

BIOCRYST PHARMACEUTICALS INC

Form 10-Q

August 04, 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 June 30, 2011  
Commission File Number 000-23186  
BIOCRYST PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

**DELAWARE**

(State of other jurisdiction of  
incorporation or organization)

**62-1413174**

(I.R.S. Employer Identification No.)

**4505 Emperor Blvd., Suite 200**

**Durham, North Carolina**

(Address of principal executive offices)

**27703**

(Zip Code)

**(919) 859-1302**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No   
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated  
filer

Accelerated filer

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

Smaller reporting  
company

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

The number of shares of Common Stock, par value \$.01, of the Registrant outstanding as of August 1, 2011 was 45,149,935

**BIOCRYST PHARMACEUTICALS, INC.**  
**INDEX**

|  | <b>Page No.</b> |
|--|-----------------|
| <u>Part I. Financial Information</u>   |                 |
| <u>Item 1. Financial Statements:</u>   | 3               |
| <u>Balance Sheets June 30, 2011(Consolidated) and December 31, 2010</u>                              | 3               |
| <u>Statements of Operations Three and Six Months Ended June 30, 2011 (Consolidated) and 2010</u>     | 4               |
| <u>Statements of Cash Flows Six Months Ended June 30, 2011(Consolidated) and 2010</u>                | 5               |
| <u>Notes to Consolidated Financial Statements</u>  | 6               |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 16              |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>                            | 28              |
| <u>Item 4. Controls and Procedures</u>   | 29              |
| <u>Part II. Other Information</u>  |                 |
| <u>Item 1A. Risk Factors</u>   | 30              |
| <u>Item 6. Exhibits</u>  | 30              |
| <u>Signatures</u>  | 31              |
| <u>EX-10.2</u>   |                 |
| <u>EX-31.1</u>   |                 |
| <u>EX-31.2</u>   |                 |
| <u>EX-32.1</u>   |                 |
| <u>EX-32.2</u>   |                 |
| <u>EX-101 INSTANCE DOCUMENT</u>  |                 |
| <u>EX-101 SCHEMA DOCUMENT</u>  |                 |
| <u>EX-101 CALCULATION LINKBASE DOCUMENT</u>  |                 |
| <u>EX-101 LABELS LINKBASE DOCUMENT</u>   |                 |
| <u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>   |                 |

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****BIOCRYST PHARMACEUTICALS, INC.****BALANCE SHEETS****June 30, 2011 (Consolidated) and December 31, 2010****(In thousands, except per share data)**

|  | <b>2011</b>        | <b>2010</b>     |
|--|--------------------|-----------------|
|  | <b>(Unaudited)</b> | <b>(Note 1)</b> |
| <b>Assets</b>  |                    |                 |
| Cash and cash equivalents  | \$ 17,008          | \$ 13,622       |
| Restricted cash  | 1,416              | 625             |
| Marketable securities  | 40,583             | 40,323          |
| Receivables from collaborations  | 15,961             | 30,227          |
| Interest reserve   | 3,000              |                 |
| Inventories  | 898                | 898             |
| Prepaid expenses and other current assets  | 260                | 1,005           |
| Deferred collaboration expense   | 751                | 719             |
| <br>   |                    |                 |
| Total current assets   | 79,877             | 87,419          |
| Marketable securities  | 12,984             | 11,771          |
| Furniture and equipment, net   | 1,537              | 1,929           |
| Deferred collaboration expense   | 7,319              | 8,328           |
| Other assets   | 6,695              |                 |
| <br>   |                    |                 |
| Total assets   | \$ 108,412         | \$ 109,447      |
| <b>Liabilities and Stockholders Equity</b>   |                    |                 |
| Accounts payable   | \$ 5,012           | \$ 8,201        |
| Accrued expenses   | 12,309             | 17,124          |
| Interest payable   | 1,318              |                 |
| Deferred collaboration revenue   | 3,321              | 2,497           |
| <br>   |                    |                 |
| Total current liabilities  | 21,960             | 27,822          |
| Deferred rent  | 151                | 178             |
| Deferred collaboration revenue   | 14,695             | 15,944          |
| Foreign currency derivative  | 2,340              |                 |
| Non-recourse notes payable   | 30,000             |                 |
| <br>   |                    |                 |
| Commitments and contingencies  |                    |                 |
| <br>   |                    |                 |
| 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 45,150 in 2011 and 44,959 in 2010 | 451                | 449             |

