BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 03, 2011
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, 2011

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 þ 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 þ 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 þ Non-accelerated filer ¨ Smaller reporting company ¨

(Do not check if a smaller reporting company)

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

The number of shares of Common Stock, par value $.01, of the Registrant outstanding as of November 1, 2011 was 45,213,369.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.

INDEX

	Page No.
Part I. Financial Information	
Item 1. Financial Statements:	3
Balance Sheets September 30, 2011(Consolidated) and December 31, 2010	3
Statements of Operations Three and Nine Months Ended September 30, 2011 (Consolidated) and 2010	4
Statements of Cash Flows Nine Months Ended September 30, 2011(Consolidated) and 2010	5
Notes to Consolidated Financial Statements	6
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures About Market Risk	28
Item 4. Controls and Procedures	28
Part II. Other Information	
Item 1A. Risk Factors	29
Item 6. Exhibits	41
Signatures	42
EX-31.1	
EX-31.2	
EX-32.1	
EX-32.2	

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

BALANCE SHEETS

September 30, 2011 (Consolidated) and December 31, 2010

(In thousands, except per share data)

	2011 (Unaudited)	2010 (Note 1)
Assets		
Cash and cash equivalents	$ 22,441	$ 13,622
Restricted cash	625	625
Marketable securities	21,558	40,323
Receivables from collaborations	11,634	30,227
Interest reserve	1,742	
Inventories	898	898
Prepaid expenses and other current assets	795	1,005
Deferred collaboration expense	753	719
Total current assets	60,446	87,419
Marketable securities	16,416	11,771
Furniture and equipment, net	1,353	1,929
Deferred collaboration expense	7,139	8,328
Other assets	7,157	
Total assets	$ 92,511	$ 109,447
Liabilities and Stockholders Equity		
Accounts payable	$ 3,583	$ 8,201
Accrued expenses	12,030	17,124
Interest payable	350	
Deferred collaboration revenue	3,370	2,497
Total current liabilities	19,333	27,822
Deferred rent	138	178
Deferred collaboration revenue	14,072	15,944
Foreign currency derivative	2,926	
Non-recourse notes payable	30,000	
Commitments and contingencies		
Stockholders equity:		
Preferred stock: 5,000 shares authorized; none issued and outstanding		
Common stock, $.01 par value: shares authorized 95,000; shares issued and outstanding 45,195 in 2011 and 44,959 in 2010	452	449
Additional paid-in capital	365,868	361,520
Accumulated other comprehensive income	50	106

Accumulated deficit	(340,328)	(296,572)
Total stockholders equity	26,042	65,503
Total liabilities and stockholders equity	$ 92,511	$ 109,447

See accompanying notes to consolidated financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

Periods Ended September 30, 2011 (Consolidated) and 2010

(In thousands, except per share data)

(Unaudited)

	Three Months		Nine Months	
	2011	2010	2011	2010
Revenues				
Product sales	$	$	$	$ 325
Royalties				711
Collaborative and other research and development	5,249	12,000	14,419	44,651
Total revenues	5,249	12,000	14,419	45,687
Expenses				
Cost of products sold				86
Research and development	14,772	19,197	41,687	58,851
General and administrative	3,282	3,793	11,277	10,799
Total expenses	18,054	22,990	52,964	69,736
Loss from operations	(12,805)	(10,990)	(38,545)	(24,049)
Interest and other income	92	126	329	397
Interest expense	(1,160)		(2,614)	
Loss on foreign currency derivative	(586)		(2,926)	
Net loss	$ (14,459)	$ (10,864)	$ (43,756)	$ (23,652)
Basic and diluted net loss per common share	$ (0.32)	$ (0.24)	$ (0.97)	$ (0.53)
Weighted average shares outstanding	45,178	44,884	45,103	44,445

See accompanying notes to consolidated financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2011 (Consolidated) and 2010

(In thousands)

(Unaudited)

	2011	2010
Operating activities		
Net loss	$ (43,756)	$ (23,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	630	1,097
Stock-based compensation expense	3,872	4,994
Amortization of debt issuance costs	246	
Change in fair value of foreign currency derivative	2,926	
Changes in operating assets and liabilities:		
Receivables from collaborations	18,593	8,158
Inventories		5,383
Prepaid expenses and other current assets	210	(131)
Deferred collaboration expense	1,155	335
Accounts payable and accrued expenses	(9,712)	(17,007)
Interest payable	350	
Interest reserve	(1,742)	
Deferred rent	(40)	(39)
Deferred collaboration revenue	(999)	(1,873)
Net cash used in operating activities	**(28,267)**	**(22,735)**
Investing activities		
Acquisitions of furniture and equipment	(54)	(312)
Purchases of marketable securities	(36,768)	(50,094)
Sales and maturities of marketable securities	50,832	42,504
Net cash provided by (used in) investing activities	**14,010**	**(7,902)**
Financing activities		
Exercise of stock options	240	492
Employee stock purchase plan sales	300	282
Purchases of treasury stock	(61)	(4)
Common stock issuance costs	(94)	(84)
Issuance of non-recourse notes payable	30,000	
Debt issuance costs	(4,309)	
Payment of foreign currency derivative collateral	(3,000)	
Net cash provided by financing activities	**23,076**	**686**
Increase (decrease) in cash and cash equivalents	8,819	(29,951)
Cash and cash equivalents at beginning of period	13,622	41,125

Cash and cash equivalents at end of period	**$ 22,441**	**$ 11,174**

See accompanying notes to consolidated financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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 therapeutic areas of interest to us. Areas of interest for the Company are determined primarily by the scientific discoveries and the potential advantages that its experienced drug discovery group develops in the laboratory along with the potential commercial opportunity of these 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-based 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 $30.0 million financing transaction the Company completed on March 9, 2011. See Note 5 for a further description of this transaction. All intercompany transactions and balances have been eliminated.

The consolidated balance sheet as of September 30, 2011, the consolidated statement of operations for the three and nine months ended September 30, 2011, the consolidated statement of cash flows for the nine months ended September 30, 2011, the statement of operations for the three and nine months ended September 30, 2010 and the statement of cash flows for the nine months ended September 30, 2010 have been prepared by the Company in accordance with accounting principles generally accepted in the United States and have not been audited. Such financial statements reflect all adjustments that are, in management s opinion, necessary to present fairly, in all material respects, the Company s financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2010 and the notes thereto included in the Company s 2010 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, 2010 has been derived from the audited financial statements included in the Company s most recent Annual Report on Form 10-K.

Reclassifications

Certain amounts in the balance sheet as of December 31, 2010 have been reclassified to conform to the presentation for 2011.

Cash and Cash Equivalents

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

Restricted Cash

Restricted cash as of September 30, 2011 includes $0.6 million the Company is required to maintain in an interest bearing money market account to serve as collateral for a corporate card program.

Marketable Securities

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

investments.

The Company classifies all of its marketable securities as available-for-sale. Unrealized gains and losses on securities available-for-sale are recognized in other comprehensive income, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its securities available-for-sale for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. At September 30, 2011, the Company believes that the costs of its securities are recoverable in all material respects.

Table of Contents

The following table summarizes the fair value of the Company s securities by type at September 30, 2011. The estimated fair value of the Company s securities was based on independent quoted market prices and represents the highest priority of Level 1 in the fair value hierarchy as defined in generally accepted accounting principles. Amounts are in thousands.

	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 1,998	$ 2	$ 15	$	$ 2,015
Obligations of U.S. government agencies	4,001	3			4,004
Corporate debt securities	11,468	91	16	(8)	11,567
Commercial paper	9,733		4		9,737
Asset backed securities	843		1		844
Certificates of deposit	1,000	8			1,008
Municipal obligations	8,711	66	26	(4)	8,799
Total marketable securities	$ 37,754	$ 170	$ 62	$ (12)	$ 37,974

The following table summarizes the scheduled maturity for the Company s securities available-for-sale at September 30, 2011. Amounts are in thousands.

	2011
Maturing in one year or less	$ 21,558
Maturing after one year through two years	15,662
Maturing after two years	754
Total marketable securities	$ 37,974

Receivables from Collaborations

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At September 30, 2011, the Company had the following receivables from collaborations. Amounts are in thousands.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 4,949	$ 6,685	$ 11,634

During the third quarter of 2011 the Company received a payment of $2.9 million from the U.S. Department of Health and Human Services (HHS) related to indirect cost rate adjustments for calendar year 2010. This adjustment is calculated as the difference between the actual indirect costs incurred against the contract during a calendar year and the indirect costs that are invoiced at a provisional billing rate during the calendar year. Because this adjustment amount represents actual costs incurred in performance of the contract and the costs are allowable, reasonable, and allocable to the contract, the Company has recorded revenue accordingly. The Company s calculations of its indirect cost rates are subject to an audit by the federal government.

The audits for the years 2007, 2008 and 2009 were conducted in 2010 and no material amounts in excess of what the Company had accrued as of December 31, 2010 were determined to be disallowed. As discussed in Note 3, on February 24, 2011, HHS awarded the Company a $55.0 million contract modification, intended to fund completion of the Phase 3 development of i.v. peramivir. In connection with negotiation of this contract modification, the Company made the business decision to settle on final indirect cost rates for years 2007, 2008 and 2009 and

agreed to a reduction of approximately $1.1 million in amounts previously billed to HHS related to indirect cost rates. Accordingly, the Company reduced collaborative and other research and development revenues and receivables from collaborations by approximately $1.1 million at December 31, 2010. The Company received payment of $4.8 million for the indirect cost rate adjustments for the years 2007, 2008 and 2009 in the second quarter of 2011.

Table of Contents

Patents and Licenses

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

Accrued Expenses

The Company records all expenses in the period incurred. In addition to recording expenses for invoices received, the Company estimates the cost of services provided by third parties or materials purchased for which no invoices have been received as of the balance sheet dates. Accrued expenses as of September 30, 2011 consisted primarily of development and clinical trial expenses payable to contract research organizations (CROs) in connection with the Company s research and development programs.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on securities available-for-sale and is disclosed as a separate component of stockholders equity. The Company had approximately $0.1 million of unrealized gains on its securities available-for-sale that are included in accumulated other comprehensive income at September 30, 2011.

Other comprehensive loss for the periods ended September 30, 2011 and 2010 appear in the following table. Amounts are in thousands.

