BIOCRYST PHARMACEUTICALS INC Form 10-Q November 08, 2012 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2012

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State of other jurisdiction of

62-1413174 (I.R.S. Employer

incorporation or organization)

Identification No.)

4505 Emperor Blvd., Suite 200

Durham, North Carolina (Address of principal executive offices)

27703 (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 \$.01, of the Registrant outstanding as of October 31, 2012 was 50,879,808.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

September 30, 2012 and December 31, 2011

(In thousands, except per share data)

	2012 (Unaudi			2011
Assets				
Cash and cash equivalents		959	\$	16,444
Restricted cash		300		625
Investments		062		25,274
Receivables from collaborations	3,	768		5,831
Interest reserve				1,742
Inventories		263		263
Prepaid expenses and other current assets		826		378
Deferred collaboration expense		404		2,301
Total current assets	46,	582		52,858
Investments	2,	513		15,382
Furniture and equipment, net		751		1,098
Deferred collaboration expense	5,	134		5,437
Other assets	9,	114		7,433
Total assets	\$ 64,	094	\$	82,208
	, ,			, , , ,
Liabilities and Stockholders Equity				
Accounts payable	\$ 2.	293	\$	2,497
Accrued expenses	. ,	035	Ψ	12,616
Interest payable		928		1,400
Deferred collaboration revenue		308		9,786
Deferred conaboration revenue	1,	500		2,700
Total current liabilities	12.	564		26,299
Deferred collaboration revenue		215		7,103
Foreign currency derivative		531		4,000
Non-recourse notes payable		000		30,000
	,			,
Commitments and contingencies				
Stockholders equity:				
Preferred stock, \$0.001 par value; shares authorized 5,000; no shares issued and outstanding				
Common stock, \$.01 par value: shares authorized 95,000; shares issued and outstanding 50,880 in 2012 and				
45,662 in 2011		509		457
Additional paid-in capital	390,	783	3	367,829
Accumulated other comprehensive income		40		40
Accumulated deficit	(381,	548)	(3	353,520)
	,			
Total stockholders equity	9,	784		14,806

Total liabilities and stockholders equity

\$ 64,094

\$ 82,208

See accompanying notes to consolidated financial statements.

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BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Periods Ended September 30, 2012 and 2011

(In thousands, except per share data-Unaudited)

			Thr	ee Months				Nin	e Months	
		2012			2011		2012			2011
Revenues										
Royalty revenue		\$ 2,848			\$		\$ 2,848			\$
Collaborative and other research and										
development		2,913			5,249		19,344			14,419
Total revenues		5,761			5,249		22,192			14,419
Expenses										
Research and development		12,072			15,101		40,374			43,042
General and administrative		1,591			2,953		4,897			9,922
Royalty expense		114					114			
Total expenses		13,777			18,054		45,385			52,964
•										
Loss from operations		(8,016)			(12,805)		(23,193)			(38,545)
Interest and other income		54			92		182			329
Interest expense		(1,166)			(1,160)		(3,486)			(2,614)
Loss on foreign currency derivative		(572)			(586)		(1,531)			(2,926)
-										
Net loss		(9,700)			(14,459)		(28,028)			(43,756)
D : 111 (1 (1										, , ,
Basic and diluted net loss per common	¢ (0.10)		ф	(0.22)		\$ (0.57)		ф	(0.07)	
share	\$ (0.19) 50,661		\$	(0.32) 45,178		+ ()		\$	(0.97)	
Weighted average shares outstanding	30,001			43,178		49,001			45,103	
Unrealized loss on investments					(42)					(56)
Comprehensive loss		\$ (9,700)			\$ (14,501)		\$ (28,028)			\$ (43,812)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONSOLDIATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2012 and 2011

(In thousands-Unaudited)

