

BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 09, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2006

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.)

2190 Parkway Lake Drive; Birmingham, Alabama 35244
(Address of principal executive offices)

(205) 444-4600

(Registrant's telephone number, including area code)

Indicate by a 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 a check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act). (Check One):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by a check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes No

The number of shares of Common Stock, par value \$.01, of the Registrant outstanding as of November 1, 2006 was 29,233,888.

BIOCRYST PHARMACEUTICALS, INC.

INDEX

	<u>Page No.</u>
Part I. Financial Information	
Item 1. <u>Financial Statements:</u>	
<u>Balance Sheets – September 30, 2006 and December 31, 2005</u>	2
<u>Statements of Operations – Three and Nine Months Ended September 30, 2006 and 2005</u>	3
<u>Statements of Cash Flows – Nine Months Ended September 30, 2006 and 2005</u>	4
<u>Notes to Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
Part II. Other Information	
Item 1. <u>Legal Proceedings</u>	21
Item 1A. <u>Risk Factors</u>	21
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	22
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<u>Signatures</u>	24

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
BALANCE SHEETS
September 30, 2006 and December 31, 2005
(In thousands, except per share data)

	2006	2005
	(Unaudited)	(Note 1)
Assets		
Cash and cash equivalents	\$ 7,733	\$ 29,157
Marketable securities	36,082	21,103
Receivable from collaboration	3,139	30,000
Prepaid expenses and other current assets	1,705	840
	<hr/>	<hr/>
Total current assets	48,659	81,100
Marketable securities	17,813	9,728
Furniture and equipment, net	2,679	2,408
Patents and licenses, net	260	187
Deferred collaboration expense	10,787	5,825
	<hr/>	<hr/>
Total assets	\$ 80,198	\$ 99,248
	<hr/>	<hr/>
Liabilities and Stockholders' Equity		
Accounts payable	\$ 7,974	\$ 8,813
Accrued expenses	1,630	1,252
Accrued vacation	602	443
Deferred revenue	2,699	874
	<hr/>	<hr/>
Total current liabilities	12,905	11,382
Deferred revenue	37,271	29,426
Stockholders' equity:		
Preferred stock: shares authorized 5,000		
Series A Convertible Preferred stock, \$.01 par value; shares authorized 1,800; shares issued and outstanding none		
Series B Junior Participating Preferred Stock, \$.001 par value; shares authorized 45; shares issued and outstanding none		
Common stock, \$.01 par value; shares authorized 45,000; shares issued and outstanding 29,232 in 2006 and 28,814 in 2005	292	288
Additional paid-in capital	215,107	210,015
Accumulated other comprehensive income	54	
Accumulated deficit	(185,431)	(151,863)
	<hr/>	<hr/>
Total stockholders' equity	30,022	58,440
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 80,198	\$ 99,248
	<hr/>	<hr/>

See accompanying notes to financial statements.

BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
Periods Ended September 30, 2006 and 2005
(In thousands, except per share data)
(Unaudited)

	Three Months		Nine Months	
	2006	2005	2006	2005
Revenues:				
Collaborative and other research and development	\$ 1,790	\$ 32	\$ 4,120	\$ 131
Expenses:				
Research and development	16,650	7,164	35,884	17,602
General and administrative	1,599	795	4,478	2,218
Total expenses	18,249	7,959	40,362	19,820
Loss from operations	(16,459)	(7,927)	(36,242)	(19,689)
Interest and other income	856	282	2,674	751
Net loss	\$ (15,603)	\$ (7,645)	\$ (33,568)	\$ (18,938)
Basic and diluted net loss per common share	\$ (.53)	\$ (.29)	\$ (1.15)	\$ (.75)
Weighted average shares outstanding	29,222	26,209	29,116	25,336

See accompanying notes to financial statements.

BIOCRYST PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2006 and 2005
(In thousands)
(Unaudited)

	<u>2006</u>	<u>2005</u>
Operating activities:		
Net loss	\$ (33,568)	\$ (18,938)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	593	657
Stock-based compensation expense	2,238	20
Changes in operating assets and liabilities:		
Receivable from collaboration	26,861	
Prepaid expenses and other current assets	(865)	55
Deferred collaboration expense	(4,962)	
Accounts payable and accrued expenses	(302)	613
Deferred revenue	9,670	
	<u>(335)</u>	<u>(17,593)</u>
Investing activities:		
Acquisitions of furniture and equipment	(859)	(179)
Purchases of patents and licenses	(78)	(38)
Purchases of marketable securities	(42,101)	(16,050)
Maturities of marketable securities	19,091	10,129
	<u>(23,947)</u>	<u>(6,138)</u>
Financing activities:		
Employee stock purchase plan sales	191	137
Exercise of stock options	2,667	1,168
Sale of common stock, net of issuance costs		22,685
	<u>2,858</u>	<u>23,990</u>
(Decrease) increase in cash and cash equivalents	(21,424)	259
Cash and cash equivalents at beginning of period	29,157	8,838
	<u>\$ 7,733</u>	<u>\$ 9,097</u>

See accompanying notes to financial statements.

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

1. Summary of Significant Accounting Policies

Basis of Presentation

The balance sheet as of September 30, 2006, the statements of operations for the three and nine months ended September 30, 2006 and 2005, and the statements of cash flows for the nine months ended September 30, 2006 and 2005 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 September 30, 2006, the results of operations for the three and nine months ended September 30, 2006 and 2005, and cash flows for the nine months ended September 30, 2006 and 2005. There were no adjustments other than normal recurring adjustments. 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.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2005 and the notes thereto included in the Company's 2005 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, 2005 has been derived from the audited financial statements included in the Company's most recent Annual Report on Form 10-K.

