BIOCRYST PHARMACEUTICALS INC
Form 10-Q
July 31, 2009

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, 2009

Commission File Number 000-23186
BIOCRYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**62-1413174**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2190 Parkway Lake Drive; Birmingham, Alabama 35244
(Address of principal executive offices) (Zip Code)
(205) 444-4600
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
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 o No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
The number of shares of Common Stock, par value $.01, of the Registrant outstanding as of July 24, 2009 was 38,470,442.

BIOCRYST PHARMACEUTICALS, INC.
INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
BALANCE SHEETS
June 30, 2009 and December 31, 2008
(In thousands, except per share data)

	2009 (Unaudited)	2008 (Note 1)
Assets		
Cash and cash equivalents	$ 13,810	$ 22,342
Marketable securities	28,446	39,186
Receivables from collaborations	8,075	11,982
Prepaid expenses and other current assets	6,744	1,137
Deferred collaboration expense	376	377
Total current assets	57,451	75,024
Marketable securities		1,786
Furniture and equipment, net	4,429	4,881
Deferred collaboration expense	2,814	3,001
Total assets	$ 64,694	$ 84,692
Liabilities and Stockholders Equity		
Accounts payable	$ 2,793	$ 5,266
Accrued expenses	7,248	8,443
Accrued vacation	842	794
Deferred rent	53	40
Deferred revenue	2,528	2,565
Total current liabilities	13,464	17,108
Deferred rent	256	220
Deferred revenue	19,689	20,938
Stockholders equity:		
Preferred stock: shares authorized 5,000 Series B Junior Participating Preferred Stock, $.001 par value; shares authorized 45; shares issued and outstanding none		
Common stock, $.01 par value: shares authorized 95,000; shares issued and outstanding 38,345 in 2009 and 38,275 in 2008	383	383
Additional paid-in capital	298,106	295,208
Accumulated other comprehensive income	40	103
Accumulated deficit	(267,244)	(249,268)
Total stockholders equity	31,285	46,426

Total liabilities and stockholders equity	$ 64,694	$ 84,692

See accompanying notes to financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
Periods Ended June 30, 2009 and 2008
(In thousands, except per share data)
(Unaudited)

	Three Months		Six Months	
	2009	**2008**	**2009**	**2008**
Revenues				
Collaborative and other research and development	$ 4,787	$ 2,659	$ 9,146	$ 13,427
Expenses				
Research and development	11,213	13,373	22,502	35,271
General and administrative	2,313	2,666	4,770	5,552
Total expenses	13,526	16,039	27,272	40,823
Loss from operations	(8,739)	(13,380)	(18,126)	(27,396)
Interest and other income	55	671	150	1,589
Net loss	$ (8,684)	$ (12,709)	$ (17,976)	$ (25,807)
Basic and diluted net loss per common share	$ (0.23)	$ (0.33)	$ (0.47)	$ (0.68)
Weighted average shares outstanding	38,232	38,117	38,218	38,088

See accompanying notes to financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
Six Months Ended June 30, 2009 and 2008
(In thousands)
(Unaudited)

	2009	2008
Operating activities		
Net loss	$ (17,976)	$ (25,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	823	756
Stock-based compensation expense	2,794	2,976
Changes in operating assets and liabilities:		
Receivables from collaborations	3,907	24,278
Prepaid expenses and other current assets	(5,607)	(489)
Deferred collaboration expense	188	456
Accounts payable and accrued expenses	(3,620)	(10,499)
Deferred rent	49	280
Deferred revenue	(1,286)	(2,367)
Net cash used in operating activities	**(20,728)**	**(10,416)**
Investing activities		
Acquisitions of furniture and equipment	(371)	(694)
Purchases of marketable securities	(500)	(28,668)
Sales and maturities of marketable securities	12,963	33,289
Net cash provided by investing activities	**12,092**	**3,927**
Financing activities		
Exercise of stock options	13	144
Employee stock purchase plan sales	91	331
Net cash provided by financing activities	**104**	**475**
Decrease in cash and cash equivalents	(8,532)	(6,014)
Cash and cash equivalents at beginning of period	22,342	31,155
Cash and cash equivalents at end of period	**$ 13,810**	**$ 25,141**

See accompanying notes to financial statements.