	Three Months		Nine Months	
	2011	**2010**	**2011**	**2010**
Net loss	$ (14,459)	$ (10,864)	$ (43,756)	$ (23,652)
Unrealized gain (loss) on securities available-for-sale	(42)	56	(56)	144
Other comprehensive loss	$ (14,501)	$ (10,808)	$ (43,812)	$ (23,508)

Revenue Recognition

The Company recognizes revenues from collaborative and other research and development arrangements, royalties 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. Peramivir is a newly introduced product and there is no historical experience that can be used to reasonably estimate product returns. Therefore, the Company defers recognition of royalty revenue when paid by Shionogi until the earlier of (1) a right of return no longer exists or (2) it has developed sufficient historical experience to estimate product returns. Royalty payments from Shionogi during the nine months ended September 30, 2011were approximately $0.8 million.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. Event payments are recognized as revenue upon the achievement of specified events if (1) the

event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue. Under the Company s contract with HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Table of Contents

Product Sales

Sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates. Product sales recognized during 2010 were not subject to a contractual right of return.

The Company recorded the following revenues from collaborations for the periods ended September 30, 2011 and 2010. Amounts are in thousands.

	Three Months		Nine Months	
	2011	2010	2011	2010
Product sales:				
NT Pharma, Co., Ltd. (Hong Kong)	$	$	$	$ 250
Other				75
Total product sales				325
Royalties:				
Shionogi (Japan)				711
Total royalties				711
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	4,614	11,167	12,387	28,780
Shionogi (Japan)	296	280	888	13,655
Mundipharma (United Kingdom)	339	422	1,058	1,460
Green Cross (Korea)		131		756
Grants (United States)			86	
Total collaborative and other research and development revenues	5,249	12,000	14,419	44,651
Total revenues	$ 5,249	$ 12,000	$ 14,419	$ 45,687

In the first quarter of 2010, the Company recorded royalty revenue of approximately $0.7 million related to sales of RAPIACTA ® in Japan, and the royalties were paid to the Company by Shionogi in the second quarter of 2010. RAPIACTA ® received accelerated approval in Japan in January 2010 so it could be made available as a treatment option during the H1N1 pandemic. At the time of approval, RAPIACTA ® stability testing was ongoing and as a result, the product sold during early 2010 had a short shelf life. During the fourth quarter of 2010, in response to requests from customers to return RAPIACTA ® due to the shelf life reaching expiration, Shionogi chose to accept returns for substantially all of the $0.7 million of product shipped early in 2010 and submitted the returns to the Company for credit. Accordingly, the Company reversed the $0.7 million of royalty revenue recorded in the first quarter of 2010. See Note 3, *Collaborative Agreements*, for a further discussion of the Company s relationship with Shionogi.

Research and Development Expenses

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

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

Table of Contents

At September 30, 2011, the Company had deferred collaboration expenses of approximately $7.9 million. Approximately $2.4 million of these deferred expenses were sub-license payments, paid to the Company s academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments from the Company s commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

The remaining $5.5 million of the deferred expenses relates to consideration provided to AECOM and IRL (collectively, the Licensors) in May 2010 for modifications made to the existing licensing agreement. Under the terms of the amendment, the Company issued consideration in the form of common stock and cash to the Licensors in exchange for a reduction in the percentage of certain future payments the Company receives from third-party sub-licensees that must be paid to the Licensors (see Note 3 for further information). Amortization of this deferred expense began in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. The Company believes that this accounting treatment is reasonable and consistent with its collaboration accounting policies.

Interest Expense and Deferred Financing Costs

Interest expense for the three and nine months ended September 30, 2011 was $1.2 million and $2.6 million, respectively. Costs directly associated with the issuance of the non-recourse PhaRMA Notes (defined in Note 5) 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 $0.1 million and $0.2 million for the three and nine months ended September 30, 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 5) 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 and therefore mark to market adjustments will be recognized in the Company s statement of operations. In conjunction with establishing the Currency Hedge Agreement in March 2011, the Company recorded an initial mark to market loss of $1.5 million. Cumulative mark to market adjustments for the nine months ended September 30, 2011 resulted in a $2.9 million loss. Mark to market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles. The Company is also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of September 30, 2011, cash collateral of $3.0 million was posted, consisting of the initial mark to market loss of $1.5 million, margin funds of $0.4 million and $1.1 million of collateral calls.

Restructuring Activities

During the fourth quarter of 2010, the Company announced a restructuring plan to consolidate core facilitates and outsource non-core activities. In connection with this plan, the Company recognized approximately $0.3 million in one-time termination benefits, of which the final payments of $0.1 million were paid in the six months ended June 30, 2011. Future costs under this plan are not expected to be material.

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options, outstanding warrants, and common shares expected to be issued under the Company s employee stock purchase plan, were anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Recent Accounting Pronouncements

The Accounting Standards Codification (ASC) includes guidance in ASC 605-25 related to the allocation of arrangement consideration to these multiple elements for purposes of revenue recognition when delivery of separate units of account occurs in different reporting periods. This guidance recently was modified by the final consensus reached on EITF 08-1 that was codified by ASU 2009-13. This change increases the

likelihood that deliverables within an arrangement will be treated as separate units of accounting, ultimately leading to less revenue deferral for many arrangements. The change also modifies the manner in which transaction consideration is allocated to separately identified deliverables. The Company adopted this guidance effective January 1, 2011. The adoption of ASU 2009-13 did not have a material impact on its financial statements.

Table of Contents

At the March 2010 meeting, the FASB ratified Emerging Issues Task Force, or EITF, Issue No. 08-9, Milestone Method of Revenue Recognition (Issue 08-9). The Accounting Standards Update resulting from Issue 08-9 amends ASC 605-28. The Task Force concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. The Company adopted this guidance effective January 1, 2011 and does not believe it will have an impact on its financial statements until the achievement, if any, of prospective milestones.

Note 2 Stock-Based Compensation

As of September 30, 2011, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan), which was amended and restated in March 2011 and approved by the Company s stockholders in May 2011, and the Employee Stock Purchase Plan (ESPP), which was amended and restated in March 2010 and approved by the Company s stockholders in May 2010. In addition, during 2007, the Company made an inducement grant outside of the Incentive Plan and ESPP to recruit a new employee to a key position within the Company. Stock-based compensation expense of $3.9 million ($3.8 million of expense related to the Incentive Plan, $0.1 million of expense related to the ESPP, and $0.05 million of expense related to the inducement grant) was recognized during the first nine months of 2011, while $5.0 million ($4.8 million of expense related to the Incentive Plan, $0.1 million of expense related to the ESPP, and $0.01 million of expense related to the inducement grant) was recognized during the first nine months of 2010.

There was approximately $8.1 million of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of September 30, 2011. That cost is expected to be recognized as follows: $0.9 million during the remainder of 2011, $3.0 million in 2012, $2.6 million in 2013, $1.4 million in 2014 and $0.2 million in 2015.

Stock Incentive Plan

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

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2010	1,858,044	6,801,542	$ 6.66
Stock option plan amendment	1,600,000		
Restricted stock awards granted	(211,141)		
Restricted stock awards cancelled	7,750		
Stock option awards granted	(1,810,935)	1,810,935	3.98
Stock option awards exercised		(160,232)	1.64
Stock option awards cancelled	396,654	(396,654)	6.65
Balance September 30, 2011	1,840,372	8,055,591	$ 6.16

For stock option awards granted under the Incentive Plan during the first nine months of 2011 and 2010, 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 these awards granted during the nine months of 2011 and 2010 was $2.75 and $4.66, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following summarizes the key

assumptions used by the Company to value the stock option awards granted during the first nine months of 2011 and 2010. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents an average of the implied volatility on the Company s publicly traded stock options, the volatility over the most recent period corresponding with the expected life, and the Company s long-term reversion volatility. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

Table of Contents

Weighted Average Assumptions for Stock Option Awards Granted to

Employees and Directors under the Incentive Plan

	2011	2010
Expected Life in Years	5.5	5.5
Expected Volatility	80.4%	89.3%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	2.2%	2.4%

Employee Stock Purchase Plan

The Company has reserved a total of 825,000 shares of common stock to be purchased under the ESPP, of which 136,567 shares remain available for purchase at September 30, 2011. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than 3,000 shares may be purchased by any one employee at the six-month purchase dates and no employee may purchase stock having a fair market value at the commencement date of $25,000 or more in any one calendar year. The Company issued 93,598 shares during the first nine months of 2011 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the look-back option were determined using a Black-Scholes option pricing model.

Stock Inducement Grant

In March 2007, the Company s Board of Directors approved a stock inducement grant of 110,000 stock option awards and 10,000 restricted stock awards to recruit a new employee to a key position within the Company. The stock option awards were granted in April 2007 with an exercise price equal to the market price of the Company s stock at the date of grant. The awards vest 25% after one year and monthly thereafter on a pro rata basis over the next three years until fully vested after four years. The stock option awards have contractual terms of 10 years. The vesting exercise provisions of both the stock option awards and the restricted stock awards granted under the inducement grant are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the respective agreements. The weighted average grant date fair value of these stock option awards was $5.25 per share. The exercise price of the stock option awards and the grant date fair value per share of the restricted stock awards granted under the inducement grant was $8.20. As of September 30, 2011, all of the shares granted under the restricted stock awards have vested.

Note 3 Collaborative Agreements

U.S. Department of Health and Human Services (HHS). In January 2007, the Company was awarded a four-year contract from HHS to develop its influenza neuraminidase inhibitor, peramivir, for the treatment of seasonal and life-threatening influenza. The contract commits $102.6 million to support manufacturing, process validation, clinical studies, and other product approval requirements for peramivir. The contract with HHS is defined as a cost-plus-fixed-fee contract. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit. HHS will make periodic assessments of progress and the continuation of the contract is based on the Company s performance, the timeliness and quality of deliverables, and other factors. The contract is terminable by the government at any time for breach or without cause.

In September 2009, HHS and the Company executed a contract modification that awarded an additional $77.2 million to the Company to complete Phase 3 development of intravenous (i.v.) peramivir, bringing the total award from HHS for the development of peramivir to $179.9 million. The modification also extended the contract term by 12 months to five years. On February 24, 2011, HHS and the Company executed a $55.0 million 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 HHS to $234.8 million and extends the contract term by 24 months through December 31, 2013, providing funding through completion of Phase 3 and the filing of a new drug application (NDA) to seek regulatory approval for i.v. peramivir in the U.S.