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|  |            |            |
|--|------------|------------|
| Additional paid-in capital                 | 364,593    | 361,520    |
| Accumulated other comprehensive income     | 92         | 106        |
| Accumulated deficit                        | (325,870)  | (296,572)  |
| <br>                                       |            |            |
| Total stockholders' equity                 | 39,266     | 65,503     |
| <br>                                       |            |            |
| Total liabilities and stockholders' equity | \$ 108,412 | \$ 109,447 |

See accompanying notes to consolidated financial statements.

3

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Table of Contents

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**Periods Ended June 30, 2011 (Consolidated) and 2010**  
**(In thousands, except per share data)**  
**(Unaudited)**

|  | <b>Three Months</b> |             | <b>Six Months</b> |             |
|--|---------------------|-------------|-------------------|-------------|
|  | <b>2011</b>         | <b>2010</b> | <b>2011</b>       | <b>2010</b> |
| <b>Revenues</b>  |                     |             |                   |             |
| Product sales  | \$                  | \$          | \$                | \$ 325      |
| Royalties  |                     |             |                   | 711         |
| Collaborative and other research and development             | 3,735               | 7,616       | 9,170             | 32,651      |
| <br>   |                     |             |                   |             |
| Total revenues   | 3,735               | 7,616       | 9,170             | 33,687      |
| <b>Expenses</b>  |                     |             |                   |             |
| Cost of products sold  |                     |             |                   | 86          |
| Research and development                                     | 13,975              | 14,737      | 26,907            | 39,654      |
| General and administrative                                   | 4,003               | 3,209       | 8,005             | 7,006       |
| <br>   |                     |             |                   |             |
| Total expenses   | 17,978              | 17,946      | 34,912            | 46,746      |
| <br>   |                     |             |                   |             |
| Loss from operations   | (14,243)            | (10,330)    | (25,742)          | (13,059)    |
| Interest and other income                                    | 136                 | 137         | 239               | 271         |
| Interest expense   | (1,166)             |             | (1,455)           |             |
| Loss on foreign currency derivative                          | (998)               |             | (2,340)           |             |
| <br>   |                     |             |                   |             |
| Net loss   | \$ (16,271)         | \$ (10,193) | \$ (29,298)       | \$ (12,788) |
| <br>   |                     |             |                   |             |
| Basic and diluted net loss per common share                  | \$ (0.36)           | \$ (0.23)   | \$ (0.65)         | \$ (0.29)   |
| <br>   |                     |             |                   |             |
| Weighted average shares outstanding                          | 45,111              | 44,517      | 45,063            | 44,222      |
| See accompanying notes to consolidated financial statements. |                     |             |                   |             |

Table of Contents

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**Six Months Ended June 30, 2011 (Consolidated) and 2010**  
(In thousands)  
(Unaudited)

|   | <b>2011</b>     | <b>2010</b>     |
|---|-----------------|-----------------|
| <b>Operating activities</b>   |                 |                 |
| Net loss  | \$ (29,298)     | \$ (12,788)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |                 |                 |
| Depreciation and amortization   | 445             | 789             |
| Stock-based compensation expense  | 2,728           | 3,566           |
| Amortization of debt issuance costs   | 137             |                 |
| Change in fair value of foreign currency derivative                         | 2,340           |                 |
| Changes in operating assets and liabilities:                                |                 |                 |
| Receivables from collaborations   | 14,266          | 13,191          |
| Inventories   |                 | 5,374           |
| Prepaid expenses and other current assets                                   | 745             | (365)           |
| Deferred collaboration expense  | 977             | 155             |
| Accounts payable and accrued expenses                                       | (8,004)         | (22,155)        |
| Interest payable  | 1,318           |                 |
| Interest reserve  | (3,000)         |                 |
| Deferred rent   | (27)            | (26)            |
| Deferred collaboration revenue  | (425)           | (1,248)         |
| <b>Net cash used in operating activities</b>                                | <b>(17,798)</b> | <b>(13,507)</b> |
| <b>Investing activities</b>   |                 |                 |
| Acquisitions of furniture and equipment                                     | (53)            | (247)           |
| Change in restricted cash   | (791)           |                 |
| Purchases of marketable securities  | (27,676)        | (29,476)        |
| Sales and maturities of marketable securities                               | 26,189          | 15,561          |
| <b>Net cash used in investing activities</b>                                | <b>(2,331)</b>  | <b>(14,162)</b> |
| <b>Financing activities</b>   |                 |                 |
| Exercise of stock options   | 238             | 480             |
| Employee stock purchase plan sales  | 170             | 173             |
| Purchases of treasury stock   | (61)            | (4)             |
| Common stock issuance costs   | (73)            | (84)            |
| Issuance of non-recourse notes payable                                      | 30,000          |                 |
| Debt issuance costs   | (4,309)         |                 |
| Payment of foreign currency derivative collateral                           | (2,450)         |                 |
| <b>Net cash provided by financing activities</b>                            | <b>23,515</b>   | <b>565</b>      |
| Increase (decrease) in cash and cash equivalents                            | 3,386           | (27,104)        |
| Cash and cash equivalents at beginning of period                            | 13,622          | 41,125          |