Table of Contents

BIOCRYST PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS (Unaudited)

Note 1 Significant Accounting Policies

Basis of Presentation

The balance sheet as of June 30, 2009, the statements of operations for the three and six months ended June 30, 2009 and 2008, and the statements of cash flows for the six months ended June 30, 2009 and 2008 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 financial position at June 30, 2009, the results of operations for the three and six months ended June 30, 2009 and 2008, and cash flows for the six months ended June 30, 2009 and 2008. 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, 2008 and the notes thereto included in the Company s 2008 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, 2008 has been derived from the audited financial statements included in the Company s most recent Annual Report on Form 10-K.

The Company has evaluated subsequent events for disclosure through July 30, 2009, the date of issuance of the accompanying interim financial statements.

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 in accordance with Statement of Financial Accounting Standards No. 95, *Statement of Cash Flows*.

Marketable Securities

In accordance with Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the Company is required to classify securities as trading, available-for-sale, or held-to-maturity. The appropriateness of each classification is assessed at the time of purchase and at each reporting date. 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.

At June 30, 2009, the Company had approximately $28,446,000 of marketable securities, all of which were classified as available-for-sale. These securities consisted primarily of U.S. Treasury bills and notes carried at estimated fair values. The estimated fair value of these securities was based on independent quoted market prices and represents the highest priority of Level 1 in the fair value hierarchy as defined in Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*. The following table summarizes by year the scheduled maturity for the securities available-for-sale at June 30, 2009 and includes accrued interest of approximately $258,000. Note that amounts are in thousands.

2009	$ 26,171
2010	2,275
	$ 28,446

At June 30, 2009, the amortized cost of securities available-for-sale, including accrued interest, was approximately $28,406,000. At June 30, 2009, gross unrealized gains on securities available-for-sale were approximately $40,000. There were no gross unrealized losses on securities available-for-sale at June 30, 2009.

Table of Contents

Receivables from Collaborations

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs and event payments. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At June 30, 2009, the Company had the following receivables from collaborations. Amounts are in thousands.

	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$ 2,465	$ 5,604	$ 8,069
Mundipharma International Holdings Limited		6	6
Total	$ 2,465	$ 5,610	$ 8,075

Unbilled receivables from the U.S. Department of Health and Human Services (HHS) are net of a reserve for costs and fees of $4,919,000 at June 30, 2009 that are uncertain of recovery and related to the voluntarily terminated Phase 3 studies of the peramivir intramuscular (i.m.) program. The Company is in discussions with HHS regarding the reimbursement of these costs and fees. To the extent that any additional recoveries are realized or become probable of realization, the reserve will be adjusted in a future period(s). Any such adjustments could have a material impact on future operating results.

Furniture and Equipment

Furniture and equipment are recorded at cost. Depreciation is computed using the straight-line method with estimated useful lives of five and seven years. Laboratory equipment, office equipment, leased equipment, and software are depreciated over a life of five years. Furniture and fixtures are depreciated over a life of seven years. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is less. In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* the Company periodically reviews its furniture and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Furniture and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Patents and Licenses

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

Accrued Expenses

The Company records all expenses in the period incurred. In addition to recording expenses for invoices received, the Company estimates the cost of services provided by third parties or materials purchased for which no invoices have been received as of each balance sheet date. Accrued expenses as of June 30, 2009 consisted primarily of development and clinical trial expenses payable to contract research organizations (CROs) in connection with the Company s research and development programs.

Income Taxes

The liability method is used in accounting for income taxes in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (Statement No. 109). Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with Statement No. 109, and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax

return.