Shionogi & Co., Ltd. (Shionogi). In March 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan in exchange for a $14.0 million up-front payment. The license provides for potential future regulatory milestone event payments (up to $21.0 million) and commercial event milestone payments (up to $95.0 million) in addition to double digit (between 10 and 20% range) royalty payments on product sales of peramivir. Generally, all payments

under the agreement are nonrefundable and non-creditable, but they are subject to audit. Shionogi will be responsible for all development, regulatory, and marketing costs in Japan. The term of the agreement is from February 28, 2007 until terminated by either party in accordance with the license agreement. Either party may terminate in the event of an uncured breach. Shionogi has the right of without cause termination. In the event of termination all license and rights granted to Shionogi shall terminate and shall revert back to the Company. The Company developed peramivir under a license from UAB and will owe sublicense payments to UAB on the upfront payment and any future event payments and/or royalties received by the Company from Shionogi.

Table of Contents

In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan and to provide rights for Shionogi to perform a Phase 3 clinical trial in Hong Kong.

The Company deferred revenue recognition of the $14.0 million up-front payment that was initially received from Shionogi. This deferred revenue began to be amortized to revenue in April 2007 and will continue through December 2018 based on the terms of the agreement and products licensed. In December 2007, the Company received a $7.0 million milestone payment from Shionogi for its initiation of a Phase 2 clinical trial with i.v. peramivir. In November 2009, the Company received a second $7.0 million milestone payment from Shionogi for its filing of a NDA in Japan to seek regulatory approval for i.v. peramivir.

In January 2010, Shionogi received marketing and manufacturing approval for i.v. peramivir in Japan, and the Company received a third and final regulatory milestone payment of $7.0 million in January 2010 as a result of this approval. 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 $0.3 million. The agreement also provides for relatively insignificant future milestone payments. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea. Both parties have the right to terminate in the event of an uncured material breach. In the event of termination all rights, data, materials, products and other information would be transferred to the Company. The Company deferred revenue recognition of the up-front payment that was received from Green Cross. This deferred revenue began to be amortized to revenue in August 2006 and continued through November 2009.

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

The Company retained the rights to forodesine in the U.S. and Mundipharma is obligated by the terms of the agreement to use commercially reasonable efforts to develop the licensed product in the territory specified by the agreement. The agreement will continue for the commercial life of the licensed products, but may be terminated by either party following an uncured material breach by the other party or in the event the pre-existing third party license with AECOM and IRL expires. It may be terminated by Mundipharma upon 60 days written notice without cause or under certain other conditions as specified in the agreement and all rights, data, materials, products and other information would be transferred back to the Company at no cost. In the event the Company terminates the agreement for material default or insolvency, the Company could have to pay Mundipharma 50% of the costs of any independent data owned by Mundipharma in accordance with the terms of the agreement.

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

The Company is currently in a dispute with Mundipharma regarding the contractual obligations of the parties with respect to certain costs related to the manufacturing and development of forodesine. The Company does not believe that it is responsible for any of the disputed amounts and, accordingly, has not accrued any obligation as of September 30, 2011. The Company is engaged in ongoing discussions to resolve this dispute. The maximum potential exposure to the Company is estimated to be approximately 1,665,110 (or approximately $2 million based on the exchange rate on September 30, 2011).

The Company has explored the interest level of potential partners as a possible path forward for the future development of forodesine in the U.S. Absent a U.S. partner, the Company does not plan to fund additional studies of forodesine. The Company shared this information with Mundipharma, along with its decision not to continue further development of forodesine in the U.S. Mundipharma has expressed disappointment regarding the development of forodesine and this outcome. On February 21, 2011, the Company received a letter from Mundipharma s legal counsel notifying it that they intended to utilize the dispute resolution provisions of the Company s agreement with them, which includes meetings of senior management and the later possibility of arbitration. No amounts have been accrued regarding this matter. The first step in the dispute resolution process is negotiation between the parties. The dispute has not progressed beyond that initial step. The Company continues to make progress in the negotiations and hopes to resolve the dispute soon.

Table of Contents

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

The Company agreed to pay certain milestone payments for each licensed product, which range in the aggregate from $1.4 million to almost $4.0 million per indication, for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from third-party sublicensees of the licensed PNP inhibitors, if any. The Company also agreed to pay annual license fees ranging from $0.2 million to $0.5 million, creditable against actual royalties and other payments due to the Licensors.

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

In consideration for the modifications to the license agreement, the Company issued to the Licensors shares of the Company s common stock with an aggregate value of approximately $5.9 million and paid the Licensors approximately $90,000 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 the Company to the Licensors under the license agreement may be made either in cash, in shares of the Company s common stock, or in a combination of cash and shares.

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

Note 4 Income Taxes

The Company has incurred net losses since inception and, consequently, has not recorded any U.S. federal and state income taxes. The majority of the Company s deferred tax assets relate to net operating loss and research and development carryforwards that can only be realized if the Company is profitable in future periods. It is uncertain whether the Company will realize any tax benefit related to these carryforwards. Accordingly, the Company has provided a full valuation allowance against the net deferred tax assets due to uncertainties as to their ultimate realization. The valuation allowance will remain at the full amount of the deferred tax assets until it is more likely than not that the related tax benefits will be realized.

As of December 31, 2010, the Company had net federal operating loss carryforwards of $201.2 million, net state operating loss carryforwards of $243.4 million, and research and development credit carryforwards of $34.1 million, all of which expire at various dates from 2011 through 2029.

The Company recognizes the impact of a tax position in its financial statements if it is more likely than not that the position will be sustained on audit based on the technical merits of the position. The Company concluded at December 31, 2010 that it had one uncertain tax position pertaining to its research and development credit carryforwards. The Company has not yet conducted an in-depth study of its research and development credits. This study could result in an increase or decrease to the Company s research and development credits. Until studies are conducted of the Company s research and development credits, no amounts are being recorded as unrecognized tax benefits. Any future changes to the Company s unrecognized tax benefits would be offset by an adjustment to the valuation allowance and there would be no impact on the Company s financial statements.

Table of Contents

Utilization of the Company s net operating loss carryforwards could be subject to a substantial annual limitation due to ownership change limitations described in Section 382 of the Internal Revenue Code and similar state provisions. The Company has performed a Section 382 change in control study and has determined there have been no changes in control that would limit the use of the Company s net operating losses through December 31, 2010.

Tax years 2006-2010 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2006 are also open to examination to the extent of loss and credit carryforwards from those years. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as components of its income tax provision. However, there have been no provisions or accruals for interest and penalties since the Company s inception.

Note 5 Royalty Monetization

Overview

On March 9, 2011, the Company completed a $30.0 million 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 approximately $23.0 million from the transaction after transaction costs of $4.0 million and the establishment of a $3.0 million interest reserve account by Royalty Sub, which will be available to help cover any interest shortfalls through September 1, 2013.

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 remains unchanged as a result of the transaction.

Non-Recourse Notes Payable

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of $30.0 million in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the PhaRMA Notes). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the Indenture), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes issued are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. Payments may also be made from the interest reserve account and certain other accounts established in accordance with the Indenture. Principal on the PhaRMA Notes is required to be paid in full by the final legal maturity date of December 1, 2020, unless the PhaRMA Notes are repaid, redeemed or repurchased earlier. The PhaRMA Notes are redeemable by Royalty Sub beginning March 9, 2012 as described below. 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. Prorated interest for the period March 9, 2011 through September 1, 2011 totaled $2.1 million. Payment of such interest was made with $0.8 million in royalty payments collected from Shionogi and a $1.3 million draw-down from the interest reserve account. As of September 30, 2011, $1.7 million remains in the interest reserve account for future interest payments.

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.

If the amounts available for payment on any Payment Date are insufficient to pay all of the interest due on a Payment Date, unless sufficient capital is contributed to Royalty Sub by the Company as permitted under the Indenture or the interest reserve account is available to make such payment, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. If such shortfall (and interest thereon) is not paid in full on or prior to the next succeeding Payment Date, an Event of Default as described in the Indenture will occur.

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.

Table of Contents

Prior to March 9, 2012, the PhaRMA Notes will not be redeemable by Royalty Sub. Thereafter, the PhaRMA Notes will be 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, 2012 to and including March 8, 2013	107.00%
From and including March 9, 2013 to and including March 8, 2014	103.50%
From and including March 9, 2014 and thereafter	100.00%

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 $2.0 million will be required if, on May 18 of the relevant year, the US dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement.

In conjunction with establishing the Currency Hedge Agreement in March 2011, the Company recorded an initial mark to market loss of $1.5 million. Cumulative mark to market adjustments for the nine months ended September 30, 2011 resulted in a $2.9 million loss. Mark to market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles. The Company is also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of September 30, 2011, cash collateral of $3.0 million was posted, consisting of the initial mark to market loss of $1.5 million, margin funds of $0.4 million and $1.1 million of collateral calls. 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 $2.0 million termination fee.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding future results, performance, or achievements of the Company. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company s Annual Report on Form 10-K , Quarterly Reports on Form 10-Q and Current Reports on Form 8-K . See Information Regarding Forward-Looking Statements.

Recent Corporate Highlights

Peramivir

Collaborative Agreements.

HHS. In January 2007, the U.S. Department of Health and Human Services (HHS) awarded us a $102.6 million, four-year contract for the advanced development of peramivir 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 i.v. peramivir program by 12 months and to increase funding by $77.2 million.

In October 2010, HHS contacted us informally regarding our proposal. During those informal communications, HHS indicated that we should explore certain changes to our currently ongoing Phase 3 i.v. peramivir study for the treatment of hospitalized patients with serious influenza, including potentially increasing the size of the study. The necessity for a second pivotal study in acute, uncomplicated outpatient populations was discussed by HHS and the FDA and was deemed unnecessary for a label indication for acute, complicated hospitalized patients. We previously disclosed that we had submitted a proposal for a second contract modification to HHS for additional funding toward completion of

the modified Phase 3 development of i.v. peramivir. This proposal included an additional outpatient efficacy study. We also previously disclosed that HHS had approved start-up activities for the Phase 3 program under the existing contract. HHS indicated that it plans to reimburse authorized start-up costs as well as termination costs related to this outpatient efficacy study. In light of these communications by HHS, we did not move forward with the outpatient study.