Certain amounts in the Statement of Cash Flows for the nine months ended September 30, 2005 have been reclassified to conform to the Statement of Cash Flows for the nine months ended September 30, 2006. The changes had no effect on the results of operations previously reported.

Revenue Recognition

The Company's revenues have generally been limited to license fees, milestone payments, research and development fees, 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, future 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 as earned 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.

Future 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.

Significant direct costs incurred upon entering into a licensing arrangement are deferred and charged to expense in proportion to the revenue recognized. 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.

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 can not 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.

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 and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive.

Marketable 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. At September 30, 2006, the Company had approximately \$53.9 million of marketable securities of which \$20.3 million is classified as available-for-sale and \$33.6 million is classified as held-to-maturity. Securities available-for-sale consisted of U.S. Agency securities carried at estimated fair values. The estimated fair value of these securities was based on independent quoted market prices. Unrealized gains and losses on securities available-for-sale are recognized in other comprehensive income. Securities held-to-maturity consisted of U.S. Treasury and Agency securities and commercial paper carried at amortized cost. The estimated fair value of these securities was approximately \$33.5 million based on independent quoted market prices. While this represents an unrealized loss position, management does not believe the loss represents an other-than-temporary impairment as the Company has the ability and intent to hold the securities until maturity, at which time the cost of the investments will be recovered.

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 \$54,251 of unrealized gains on its securities that are included in accumulated other comprehensive income at September 30, 2006. Other comprehensive income for the three and nine months ended September 30, 2006 appears in the following table. Note that amounts are in thousands.

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Net loss	\$ (15,603)	\$ (33,568)
Unrealized gain on securities available-for-sale	45	54
Other comprehensive income	\$ (15,558)	\$ (33,514)

Stock-Based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (Statement No. 123R), which revises Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (Statement No. 123), supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), and amends Statement of Financial Accounting Standard No. 95, *Statement of Cash Flows*. Generally, the approach in Statement No. 123R is similar to the approach described in Statement No. 123. However, Statement No. 123R requires all share-based payments to employees, including grants of stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure, allowed by Statement No. 123, is no longer an alternative.

In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107, *Share-Based Payment*, which provided further clarification on the implementation of Statement No. 123R. Statement No. 123R originally required adoption no later than July 1, 2005. In April 2005, the Securities and Exchange Commission issued a release that delayed the effective date for Statement No. 123R until January 1, 2006.

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

Statement No. 123R permits companies to adopt its requirements using one of two methods, a modified prospective transition method or a modified retrospective transition method. Both methods are similar, except that the modified retrospective transition method permits entities to restate, based on the amounts previously recognized under Statement No. 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

At September 30, 2006, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (the Plan) and the Employee Stock Purchase Plan (the ESPP), which are described in more detail below. Prior to January 1, 2006, the Company accounted for those plans under the recognition and measurement provisions of APB No. 25 and other related Interpretations, as permitted by Statement No. 123. No stock-based compensation cost related to the Company's employees was recognized in the Statements of Operations for any period ending prior to January 1, 2006, as all options granted by the Company had exercise prices equal to the market value of the underlying common stock on the date of grant. Effective January 1, 2006, the Company adopted the fair value recognition provisions of Statement No. 123R, using the modified prospective transition method. Under that transition method, total compensation cost of \$2,237,538 (\$2,167,629 of expense related to the Plan and \$69,909 of expense related to the ESPP) was recognized during the first nine months of 2006 and includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123R. In accordance with the modified prospective transition method adopted, results for prior periods have not been restated. The following table illustrates the pro forma effect on net loss and net loss per share had the Company applied the fair value recognition provisions of Statement No. 123R for the three and nine month periods ended September 30, 2005. For purposes of the pro forma disclosure, the value of the options was estimated using a Black-Scholes option pricing model and amortized to expense over the vesting periods of the options using a straight-line expense attribution method. Note that amounts are in thousands, except per share data.

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
	<u> </u>	<u> </u>
Net loss as reported	\$ (7,645)	\$ (18,938)
Add stock-based compensation expense for consultants included in reported net loss	7	20
Deduct total stock-based compensation expense for employees and consultants as determined under Statement No. 123	(449)	(1,312)
	<u> </u>	<u> </u>
Pro forma net loss	\$ (8,087)	\$ (20,230)
	<u> </u>	<u> </u>
Amounts per common share:		
Net loss per share, as reported	\$ (.29)	\$ (.75)
Pro forma net loss per share	\$ (.31)	\$ (.80)

For each option award granted under the Plan during the first nine months of 2005, the Black-Scholes option pricing model used the assumptions in the table below.

Weighted Average Assumptions for Options Granted January 1, 2005 September 30, 2005

Expected Life	5.00
Expected Volatility	96.69%
Expected Dividend Yield	0.00%
Risk-Free Interest Rate	3.89%

The weighted average grant date fair value of the options granted under the Plan during the first nine months of 2005 was \$3.40.

Statement 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.

Stock Incentive Plan

The Company grants stock option incentive awards to employees, directors, and consultants of the Company under the Plan. The Plan most recently amended and restated the Company's 1991 Stock Incentive Plan and was subsequently approved by the Company's stockholders on May 17, 2006. The Plan permits the Company to issue stock options to its employees, directors, and consultants for approximately 5 million shares of common stock. Under the Plan, option incentive awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Options granted to employees and consultants 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. Options granted to non-employee directors of the Company generally vest over one year. All options have contractual terms of 10 years. The vesting exercise provisions of options granted under the 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 Plan.