Table of Contents

Accumulated Other Comprehensive Income

Accumulated other comprehensive income 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 $40,000 of unrealized gains on its securities available-for-sale that are included in accumulated other comprehensive income at June 30, 2009.

Other comprehensive loss for the periods ended June 30, 2009 and 2008 appear in the following table. Amounts are in thousands.

	Three Months		Six Months	
	2009	**2008**	**2009**	**2008**
Net loss	$ (8,684)	$ (12,709)	$ (17,976)	$ (25,807)
Unrealized loss on securities available-for-sale	(28)	(474)	(63)	(126)
Other comprehensive loss	$ (8,712)	$ (13,183)	$ (18,039)	$ (25,933)

Revenue Recognition

The Company s revenues have generally been limited to license fees, event payments, research and development fees, government contracts, and interest income. Revenue is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104), and Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF Issue 00-21). License fees, 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 in accordance with EITF Issue 00-21. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under the guidance of Emerging Issues Task Force Issue 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent* (EITF Issue 99-19), and Emerging Issues Task Force Issue 01-14, *Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses* (EITF Issue 01-14), 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.

Royalty revenue is recognized based on estimates of royalties earned during the applicable period and adjusted for differences between the estimated and actual royalties in the following period. If royalties cannot be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. The Company has not received any royalties from the sale of licensed pharmaceutical products.

The Company recorded the following revenues from collaborations for the periods ended June 30, 2009 and 2008. Amounts are in thousands.

	Three Months		Six Months	
	2009	**2008**	**2009**	**2008**
U.S. Department of Health and Human Services	$ 4,148	$ 832	$ 7,806	$ 10,075
Shionogi	296	449	605	798
Mundipharma	324	915	697	1,630
Roche		444		886

Other	19	19	38	38
Total	$ 4,787	$ 2,659	$ 9,146	$ 13,427

Table of Contents

Research and Development Expenses

The Company records expenses in accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs* (Statement No. 2), and Emerging Issues Task Force Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods and Services Received for Use in Future Research and Development Activities* (EITF Issue 07-3). Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by clinical research organizations (CROs), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company s manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company s on-going review of the level of services actually performed.

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

The Company s accounting for deferred sublicense payments related to revenues that have been deferred is based on the guidance in SAB No. 104, which states that the incremental direct costs incurred related to the acquisition or origination of a contract in a transaction that results in the deferral of revenue may either be expensed as incurred or accounted for in accordance with paragraph 4 of Financial Accounting Standards Board (FASB) Technical Bulletin 90-1, *Accounting for Separately Priced Extended Warranty and Product Maintenance Costs* (FTB 90-1). At June 30, 2009, the Company had deferred collaboration expenses of approximately $3,190,000. 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.

Stock-Based Compensation

In accordance with Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (Statement No. 123R), all share-based payments, including grants of stock option awards and restricted stock awards, are recognized in the Company s income statement based on their fair values. Under the fair value recognition provisions of Statement No. 123R, stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award.

As of June 30, 2009, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (Incentive Plan), which was amended and restated in February 2009 and approved by the Company s stockholders in April 2009, and the Employee Stock Purchase Plan (ESPP), which was amended and restated in February 2008 and approved by the Company s stockholders in May 2008. 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 approximately $2,794,000 ($2,614,000 of expense related to the Incentive Plan, $105,000 of expense related to the ESPP, and $75,000 of expense related to the inducement grant) was recognized during the first six months of 2009, while approximately $2,976,000 ($2,825,000 of expense related to the Incentive Plan, $77,000 of expense related to the ESPP, and $74,000 of expense related to the inducement grant) was recognized during the first six months of 2008.

As of June 30, 2009, there was approximately $7,718,000 of total unrecognized compensation cost related to non-vested stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: $2,522,000 in the remainder of 2009, $3,711,000 in 2010, $1,145,000 in 2011, $300,000 in 2012, and $40,000 in 2013.