On January 13, 2011, we announced that, based on those recent discussions between HHS and the FDA, we had submitted a revised contract proposal to HHS seeking additional funding to enable completion of the Phase 3 development plan for i.v. peramivir. In the revised contract proposal, we identified changes to the design of our ongoing 301 study that could increase the likelihood of a positive clinical outcome.

Table of Contents

On February 24, 2011, we announced that HHS had awarded us a $55.0 million 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 HHS to $234.8 million and extends the contract term by 24 months through December 31, 2013, providing funding through completion of Phase 3 and the filing of an NDA to seek regulatory approval for i.v. peramivir in the U.S. Through September 30, 2011, approximately $170.0 million has been recognized as revenue under the contract with HHS to support activities related to the i.v. peramivir development program.

This contract modification supports implementation of our proposed changes to study 301. The modifications to the study include:

- Changing the primary efficacy analysis of the study to focus on a subset of approximately 160 patients not treated with neuraminidase inhibitors as standard of care, in order to provide the greatest opportunity to demonstrate a statistically significant peramivir treatment effect.

- Increasing the total study target enrollment to 600 subjects from the current target of 445 subjects.

- Adding at least 45 more clinical site locations in additional countries.

These changes are expected to increase the amount of time required to complete enrollment in this ongoing study. The actual time to reach completion of enrollment will depend on the prevalence and severity of influenza, as well as the ability of the more than 265 investigator sites to successfully enroll patients.

Under the defined scope of work in the contract with HHS for the development of peramivir, a process was undertaken to validate a U.S.-based manufacturer and the related method for producing commercial batches of peramivir active pharmaceutical ingredient (API). As a required outcome of this validation process, large quantities of peramivir API were produced. In accordance with our accounting practices, we recorded all costs associated with this validation process as research and development expenses in our Statements of Operations. Simultaneously, revenue from the HHS contract was also recorded in our Statement of Operations. HHS subsequently reimbursed us for these costs and upon reimbursement from HHS, the associated peramivir API became property of the U.S. government.

Under the terms of the contract, if we determine the amount of peramivir API produced under the contract is in excess of what is necessary to complete the contract, we can acquire any excess peramivir API at cost to use for our own purposes. We believe that as a result of the manufacturing campaign described above, more peramivir API has been produced than is required to support U.S. regulatory approval. If we use any amount of excess API for our other contracts or activities, we will work with HHS to determine the appropriate acquisition process.

In January 2006, the Company received FDA Fast Track designation for peramivir. In September 2009, we received a Request for Proposal (RFP) from HHS for the supply of i.v. peramivir for the treatment of critically ill influenza patients. In October 2009, the FDA granted an Emergency Use Authorization (EUA) for i.v. peramivir, which expired in June 2010 with the expiration of the declared emergency. As a result, peramivir is now only available in the U.S. through clinical trials. On November 4, 2009 we received an initial order for 10,000 courses of i.v. peramivir (600 mg once-daily for five days) for an aggregate purchase price of $22.5 million. We shipped the entire order from existing i.v. peramivir inventory to HHS on November 4, 2009.

Under the Indefinite Delivery Indefinite Quantity contract issued to us on November 3, 2009, the minimum and maximum quantities of i.v. peramivir that may have been ordered by HHS were 1,000 and 40,000 treatment courses, at the same unit price as the first order. We were also required to maintain the ability to manufacture additional courses for treatment or prophylaxis, dependent on the volume and size of anti-viral orders received from HHS. Based on the RFP, we initiated manufacture of approximately 130,000 courses of i.v. peramivir at a cost of approximately $10.0 million, so that we would have additional inventory available in advance of potential orders. In addition, we have sufficient quantities of API of i.v. peramivir available to produce up to 350,000 additional courses. This agreement expired on November 3, 2011.

Shionogi. Effective February 28, 2007, we entered into a License, Development and Commercialization Agreement, as amended, supplemented or otherwise modified (the Shionogi Agreement), an exclusive license agreement with Shionogi & Co., Ltd. (Shionogi) to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. In October 2008, we and Shionogi amended the Shionogi 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.

In January 2010, Shionogi received marketing and manufacturing approval for i.v. peramivir in Japan, and we received a third and final regulatory milestone payment of $7.0 million that month as a result of this approval. We may receive future commercial event milestone payments of up to $95.0 million from Shionogi. Shionogi has commercially launched peramivir under the commercial name RAPIACTA ® in Japan. In October 2010, we announced that Shionogi had received approval of an additional indication for use of i.v. peramivir to treat children and infants with influenza in Japan.

On March 9, 2011, we announced that JPR Royalty Sub LLC, our newly created wholly-owned subsidiary (the Royalty Sub), had completed a private placement to institutional investors of $30.0 million in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the PhaRMA Notes). This private placement was exempt from registration under the Securities Act of 1933, as amended (the Securities Act). The PhaRMA Notes, which are obligations of Royalty Sub, are secured by (i) Royalty Sub s rights to receive royalty payments from Shionogi in respect of commercial sales of RAPIACTA ® in Japan and, if approved for commercial sale, Taiwan (the Territory), as well as future milestone payments payable by Shionogi under the Shionogi Agreement and all of Royalty Sub s other assets, and (ii) a

Table of Contents

pledge by us of our equity interest in Royalty Sub. See Note 5 Royalty Monetization to the consolidated financial statements in this Quarterly Report on Form 10-Q and our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 4, 2011 for a further description of the terms and conditions of this financing transaction.

Green Cross. On August 16, 2010, we announced that our partner Green Cross Corporation (Green Cross) had received marketing and manufacturing approval from the Korean Food & Drug Administration for i.v. peramivir to treat patients with influenza A & B viruses, including pandemic H1N1 and avian influenza. Green Cross received the indication of single dose administration of 300 mg i.v. peramivir. Green Cross intends to launch peramivir under the commercial name PeramiFlu ® in Korea.

Other Collaborations. In addition to Shionogi and Green Cross, we have arrangements with several companies outside the U.S. to represent us and peramivir primarily for stockpiling purposes.

Clinical Trials. In July 2007, we initiated a Phase 2 clinical trial of i.v. peramivir to compare the efficacy and safety of i.v. peramivir to orally administered oseltamivir in patients who require hospitalization due to acute influenza. The primary objective of the study was to evaluate time to clinical stability, which is a composite endpoint comprised of normalization of temperature, oxygen saturation, respiratory rate, systolic blood pressure and heart rate. This type of endpoint has previously been used in pneumonia studies, but not in influenza. Secondary objectives of the study included evaluation of viral shedding, mortality, clinical relapse and time to resumption of usual activities. We presented the results at the XI International Symposium on Respiratory Viral Infection held in Bangkok, Thailand in February 2009, with additional analyses (as noted above) presented at the 48th Annual IDSA meeting on October 22, 2010.

In September 2009, we announced that we were initiating two Phase 3 studies of i.v. peramivir for the treatment of hospitalized patients with serious influenza. The combined enrollment target for these studies was approximately 700 patients, and approximately 300 study locations are targeted to participate in these studies globally. These studies are intended to support U.S. regulatory approval of i.v. peramivir as a treatment for influenza.

On January 13, 2011, we announced top-line results from our completed 303 study. This study was an open-label, randomized trial of the anti-viral activity, safety and tolerability of i.v. peramivir administered either as a once-daily infusion of 600 mg or a twice-daily infusion of 300 mg to adult and adolescent subjects hospitalized with confirmed or suspected influenza infection. Treatment was planned for 5 days with an extension to 10 days in patients who needed additional treatment.

The study enrolled 234 patients aged 14 to 92 years during the 2009-2010 H1N1 pandemic of whom 200 patients (85%) had a duration of illness of more than 48 hours. Peramivir was administered to 230 patients; 170 patients (74%) had received prior treatment with oseltamivir. At study entry 158 patients (69%) needed supplemental oxygen and 39 patients (17%) were in intensive care. The median duration of peramivir treatment was five days (range, 1-11 days). The ITTI population consisted of 127 patients with influenza confirmed by RT-PCR, viral culture, or serology.

The primary endpoint of the study was the change in influenza virus titer in nasopharyngeal samples, measured by TCID50. Forty-four patients had a positive baseline culture, 20 for the 300 mg twice-daily group and 24 for the 600 mg once-daily group. Similar reductions in log10 TCID50 viral titer were observed over the first 48 hours in the two treatment groups, -1.66 (95% CI -2.32, -0.61) for 300 mg peramivir twice-daily and -1.47 (95% CI -1.89, -0.75) for peramivir 600 mg once-daily.

Both dose regimens of i.v. peramivir were generally safe and well-tolerated. The frequency and severity of adverse events was similar in the two groups, and was consistent with the profile of influenza patients hospitalized during the 2009-2010 pandemic. SAEs were reported in 20 percent of patients. Of the total SAEs reported, one case of elevated liver enzymes was attributed to the study drug and all other SAEs were attributed to other factors. The most common SAEs reported were respiratory failure, acute respiratory distress syndrome, septic shock and acute renal failure. Overall mortality within 28 days of initial peramivir treatment was 8.7 percent; no deaths were attributed to study drug. No safety signals were identified.

The analysis of the combined ITTI population showed median time to resolution of fever was 25.3 hours; time to clinical resolution, 92.0 hours; time to alleviation of symptoms, 145 hours; and time to resumption of usual activities, 26.8 days. Further analyses of the data are ongoing, and we will submit detailed analyses for presentation at an upcoming medical meeting.

Our 301 study is an ongoing, multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of 600 mg i.v. peramivir administered once-daily for five days in addition to SOC, compared to SOC alone, in adults and adolescents who are hospitalized due to serious influenza. The modification to our contract with HHS announced on February 24, 2011 provides for the following changes to study 301:

Changing the primary efficacy analysis of the study to focus on a subset of approximately 160 patients not treated with neuraminidase inhibitors as SOC, in order to provide the greatest opportunity to demonstrate a statistically significant peramivir treatment effect.

Increasing the total study target enrollment to 600 subjects from the current target of 445 subjects.