	2012	2011
Operating activities		
Net loss	\$ (28,028)	\$ (43,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	461	630
Stock-based compensation expense	3,345	3,872
Amortization of debt issuance costs	329	246
Change in fair value of foreign currency derivative	1,531	2,926
Changes in operating assets and liabilities:		
Receivables from collaborations	2,063	18,593
Prepaid expenses and other current assets	(393)	210
Deferred collaboration expense	2,200	1,155
Accounts payable and accrued expenses	(3,779)	(9,752)
Interest payable	(472)	350
Interest reserve	1,742	(1,742)
Deferred collaboration revenue	(9,366)	(999)
Net cash used in operating activities	(30,367)	(28,267)
Investing activities	(00,007)	(=0,=0.7)
Acquisitions of furniture and equipment	(115)	(54)
Change in restricted cash	325	(5.1)
Purchases of investments	(14,487)	(36,768)
Sales and maturities of investments	35,515	50,832
	20,010	0 0,000
Net cash provided by investing activities	21,238	14,010
Financing activities		
Exercise of stock options	522	240
Employee stock purchase plan sales	321	300
Purchases of treasury stock		(61)
Sale of common stock, net	17,811	(94)
Issuance of non-recourse notes payable, net		25,691
Payment of foreign currency derivative collateral	(2,010)	(3,000)
Net cash provided by financing activities	16,644	23,076
Increase in cash and cash equivalents	7,515	8,819
Cash and cash equivalents at beginning of period	16,444	13,622
Cash and cash equivalents at end of period	\$ 23,959	\$ 22,441

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

(In thousands, except per share amounts)

Note 1 Significant Accounting Policies

The Company

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

Basis of Presentation

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

The Company s financial statements became consolidated beginning in March 2011 with the creation of Royalty Sub, and have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Such financial statements reflect all adjustments that are, in management s opinion, necessary to present fairly, in all material respects, the Company s financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2011 and the notes thereto included in the Company s 2011 Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 2011 has been derived from the audited consolidated financial statements included in the Company s most recent Annual Report on Form 10-K.

Reclassifications

In the fourth quarter of 2011, the Company changed its classification of patent costs. This change resulted in \$237 and \$1,095 of patent expenses reclassified from general and administrative expense to research and development expense for the three months and nine months ended September 30, 2011, respectively. Additionally, during the second quarter of 2012, the Company changed its classification of facilities costs and other costs directly related to its laboratory facility in Birmingham, Alabama from general and administrative expense to research and development expense. This change resulted in \$93 and \$269 of expenses being reclassified from general and administrative expense to research and development expense for the three months and nine months ended September 30, 2011, respectively. These reclassifications had no effect on previously reported operating expenses or net loss amounts. Certain other balance sheet amounts as of December 31, 2011 have been reclassified to conform to the 2012 presentation.

Cash and Cash Equivalents

The Company generally considers cash equivalents to be all cash held in commercial checking accounts, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Restricted Cash

Restricted cash represents cash maintained in an interest bearing money market account to serve as collateral for a corporate credit card program.

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Investments

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. The objective of the Company s investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of its credit exposure. Per its policy, the Company is able to invest in marketable debt securities that may consist of U.S. government and government agency securities, money market and mutual fund investments, municipal and corporate notes and bonds, commercial paper and asset or mortgage-backed securities, among others. The Company s investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of three years and requires an average portfolio maturity of no more than two years. Some of the securities the Company invests in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. Generally, the Company s investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At September 30, 2012, the Company believes that the costs of its investments are recoverable in all material respects.

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

					Septem	ber 30, 2012			
					(Gross	Gross		
	Aı	mortized	Ac	crued	Uni	realized	Unrealized	Es	timated
		Cost	In	terest	(Jains	Losses	Fai	ir Value
U.S. Treasury securities	\$	1,999	\$	2	\$	5	\$	\$	2,006
Obligations of U.S. government and its agencies		4,508		3		2			4,513
Corporate debt securities		5,647		51		13			5,711
Commercial paper		900							900
Municipal obligations		6,377		48		20			6,445
Total investments	\$	19,431	\$	104	\$	40	\$	\$	19,575

