2013 public offering, $5.2 million in net proceeds derived from the sale of approximately 2.9 million shares of common stock through our At-the-Market (ATM) financing facility and $3.3 million in cash collateral collected under our foreign currency hedge associated with changes in exchange rates. Our principal sources of liquidity at September 30, 2013 were approximately $26.2 million in cash and cash equivalents; approximately $17.2 million in investments considered available-for-sale; and approximately $2.4 million in BARDA/HHS and NIAID receivables. As of September 30, 2013, we have sold an aggregate amount of 7.8 million shares of common stock at an average price of $3.18 pursuant to the ATM for net proceeds of $24.2 million. There were no sales of common stock under our ATM arrangement in the third quarter of 2013.

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 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, 2012, we had long-term operating lease obligations, which provide for aggregate minimum payments of approximately $1.0 million in 2013, $1.0 million in 2014 and $0.4 million in 2015. These obligations include the future rental of our operating facilities.

We plan to finance our needs principally from the following:

payments under our contract with BARDA/HHS, NIAID and from other U.S. Government entities;

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 product candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and cash burn rate could vary significantly

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depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount and timing of funding we receive from BARDA/HHS for peramivir and NIAID for BCX4430, the amount of funding or assistance, if any, we receive from other governmental agencies or other new partnerships with third parties for the development of our product candidates, the progress and results of our current and proposed clinical trials for our most advanced product candidates, the progress made in the manufacturing of our lead product candidates and the progression of our other programs.

With the funds available at September 30, 2013, future amounts that are expected to be received from BARDA/HHS and NIAID, and our other financing sources, we believe these resources will be sufficient to fund our operations through 2014. 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 contracts with BARDA/HHS and NIAID and receive reimbursement;
- the progress, number of programs and magnitude of our research, drug discovery and development activities;
- changes in existing collaborative relationships or government contracts;
- our ability to establish new and 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 product candidates or a decision to build or expand internal development and commercial capabilities;
- our, or our partners , ability to obtain regulatory approval of our product candidates;
- 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 product candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our product candidates to support our preclinical research and clinical trials;
- changes in personnel and related costs to support the development of our product candidates;

the scope of manufacturing of our drug substance and drug products required for future NDA filings;

competitive and technological advances;

the time and costs involved in obtaining regulatory approvals; and

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

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time we deem market conditions to be favorable. Additional funding, whether through additional sales of equity or debt securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from the BARDA/HHS and NIAID contracts 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 and NIAID of our BCX4403 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 product 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 product 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.

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Financial Outlook for 2013

Based upon our strategic and development operations, we expect 2013 operating cash usage to be in the range of $22 to $26 million, and expect our total 2013 operating expenses to be in the range of $45 to $55 million. Our operating cash forecast remains unchanged from the guidance originally provided in February 2013. Our operating expense range increased from our February guidance range of $25 to $35 million based upon the incremental operating expenses associated with the pending peramivir NDA filing and the write-off of deferred collaboration costs associated with our PNP agreement. Our operating cash forecast excludes any impact of our royalty monetization, hedge collateral posted or returned, sale of stock in the marketplace, and any other non-routine cash outflows or inflows, such as restructuring and transaction costs. 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 section located elsewhere in this report.

Off-Balance Sheet Arrangements

As of September 30, 2013, 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 2012 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.

Accrued Expenses

We 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 an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost 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 based on the 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 clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort 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 these costs, our actual expenses could differ from our estimates.

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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 is 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. 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.

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

Product Sales

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 September 30, 2013, we had deferred collaboration expenses of approximately $0.3 million. These deferred expenses were sub-license payments, paid to our academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments 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.

We group our R&D expenses into two major categories: direct external expenses and indirect expenses. Direct expenses consist of compensation for R&D personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, patent-related costs, as well as other costs related to our clinical and preclinical studies. These costs are accumulated and tracked by program. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. These costs apply to work on our clinical and preclinical candidates as well as our discovery research efforts.

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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 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 Agreement. 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 would be $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 Statement of Comprehensive Loss. Cumulative mark-to-market adjustments for the nine months ended September 30, 2013 resulted in a $3.2 million gain. 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 Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds and $1.9 million was posted under the agreement as of September 30, 2013.

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 jurisdictions 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 o 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;

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the potential funding from our contract with BARDA/HHS for the development and support of the NDA filing for peramivir and the potential funding from our contract with NIAID for the development of BCX4430;

the NDA filing or FDA approval 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, H5N1 and H7N9 or other strains of influenza;

the further preclinical or clinical development and commercialization of our product candidates, including our HAE program, peramivir, BCX4430, forodesine, ulodesine and other PNP inhibitor development programs;

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

our ability to establish and maintain collaborations or out-license rights to our drug candidates;

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

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 product 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, including our financial outlook for the remainder of 2013;

the timing or likelihood of regulatory filings and approvals;

our ability to raise additional capital to fund our operations

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 PhaRMA Notes.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. 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

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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.

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 September 30, 2013, 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 September 30, 2013 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 losses since our inception, expect to continue to incur such losses, and may never be profitable.