Adding at least 45 more clinical site locations in geographical regions where neuraminidase inhibitors are not widely used, possibly including sites in India and China.

Table of Contents

The actual time to reach completion of enrollment will depend on the prevalence and severity of influenza, as well as the ability of the more than 265 investigator sites to successfully enroll patients. We have activated over 50 additional clinical sites to support enrollment in the study. Sites in Europe, North America and India are prepared to enroll patients during the upcoming Northern Hemisphere flu season. A planned interim analysis to confirm or revise the study s current enrollment target of 160 patients for the primary efficacy analysis population is expected to be conducted no later than mid-2012.

Data related to i.v. peramivir was presented at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Meeting on September 15, 2010. The first poster presentation concluded that there is no evidence of a pharmacokinetic interaction between i.v. peramivir (600 mg) with oral oseltamivir (75 mg) or oral rimantadine (100 mg) when administered simultaneously in hospitalized patients with influenza. The second poster presentation concluded that i.v. peramivir administered at two single doses (600 mg and 1200 mg) was not associated with QTc prolongation or other repolarization abnormalities, and that peramivir was generally safe and well-tolerated.

Additional data related to i.v. peramivir was presented at the 48th Annual Infectious Diseases Society of America (IDSA) meeting on October 22, 2010. The first poster presentation concluded that peramivir and oseltamivir treatment resulted in similar clinical outcomes in patients hospitalized with influenza in the overall study population (N=137). However, in the sub-group of influenza B infected patients (N=32), peramivir treatment resulted in significantly faster reduction of viral replication and showed a trend to more rapid normalization of clinical outcomes compared to oral oseltamivir treatment. This presentation concluded that the resumption of normal activities four days earlier in the peramivir-treated subjects may be a clinically meaningful outcome, that these findings may reflect superior anti-viral activity of peramivir compared to oseltamivir against influenza B, and that the findings should be further investigated. The second poster presentation described the effects of influenza infection on lymphocyte and neutrophil populations, and concluded that in placebo- or oseltamivir-controlled trials, peramivir had no apparent effects on leukocyte counts or risk of neutropenia in patients with influenza. Results were drawn from an analysis of data from five randomized Phase 2 and Phase 3 clinical trials which included over 2,200 influenza patients treated with peramivir or a control.

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

In July 2009, Shionogi announced positive results in two Phase 3 clinical trials of i.v. peramivir. The studies were sponsored by Shionogi and conducted during the 2008-2009 influenza season. Shionogi and Green Cross co-conducted the portion of the studies in Korea. Doses of i.v. peramivir of 300 mg and 600 mg, administered in single and multiple doses, were found to be generally safe and well-tolerated in these trials. Shionogi presented the data at the 2009 ICAAC / IDSA annual meeting in San Francisco, California.

BCX4208

In September 2009, we announced the initiation of a clinical study of BCX4208 for the treatment of gout, which is caused by elevated levels of uric acid in blood. We believe that BCX4208 is a good candidate to control gout because data from a prior Phase 2 clinical trial of BCX4208 for psoriasis indicated a dose related reduction in uric acid that was sustained for the duration of drug exposure. Our initial gout clinical trial, Study 201 was a Phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered BCX4208 in subjects with gout. The trial contained two parts: part one, which was a parallel-group study of multiple doses of BCX4208 randomized against a placebo and part two, which was a sequential-group study of escalating doses of BCX4208, randomized against placebo.

On April 28, 2010 we announced positive top-line results from a planned interim analysis of part one of this clinical study. The study s primary endpoint was the change in sUA concentration after 21 days of treatment compared to baseline concentration prior to treatment. Part one of the study randomized 60 gout patients with sUA concentrations greater than or equal to 8 mg/dL to placebo or to one of three different doses of BCX4208, a PNP inhibitor, administered once-daily for 21 days. All three doses of BCX4208 demonstrated a statistically significant reduction in sUA levels compared to placebo at day 22. BCX4208 doses of 40 mg, 80 mg and 120 mg per day showed median reductions in sUA levels of 2.7, 3.3 and 3.4 mg/dL, respectively.

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

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

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

Table of Contents

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

All doses of BCX4208 evaluated met the primary endpoint of the study, including both doses studied in part two. BCX4208 doses of 160 mg and 240 mg per day showed LSM reductions in sUA levels of 3.6 and 4.5 mg/dL at day 22 ($p<0.001$ for both doses), compared to placebo change of -0.02 mg/dL. The LSM reduction of sUA concentration percent change from baseline level was 35.7% for the 160 mg dose and 46.0% for the 240 mg dose ($p<0.001$ for both doses). BCX4208 also demonstrated a statistically significant difference in the proportion of subjects with sUA levels less than 6 mg/dL, compared to subjects treated with placebo, on day 22. The proportion of subjects achieving sUA levels less than 6 mg/dL was 47% for the 160 mg dose and 77% for the 240 mg dose, compared to 0% in the placebo group.

BCX4208 was generally safe and well-tolerated at all doses evaluated in this study. Reductions in peripheral blood lymphocytes were observed in patients treated with BCX4208. The protocol included individual subject stopping criteria for CD4+ cell counts below certain thresholds; no subjects were discontinued for this reason. Overall, the frequency of adverse events in each of the BCX4208 treatment groups was comparable to that observed in the placebo group. Additional studies designed to evaluate longer-term exposure are needed to further define the safety and tolerability profile of BCX4208.

Detailed results from this clinical study were presented at the American College of Rheumatology meeting in Atlanta, Georgia on November 8, 2010. The poster concluded that BCX4208 doses administered at 40, 80, 120, 160 and 240 mg once-daily monotherapy rapidly and significantly reduced sUA in patients with gout. BCX4208 was generally safe and well-tolerated at all doses evaluated in the study.

Additionally, on June 1, 2010, we announced that we were initiating a Phase 2 study of BCX4208 alone and in combination with allopurinol in patients with gout. On September 16, 2010, we announced positive top-line results from this randomized, double-blind, multi-center, placebo-controlled Phase 2 study. The study was designed to evaluate the urate-lowering activity and safety of several doses of BCX4208 alone and in combination with selected doses of allopurinol administered once-daily.

The study utilized a factorial design. The primary endpoint was change in sUA after 21 days of treatment compared to baseline concentration prior to treatment. Eighty-seven gout patients with sUA concentrations greater than or equal to 8 mg/dL were randomized to receive BCX4208 at daily doses of 20 mg, 40 mg and 80 mg administered orally as monotherapy or in combination with allopurinol at daily doses of 100 mg, 200 mg and 300 mg administered orally. A dose-response was demonstrated for both BCX4208 and allopurinol, and the combination of BCX4208 and allopurinol was shown to be superior to either drug alone in sUA reduction. In five of these nine combination groups, 80% or more of the patients achieved a sUA concentration of less than 6 mg/dL. Combinations of lower doses of BCX4208 with allopurinol showed additive or synergistic effects in sUA reduction. The doses of BCX4208 alone and in combination with allopurinol were generally safe and well-tolerated. Consistent with prior BCX4208 clinical studies, reductions in peripheral blood lymphocytes were observed in patients treated with BCX4208. The protocol included stopping rules for CD4+ cell counts below certain thresholds; no subjects were discontinued for this reason.

On May 26, 2011, we presented positive data from our two completed, randomized, double-blind, placebo-controlled Phase 2 studies of BCRX4208 at the Annual European Congress of Rheumatology in London, U.K. The first poster reported efficacy findings from the Company s Phase 2 study evaluating BCRX4208 alone and in combination with allopurinol. The poster concluded that the combination of BCX4208 and allopurinol brought a larger proportion of gout patients to serum uric acid level below 6 mg/dL than allopurinol alone. There were no pharmacokinetic drug-drug interactions between BCX4208 and either allopurinol or its active metabolite, oxypurinol. The second poster pooled safety results from this combination study and the Company s Phase 2 monotherapy study. The poster concluded that the adverse event profile was similar in recipients of BCX4208, allopurinol, placebo or both drugs combined; the most common adverse events being diarrhea and headache. The rate of infections was similar between BCX4208 alone and in combination with allopurinol compared to placebo. The combination of BCX4208 and allopurinol did not alter the safety profile compared with either agent administered alone.

On December 22, 2010, we announced the initiation of a Phase 2b study of BCX4208 as add-on therapy in gout patients who have not responded to allopurinol therapy alone. On October 5, 2011, we announced positive top-line results from this Phase 2b study of BCX 4208 as an add-on therapy in gout patients who had failed to reach the clinically important serum acid (sUA) goal of <6 mg/dL on allopurinol alone. Detailed study findings will be shared during a late-breaker oral session at the American College of Rheumatology (ACR) meeting on November 8, 2011. The study randomized 279 patients to five study arms: BCX4208 at doses of 5 mg, 10 mg, 20 mg, 40 mg and placebo, administered once-daily for 12-weeks. Allopurinol 300 mg once-daily was administered in all study arms. The primary endpoint of the study was the proportion of patients with sUA <6 mg/dL at day 85.

The primary endpoint of the study was successfully achieved. When added to allopurinol 300 mg, BCX4208 was superior to allopurinol plus placebo ($p=0.009$ overall). BCX4208 doses evaluated in the study showed response rates ranging from 33% to 49%, compared to 18% for

placebo.

Table of Contents

Adding BCX4208 to allopurinol was generally safe and well-tolerated at all doses studied. Both the frequency and types of adverse events, including infections, were similar between the groups treated with BCX4208 and placebo. No opportunistic or unusual infections were reported in either the BCX4208 treated groups or placebo. As expected, a dose-dependent effect on lymphocyte counts was observed and this effect appeared to plateau within 12 weeks of treatment. No patients from the placebo, 5 mg or 10 mg cohorts discontinued study drug due to confirmed lymphocyte or CD4+ cell counts below certain pre-specified thresholds. Two patients were discontinued from the 20 mg group and eight patients from the 40 mg group due to pre-specified stopping rules based on CD4+ cell counts.

Over half of the patients originally randomized into this study continued treatment into a 3-month extension phase, totaling 6-months of uninterrupted BCX-4208 add-on treatment. We are also conducting a Phase 1 study to evaluate the metabolic profile of BCX 4208. Results from both of these studies are expected in January 2012.