For each option award granted under the Plan during the first nine months of 2006, the fair value was estimated on the date of grant using a Black-Scholes option pricing model using the assumptions noted in the table below. The fair value expense of those options is amortized to expense over the vesting periods of the options using a straight-line expense attribution method. The expected life is based on the average of the assumption that all outstanding options will be exercised at full vesting and the assumption that all outstanding options will be exercised at the midpoint of the valuation date and the full contractual term. The expected volatility represents an average of the implied volatility on the Company's publicly traded 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.

Weighted Average Assumptions for Options Granted
January 1, 2006 September 30, 2006

Expected Life	5.92
Expected Volatility	82.48%
Expected Dividend Yield	0.00%
Risk-Free Interest Rate	4.98%

Related stock option activity under the Plan is as follows:

	Options Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2005	443,047	3,241,351	\$ 7.60
Options plan amended	1,500,000		
Options granted	(1,115,904)	1,115,904	12.43
Options exercised		(394,115)	6.85
Options canceled	1,800	(1,800)	22.81
Balance September 30, 2006	828,943	3,961,340	9.03

The total intrinsic value of options exercised under the Plan during the first nine months of 2006 was \$4,595,829. The intrinsic value represents the total proceeds (fair market value at the date of exercise, less the exercise price, times the number of options exercised) received by all individuals who exercised options during the period.

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

The following table summarizes, at September 30, 2006, by price range: (1) for options outstanding under the Plan, the number of options outstanding, their weighted average remaining life and their weighted average exercise price; and (2) for options exercisable under the Plan, the number of options exercisable and their weighted average exercise price:

Range	Outstanding			Exercisable	
	Number	Life	Price	Number	Price
\$0 to 3	469,907	6.2	\$ 1.15	421,769	\$ 1.18
3 to 6	708,627	7.9	4.18	379,426	4.02
6 to 9	1,156,469	5.1	7.78	930,633	7.68
9 to 12	121,453	9.7	10.33	9,953	9.88
12 to 15	1,196,617	8.1	12.88	249,604	13.79
15 to 18	78,327	1.0	16.34	75,827	16.32
18 to 21	6,200	9.4	19.34		
21 to 24	204,120	3.2	22.84	204,120	22.84
24 to 30	19,620	3.6	26.83	19,620	26.83
\$0 to 30	3,961,340	6.6	9.03	2,290,952	8.36

The weighted average remaining contractual life of options exercisable under the Plan at September 30, 2006 is 4.8 years.

The aggregate intrinsic value of options outstanding under the Plan at September 30, 2006 is \$35,754,032. The aggregate intrinsic value of options currently exercisable under the Plan at September 30, 2006 is \$19,141,482. The aggregate intrinsic value represents the value (the period's closing market price, less the exercise price, times the number of in-the-money options) that would have been received by all option holders under the Plan had they exercised their options at the end of the period.

The following table summarizes, at September 30, 2006 the number of non-vested options under the Plan and their weighted average grant date fair value:

	Number	Weighted Average Grant Date Fair Value
Balance December 31, 2005	1,042,181	\$ 3.82
Options granted	1,115,904	8.70
Options vested	(487,697)	3.82
Options canceled		
Balance September 30, 2006	1,670,388	7.08

The total fair value of the options vested under the Plan during the first nine months of 2006 was \$1,861,806.

The number of options vested and expected to vest as of September 30, 2006 is 3,719,481. The weighted average exercise price of those options is \$9.05 and their weighted average remaining contractual life is 6.5 years.

Employee Stock Purchase Plan

The ESPP was originally approved by the Company's stockholders on May 29, 1995 and most recently amended on May 12, 2002. The Company has reserved a total of 400,000 shares of common stock to be purchased under the ESPP, of which 99,613 shares remain available for purchase at September 30, 2006. 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 25,988 shares during the first nine months of 2006 under the ESPP. Expense of \$69,909 related to the ESPP was recognized during the first nine months of 2006, while expense of \$51,372 related to the ESPP would have been recognized during the first nine months of 2005 had the Company not followed the guidance of APB No. 25. For both periods, expense was determined using a Black-Scholes option pricing model.

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

As of September 30, 2006, there was approximately \$9,754,430 of total unrecognized compensation cost related to non-vested employee stock option awards granted under the Plan and the ESPP. That cost is expected to be recognized as follows: \$1,077,213 in the remainder of 2006, \$3,370,558 in 2007, \$2,533,441 in 2008, \$2,011,857 in 2009, and \$761,361 in 2010.

2. Collaborative Agreements

In November 2005 and February 2006, the Company announced collaborative relationships with F.Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (Roche) and Mundipharma International Holdings Limited (Mundipharma), respectively. For these license agreements, the Company has decided to defer the upfront payments over the remaining life of the patents of the compounds licensed, which is through August 2023 for the Roche agreement and through October 2017 for the Mundipharma agreement. These upfront payments have been classified as deferred revenue on the balance sheet and the significant direct costs incurred upon entering into these licensing agreements related to sublicense fees paid to Albert Einstein College of Medicine (AECOM) and Industrial Research, Ltd. (IRL) have been recorded as deferred assets on the balance sheet. As the Company recognizes the revenue related to these agreements, which began in February 2006 for the Mundipharma agreement and is expected to begin in the fourth quarter of 2006 for the Roche agreement, the Company will also recognize the proportionate amount of expense related to the deferred assets.