|   |                  |                  |
|---|------------------|------------------|
| <b>Cash and cash equivalents at end of period</b> | <b>\$ 17,008</b> | <b>\$ 14,021</b> |
|---|------------------|------------------|

See accompanying notes to consolidated financial statements.

5

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**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 June 30, 2011, the consolidated statement of operations for the three and six months ended June 30, 2011, the consolidated statement of cash flows for the six months ended June 30, 2011, the statement of operations for the three and six months ended June 30, 2010 and the statement of cash flows for the six months ended June 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 June 30, 2011 includes \$0.8 million in royalty revenue paid by Shionogi & Co., Ltd. (Shionogi) designated for payment of principal and interest on the PhaRMA Notes (defined in Note 5) and \$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 June 30, 2011, the Company believes that the costs of its securities are recoverable in all material respects.

The following table summarizes the fair value of the Company's securities by type at June 30, 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.

**Table of Contents**

|   | <b>Amortized<br/>Cost</b> | <b>Accrued<br/>Interest</b> | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Gross<br/>Unrealized<br/>Losses</b> | <b>Estimated<br/>Fair<br/>Value</b> |
|---|---------------------------|-----------------------------|---------------------------------------|--|-------------------------------------|
| U.S. Treasury securities                | \$ 7,499                  | \$ 20                       | \$ 20                                 | \$                                     | \$ 7,539                            |
| Obligations of U.S. government agencies | 5,011                     | 29                          | 3                                     |  | 5,043                               |
| Corporate debt securities               | 14,189                    | 145                         | 42                                    | (4)                                    | 14,372                              |
| Commercial paper                        | 18,126                    | 7                           | 12                                    |  | 18,145                              |
| Asset backed securities                 | 1,172                     |                             | 2                                     |  | 1,174                               |
| Certificates of deposit                 | 1,000                     | 8                           | 1                                     |  | 1,009                               |
| Municipal obligations                   | 6,218                     | 50                          | 20                                    | (3)                                    | 6,285                               |
| <b>Total marketable securities</b>      | <b>\$ 53,215</b>          | <b>\$ 259</b>               | <b>\$ 100</b>                         | <b>\$ (7)</b>                          | <b>\$ 53,567</b>                    |

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

|   | <b>2011</b>      |
|---|------------------|
| Maturing in one year or less              | \$ 40,583        |
| Maturing after one year through two years | 10,658           |
| Maturing after two years                  | 2,326            |
| <b>Total marketable securities</b>        | <b>\$ 53,567</b> |

**Receivables from Collaborations**

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

|  | <b>Billed</b>   | <b>Unbilled</b>  | <b>Total</b>     |
|--|-----------------|------------------|------------------|
| U.S. Department of Health and Human Services | \$ 2,819        | \$ 13,012        | \$ 15,831        |
| Other  | 130             |                  | 130              |
| <b>Total</b>                                 | <b>\$ 2,949</b> | <b>\$ 13,012</b> | <b>\$ 15,961</b> |

Included in unbilled receivables from the U.S. Department of Health and Human Services (HHS) is \$2.9 million 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 at the balance sheet date 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.