We have also opened enrollment of patients into a 12-week Phase 2 study of BCX4208 in patients with gout and moderately impaired renal function.

On October 25, 2011 we announced that results from this Phase 2b study of BCX4208 have been accepted as a late-breaker oral presentation at the 2011 Annual Scientific Meeting of the American College of Rheumatology and the Association of Rheumatology Health Professionals (ACR/ARHP).

Forodesine

On September 15, 2010, we announced preliminary top-line results from our pivotal multinational, open-label, single-arm trial evaluating 200 mg once-daily oral forodesine in the treatment of relapsed or refractory CTCL. The study s primary endpoint was objective response rate, defined as complete or partial cutaneous response that is sustained for at least 28 days, in patients with later stage (stage IIB, III and IVA) disease who had previously received at least three systemic therapies for their disease. Eleven of 101 (11% (95% confidence interval: 6-19%)) later stage patients enrolled achieved a partial cutaneous response, while no patients achieved a complete response. Of the remaining later stage patients, 56 (55%) had stable disease as their best response, 30 (30%) had progressive disease, with a median time to progression of 353 days, and four (4%) were not evaluable. The median number of prior systemic therapies was four (range 3-15) among patients with later stage disease. Oral forodesine was generally safe and well-tolerated in this study, and was administered daily for up to 839 days.

Eligible patients were those with CTCL of stages IB through IVA whose disease was persistent, progressive or recurrent during or after treatment with at least three systemic therapies, one of which must have been oral bexarotene. A total of 144 patients with CTCL, with a median duration of illness of 52.5 months, were enrolled. The most common adverse events reported were peripheral edema, fatigue, insomnia, diarrhea, headache and nausea.

Also on September 15, 2010, we announced interim results from our exploratory Phase 2 study to investigate the efficacy and safety of forodesine as monotherapy for CLL. In this open-label, single-arm, multi-center study, forodesine was administered orally at 200 mg twice-daily for 28-day cycles in 25 previously treated CLL patients. The primary endpoint of the study was overall response rate. Consistent with results of previous clinical trials, forodesine was generally safe and well-tolerated in this study.

On December 4, 2010, we presented new data from this study that confirmed forodesine s clinical activity in the treatment of CLL at the 52nd Annual American Society of Hematology Meeting & Exposition held in Orlando, Florida. An analysis conducted after all patients were followed through ³6 months showed that six of 23 response-evaluable patients demonstrated a partial response to forodesine, resulting in a response rate of 26 percent. Forodesine 200 mg orally-administered twice-daily was generally safe and well-tolerated in this study. The pattern, frequencies and severity distribution of adverse events were generally consistent with CLL-associated poor bone marrow function and immunodeficiency, prior therapies and co-morbidities.

We are currently in a dispute with Mundipharma regarding the contractual obligations of the parties with respect to certain costs related to the manufacturing and development of forodesine. We do not believe we are responsible for any of the disputed amounts and accordingly, have not accrued any obligation as of September 30, 2011. We are engaged in ongoing discussions to resolve this dispute. The maximum potential exposure to us is estimated to be approximately 1,665,110 (or approximately $2 million based on the exchange rate on September 30, 2011).

We have explored the interest level of potential partners as a possible path forward for the future development of forodesine in the U.S. Absent a U.S. partner, we do not plan to fund additional studies of forodesine. We shared this information with Mundipharma, along with our decision not to continue further development of forodesine in the U.S. Mundipharma has expressed disappointment regarding the development of forodesine and this outcome. On February 21, 2011, we received a letter from Mundipharma s legal counsel notifying us that they intended to utilize the dispute resolution provisions of our agreement with them, which includes meetings of senior management and the later possibility of arbitration.

No amounts have been accrued regarding this matter. The first step in the dispute resolution process is negotiation between the parties. The dispute has not progressed beyond that initial step. We continue to make progress in the negotiations and hope to resolve the dispute soon.

Table of Contents

Results of Operations (three months ended September 30, 2011 compared to the three months ended September 30, 2010)

For the three months ended September 30, 2011, total revenues decreased to $5.2 million compared to $12.0 million for the three months ended September 30, 2010. This $6.8 million decrease was driven primarily by less revenue recognized under the contract with HHS for the continued development of i.v. peramivir, primarily due to the completion of two clinical studies and the realignment of existing clinical studies.

Research and development (R&D) expenses decreased to $14.8 million for the third quarter of 2011 from $19.2 million in the same quarter of last year. The $4.4 million decrease was driven primarily by lower development costs associated with our peramivir development program and lower costs associated with our forodesine clinical programs associated with completion of clinical trials in 2010, partially offset by higher development costs associated with the BCX4208 program for the treatment of gout.

General and administrative (G&A) expenses decreased to $3.3 million for the third quarter of 2011 compared to $3.8 million in the same quarter as last year, primarily resulting from less consulting services in 2011 as compared the same period in the prior year.

During the three months ended September 30, 2011, the Company incurred $1.2 million in interest expense related to the issuance of the PhaRMA Notes on March 9, 2011 in conjunction with the financing transaction to monetize certain future royalty and milestone payments. In addition, the Company recognized a $0.6 million mark to market loss on its Currency Hedge Agreement associated with the issuance by Royalty Sub of the PhaRMA Notes. The Company entered into a foreign currency hedge arrangement to hedge changes in the value of the Japanese yen relative to the U.S. dollar. The currency hedge does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in earnings.

Results of Operations (nine months ended September 30, 2011 compared to the nine months ended September 30, 2010)

For the nine months ended September 30, 2011, total revenues decreased to $14.4 million compared to $45.7 million for the nine months ended September 30, 2010. This $31.3 million decrease was driven primarily by a decrease in revenue from the contract with HHS for the continued development of i.v. peramivir, primarily resulting from the completion of two clinical studies and the realignment of existing clinical studies, plus the impact of a change in estimate discussed below. In addition, the decrease also relates to a $7.0 million milestone payment from Shionogi related to its achievement in obtaining marketing and manufacturing approval of i.v. peramivir in Japan and the sale of $6.4 million of peramivir API to collaborators Shionogi and Green Cross, both of which occurred in 2010.

The decrease in revenue from the contract with HHS also reflects the impact of a change in estimate relating to a final cost reconciliation of a completed clinical study performed by a contract research organization (CRO) providing services on behalf of the Company. At the end of 2010, the Company estimated expenses related to this clinical study and the associated revenue the Company expected to receive from HHS, based on per patient cost experience from the initial recruitment in the study. Cost estimates used during the pendency of the study considered the ongoing influenza pandemic and the estimated costs of enrolling much sicker patients than originally expected. This resulted in a higher per patient cost than what was realized. Revisions to the estimated costs were based on the final cost reconciliation provided by the CRO in late March 2011 and resulted in a $3.0 million reduction of peramivir R&D expenses and a $3.6 million reduction to collaboration revenue during the three months ended March 31, 2011, resulting in a net impact of $0.6 million to net loss.

Research and development (R&D) expenses decreased to $41.7 million for nine months ended September 30, 2011 from $58.9 million in the same period as last year. The $17.2 million decrease was driven by lower development costs associated with our peramivir development program and lower costs associated with our forodesine clinical programs, partially offset by higher development costs associated with the BCX4208 program for the treatment of gout. Additionally, peramivir costs during the nine months ended September 30, 2010 included $6.3 million of manufacturing costs associated with peramivir API production for Shionogi and Green Cross.

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

22

Table of Contents

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,	
	2011	2010	2011	2010
Direct external R&D expenses by program:				
PNP Inhibitor (forodesine)	$ 373	$ 1,402	$ 1,249	$ 5,077
Neuraminidase Inhibitor (peramivir)	3,907	8,906	9,200	28,514
PNP Inhibitor (4208)	4,114	3,165	12,232	7,077
Other	965	422	2,345	981
Indirect R&D expenses	5,413	5,302	16,661	17,202
Total R&D expenses	$ 14,772	$ 19,197	$ 41,687	$ 58,851

General and administrative (G&A) expenses increased to $11.3 million for the nine months ended September 30, 2011 compared to $10.8 million in the same period as last year, primarily resulting from the transition of the Company s headquarters to Durham, North Carolina and consulting services relating to portfolio management and collaboration strategies.

During the nine months ended September 30, 2011, the Company incurred $2.6 million in interest expense related to the issuance of the PhaRMA notes on March 9, 2011. In addition, the Company recognized a $2.9 million mark to market loss on its Currency Hedge Agreement associated with the issuance by Royalty Sub of the PhaRMA Notes . The Company entered into the foreign currency hedge arrangement to hedge changes in the value of the Japanese yen relative to the U.S. dollar. The currency hedge does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in earnings.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception and we expect this to continue through the remainder of 2011. Our operations have principally been funded through public offerings and private placements of equity and cash from collaborative and other research and development agreements, including government contracts. On February 24, 2011, we announced that HHS had awarded us a $55.0 million contract modification intended to fund completion of the Phase 3 development of i.v. peramivir and on March 9, 2011, we completed a $30.0 million financing transaction to monetize certain future royalty and milestone payments. See *Recent Corporate Highlights, Peramivir* above for further discussion and details regarding the implication of these transactions.

On June 28, 2011, we filed a Registration Statement on Form S-3 with the Securities and Exchange Commission (SEC) for the issuance and sale of up to $70.0 million of equity or other securities, proceeds from which will be used for general corporate purposes. The Form S-3 became effective on July 13, 2011 and provides additional financial flexibility for the Company to sell shares as needed at any time. To date, no securities have been issued under this registration statement.

We have attempted to contain costs and reduce cash flow requirements by renting scientific equipment and facilities, contracting with other parties to conduct certain research and development projects and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities in general and specifically related to our clinical trial activity. We also expect to incur substantial expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical products advance through later stages of development.

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

At December 31, 2010, we had long-term operating lease obligations, which provide for annual aggregate minimum payments of $0.9 million in 2011, 2012 and 2013. These obligations include the future rental of our operating facilities.

We plan to finance our needs principally from the following:

payments under our contract with HHS;

our existing capital resources;

payments under collaborative and licensing agreements with corporate partners, including future collaborative or out-licensing initiatives; and

lease or loan financing and future public or private financing.