Since our inception, 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. We expect that such losses will fluctuate from quarter to quarter and losses and fluctuations may be substantial.

To become profitable, we, or our collaborative partners, must successfully manufacture and develop 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.

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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 clinical 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. Regulatory authorities may interrupt, delay or halt clinical trials for a product candidate for any number or reasons.

Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability.

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

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

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Lack of adequate drug supply or delays in patient enrollment, including in our planned trials for HAE, 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, including with respect to our planned NDA filing for peramivir.

Our clinical trials may not adequately show that our drugs are safe or effective.

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the trial protocols. Failure to achieve either of these in any of our programs, including BCX4161, could result in delays in our trials or 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 or the termination of programs.

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 are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, or development and commercial diligence obligations, are unable or fail to make milestone payments or material data use 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 or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

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

As our programs advance, our costs are likely to increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements, and additional personnel resources and testing required for supporting the development of our product candidates will consume significant capital resources. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to raise additional capital; the development progress of our collaborative agreements for our product candidates; the amount of funding we receive from BARDA/HHS for peramivir; the amount of funding or assistance we receive from the National Institute of Allergy and Infectious Diseases (NIAID) or other government agencies for BCX4430 or from other new partnerships with third parties for the development of our product candidates including ulodesine or BCX4161; the amount or profitability of any orders for peramivir or BCX4430 by any government agency or other party; the progress and results of our current and proposed clinical trials for our most advanced drug product candidates, including BCX4161; 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 enter into one or more acceptable partnership arrangements in order to complete the development of ulodesine for the treatment of gout. The inability to enter into sufficient acceptable partnership arrangements may require us to terminate the development of ulodesine.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from any BARDA/HHS or NIAID 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.

In order to continue future operations and continue our drug development programs, we will be required to raise additional capital. In addition to seeking strategic partnerships, transactions and government funding, we may decide to access the equity or debt markets or seek other sources to meet liquidity needs. Our ability to raise additional capital may be limited and may greatly depend upon the success of ongoing development related to our current drug development programs, including the planned NDA filing for peramivir, the Phase 2a clinical trial of BCX4161, progress of our second generation HAE compounds, and funding for and continued successful development of BCX4430. In addition, constriction and volatility in the equity and debt markets may restrict our future flexibility to raise capital when such needs arise. Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, and the U.S. Government) which may be unstable or may become unstable in the current economic and political environment. Any such instability may impact these parties ability to fulfill contractual obligations to us or they might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted. Any such unfavorable outcomes in our current programs or unfavorable economic conditions could place severe downward pressure on the stock and credit markets, which could reduce the return available on invested corporate cash, which if severe and sustained could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development of our product candidates.

If BARDA/HHS were to eliminate, reduce or delay funding from our 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 continued development or regulatory registration of this product 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 that 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

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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 U.S. 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 government contracts with BARDA/HHS and NIAID have 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. We have also entered into a contract with NIAID for the development of BCX4430 as a treatment for Marburg virus disease.

In contracting with these government agencies, 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 that 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 typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, each of 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 do not permit these recoveries. In the event of termination, the U.S. Government may dispute wind down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. Government for denying certain payments under the contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, if the U.S. 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.

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. Audits conducted by the U.S. Government for the BARDA/HHS contract have been performed and concluded through fiscal 2009; all subsequent fiscal years are still open and auditable. 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 or NIAID 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 or NIAID would be entitled to recoup any overpayment from us 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 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 product candidates or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product

candidates could be reduced, delayed or eliminated.

Our business strategy is to increase the asset value of our product 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 product candidates.

Currently, we have established collaborative relationships with Mundipharma for the development and commercialization of forodesine and with each of Shionogi and Green Cross for the development and commercialization of peramivir. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

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

- our contracts for collaborative arrangements may expire;

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- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day to day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our product candidates would severely affect our business, because if our product 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.

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, have significantly more resources, and their products could reach the market before ours, be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our Company and our products;

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

our ability to successfully commercialize our products is 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 from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and 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 product candidates will be delayed or stopped.

We rely heavily upon other parties for many important stages of our product 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 product candidates;

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

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- management of our clinical trials, including medical monitoring and data management;
- execution of additional toxicology studies that may be required to obtain approval for our product candidates; and
- manufacturing the starting materials and drug substance required to formulate our drug products and the product 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 product candidates.

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

Our development of peramivir for influenza is subject to all disclosed drug development and potential commercialization risks and numerous additional risks. Any potential revenue benefits to us are highly speculative.

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

- i.v. peramivir may not prove to be safe and sufficiently effective for market approval in the United States or other major markets.
- necessary government or other third party funding and clinical testing for further development of peramivir may not be available timely, at all, or in sufficient amounts;
- 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.

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.

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

To the extent that peramivir is used as a treatment for influenza, 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.

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

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

- inconsistent production yields;
- product liability claims;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- scheduling of plant time with other vendors or unexpected equipment failure;
- potential catastrophes that could strike their facilities 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 or cooperation with regulations and specifications or requests set forth by the FDA or other foreign regulatory agencies, particularly associated with our pending peramivir NDA.