Statement No. 123R also requires that the benefits from tax deductions in excess of recognized compensation cost should be reported as a financing cash flow rather than as an operating cash flow. The Company has never recognized

any benefits from such tax deductions, as the Company has always maintained a loss position.

Table of Contents

Net Loss Per Share

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards No. 128, *Earnings 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 management to make estimates and assumptions that affect the amounts reported in the financial statements. Examples include accrued clinical and preclinical expenses. Actual results could differ from those estimates.

Note 2 Stock-Based Compensation

Stock Incentive Plan

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

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2008	1,114,630	5,477,649	$ 8.30
Plan Amendment	1,540,000		
Stock option awards granted	(1,457,400)	1,457,400	1.44
Stock option awards exercised		(13,409)	1.05
Stock option awards canceled	407,806	(407,806)	7.46
Balance June 30, 2009	1,605,036	6,513,834	6.83

For stock option awards granted under the Incentive Plan during the first six months of 2009 and 2008, 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 of these awards granted during the first six months of 2009 and 2008 was $1.10 and $2.28, 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 2009 and 2008. 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 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.

9

Table of Contents

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

	2009	2008
Expected Life in Years	5.6	5.5
Expected Volatility	104.7%	78.7%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	2.1%	2.7%

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

During the second quarter of 2008, the Company also granted 76,536 restricted stock awards under the Incentive Plan with a grant date fair value of $3.12. All of these restricted stock awards will vest on December 31, 2009.

Employee Stock Purchase Plan

The Company has reserved a total of 600,000 shares of common stock to be purchased under the ESPP, of which 123,715 shares remain available for purchase at June 30, 2009. 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 56,136 shares during the first six months of 2009 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. The exercise price of the stock option awards and the grant date fair value of the restricted stock awards granted under the inducement grant was $8.20. As of June 30, 2009, 5,416 shares granted under the restricted stock awards have vested.

Note 3 Collaborative Agreements

U.S. Department of Health and Human Services. 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 reasonable and allowable costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit. HHS makes periodic assessments of progress and the continuation of the contract is based on the Company s performance, timeliness and quality of deliverables, and other factors. The government has rights under certain contract clauses to terminate this contract. The contract is terminable by the government at any time for breach or without cause.

In January 2008, the Company announced that the development plan for peramivir had changed and that it would no longer pursue the Phase 3 i.m. program in peramivir in that particular influenza season, but would move forward in evaluating higher doses than used in previous studies. Also in January 2008, the Company announced that the program would cost in excess of the $102.6 million contract and that any funding above the $102.6 million may be the

responsibility of the Company. Since then, HHS and the Company have been working in collaboration through various contract modifications to maximize resources by stopping work on some projects (e.g. the Phase 3 i.m. program) and capping expenditures on other projects in order to maximize remaining funds. HHS and the Company executed a contract modification that fully funds the Company through the completion of both the Phase 2 studies in outpatients

Table of Contents

treated with i.m. peramivir, the Phase 2 study in hospitalized patients with intravenous (i.v.) peramivir, and certain manufacturing and toxicology components of the program. The modification also allows the Company and HHS to agree on additional development activities for peramivir within the confirmed $102.6 million funding. All temporary restraints, effected through a stop work order, have now been removed.

Based on discussions with the U.S. Department of Health and Human Services/Biomedical Advanced Research and Development Authority, the Company announced in May 2009 that it was preparing a portion of its inventory of finished peramivir for addition to the U.S. Centers for Disease Control and Prevention Strategic National Stockpile. This inventory is sufficient for the treatment of approximately one thousand patients and will be delivered in the event that the government so instructs. The pre-emergency use authorization (EUA) review of i.v. peramivir announced in May 2009 has continued to progress. Government agencies are considering the future option of providing peramivir through an EUA in the event of a severe influenza outbreak with significant hospitalizations.