As of September 30, 2011, we held cash, cash equivalents and securities of $61.0 million, a decrease of $5.3 million as compared to December 31, 2010. The net proceeds of $23.0 million from the royalty monetization transaction and cash received from collaborations were, offset by monthly cash burn from operations and posting collateral related to the Currency Hedge Agreement. We expect that our operating cash utilization in 2011 will be approximately $35 million, which excludes the impact of the royalty monetization. Our cash use will vary depending on clinical outcomes and could vary significantly from our expectations depending on the timing of our expenses and the related reimbursement from our collaborators.

Table of Contents

As our clinical programs continue to progress and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing development of our drug candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and burn rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our drug candidates, the amount and timing of funding we receive from HHS for peramivir, the amount of funding or assistance, if any, we receive from other governmental agencies or other new partnerships with third parties for the development of our drug candidates, the progress and results of our current and proposed clinical trials for our most advanced drug products, the progress made in the manufacturing of our lead products and the progression of our other programs.

With the funds available at September 30, 2011 and future amounts that are expected to be received from HHS and our other collaborators, we believe that our resources are sufficient to fund our operations beyond fiscal 2012. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time.

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

- our ability to perform under the contract with HHS and receive reimbursement;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;
- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;
- the extent to which our partners, including governmental agencies, will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for certain drug candidates or a decision to build or expand internal development and commercial capabilities;
- successful commercialization of marketed products by either us or a partner;
- the scope and results of preclinical studies and clinical trials to identify and evaluate drug candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our drug candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development of our drug candidates;

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

competitive and technological advances;

the time and costs involved in obtaining regulatory approvals;

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; and

The posting of collateral to support our potential hedge obligation.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time we deem market conditions to be favorable. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from the HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

Table of Contents

Off-Balance Sheet Arrangements

As of September 30, 2011, we are not involved in any unconsolidated entities or off-balance sheet arrangements.

Contractual Obligations

Our contractual obligations as of December 31, 2010 are described in our Annual Report on Form 10-K for the year ended December 31, 2010. Material changes to our contractual obligations have resulted from the $30.0 million financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement completed on March 9, 2011 as noted below.

Debt Service Obligations of Royalty Sub

Royalty Sub issued $30.0 million in aggregate principal amount of its PhaRMA Notes. Principal and interest on the PhaRMA Notes are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. Payments may also be made from the interest reserve account. Principal on the PhaRMA Notes is required to be paid in full by the final legal maturity date of December 1, 2020, unless the PhaRMA Notes are repaid, redeemed or repurchased earlier. The PhaRMA Notes bear interest at the rate of 14% per annum, payable annually in arrears on September 1st of each year, beginning on September 1, 2011. Principal and interest payments on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including us, except to the extent of our pledge of our equity interests in Royalty Sub in support of the PhaRMA Notes.

Foreign Currency Hedge Obligations of the Company

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 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. Additionally, the Company may be required to post cash for mark to market risk or pay significant premiums or a termination fee under the foreign Currency Hedge Agreement entered into by it in connection with the issuance by Royalty Sub of the PhaRMA Notes. In conjunction with establishing the hedge in March 2011, the Company was required to post cash collateral of $1.5 million reflecting the value of the initial mark to market adjustment at that time, margin funds of $0.4 million. As of September 30, 2011, cash collateral of $3.0 million was posted, consisting of the initial mark to market loss of $1.5 million, margin funds of $0.4 million and $1.1 million of collateral calls.

Critical Accounting Policies

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

While our significant accounting policies are more fully described in Note 1 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010, and Note 1 to our financial statements included in Part I, Item I of this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Revenue Recognition

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

Collaborative and Other Research and Development Arrangements

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.

Table of Contents

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. Peramivir is a newly introduced product and there is no historical experience that can be used to reasonably estimate product returns. Therefore, the Company defers recognition of royalty revenue when paid by Shionogi until the earlier of (1) a right of return no longer exists or (2) it has developed sufficient historical experience to estimate product returns.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. Event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue. Under the Company s contract with 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. Product sales recognized during 2010 were not subject to a contractual right of return.

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 the University of Alabama at Birmingham (UAB), which require fees related to sublicense agreements or maintenance fees. Generally, we expense sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. We expense maintenance payments as incurred.

At September 30, 2011, we had deferred collaboration expenses of approximately $7.9 million. Approximately $2.4 million of these deferred expenses were sub-license payments, paid to our academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

The remaining $5.5 million of the deferred expenses relates to consideration provided to Licensors in May 2010 for modifications made to the existing licensing agreement. Under the terms of the amendment, we issued consideration in the form of common stock and cash to the Licensors in exchange for a reduction in the percentage of certain future payments we receive from third-party sub-licensees that must be paid to the Licensors. Amortization of this deferred expense began in May 2010 and will end in September 2027, which is the expiration date for the last-to-expire patent covered by the agreement. We believe that this accounting treatment is reasonable and consistent with our collaboration accounting policies.

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

drug candidates, which drug candidates will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Table of Contents

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot be certain that any of our drug candidates will prove to be safe and effective or will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory clearance. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our products under development. Delays or rejections may be encountered based on additional governmental regulation, legislation, administrative action or changes in FDA or other regulatory policy during development or the review process. Other risks associated with our product development programs are described in our Annual Report on Form 10-K for the year ended December 31, 2010 as updated from time to time in our subsequent periodic reports and current reports filed with the SEC. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of completion of any of our product development programs and the period in which material net cash inflows from any of our product development programs will commence are unavailable.

Stock-Based Compensation

All grants of stock option awards and restricted stock awards are recognized in our income statement based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the life of an award, the stock price volatility, and the expected term.

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. The Currency Hedge Agreement will not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in the Company s statement of operations. In conjunction with establishing the Currency Hedge Agreement in March 2011, the Company recorded an initial mark to market loss of $1.5 million. Cumulative mark to market adjustments for the nine months ended September 30, 2011 resulted in a $2.9 million loss. Mark to market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles. The Company is also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of September 30, 2011, cash collateral of $3.0 million was posted, consisting of the initial mark to market loss of $1.5 million, margin funds of $0.4 million and a $1.1 million of collateral calls.

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 Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical testing, clinical trials, and other research and development efforts;
- the potential funding from our contract with HHS for the development of peramivir;
- the potential for a stockpiling order or profit from any order for peramivir;
- the potential use of peramivir as a treatment for H1N1 flu (or other strains of flu);

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

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

our ability to establish and maintain collaborations;

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

Table of Contents

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, future revenues, capital requirements and our needs for additional financing;

the timing or likelihood of regulatory filings and approvals;

our financial performance; and

competitive companies, technologies and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors. Any forward-looking statement reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

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

As of September 30, 2011, the aggregate fair value of our non-recourse PhaRMA Notes was estimated at $30.0 million, which approximates the carrying value since the negotiated terms and conditions at the time of closing on March 9, 2011 were consistent with current market rates. The notes bear interest at a fixed rate of 14% per annum and therefore are subject to interest rate risk because the fixed interest rate may exceed current interest rates.

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, 2011, the Company s disclosure controls

Table of Contents

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, 2011 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 consider carefully 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. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also adversely affect our business, financial condition or results of operations.

Risks Relating to Our Business

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

Since our inception in 1986, we have not been profitable. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. To become profitable, we must successfully manufacture and develop drug product candidates, receive regulatory approval, and successfully commercialize or enter into profitable agreements with other parties. It could be several years, if ever, before we receive significant royalties from any current or future license agreements or revenues directly from product sales.

Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future losses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process.

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Clinical trials may not be adequately designed or executed, which could affect the potential outcome and analysis of study results. Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability.

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

- our ability to find suitable clinical sites and investigators to enroll patients;

the availability of and willingness of patients to participate in our clinical trials;

difficulty in maintaining contact with patients to provide complete data after treatment;

our product candidates may not prove to be either safe or effective;

clinical protocols or study procedures may not be adequately designed or followed by the investigators;

manufacturing or quality control problems could affect the supply of drug product for our trials; and

delays or changes in requirements by governmental agencies.

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Delays in patient enrollment can result in increased costs and longer development times. Even if we or our partners successfully complete

Table of Contents

clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidate.

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

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety profiles and show positive therapeutic effects in the patients being treated by achieving pre-determined endpoints according to the trial protocols. Failure to achieve either of these could result in delays in our trials or even require the performance of additional unplanned trials. This could result in delays in the development of our product candidates and could result in significant unexpected costs.

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

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements, and additional personnel resources and testing required for supporting the development of our product candidates will consume significant capital resources. Our expenses, revenues and burn rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount of funding we receive from HHS for peramivir, the amount of funding or assistance, if any, we receive from other governmental agencies or other new partnerships with third parties for the development of our product candidates, the amount or profitability of any orders for peramivir by any government agency or other party, the progress and results of our current and proposed clinical trials for our most advanced drug products, the progress made in the manufacturing of our lead products and the progression of our other programs.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time we deem market conditions to be favorable. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies, in general and from any HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

If HHS were to eliminate, reduce or delay funding from our contract, or dispute some of our incurred costs or other actions taken under the contract, this would have a significant negative impact on our revenues, cash flows and the development of peramivir.

Our projections of revenues and incoming cash flows are substantially dependent upon HHS reimbursement for the costs related to our peramivir program. If HHS were to eliminate, reduce or delay the funding for this program or disallow some of our incurred costs, we would have to obtain additional funding for development of this drug candidate or significantly reduce or stop the development effort. Further, HHS may challenge actions that we have taken or may take under our contract, which could negatively impact our operating results and cash flows.

In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. U.S. government contracts typically contain extraordinary provisions which would not typically be found in commercial contracts. For instance, government contracts permit unilateral modification by the government, interpretation of relevant regulations (i.e., federal acquisition regulation clauses), and the ability to terminate for convenience. 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 also subject to audit and modification by the government at its sole discretion. If the government terminates its contract with us for its convenience or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

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

We have entered into a contract with HHS for the advanced development of our neuraminidase inhibitor, peramivir. In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract. U.S. government contracts typically contain unfavorable termination

30

Table of Contents

provisions and are subject to audit, in process review and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

- terminate or reduce the scope of our contract; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

The U.S. government may terminate its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit, if entitled to profit under the contract, on the work completed prior to termination. Termination for default provisions does not permit these recoveries.

As a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our contract-related costs and fees, including allocated indirect costs. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our drug product candidates or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.