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

If we are unable to maintain current manufacturing or other contract relationships, or enter into new agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance or failure to comply with any regulatory agency on the part of any of our third-party manufacturers, we may not be able to complete development of, seek timely approval of, or market, our product candidates.

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

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Royalties and milestone payments from Shionogi under the Company s license agreement with Shionogi (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.

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, 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, 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 any 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. 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.

On September 3, 2013, we paid $1.8 million of interest on the PhaRMA Notes from royalty payments received from RAPIACTA® sales from the preceding four calendar quarters. This payment resulted in an obligation shortfall of $2.4 million associated with accrued interest due September 3, 2013. As stipulated under the PhaRMA Notes indenture, if the amount available for payment is insufficient to pay all of the interest due on a Payment Date, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Accordingly, commencing on September 3, 2013, we began accruing interest at 14% per annum on the interest shortfall of $2.4 million. Under the terms of the indenture relating to the PhaRMA Notes, the inability to pay the full amount of interest payable on September 3, 2013 did not constitute an event of default under the PhaRMA Notes unless we fail 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, 2014. Based on sales forecasts of RAPIACTA® provided to us by Shionogi, we currently estimate sufficient royalties will be received to fund the September 3, 2013 interest shortfall prior to September 1, 2014, however, no assurances can be given that these royalties will be received and available for payment of the interest shortfall.

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, the 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 Agreement 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 Agreement.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a foreign 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 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 Agreement remains in effect, 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. 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

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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 September 30, 2013, we have realized a foreign currency hedge gain of approximately $3.2 million and posted cash collateral of approximately $1.9 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. The FDA has not approved any of our 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. There are many companies seeking to develop products for the same indications that we are working on. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced marketing and manufacturing organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the licensing of desirable disease targets, licensing of desirable product candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

other drug development technologies;

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

new small molecule or other classes of therapeutic agents.

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

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We and our partners are performing research on or developing products for the treatment of several disorders including influenza, gout, HAE, and recurrent/refractory peripheral t-cell lymphoma, as well as broad spectrum antivirals which may be developed as medical countermeasures. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required funding or government support, obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai Co. Ltd. s TARGRETIN ® for CTCL and the current neuraminidase inhibitors marketed by GSK and Roche for influenza and CINRYZE, for HAE, marketed by ViroPharma Incorporated. 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, HAE, 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 impede our funding efforts, render technology and product candidates non-competitive or eliminate or reduce demand for our product candidates.

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, trademark 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 may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no guarantee that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

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

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a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

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

We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- if patents do issue we 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.

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 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;

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

withdrawal of clinical trial volunteers or patients;

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

regulatory investigations that could require costly recalls or product modifications;

litigation costs; and

the diversion of management s attention from managing our business.

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 store clinical and stability samples at our facility that could be damaged if our facility incurs 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 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 product candidates and the expansion of our business will be delayed or stopped.

We are highly dependent upon our senior management and scientific team, the unexpected loss of whose services might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, operational and scientific personnel will harm our business because we rely upon these personnel for many critical functions of our business.

Our 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.

We have a number of shareholders who own greater than 5% 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.

Our stock price has been, and is likely to continue to be, highly volatile, which could result in the value of an investment to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended September 30, 2013, the 52-week range of the market price of our stock was from $1.08 to $7.59 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;

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

announcements relating to the status of our programs;

developments and announcements regarding new and virulent strains of influenza;

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

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

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

regulatory developments in both the United States and foreign countries;

public concern as to the safety of pharmaceutical products;

actual or anticipated fluctuations in our operating results;

changes in financial estimates or recommendations by securities analysts;

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

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

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

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

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

period-to-period fluctuations in our financial results.

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 October 31, 2013, there were 59,091,393 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition.

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 $70.0 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 September 30, 2013, we have issued approximately $24.9 million of common stock under this shelf registration utilizing an ATM facility. In addition, we issued 4,600,000 shares of common stock for gross proceeds of $20.2 million, under this shelf registration on August 6, 2013 in a public offering.

As of October 31, 2013, there were 9,557,570 stock options and shares of restricted stock outstanding and 958,958 shares available for issuance under our Amended and Restated Stock Incentive Plan and 87,535 shares available for issuance under our Employee Stock Purchase Plan and we could also make equity compensation grants outside of our Stock Incentive 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.

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 or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

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Item 6. Exhibits

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 8th day of November, 2013.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer (Principal Executive Officer)

/s/ Thomas R. Staab, II
Thomas R. Staab, II
Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Principal Accounting Officer)

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INDEX TO EXHIBITS

Number	Description
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed July 24, 2007.
3.3	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)*	Amendment #15 to the Agreement between BioCryst Pharmaceuticals, Inc. and the U.S. Department of Health and Human Services dated September 5, 2013.
(10.2)*	Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases dated September 12, 2013.
(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 nine months ended September 30, 2013, 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.
* Confidential treatment requested.