In addition, in June 2006, the Company announced a collaborative relationship with Green Cross Corporation (Green Cross). Consistent with the accounting treatment in the Roche and Mundipharma license arrangements, the Company has deferred the upfront payment made by Green Cross and the sublicense fee payable by the Company to the University of Alabama at Birmingham (UAB). The recognition of the revenue and the expense from the Green Cross agreement began in August 2006 and will continue through November 2009.

3. Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (Statement No. 157). The standard provides enhanced guidance for using fair value to measure assets and liabilities and also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. While the standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, it does not expand the use of fair value in any new circumstances. Statement No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Management of the Company is evaluating the impact of this standard, but does not anticipate that it will have a significant impact on its financial statements.

Also in September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB No. 108). This bulletin expresses the Staff's views regarding the process of quantifying financial statement misstatements. The interpretations in this bulletin were issued to address diversity in practice in quantifying financial statement misstatements and the potential under current practice for the accumulation of improper amounts on the balance sheet. SAB No. 108 is effective for annual financial statements starting with the year ending December 31, 2006. The Company is evaluating the impact of this bulletin and based on current information, the Company does not believe that it will have a material impact on its financial statements.

In July 2006, the FASB issued Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* (FIN No. 48). This interpretation creates a single model to address uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. The interpretation also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for years beginning after December 15, 2006. Management of the Company is evaluating the impact of this pronouncement, but does not anticipate that it will have a significant impact on its financial statements.

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.

Overview

Since our inception in 1986, we have been engaged in research and development activities and organizational efforts, including:

identifying and licensing enzyme targets;

drug discovery;

structure-based design of drug candidates;

small-scale synthesis of compounds;

conducting preclinical studies and clinical trials;

establishing collaborative relationships with third parties for contract research related to the development of our drug candidates to support manufacturing, clinical development and regulatory compliance;

establishing collaborative relationships with biotechnology or pharmaceutical companies and governmental agencies or other third parties for the further development and potential commercialization of our compounds;

recruiting our scientific and management personnel;

establishing laboratory facilities; and

raising capital.

Our revenues have generally been limited to license fees, milestone payments, research and development fees, and interest income. Revenue is recognized in accordance with SAB No. 104 and EITF Issue 00-21. License fees, future event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations, or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized as earned over an estimated period determined by management based on the terms of the agreement and the products licensed. For example, in the Roche and Mundipharma license agreements announced in November 2005 and February 2006, respectively, we have determined to defer the upfront payments over the remaining life of the patents which are 17 years (through August 2023) for the Roche license agreement and 12 years (through October 2017) for the Mundipharma license agreement. In the event a license agreement contains multiple deliverables, we evaluate 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.

Future 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.

Significant direct costs incurred upon entering into a licensing arrangement, such as our sublicense fees to AECOM and IRL, are deferred and charged to expense in proportion to the revenue recognized. Under the guidance of EITF Issue 99-19 and 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.

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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 can not be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. We have not received any royalties from the sale of licensed pharmaceutical products.

It could be several years, if ever, before we will recognize significant revenue from royalties received pursuant to our license agreements or revenue directly from product sales. Future revenues, if any, are likely to fluctuate substantially from quarter to quarter.

We have incurred operating losses since our inception. Our accumulated deficit at September 30, 2006 was \$185.4 million. We expect to incur substantial expenditures relating to the development of our current and future drug candidates. During the three years ended December 31, 2005, we spent 54.6% of our research and development expenses on contract research and development, including:

- payments to consultants;
- funding of research at academic institutions;
- toxicology studies on existing and potential drugs;
- manufacturing of our raw materials, drug substance and drug products;
- large scale synthesis and formulation of compounds;
- preclinical studies;
- engaging investigators to conduct clinical trials;
- hiring contract research organizations for regulatory and clinical functions; and
- using statisticians to evaluate the results of clinical trials.

The above expenditures for contract research and development for our current and future drug candidates will vary from quarter-to-quarter depending on the status of our research and development projects. For example, we began clinical development of our neuraminidase inhibitor, peramivir, by starting the first clinical trial with an intravenous formulation during the first quarter of 2006. We also began the scale-up manufacturing required for validation of the manufacturing process for both peramivir and our lead product Fodosine, BCX-1777, an inhibitor of the enzyme purine nucleoside phosphorylase (PNP). Fodosine is currently in various stages of clinical development in multiple oncology indications, including a Phase IIa trial in T-cell leukemia. We plan to initiate a pivotal Phase IIb trial with Fodosine by the end of 2006 under the terms of a Special Protocol Assessment (SPA) letter from the U.S. Food and Drug Administration (FDA) and we are also in the process of initiating Phase II trials with peramivir for the 2006-2007 flu season. As these trials progress and additional trials are started, our costs for clinical studies will increase significantly.

Changes in our existing and future research and development and collaborative relationships also will impact the status of our research and development projects. For example, in November 2005 we entered into a license agreement with Roche for the worldwide development and commercialization for our second PNP inhibitor, BCX-4208. In addition to an upfront payment plus an advance payment for specific manufacturing we performed, Roche has assumed financial responsibility for the future development costs associated with this program. In February 2006, we licensed Fodosine to Mundipharma for the development and commercialization of this drug in Europe, Asia and Australasia. In addition to the upfront payment of \$10 million, Mundipharma will pay 50% of the clinical development costs we will incur for Fodosine on existing and planned clinical trials, but their portion shall not exceed \$10 million.