***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.

**Table of Contents*****Accrued Expenses***

The Company records all expenses in the period incurred. In addition to recording expenses for invoices received, the Company estimates the cost of services provided by third parties or materials purchased for which no invoices have been received as of the balance sheet dates. Accrued expenses as of June 30, 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 June 30, 2011.

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

|   | <b>Three Months</b> |             | <b>Six Months</b> |             |
|---|---------------------|-------------|-------------------|-------------|
|   | <b>2011</b>         | <b>2010</b> | <b>2011</b>       | <b>2010</b> |
| Net loss  | \$ (16,271)         | \$ (10,193) | \$ (29,298)       | \$ (12,788) |
| Unrealized gain (loss) on securities available-for-sale | 9                   | (14)        | (14)              | 88          |
| Other comprehensive loss                                | \$ (16,262)         | \$ (10,207) | \$ (29,312)       | \$ (12,700) |

***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.

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 six months ended June 30, 2011 were 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.

*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.

**Table of Contents**

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

|   | <b>Three Months</b> |             | <b>Six Months</b> |             |
|---|---------------------|-------------|-------------------|-------------|
|   | <b>2011</b>         | <b>2010</b> | <b>2011</b>       | <b>2010</b> |
| Product sales:  |                     |             |                   |             |
| NT Pharma, Co., Ltd. (Hong Kong)                                | \$                  | \$          | \$                | \$ 250      |
| Other   |                     |             |                   | 75          |
| <br>  |                     |             |                   |             |
| Total product sales   |                     |             |                   | 325         |
| Royalties:  |                     |             |                   |             |
| Shionogi (Japan)  |                     |             |                   | 711         |
| <br>  |                     |             |                   |             |
| Total royalties   |                     |             |                   | 711         |
| Collaborative and other research and development revenues:      |                     |             |                   |             |
| U.S. Department of Health and Human Services                    | 3,111               | 6,924       | 7,772             | 17,613      |
| Shionogi (Japan)  | 296                 | 296         | 592               | 13,375      |
| Mundipharma (United Kingdom)                                    | 328                 | 396         | 720               | 1,038       |
| Green Cross (Korea)   |                     |             |                   | 625         |
| Grants (United States)  |                     |             | 86                |             |
| <br>  |                     |             |                   |             |
| Total collaborative and other research and development revenues | 3,735               | 7,616       | 9,170             | 32,651      |
| <br>  |                     |             |                   |             |
| Total revenues  | \$ 3,735            | \$ 7,616    | \$ 9,170          | \$ 33,687   |

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.

At June 30, 2011, the Company had deferred collaboration expenses of approximately \$8.0 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 \$5.6 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.

**Table of Contents*****Interest Expense and Deferred Financing Costs***

Interest expense for the three and six months ended June 30, 2011 was \$1.2 million and \$1.5 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 \$31,000 and \$106,000 for the three and six months ended June 30, 2011.

***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 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 six months ended June 30, 2011 resulted in a \$2.3 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 June 30, 2011, cash collateral of \$2.5 million was posted, consisting of the initial mark to market loss of \$1.5 million, margin funds of \$0.4 million and a \$0.6 million collateral call in June 2011.

***Restructuring Activities***

During the fourth quarter of 2010, the Company announced a restructuring plan to consolidate core facilities 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.

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.

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

As of June 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 \$2.7 million (\$2.6 million of expense related to the Incentive Plan, \$0.09 million of expense related to the ESPP, and \$0.05 million of expense related to the inducement grant) was recognized during the first six months of 2011, while \$3.6 million (\$3.4 million of expense related to the Incentive Plan, \$0.08 million of expense related to the ESPP, and \$0.08 million of expense related to the inducement grant) was recognized during the first six months of 2010.