The Company is advancing the clinical development of i.v. peramivir under the terms of the original $102.6 million, four-year contract from HHS. The Company continues its dialogue with HHS regarding additional funding beyond the $102.6 million for peramivir development through U.S. licensure. The Company has determined that there is an excess of approximately $5.0 million dollars of peramivir active pharmaceutical ingredient (API) beyond that necessary to support U.S. regulatory approval. As permitted under the contract, the Company has purchased the excess API from HHS. HHS has indicated that it is in the process of reviewing the purchase in light of the clinical development plan to complete U.S registration.

The Company is currently finalizing its plans for i.v. peramivir Phase 3 studies intended to support U.S. regulatory approval for uncomplicated influenza and influenza requiring hospitalization.

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 the Company s lead PNP inhibitor, forodesine, 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 possible 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 2b 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.

In accordance with SAB No. 104 and EITF Issue 00-21, the Company deferred 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. In accordance with EITF Issue 99-19 and EITF Issue 01-14, the costs reimbursed by Mundipharma for the

Table of Contents

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. The Company is engaged in ongoing discussions to resolve this dispute. The maximum potential exposure to the Company is estimated to be approximately $2.5 million. Because of the preliminary nature of the discussions, no amounts have been accrued as of June 30, 2009.

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 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 them on 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.

In accordance with SAB No. 104 and EITF Issue 00-21, the Company deferred the $14.0 million up-front payment that was 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 their initiation of a Phase 2 clinical trial with i.v. peramivir.

Green Cross Corporation (Green Cross). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The Company received a one-time license fee of $250,000. 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. In accordance with SAB No. 104 and EITF Issue 00-21, the Company deferred the up-front payment that was received from Green Cross. This deferred revenue began to be amortized to revenue August 2006 and will continue through November 2009.

F. Hoffman-La Roche Ltd. and Hoffman-La Roche Inc. (Roche). In November 2005, the Company entered into an exclusive license with Roche for the development and commercialization of the Company s second generation PNP inhibitor, BCX-4208, for the prevention of acute rejection in transplantation and for the treatment of autoimmune diseases. However, in May 2008, the Company received notice that Roche was exercising the no cause termination right under the license agreement for BCX-4208. The license agreement was terminated during the fourth quarter of 2008.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL. The lead drug candidates from this collaboration are Forodesine and BCX-4208. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, drug candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or

employees of AECOM and IRL. The Company has agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from $1.4 million to almost $4.0 million per indication) for future development of these inhibitors, single

Table of Contents

digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from $150,000 to $500,000, that are creditable against actual royalties and other payments due to AECOM and IRL. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by AECOM and IRL.

The University of Alabama at Birmingham. The Company currently has agreements with UAB for influenza neuraminidase and complement inhibitors. Under the terms of these agreements, UAB performed specific research for the Company in return for research payments and license fees. UAB has granted the Company certain rights to any discoveries in these areas resulting from research developed by UAB or jointly developed with the Company. The Company has agreed to pay single digit royalties on sales of any resulting product and to share in future payments received from other third-party partners. The Company has completed the research under the UAB agreements. These two agreements have initial 25-year terms, are automatically renewable for five-year terms throughout the life of the last patent and are terminable by the Company upon three months notice and by UAB under certain circumstances. Upon termination both parties shall cease using the other parties proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi and Green Cross agreements, or commercialize products related to these programs, we will owe sublicense fees or royalties on amounts we receive.

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

Effective January 1, 2007, the Company adopted the provisions of FIN No. 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with Statement No. 109 and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements. Tax years 2005-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2005 are also open to examination to the extent of loss and credit carryforwards from those years.

As of June 30, 2009, the majority of the Company s deferred tax assets relate to net operating loss (NOL) 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 the NOL carryforwards. Accordingly, the Company has provided a 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 asset until it is more likely than not that the related tax benefits will be realized.