Although we may, in some cases, be able to control the timing of development expenses, in part by accelerating or decelerating certain of these costs, many of these costs will be incurred irrespective of whether we are able to discover drug candidates or obtain collaborative partners for commercialization. As a result, we believe that quarter-to-quarter comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance. If we fail to meet the research, clinical and financial expectations of securities analysts and investors, it could have a material adverse effect on the price of our common stock.

Results of Operations (three months ended September 30, 2006 compared to the three months ended September 30, 2005)

Collaborative and other research and development revenues increased to \$1,790,000 in the three months ended September 30, 2006 compared to \$32,000 in the three months ended September 30, 2005, due to the recognition of revenue related to our collaboration with Mundipharma for the development and commercialization of fodosine hydrochloride (Fodosine) in Europe and Asia. For this collaboration, we began recognizing the \$10 million up front payment in February 2006, which will continue until it is fully recognized in October 2017. In addition, we recognized revenue for the portion of clinical expenses incurred during the quarter that will be reimbursed by Mundipharma and Roche according to the terms of the respective collaborations.

Research and development (R&D) expenses increased 132.4% to \$16,650,000 in the three months ended September 30, 2006 from \$7,164,000 in the three months ended September 30, 2005. The increase is primarily attributable to expenses for contract research and synthesis of compound related to the clinical development and manufacturing of our drug candidates, Fodosine and peramivir. We are currently in several additional clinical trials with Fodosine as compared to the same period in 2005 and we initiated clinical testing of peramivir late in the first quarter of 2006. In addition, we have also started the process of manufacturing validation for both Fodosine and peramivir. There was also an increase in compensation cost for the third quarter of 2006 compared to the third quarter of 2005, primarily related to the Company's adoption of Statement No. 123R, which resulted in \$501,000 of share-based compensation expense for the third quarter 2006, and the increase in headcount during 2006.

General and administrative expenses for the three months ended September 30, 2006 increased 87.5% to \$1,599,000 as compared to \$795,000 for the same period in 2005, primarily due to \$560,000 of share-based compensation expense related to the adoption of Statement No. 123R, additional employment expenses related to an increase in personnel, and an increase in professional fees.

Interest income for the three months ended September 30, 2006 was \$856,000, a 203.5% increase as compared to the same period in 2005. This increase was due to a higher average cash balance during the third quarter of 2006.

Results of Operations (nine months ended September 30, 2006 compared to the nine months ended September 30, 2005)

Collaborative and other research and development revenues increased to \$4,120,000 for the nine months ended September 30, 2006 compared to \$131,000 for the nine months ended September 30, 2005, due to the recognition of revenue related to our collaboration with Mundipharma for the development and commercialization of Fodosine in Europe and Asia. For this collaboration, we began recognizing the \$10 million up front payment in February 2006, which will continue until it is fully recognized in October 2017. In addition, we recognized revenue for clinical expenses that will be reimbursed by Mundipharma and Roche according to the terms of the respective collaborations.

R&D expenses increased 103.9% to \$35,884,000 for the nine months ended September 30, 2006 from \$17,602,000 for the nine months ended September 30, 2005. The increase is primarily attributable to expenses for contract research and synthesis of compounds related to the clinical development and manufacturing of our drug candidates, Fodosine and peramivir. We are currently in several additional clinical trials with Fodosine as compared to the same period in 2005 and we initiated clinical testing of peramivir late in the first quarter of 2006. In addition, we have also started the process of manufacturing validation for both Fodosine and peramivir. There was also an increase in compensation cost for the first nine months of 2006 compared to the first nine months of 2005, primarily related to the Company's adoption of Statement No. 123R, which resulted in \$1,017,000 of share-based compensation expense, and the increase in headcount during 2006.

General and administrative expenses for the nine months ended September 30, 2006 increased 101.9% to \$4,478,000 as compared to \$2,218,000 for the same period in 2005, primarily due to \$1,221,000 of share-based compensation expense related to the adoption of Statement No. 123R, additional compensation expense related to an increase in personnel, and an increase in professional fees primarily related to our recent collaborations.

Interest income for the nine months ended September 30, 2006 was \$2,674,000, a 256.1% increase as compared to the same period in 2005. This increase was due to a higher average cash balance during the third quarter of 2006 resulting from receipt of the upfront payments related to the Roche and Mundipharma collaborations.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception. Our operations have principally been funded through public offerings and private placements of equity and debt securities. For example, during December 2005, we raised \$30.0 million (approximately \$29.9 million net of expenses) through a sale of 2,228,829 shares of our common stock. Other sources of funding have included the following:

- collaborative and other research and development agreements (such as the Roche, Mundipharma and Green Cross license agreements);

- equipment lease financing;

- facility leases;

- research grants; and

- interest income.

In addition, 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 and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities, undertake additional preclinical studies and clinical trials of compounds which have been or may be discovered and as we validate the manufacturing process of our lead compounds. 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.

We invest our excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. These investments are generally not collateralized and mature within two years. We have not realized any losses from such investments.

We have financed some of our equipment purchases with lease lines of credit. In July 2000, we renegotiated our lease for our current facilities, which will expire on June 30, 2010. We have an option to renew the lease for an additional five years at the current market rate in effect on June 30, 2010 and a one-time option to terminate the lease on June 30, 2008 for a termination fee of approximately \$124,000. The lease, as amended effective December 1, 2005 for a reduction of 7,200 square feet, requires us to pay monthly rent starting at \$36,855 per month in December 2005 and escalating annually to a minimum of \$41,481 per month in the final year, plus our pro rata share of operating expenses and real estate taxes in excess of base year amounts. As part of the lease, we have deposited a U.S. Treasury security in escrow for the payment of rent and performance of other obligations specified in the lease. This pledged amount is currently \$132,000, which can be decreased by \$65,000 annually throughout the term of the lease. Currently, we have approximately 3,600 square feet being subleased, which can be terminated with 30 days written notice.