There was approximately \$8.5 million of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of June 30, 2011. That cost is expected to be recognized as follows: \$1.7 million in 2011, \$2.9 million in 2012, \$2.5 million in 2013, \$1.2 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:

|                                   | <b>Awards<br/>Available</b> | <b>Options<br/>Outstanding</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> |
|-----------------------------------|-----------------------------|--------------------------------|--|
| Balance December 31, 2010         | 1,858,044                   | 6,801,542                      | \$ 6.66  |
| Stock option plan amendment       | 1,600,000                   |                                |  |
| Restricted stock awards granted   | (186,141)                   |                                |  |
| Restricted stock awards cancelled | 750                         |                                |  |
| Stock option awards granted       | (1,416,435)                 | 1,416,435                      | 4.13   |
| Stock option awards exercised     |                             | (160,232)                      | 1.64   |
| Stock option awards cancelled     | 225,325                     | (225,325)                      | 6.64   |
| Balance June 30, 2011             | 2,081,543                   | 7,832,420                      | \$ 6.31  |

For stock option awards granted under the Incentive Plan during the six three 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 six months of 2011 and 2010 was \$2.75 and \$4.69, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following summarizes the key assumptions used by the Company to value the stock option awards granted during the first six months of 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.

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

|                         | <b>2011</b> | <b>2010</b> |
|-------------------------|-------------|-------------|
| Expected Life in Years  | 5.5         | 5.5         |
| Expected Volatility     | 80.1%       | 89.3%       |
| Expected Dividend Yield | 0.0%        | 0.0%        |
| Risk-Free Interest Rate | 2.2%        | 2.4%        |

**Table of Contents**

During 2007, the Company granted 50,000 restricted stock awards under the Incentive Plan with a grant date fair value of \$11.81 per share. During the first quarter of 2009, 25,000 of these restricted stock awards vested. The remainder of these restricted stock awards vested during the first quarter of 2011.

**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 181,538 shares remain available for purchase at June 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 48,627 shares during the first six 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 June 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.

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. 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.

**Table of Contents**

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.

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

The Company deferred 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 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 June 30, 2011. The Company is engaged in ongoing discussion to resolve this dispute. The maximum potential exposure to the Company is estimated to be approximately 1,665,110 (or approximately \$2.4 million based on the exchange rate on June 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.

*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.

**Table of Contents**

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, separate from the valuation allowance against deferred tax assets. Any future changes to the Company's unrecognized tax benefits would be offset by an adjustment to the valuation allowance and there would be no impact on the Company's financial statements.

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 2006-2009 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 no provisions or accruals for interest and penalties since the Company's inception.

**Table of Contents****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 be 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.

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.

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:

| <b>Payment Dates (Between Indicated Dates)</b>                  | <b>Redemption Percentage</b> |
|---|------------------------------|
| 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 six months ended June 30, 2011 resulted in a \$2.3 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 June 30, 2011, cash collateral of \$2.5 million was posted, consisting of the initial mark to market loss of \$1.5 million, margin funds of \$0.4 million and a \$0.6 million collateral call in June 2011. 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.

**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This Quarterly Report on Form 10-Q contains forward-looking statements, including statements regarding future results, performance, or achievements of the Company. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below 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.

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 June 30, 2011, approximately \$165.4 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.

**Table of Contents**

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 be ordered by HHS are 1,000 and 40,000 treatment courses, at the same unit price as the first order. We are 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.

*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<sup>®</sup> 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<sup>®</sup> in Japan and, if approved for commercial sale, Taiwan (the *Territory* ), as well as future milestone payments payable by Shionogi under the *Shionogi Agreement* (as defined below) and all of *Royalty Sub*'s other assets, and (ii) a pledge by us of our equity interest in *Royalty Sub*.

In connection with the issuance of the *PhaRMA Notes* by *Royalty Sub*, we entered into a purchase and sale agreement (the *Purchase and Sale Agreement* ) dated as of March 9, 2011, between us and *Royalty Sub*. Under the terms of the *Purchase and Sale Agreement*, we transferred to *Royalty Sub*, among other things, (i) our 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 us in connection with the transaction. Of the \$30.0 million in gross proceeds from the sale of the *PhaRMA Notes* by *Royalty Sub*, \$3.0 million was used to fund an interest reserve account, and after fees and financing expenses in connection with the transaction the net proceeds to us were approximately \$23.0 million. We and *Royalty Sub* have agreed to certain covenants in the *Purchase and Sale Agreement* that are intended to preserve the value of the assets purchased from us by *Royalty Sub*. The *Purchase and Sale Agreement* includes customary representations, warranties and covenants by us and customary indemnification and other provisions typical for asset sale agreements in structured financing transactions for pharmaceutical royalty payments.