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	Ar	nortized Cost	ccrued iterest	Uni	er 31, 2011 Gross realized Gains	Un	Gross realized Losses	timated ir Value
U.S. Treasury securities	\$	1,998	\$ 2	\$	14	\$		\$ 2,014
Obligations of U.S. government and its agencies		5,000	10					5,010
Corporate debt securities		10,924	80		15		(9)	11,010
Commercial paper		10,939			2		(1)	10,940
Asset-backed securities		611						611
Certificate of deposit		801	1					802
Municipal obligations		10,182	68		21		(2)	10,269
Total investments	\$	40,455	\$ 161	\$	52	\$	(12)	\$ 40,656

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

Maturing in one year or less	\$ 17,062
Maturing after one year through two years	2,513
Total investments	\$ 19,575

Receivables from Collaborations

Receivables are recorded for amounts due to the Company, primarily related to reimbursable research and development costs. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At September 30, 2012, the Company had the following receivables from collaborations.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	\$ 950	\$ 2,818	\$ 3,768
•			
Total receivables from collaborations	\$ 950	\$ 2,818	\$ 3,768

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

Inventory

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

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

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

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

Patents and Licenses

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

Accrued Expenses

The Company generally enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company 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 to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Accrued expenses as of September 30, 2012 and December 31, 2011 included \$5,861 and \$8,622, respectively, of research and development costs.

Income Taxes

The liability method is used in the Company s accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

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Accumulated Other Comprehensive (Loss) Income

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

Revenue Recognition

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

Collaborative and Other Research and Development Arrangements and Royalties

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

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

Royalty revenue paid by Shionogi on their product sales is subject to returns. 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. As of June 30, 2012, the Company deferred recognition of all RAPIACTA® royalty revenue from Shionogi sales in 2011 and the first six months of 2012. 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. Prospectively, the Company expects to have sufficient information to recognize royalty revenue on a quarterly basis, net of an allowance of estimate returns.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue. Under the Company s contract with BARDA/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

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

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

	Three I	Months	Nine Months		
	2012	2011	2012	2011	
Royalty revenue	\$ 2,848	\$	\$ 2,848	\$	
Collaborative and other research and development revenues:					
U.S. Department of Health and Human Services	2,618	4,614	10,690	12,387	
Shionogi (Japan)	295	296	888	888	
Mundipharma (United Kingdom)		339	7,766	1,058	
Grants (United States)				86	

Total revenues \$5,761 \$5,249 \$22,192 \$14,419

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Research and Development Expenses

The Company s research and development costs are charged to expense when incurred. Research and development expenses include all direct and indirect development costs related to the development of the Company s portfolio of drug candidates. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company s manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company s on-going review of the level of services actually performed.

Additionally, the Company has license agreements with third parties, such as Albert Einstein College of Medicine of Yeshiva University (AECOM), Industrial Research, Ltd. (IRL), and the University of Alabama at Birmingham (UAB), which require fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. The Company expenses maintenance payments as incurred.

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

Stock-Based Compensation

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

Interest Expense and Deferred Financing Costs

Interest expense for each of the three months ended September 30, 2012 and 2011 was \$1,166 and \$1,160, respectively and \$3,486 and \$2,614 for the nine months ended September 30, 2012 and 2011, respectively, and relates to the issuance of the PhaRMA Notes (defined in Note 4). Costs directly associated with the issuance of the PhaRMA Notes have been capitalized and are included in other non-current assets on the consolidated balance sheet. These costs are being amortized to interest expense over the term of the PhaRMA Notes using the effective interest rate method. Amortization of deferred financing costs included in interest expense was \$110 for each of the three months ended September 30, 2012 and 2011, respectively, and \$329 and \$246 for the nine months ended September 30, 2012 and 2011, respectively.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement (defined in Note 4) to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments resulted in a loss of \$572 and \$586 for the three months ended September 30, 2012 and 2011, respectively, and a loss of \$1,531 and \$2,926 for the nine months ended September 30, 2012 and 2011, respectively. Mark-to-market adjustments are determined by a third party pricing model which uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on thresholds defined in the Currency Hedge Agreement. As of September 30, 2012, \$5,490 of hedge collateral was posted under the agreement and is recorded in other assets.