In August 2006, we opened an office in Cary, North Carolina where we are currently leasing 3,375 square feet of office space for \$4,500 per month.

We have not incurred any significant charges related to building renovations since 2001, but we currently have plans for some renovations and for the purchase of additional scientific equipment. Our anticipated capital expenditures for 2006 related to these items are not expected to exceed \$1.5 million.

At December 31, 2005, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$533,904 in 2006, \$486,119 in 2007 and \$496,834 in 2008. These obligations include the future rental of our operating facility.

We plan to finance our needs principally from the following:

- our existing capital resources and interest earned on that capital;
- payments under collaborative and licensing agreements with corporate partners; and
- lease or loan financing and future public or private financing.

As of September 30, 2006, we had \$61.6 million in cash, cash equivalents and securities. We believe that our currently available funds will be sufficient to fund our operations for at least the next twelve 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:

- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships;
- 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 collaborators, including governmental agencies will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for our drug candidates;
- the scope and results of preclinical studies and clinical trials to identify and evaluate drug candidates;
- the scope of manufacturing of our drug candidates to support our preclinical research and clinical trials;
- the scope of validation for the 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 preparing, filing, prosecuting, maintaining and enforcing patent claims;
- our dependence on others for development and commercialization of our product candidates; and
- successful commercialization of our products consistent with our licensing strategy.

To date, we have financed our operations primarily from sale of our equity securities and cash from collaborations and, to a lesser extent, interest. For the third quarter 2006, our average monthly cash burn from normal operations was approximately \$4.4 million. For the year, our cash, cash equivalents and securities balance has increased from \$60 million as of December 31, 2005 to \$61.6 million as of September 30, 2006, primarily due to cash received from collaborations, totaling approximately \$31.8 million net of sublicense fees, less the monthly cash burn from operations.

In June 2006 the Department of Health and Human Services (HHS) issued a Request for Proposal (RFP) for the potential funding of companies with antiviral drugs in development for both seasonal and avian influenza. We believe our peramivir program meets substantially all of the requirements outlined in the RFP and therefore we submitted a proposal to HHS on July 20, 2006 and we hope to be considered a competitive candidate for some of the funding to be made available under the RFP. We have made certain commitments related to the advancement of peramivir for both our intramuscular and intravenous formulations and we are currently preparing to begin two Phase II trials to be executed during the 2006-2007 influenza season using intravenous and intramuscular formulations. We are currently completing the Phase I trials to support these planned Phase II trials.

In addition, on August 7, 2006, we announced that we had received a SPA letter from the FDA for the initiation of a pivotal clinical trial of our lead anti-cancer compound Fodosine . The SPA letter documents the agreement between the FDA and the Company regarding the trial design s suitability to support regulatory approval. We expect to initiate a multi-center, open-label pivotal clinical trial later this year with the goal of enrolling 100 patients.

Primarily as a result of the Phase II peramivir clinical trials during the 2006-7 influenza season, we estimate our monthly average cash burn rate will increase approximately \$1 million from the third quarter 2006 rate, until completion of the peramivir Phase II trials. This estimate does not include potential funding, if any, which we may receive from HHS from our proposal in response to the RFP. We are hopeful that our proposal response to the RFP will be acceptable for funding, which would offset our projected burn rate if and when it became effective. In addition, we expect to achieve one milestone related to our collaboration with Mundipharma in 2006 or early 2007 and we will continue to be reimbursed for our clinical development costs up to the \$10 million defined in our agreement. We currently have a balance receivable of approximately \$3.1 million for their portion of the funding related to the clinical development of Fodosine , which we expect to receive early in 2007.

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related manufacturing, personnel resources and testing required to support these trials will consume significant capital resources and will increase our expenses and our net loss.

Our 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 of funding or assistance, if any, we receive from governmental agencies or other new partnerships with third parties for the development of our drug candidates in general and for peramivir specifically, 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.

The collaboration with Roche for the worldwide development and commercialization of BCX-4208 provided an upfront payment plus an advance payment for specific manufacturing we performed. The initial \$30 million was recorded as a receivable on our balance sheet at December 31, 2005 and was received in January 2006. Roche will take over the development and pay all costs associated with this program. The agreement also provides for future event payments and royalties to be made by Roche upon the achievement of certain clinical, regulatory and sales events.

In February 2006, we licensed Fodosine to Mundipharma for the development and commercialization of this drug in Europe, Asia and Australasia. In addition to the upfront payment of \$10 million which was received in February 2006, Mundipharma will pay 50% of the clinical development costs we will incur for Fodosine on existing and planned clinical trials, but their portion shall not exceed \$10 million. In addition, Mundipharma will conduct additional clinical trials at their own cost up to a maximum of \$15 million. The agreement also provides for future event payments and royalties to be made by Mundipharma upon the achievement of certain clinical, regulatory and sales events.

For the Roche and Mundipharma collaborations, we will owe sublicense payments to AECOM and IRL on all upfront, future event payments and royalties. For the first nine months of 2006, we have paid approximately \$8.2 million related to these agreements. The revenue from these agreements has been recorded as deferred revenue on our balance sheet and will be recognized over the remaining patent life of the related drug candidate. The payments to AECOM and IRL have been recorded as deferred assets on our balance sheet and will be recognized over the period of the related revenue recognition. Due to the nature of the potential milestones in our collaborations, it is difficult to predict if and when particular milestones will be achieved by us or our collaborators.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates. 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 RFP 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 part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of September 30, 2006, we are not involved in any material unconsolidated entities or off-balance sheet arrangements.