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 (the *Trustee* ). Principal and interest on the

PhARMA Notes issued by Royalty Sub are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by us 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 the rate of 14% per annum, payable annually in arrears on September 1st of each year, beginning on September 1, 2011 (each, a Payment Date ).

Royalty Sub's obligations to pay principal and interest on the PhARMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including us, except to the extent of our pledge of our equity interests in Royalty Sub in support of the PhARMA Notes.

Various accounts have been established in accordance with the Indenture, including, among others, the interest reserve account as well as a collections account into which royalty and milestone payments under the Shionogi Agreement will be made. In addition, we may, but are not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhARMA Notes.

On each Payment Date in respect of the PhARMA Notes, funds will be applied by the Trustee in the order of priority set forth below:

first, to Royalty Sub for the payment of all taxes owed by Royalty Sub, if any;

second, to the payment of certain expenses of Royalty Sub not previously paid or reimbursed;

**Table of Contents**

third, to the Trustee for distribution to the holders, all interest due and payable on the PhaRMA Notes, including any accrued and unpaid interest due on prior Payment Dates, and any accrued and unpaid interest on such unpaid interest, compounded annually, taking into account any amounts paid from the interest reserve account and capital account on such Payment Date;

fourth, as long as no event of default has occurred and is continuing, on the September 1, 2014 Payment Date, the September 1, 2015 Payment Date or the September 1, 2016 Payment Date, to the interest reserve account, the amount (if any) set forth in a written direction to the Trustee from Royalty Sub; provided, that such application of funds, together with any such prior application of funds, shall not exceed \$2.1 million in the aggregate;

fifth, to the Trustee for distribution to the holders of the PhaRMA Notes, principal payments on the PhaRMA Notes (without premium or penalty), allocated pro rata among the holders of the PhaRMA Notes, until the outstanding principal balance of such PhaRMA Notes has been paid in full;

sixth, after the PhaRMA Notes have been paid in full, to the Trustee for the payment of principal of, and interest on, subordinated notes, if any, issued by Royalty Sub as permitted by the Indenture for the PhaRMA Notes in certain circumstances;

seventh, after the PhaRMA Notes have been paid in full, to the ratable payment of all other obligations under the Indenture for the PhaRMA Notes until all such amounts are paid in full; and

eighth, after the PhaRMA Notes and all amounts owing under the Indenture have been paid in full, to Royalty Sub, all remaining amounts.

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 us 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 under the Indenture will occur. Events of Default under the Indenture include, but are not limited to, the following:

failure to pay interest on the PhaRMA Notes due on any Payment Date (other than the final legal maturity date or any redemption date) in full on or prior to the next succeeding Payment Date, together with any additional accrued and unpaid interest on any interest not paid on the Payment Date on which it was originally due;

failure to pay principal and premium, if any, and accrued and unpaid interest on the PhaRMA Notes on the final legal maturity date, or failure to pay the redemption price when required on any redemption date;

failure to pay any other amount due and payable under the Indenture and the continuance of such default for a period of 30 or more days after written notice thereof is given to Royalty Sub by the Trustee;

failure by Royalty Sub to comply with certain covenants set forth in the Indenture or the PhaRMA Notes, provided, that, if the consequences of the failure can be cured, such failure continues for a period of 30 days or more after written notice of the failure has been given to Royalty Sub by the Trustee at the direction of holders of a majority of the outstanding principal balance of PhaRMA Notes, and, except in respect of a covenant, obligation, condition or provision already qualified in respect of Material Adverse Change (as defined in the Indenture), such failure is a Material Adverse Change;

Royalty Sub becomes subject to a Voluntary Bankruptcy or an Involuntary Bankruptcy (each as defined in the Indenture);

any judgment or order for the payment of money in excess of \$1.0 million (not paid or covered by insurance) shall be rendered against Royalty Sub and either (i) enforcement proceedings have been commenced by any creditor upon such judgment or order or (ii) there is any period of 30 consecutive days during which a stay of enforcement of such judgment or order, by reason of a pending appeal or otherwise, shall not be in effect;

Royalty Sub is classified as a corporation or publicly traded partnership taxable as a corporation for U.S. federal income tax purposes;

Royalty Sub becomes an investment company required to be registered under the Investment Company Act of 1940, as amended;

we shall have failed to perform any of our covenants under the Purchase and Sale Agreement and such failure is a Material Adverse Change; or

the Trustee shall fail to have a first-priority perfected security interest in any of the collateral securing the Pharma Notes or in any of the equity in Royalty Sub pledged by us.