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options 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 nine months ended September 30, 2012 and 2011 does not include 9,100 and 8,369, respectively, of such potential common shares, as their impact would be anti-dilutive.

Use of Estimates

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

Concentration of Market Risk

The Company s primary source of revenue that has an underlying cash flow stream is reimbursement of peramivir development expenses, which was earned under the cost-plus-fixed-fee contract with BARDA/HHS. The Company relies on BARDA/HHS to reimburse predominantly all of the development costs for its peramivir program. Accordingly, reimbursement of these expenses represents a significant portion of the Company s collaborative and other research and development revenues. The completion or termination of this program/collaboration could negatively impact the Company s future Consolidated Statements of Comprehensive Loss and Cash Flows. In addition, the Company also recognizes royalty revenue from the net sales of RAPIACTA®; however, the underlying cash flow from these royalty payments go 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 Sheet. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 24 months or less.

Recent Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurements and Disclosure Requirement in U.S. GAAP and IFRS. This ASU modifies the existing standards to include disclosure of all transfers between Level 1 and Level 2 asset and liability fair value categories. In addition, the ASU provides guidance on measuring the fair value of financial instruments managed within a portfolio and the application of premiums and discounts on fair value measurements. The ASU requires additional disclosure for Level 3 measurements regarding the sensitivity of fair value to changes in unobservable inputs and any interrelationships between those inputs. The Company adopted this guidance effective January 1, 2012. The adoption of this ASU did not have a material impact on the Company s consolidated financial statements.

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

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

Note 2 Stock-Based Compensation

As of September 30, 2012, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan), which was amended and restated in March 2012 and approved by the Company s stockholders in May 2012, and the Employee Stock Purchase Plan (ESPP), which was amended and restated in March 2012 and approved by

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the Company s stockholders in May 2012. In addition, during 2007, the Company made an inducement grant outside of the Incentive Plan and ESPP to recruit a new employee to a key position within the Company. Stock-based compensation expense of \$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, while \$3,872 (\$3,717 of expense related to the Incentive Plan, \$118 of expense related to the ESPP, and \$37 of expense related to an inducement grant) was recognized during the first nine months of 2011.

There was approximately \$8,855 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of September 30, 2012. That cost is expected to be recognized as follows: \$1,051 during the remainder of 2012, \$3,690 in 2013, \$2,508 in 2014, \$1,412 in 2015, and \$194 in 2016.

Stock Incentive Plan

The Company grants stock option awards and restricted stock awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the closing market price of the Company's stock at the date of grant. Prior to March 1, 2011, stock option awards granted to employees generally vest 25% after one year and monthly thereafter on a pro rata basis over the next three years until fully vested after four years. Commencing March 1, 2011, stock option awards granted to employees generally vest 25% each year until fully vested after four years. Stock option awards granted to non-employee directors of the Company generally vest monthly over one year. All stock option awards have contractual terms of 10 years. The vesting exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Av Ex	eighted verage xercise Price
Balance December 31, 2011	2,010	7,858	\$	6.21
Plan amendment	1,700			
Restricted stock awards granted	(415)			
Restricted stock awards cancelled	17			
Stock option awards granted	(1,617)	1,617		4.65
Stock option awards exercised		(337)		1.61
Stock option awards cancelled	482	(482)		8.02
Balance September 30, 2012	2,177	8,656	\$	5.99

For stock option awards granted under the Incentive Plan during the first nine months of 2012 and 2011, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the first nine months of 2012 and 2011 was \$3.24 and \$2.75, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following table summarizes the key assumptions used by the Company to value the stock option awards granted during the first nine months of 2012 and 2011. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents the historical volatility on the Company is 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