Contractual Obligations

Our contractual obligations as of December 31, 2005 are described in our Annual Report on Form 10-K. There have been no material changes in contractual obligations outside the ordinary course of business since December 31, 2005.

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, 2005, 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

Our revenues have generally been limited to license fees, milestone payments, research and development fees, and interest income. Revenue is recognized in accordance with SAB No. 104 and EITF Issue 00-21. License fees, future event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations, or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized as earned over an estimated period determined by management based on the terms of the agreement and the products licensed. For example, in the Roche and Mundipharma licenses agreements, we have determined to defer the upfront payments over the remaining life of the patents which are 17 years (through August 2023) for the Roche license agreement and 12 years (through October 2017) for the Mundipharma license agreement. In the event a license agreement contains multiple deliverables, we evaluate 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.

Future 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.

Significant direct costs incurred upon entering into a licensing arrangement, such as our sublicense fees to AECOM and IRL, are deferred and charged to expense in proportion to the revenue recognized. Under the guidance of EITF Issue 99-19 and 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.

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 can not be reasonably estimated, revenue is recognized upon receipt of royalty statements from the licensee. We have not received any royalties from the sale of licensed pharmaceutical products.

Research and Development Expenses

Major components of R&D expenses consist of personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by contract research organizations (CROs), materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. We charge these costs to expense when incurred, consistent with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs*. These costs are a significant component of R&D expenses. Most of our manufacturing and our clinical and preclinical studies are performed by third-party CROs. We accrue costs for studies performed by CROs over the service periods specified in the contracts and adjust our estimates, if required, based upon our on-going review of the level of services actually performed. We expense both our internal and external research and development costs as incurred. We expect our research and development expense to increase as we continue to develop our drug candidates.

Additionally, we have license agreements with third parties, such as AECOM and IRL that require maintenance fees or fees related to sublicense agreements. These fees are generally expensed as incurred unless they are related to revenues that have been deferred in which case the expenses will be deferred and recognized over the related revenue recognition period.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

fees paid to contract research organizations in connection with preclinical and toxicology studies and clinical trials;

fees paid to investigative sites in connection with clinical trials;

fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and drug products; and professional service fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Stock-Based Compensation

At September 30, 2006, we have two stock-based employee compensation plans, the Stock Incentive Plan (the Plan) and the Employee Stock Purchase Plan (the ESPP). Prior to January 1, 2006, we accounted for those plans under the recognition and measurement provisions of APB No. 25 and other related Interpretations, as permitted by Statement No. 123. No stock-based compensation cost related to our employees was recognized in the Statements of Operations for any period ending prior to January 1, 2006, as all options granted had exercise prices equal to the market value of the underlying common stock on the date of grant. Effective January 1, 2006, we adopted the fair value recognition provisions of Statement No. 123R, using the modified prospective transition method. Under that transition method, total compensation cost of \$2,237,538 (\$2,167,629 of expense related to the Plan and \$69,909 of expense related to the ESPP) was recognized during the first nine months of 2006 and includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of Statement No. 123, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of Statement No. 123R. Results for prior periods have not been restated.

As of September 30, 2006, there was approximately \$9,754,430 of total unrecognized compensation cost related to non-vested employee stock option awards granted under the Plan and the ESPP. That cost is expected to be recognized as follows: \$1,077,213 in the remainder of 2006, \$3,370,558 in 2007, \$2,533,441 in 2008, \$2,011,857 in 2009, and \$761,361 in 2010.

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 over the requisite service period of the award. Consistent with the valuation method we used for disclosure-only purposes under the provisions of Statement No. 123, we use the Black-Scholes option pricing model to estimate fair value under Statement No. 123R. 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. Compensation cost is recognized on a straight-line basis over the requisite service period.

Information Regarding Forward-Looking Statements

This filing contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These forward-looking statements can generally be identified by the use of words such as may, will, intends, plans, believes, anticipates, expects, estimates, predicts, potential, the 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:

the initiation, timing, progress and results of our preclinical and clinical trials, research and development programs;

the potential for funding from HHS for the clinical development of peramivir from the RFP;

the further preclinical or clinical development and commercialization of our product candidates;

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

our ability to establish and maintain collaborations with biotechnology or pharmaceutical companies and governmental agencies or other third parties;

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 reflect our current views with respect to future events and BioCryst has no obligation to update or revise the statements. BioCryst cautions that you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail in Risk Factors.

You should read this discussion completely and with the understanding that our actual future results may be materially different from what we expect. We may not update these forward-looking statements, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing our risk. We invest excess cash principally in U.S. marketable securities from a diversified portfolio of institutions with strong credit ratings and in U.S. government and agency bills and notes, and by policy, limit the amount of credit exposure at any one institution. 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 believe we have no material exposure to interest rate risk arising from our investments. Therefore, no quantitative tabular disclosure is provided.

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 Securities Exchange Act is recorded, processed, summarized and reported in a timely manner under the Securities Exchange Act of 1934. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2006, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by BioCryst in the reports filed or submitted by it under the Securities Exchange Act of 1934, as amended, 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 BioCryst in such reports is accumulated and communicated to the Company's management, including the Chairman and Chief Executive Officer and Chief Financial Officer of BioCryst, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, BioCryst's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings:

None

Item 1A. Risk Factors:

Our 2005 Annual Report on Form 10-K includes a detailed discussion of our risk factors. The risk factors described below were disclosed on the Form 10-K. This discussion updates certain information as of September 30, 2006. It should be read in conjunction with all the risk factors and information disclosed in that Form 10-K.