**Table of Contents**

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, the above-described 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.

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:

| <b>Payment Dates (between indicated dates)</b>                  | <b>Redemption Percentage</b> |
|---|------------------------------|
| 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%                      |

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into the Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of \$2.0 million will be required if, on May 18 of the relevant year, the 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, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our earnings as a result. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. As of June 30, 2011 we provided funds of approximately \$2.5 million in collateral to support our potential hedge obligations. Subject to certain obligations we have in connection with the PhaRMA Notes, we have the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and payment of a \$2.0 million termination fee.

*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 TCID<sub>50</sub>. 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 log<sub>10</sub> TCID<sub>50</sub> 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.

**Table of Contents**

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.

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.

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.

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.

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.

***BCX4208***

In September 2009, we announced the initiation of a clinical study of BCX4208 for the treatment of gout, which is caused by elevated levels of uric acid in blood. We believe that BCX4208 is a good candidate to control gout because data from a prior Phase 2 clinical trial of BCX4208 for psoriasis indicated a dose related reduction in uric acid that

was sustained for the duration of drug exposure. Our gout clinical trial was a Phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of orally administered BCX4208 in subjects with gout. The trial contained two parts: part one, which was a parallel-group study of multiple doses of BCX4208 randomized against a placebo and part two, which was a sequential-group study of escalating doses of 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.

**Table of Contents**

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

We announced on August 5, 2010 that we achieved positive top-line results in part two of 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.

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.

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. This randomized, double-blind, dose-response 250-patient study is designed to evaluate the safety and efficacy of BCX4208 in combination with allopurinol in gout patients who have failed to reach the sUA objective of <6 mg/dL following treatment with allopurinol 300 mg alone. The primary endpoint of the study is the proportion of subjects with sUA <6 mg/dL at day 85. The study utilizes a parallel-group design, evaluating BCX4208 at doses of 5 mg, 10 mg, 20 mg, 40 mg and placebo administered once-daily for 12 weeks, in combination with allopurinol's standard dose of 300 mg. The Company announced on May 26, 2011 that its ongoing Phase 2b study of BXC4208 as add-on therapy in gout patients who have not responded to allopurinol therapy alone is progressing well and that the Company has

**Table of Contents**

exceeded target enrollment and will report both full 12-week and partial 6-month data later this year. In addition, the ongoing Phase 2b study was amended to add an additional 3 months of treatment to further evaluate long-term safety.

**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  $\geq 6$  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 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 June 30, 2011. We are engaged in ongoing discussion to resolve this dispute. The maximum potential exposure to us is estimated to be approximately 1,665,110 (or approximately \$2.4 million based on the exchange rate on June 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.

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

For the three months ended June 30, 2011, total revenues decreased to \$3.7 million compared to \$7.6 million for the three months ended June 30, 2010. This \$3.9 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 \$14.0 million for the second quarter of 2011 from \$14.7 million in the same quarter of last year. The \$0.7 million decrease was driven primarily 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.

General and administrative (G&A) expenses increased to \$4.0 million for the second quarter of 2011 compared to \$3.2 million in the same quarter 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 three months ended June 30, 2011, the Company recognized a \$1.0 million mark to market loss on its Currency Hedge Agreement. In connection with the issuance by Royalty Sub of the Pharma Notes on March 9, 2011, the Company 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. The currency hedge does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in earnings.

During the three months ended June 30, 2011, the Company incurred \$1.2 million in interest expense related to the non-recourse notes payable issued on March 9, 2011 in conjunction with the financing transaction to monetize certain future royalty and milestone payments.

**Table of Contents****Results of Operations (six months ended June 30, 2011 compared to the six months ended June 30, 2010)**

For the six months ended June 30, 2011, total revenues decreased to \$9.2 million compared to \$33.7 million for the six months ended June 30, 2010. This \$24.5 million decrease was driven primarily by the recognition during the six months ended June 30, 2010 of 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. Also contributing to the decrease in revenue from the prior year is a \$9.7 million 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.

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 \$26.9 million for first half of 2011 from \$39.7 million in the same period as last year. The \$12.8 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 six months ended June 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 and 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.