Our business strategy is to increase the asset value of our drug candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third-party alliances could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our drug product candidates.

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- 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.

Table of Contents

If any partner fails to fulfill its responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our compounds would severely affect our business, because if our compounds do not progress through the development process or reach the market in a timely manner, or at all, we may not receive additional future event payments and may never receive product or royalty payments.

We have not commercialized any products or technologies and our future revenue generation is uncertain.

We have not commercialized any products or technologies, and we may never be able to do so. We currently have no marketing capability and no direct or third-party sales or distribution capabilities and may be unable to establish these capabilities for products we plan to commercialize. In addition, our revenue from collaborative agreements is dependent upon the status of our preclinical and clinical programs. If we fail to advance these programs to the point of being able to enter into successful collaborations, we will not receive any future event or other collaborative payments.

Our ability to receive revenue from products we commercialize presents several risks, including:

- we or our collaborators may fail to successfully complete clinical trials sufficient to obtain FDA marketing approval;
- many competitors are more experienced and have significantly more resources and their products could be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products are affected by the competitive landscape, which cannot be fully known at this time;
- reimbursement is constantly changing which could greatly affect usage of our products; and
- any future revenue directly from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, manufacture, market and commercialize any approved drugs.

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

We rely heavily upon other parties for many important stages of our drug development programs, including but not limited to:

- discovery of compounds that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;

licensing or design of enzyme inhibitors for development as drug product candidates;

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

management of our clinical trials, including medical monitoring and data management;

execution of additional toxicology studies that may be required to obtain approval for our product candidates; and

manufacturing the starting materials and drug substance required to formulate our drug products and the drug products to be used in both our clinical trials and toxicology studies.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our product development efforts would suffer. Similarly, if the contract research organizations that conduct our initial or late-stage clinical trials, conduct our toxicology studies, manufacture our starting materials, drug substance and drug products

Table of Contents

or manage our regulatory function breached their obligations to us or perform their services inconsistent with industry standards and not in accordance with the required regulations, this would delay or prevent the development of our product candidates.

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

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

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

- the peramivir i.v. currently in clinical development may not prove to be safe and sufficiently effective for market approval in the United States or other major markets;
- necessary government or other third party funding and clinical testing for further development of peramivir may not be available timely, at all, or in sufficient amounts;
- the flu prevention or pandemic treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines or other antivirals, including competitive i.v. antivirals, could substantially replace potential demand for peramivir;
- any substantial demand for pandemic or seasonal flu treatments may occur before peramivir can be adequately developed and tested in clinical trials;
- peramivir may not prove to be accepted by patients and physicians as a treatment for seasonal influenza compared to the other currently marketed antiviral drugs, which would limit revenue from non-governmental entities;
- numerous large and well-established pharmaceutical and biotech companies will be competing to meet the market demand for flu drugs and vaccines;
- the only major markets in which patents relating to peramivir have issued or been allowed are the United States, Canada, Japan, Australia and many contracting and extension states of the European Union, while no patent applications or issued patents for peramivir exist in other potentially significant markets;

- regulatory authorities may not make needed accommodations to accelerate the drug testing and approval process for peramivir; and

- in the next few years, it is expected that a limited number of governmental entities will be the primary potential customers for peramivir and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues from stockpiling orders from these entities.

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

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

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

Table of Contents

markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

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

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

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

- inconsistent production yields;
- product liability claims;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- scheduling of plant time with other vendors or unexpected equipment failure;
- potential catastrophes, such as the recent earthquake in Japan, that could strike their facilities or have an effect on infrastructure;
- potential impurities in our drug substance or drug products that could affect availability of product for our clinical trials or future commercialization;
- poor quality control and assurance or inadequate process controls; and
- lack of compliance with regulations and specifications set forth by the FDA or other foreign regulatory agencies.

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

we or they may be subject to regulatory action, civil actions or penalties.

If we are unable to enter into agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance on the part of our third-party manufacturers, we may not be able to complete development of, or market, our product candidates.

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

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

Table of Contents

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, investors may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub, in which case we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes.

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

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

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

We may be required to pay significant premiums under the foreign currency hedge arrangement entered into by us in connection with the issuance by Royalty Sub 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 earnings attributable to the foreign currency hedge arrangement.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a foreign currency hedge arrangement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the currency hedge arrangement, we may be required to pay a premium in the amount of $2.0 million in each year beginning in May 2014 and, provided the currency hedge arrangement remains in effect, continuing through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the currency hedge arrangement) is such that the U.S. dollar is worth 100 yen or less. We will be required to mark-to-market our potential obligations under the currency hedge, which may cause us to experience additional quarterly volatility in our earnings as a result. Additionally, we may be required to post cash for mark to market risk, pay significant premiums or a termination fee under the foreign currency hedge agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes.

35

Table of Contents

If we or our partners do not obtain and maintain governmental approvals for our products under development, we or our partners will not be able to sell these potential products, which would significantly harm our business because we will receive no revenue.

We or our partners must obtain regulatory approval before marketing or selling our future drug products. If we or our partners are unable to receive regulatory approval and do not market or sell our future drug products, we will never receive any revenue from such product sales. In the United States, we or our partners must obtain FDA approval for each drug that we intend to commercialize. The process of preparing for and obtaining FDA approval may be lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation and export laws of the U.S. Neither the FDA nor foreign regulatory agencies have approved any of our drug product candidates. Because of the risks and uncertainties in biopharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our product candidates, our management s credibility, our company s value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a product candidate, the approval may limit the indicated uses for a product candidate and/or may require post-marketing studies.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage. If we get approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

adverse drug experience reporting regulations;

product promotion;

product manufacturing, including good manufacturing practice requirements; and

product changes or modifications.

Our failure to comply with existing or future regulatory requirements, or our loss of, or changes to, previously obtained approvals, could have a material adverse effect on our business because we will not receive product or royalty revenues if we or our partners do not receive approval of our products for marketing.

In June 1995, we notified the FDA that we submitted incorrect data for our Phase II studies of BCX-34 applied to the skin for CTCL and psoriasis. In November 1995, the FDA issued a List of Inspectional Observations, Form FDA 483, which cited our failure to follow good clinical practices. The FDA also inspected us in June 1996. The focus was on the two 1995 Phase 2 dose-ranging studies of topical BCX-34 for the treatment of CTCL and psoriasis. As a result of the investigation, the FDA issued us a Form FDA 483, which cited our failure to follow good clinical practices. We are no longer developing BCX-34; however, as a consequence of these two investigations, our ongoing and future clinical studies may receive increased scrutiny, which may delay the regulatory review process.

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

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

other drug development technologies;

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

new small molecule or other classes of therapeutic agents.

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

We and our partners are performing research on or developing products for the treatment of several disorders including T-cell mediated disorders (T-cell cancers and other autoimmune indications), gout, CTCL, CLL, influenza, and hepatitis C. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that

Table of Contents

complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai s Targretin for CTCL and the current neuraminidase inhibitors marketed by Glaxo Smith Kline and Roche for influenza. With respect to the neuraminidase inhibitors, these companies may develop i.v. formulations that could compete with peramivir. Further, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and in the fields of PNP, influenza, hepatitis C, and in other therapeutic areas where we have discovery efforts ongoing. If one or more of our competitors products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

Any of these competitive factors could reduce demand for our products.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish.

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including but not limited to trade name, trade mark and patent protection for our company and its products, methods, processes and other technologies we may license or develop, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office (USPTO), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we do not have worldwide patent protection for our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. The validity, scope, enforceability and commercial value of these rights, therefore, is highly uncertain.

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

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

Table of Contents

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- if patents do issue we can not be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in those patents; or
- pay damages.

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

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

There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our clinical trials in the amount of approximately $11.0 million. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;

withdrawal of clinical trial volunteers or patients;

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

regulatory investigations that could require costly recalls or product modifications;

litigation costs; and

the diversion of management s attention from managing our business.

Table of Contents

If our facility incurs damage or power is lost for a significant length of time, our business will suffer.

We currently store numerous clinical and stability samples at our facility that could be damaged if our facility incurred physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to maintain power to all critical functions, but any loss of these samples could result in significant delays in our drug development process.

In addition, we currently store most of our preclinical and clinical data at our facility. Duplicate copies of most critical data are stored off-site in a bank vault. Any significant degradation or failure of our computer systems or vendor systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our drug product candidates and the expansion of our business will be delayed or stopped.

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

Our stock price is likely to be highly volatile and the value of your investment could decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended September 30, 2011, the 52-week range of the market price of our stock was from $2.30 to $5.86 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales of our common stock or other derivative securities;
- status of new or existing licensing or collaborative agreements and government contracts;
- announcements relating to the status of our programs;
- we or our partners achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;
- regulatory developments in both the United States and foreign countries;

public concern as to the safety of pharmaceutical products;

actual or anticipated fluctuations in our operating results;

changes in financial estimates or recommendations by securities analysts;

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

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

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

Table of Contents

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.

If, because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result and any liabilities could exceed our resources. Compliance with environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Item 6. Exhibits

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 3rd day of November, 2011.

BIOCRYST PHARMACEUTICALS, INC.

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

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

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

Officer

Table of Contents

INDEX TO EXHIBITS

Number	Description
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed July 24, 2007.
3.3	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company s Form 8-K filed November 4, 2008.
3.4	Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company s Form 8-K filed November 4, 2008.
4.1	Rights Agreement, dated as of June 17, 2002, by and between the Company and American Stock Transfer & Trust Company, as Rights Agent, which includes the Certificate of Designation for the Series B Junior Participating Preferred Stock as Exhibit A and the form of Rights Certificate as Exhibit B. Incorporated by reference to Exhibit 4.1 to the Company s Form 8-A filed June 17, 2002.
4.2	Amendment to Rights Agreement, dated as of August 5, 2007. Incorporated by reference to Exhibit 4.2 of the Company s Form 10-Q filed August 9, 2007.
4.3	Indenture, dated as of March 9, 2011 by and between JPR Royalty Sub LLC and U.S. Bank National Association, as trustee. Incorporated by reference to Exhibit 4.3 of the Company s Form 10-Q filed May 6, 2011.
(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 months ended September 30, 2011, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.*

( ) Filed herewith.

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