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

To date, we have financed our operations primarily from sale of our equity securities and cash from collaborations and, to a lesser extent, interest. For the third quarter 2006, our average monthly cash burn from normal operations was approximately \$4.4 million. For the year, our cash, cash equivalents and securities balance has increased from \$60 million as of December 31, 2005 to \$61.6 million as of September 30, 2006, primarily due to cash received from collaborations, totaling approximately \$31.8 million net of sublicense fees, less the monthly cash burn from operations.

In June 2006 the Department of Health and Human Services (HHS) issued a Request for Proposal (RFP) for the potential funding of companies with antiviral drugs in development for both seasonal and avian influenza. We believe our peramivir program meets substantially all of the requirements outlined in the RFP and therefore we submitted a proposal to HHS on July 20, 2006 and we hope to be considered a competitive candidate for some of the funding to be made available under the RFP. We have made certain commitments related to the advancement of peramivir for both our intramuscular and intravenous formulations and we are currently preparing to begin two Phase II trials to be executed during the 2006-2007 influenza season using intravenous and intramuscular formulations. We are currently completing the Phase I trials to support these planned Phase II trials.

In addition, on August 7, 2006, we announced that we had received a SPA letter from the FDA for the initiation of a pivotal clinical trial of our lead anti-cancer compound Fodosine . The SPA letter documents the agreement between the FDA and the Company regarding the trial design 's suitability to support regulatory approval. We expect to initiate a multi-center, open-label pivotal clinical trial later this year with the goal of enrolling 100 patients.

Primarily as a result of the Phase II peramivir clinical trials during the 2006-7 influenza season, we estimate our monthly average cash burn rate will increase approximately \$1 million from the third quarter 2006 rate, until completion of the peramivir Phase II trials. This estimate does not include potential funding, if any, which we may receive from HHS from our proposal in response to the RFP. We are hopeful that our proposal response to the RFP will be acceptable for funding, which would offset our projected burn rate if and when it became effective. In addition, we expect to achieve one milestone related to our collaboration with Mundipharma in 2006 or early 2007 and we will continue to be reimbursed for our clinical development costs up to the \$10 million defined in our agreement. We currently have a balance receivable of approximately \$3.1 million for their portion of the funding related to the clinical development of Fodosine , which we expect to receive early in 2007.

As our clinical programs continue to grow and patient enrollment increases, our costs will increase. Our current and planned clinical trials plus the related manufacturing, personnel resources and testing required to support these trials will consume significant capital resources and will increase our expenses and our net loss.

Our 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 of funding or assistance, if any, we receive from governmental agencies or other new partnerships with third parties for the development of our drug candidates in general and for peramivir specifically, 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. Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

Edgar Filing: BIOCRYST PHARMACEUTICALS INC - Form 10-Q

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

changes in existing collaborative relationships;

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

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

our ability to obtain funding for our peramivir program from the RFP issued by HHS;

our ability to negotiate favorable development and marketing alliances for our drug product candidates;

the magnitude of our research and development programs;

the scope and results of preclinical studies and clinical trials to identify drug product candidates and the costs of manufacturing drug product to support these studies and trials;

competitive and technological advances;

the time and costs involved in obtaining regulatory approvals;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

our dependence on others for development and commercialization of our product candidates; and

successful commercialization of our products consistent with our licensing strategy.

We will be required to raise additional capital to complete the development and commercialization of our current product candidates. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners, governmental agencies or from other sources, 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 as described in the following risk factor related to collaborative relationships. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

2. The second paragraph of the risk factor entitled "If the clinical trials of our drug product candidates fail, our product candidates will not be marketed, which would result in a complete absence of product related revenue" is updated to read in full as follows:

We have negotiated a special protocol assessment, or SPA letter with the FDA, for the initiation of a pivotal clinical trial of our lead anti-cancer compound, Fodosine . An SPA is an agreement between an applicant and the FDA on the design and the size of clinical trials that is intended to form the basis of a New Drug Application (NDA). Once the FDA and an applicant reach an agreement on an SPA, the SPA cannot be changed after the clinical trial begins, except in limited circumstances such as a change in the science or clinical knowledge about the conditions being studied. Any significant change to the protocols for a clinical trial subject to an SPA would require prior FDA approval, which could delay implementation of such a change and continuation and completion of the related clinical trial. Receipt of the SPA does not ensure that Fodosine will receive FDA approval or that the process will be accelerated.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds:

None

Item 3. Defaults Upon Senior Securities:

None

Item 4. Submission of Matters to a Vote of Security Holders:

None

Item 5. Other Information:

None

Item 6. Exhibits:

a. Exhibits:

Number	Description
3.1	Composite Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
3.2	Bylaws of Registrant as amended December 15, 2005. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 16, 2005.
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 dated June 17, 2002.
10.1	Stock Incentive Plan, as amended and restated effective March 7, 2006. Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q dated August 9, 2006.
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.

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 9th day of November, 2006.

BIOCRYST PHARMACEUTICALS, INC.

/s/Charles E. Bugg

Charles E. Bugg, Ph.D.
Chairman and Chief Executive Officer

/s/Michael A. Darwin

Michael A. Darwin
Chief Financial Officer (Principal Financial and Accounting Officer), Secretary and Treasurer