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

|  | <b>Three Months Ended</b> |             | <b>Six Months Ended</b> |             |
|--|---------------------------|-------------|-------------------------|-------------|
|  | <b>June 30,</b>           |             | <b>June 30,</b>         |             |
|  | <b>2011</b>               | <b>2010</b> | <b>2011</b>             | <b>2010</b> |
| Direct external R&D expenses by program: |                           |             |                         |             |
| PNP Inhibitor (forodesine)               | \$ 346                    | \$ 1,174    | \$ 876                  | \$ 3,675    |
| Neuraminidase Inhibitor (peramivir)      | 2,655                     | 4,547       | 5,293                   | 19,608      |
| PNP Inhibitor (4208)                     | 4,900                     | 2,383       | 8,118                   | 3,913       |
| Other                                    | 798                       | 488         | 1,380                   | 564         |
| Indirect R&D expenses                    | 5,276                     | 6,145       | 11,240                  | 11,894      |

|                    |           |           |           |           |
|--------------------|-----------|-----------|-----------|-----------|
| Total R&D expenses | \$ 13,975 | \$ 14,737 | \$ 26,907 | \$ 39,654 |
|--------------------|-----------|-----------|-----------|-----------|

General and administrative (G&A) expenses increased to \$8.0 million for the first half of 2011 compared to \$7.0 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 six months ended June 30, 2011, the Company recognized a \$2.3 million mark to market loss on its Currency Hedge Agreement. In connection with the issuance by Royalty Sub of the PhaRMA Notes on March 9, 2011, the Company 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. The currency hedge does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in earnings.

During the six months ended June 30, 2011, the Company incurred \$1.5 million in interest expense related to the non-recourse notes payable issued on March 9, 2011 in conjunction with the financing transaction to monetize certain future royalty and milestone payments.

### **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

**Table of Contents**

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; and

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

As of June 30, 2011, we held cash, cash equivalents and securities of \$72.0 million, an increase of \$5.7 million as compared to December 31, 2010, primarily resulting from net proceeds of \$23.0 million from the royalty monetization transaction and cash received from collaborations partially offset by monthly cash burn from operations and posting collateral related to the Currency Hedge Agreement. We expect that our cash utilization in 2011 will be approximately \$35 million, excluding 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.

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

With the funds available at June 30, 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 for at least the next 24 months. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time.

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

- our ability to perform under the contract with HHS and receive reimbursement;

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

- changes in existing collaborative relationships or government contracts;

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

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

**Table of Contents**

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.

**Off-Balance Sheet Arrangements**

As of June 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

**Table of Contents**

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 and a \$0.6 million cash collateral call in June 2011.

**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.

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.

**Table of Contents**

At June 30, 2011, we had deferred collaboration expenses of approximately \$8.0 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 \$5.6 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.

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 six months ended June 30, 2011 resulted in a \$2.3 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 June 30, 2011, cash collateral of \$2.5 million was posted, consisting of the initial mark to market loss of \$1.5 million, margin funds of \$0.4 million and a \$0.6 million collateral call in June 2011.

**Information Regarding Forward-Looking Statements**

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

**Table of Contents**

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;

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 June 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

**Table of Contents**

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 June 30, 2011, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

There have been no material changes to the Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2010 during the six month period ended June 30, 2011.

**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 4th day of August, 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*

31

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**Table of Contents**

**INDEX TO EXHIBITS**

| <b>Number</b> | <b>Description</b>  |
|---------------|---|
| 3.1           | Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.  |
| 3.2           | Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.  |
| 3.3           | Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 4, 2008.   |
| 3.4           | Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed November 4, 2008.  |
| 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.  |
| 10.1&         | Amended and Restated Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K, filed May 17, 2011.   |
| (10.2&)       | Employment Letter Agreement between Thomas R. Staab II and BioCryst Pharmaceuticals, Inc., dated May 23, 2011. Incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed May 25, 2011.  |
| 10.3          | At Market Issuance Sales Agreement, dated June 28, 2011, by and between BioCryst Pharmaceuticals, Inc. and McNicoll, Lewis & Vlask LLC. Incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed June 28, 2011 (File No. 333-175182).   |
| (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)         |   |

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Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three months ended June 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.

& Management contracts.

\* 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.