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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, 2007

Commission File Number 000-23186

**BIOCRIST 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 July 31, 2007 was 29,535,580.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**BIOCRYST PHARMACEUTICALS, INC.**  
**BALANCE SHEETS**  
**June 30, 2007 and December 31, 2006**  
**(In thousands, except per share data)**

	<u>2007</u> <u>(Unaudited)</u>	<u>2006</u> <u>(Note 1)</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 7,178	\$ 4,418
Marketable securities	23,690	33,040
Receivables from collaborations — billed	3,460	249
Receivables from collaborations — unbilled	14,813	4,307
Prepaid expenses and other current assets	2,287	3,776
Total current assets	<u>51,428</u>	<u>45,790</u>
Marketable securities	11,643	8,778
Furniture and equipment, net	3,169	3,029
Patents and licenses, net	314	290
Deferred collaboration expense	11,872	10,598
Total assets	<u>\$ 78,426</u>	<u>\$ 68,485</u>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 10,578	\$ 5,887
Accrued expenses	1,249	1,507
Accrued vacation	710	641
Deferred revenue	4,620	2,699
Total current liabilities	<u>17,157</u>	<u>10,734</u>
Deferred revenue	51,926	36,596
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 — 29,526 in 2007 and 29,249 in 2006	295	292
Additional paid-in capital	220,321	216,311
Accumulated other comprehensive (loss) income	(4)	33
Accumulated deficit	(211,269)	(195,481)
Total stockholders' equity	<u>9,343</u>	<u>21,155</u>
Total liabilities and stockholders' equity	<u>\$ 78,426</u>	<u>\$ 68,485</u>

See accompanying notes to financial statements.

**BIOCRYST PHARMACEUTICALS, INC.**  
**STATEMENTS OF OPERATIONS**  
**Periods Ended June 30, 2007 and 2006**  
**(In thousands, except per share data)**  
**(Unaudited)**

	Three Months		Six Months	
	2007	2006	2007	2006
<b>Revenues:</b>				
Collaborative and other research and development	\$ 13,444	\$ 1,558	\$ 22,603	\$ 2,330
<b>Expenses:</b>				
Research and development	19,013	11,190	35,208	19,234
General and administrative	2,013	1,384	4,385	2,879
Total expenses	<u>21,026</u>	<u>12,574</u>	<u>39,593</u>	<u>22,113</u>
Loss from operations	(7,582)	(11,016)	(16,990)	(19,783)
Interest and other income	<u>619</u>	<u>933</u>	<u>1,202</u>	<u>1,818</u>
Net loss	<u>\$ (6,963)</u>	<u>\$ (10,083)</u>	<u>\$ (15,788)</u>	<u>\$ (17,965)</u>
Basic and diluted net loss per common share	<u>\$ (.24)</u>	<u>\$ (.35)</u>	<u>\$ (.54)</u>	<u>\$ (.62)</u>
Weighted average shares outstanding	29,420	29,184	29,371	29,061

See accompanying notes to financial statements.

**BIOCRIST PHARMACEUTICALS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**Six Months Ended June 30, 2007 and 2006**  
**(In thousands)**  
**(Unaudited)**

	2007	2006
<b>Operating activities:</b>		
Net loss	\$ (15,788)	\$ (17,965)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	475	424
Stock-based compensation expense	2,810	1,177
Changes in operating assets and liabilities:		
Receivables from collaborations	(13,717)	28,025
Prepaid expenses and other current assets	1,489	(3,664)
Deferred collaboration expense	(1,274)	(1,999)
Accounts payable and accrued expenses	4,502	(3,218)
Deferred revenue	17,251	9,896
<b>Net cash (used in) provided by operating activities</b>	<b>(4,252)</b>	<b>12,676</b>
<b>Investing activities:</b>		
Acquisitions of furniture and equipment	(609)	(684)
Purchases of patents and licenses	(30)	(64)
Purchases of marketable securities	(13,584)	(29,958)
Maturities of marketable securities	20,032	11,196
<b>Net cash provided by (used in) investing activities</b>	<b>5,809</b>	<b>(19,510)</b>
<b>Financing activities:</b>		
Employee stock purchase plan sales	129	100
Exercise of stock options	1,074	2,632
<b>Net cash provided by financing activities</b>	<b>1,203</b>	<b>2,732</b>
Increase (decrease) in cash and cash equivalents	2,760	(4,102)
Cash and cash equivalents at beginning of period	4,418	29,157
<b>Cash and cash equivalents at end of period</b>	<b>\$ 7,178</b>	<b>\$ 25,055</b>

See accompanying notes to financial statements.

**BIOCRIST PHARMACEUTICALS, INC.**  
**NOTES TO FINANCIAL STATEMENTS (Unaudited)**

**Note 1 — Significant Accounting Policies**

***Basis of Presentation***

The balance sheet as of June 30, 2007, the statements of operations for the three and six months ended June 30, 2007 and 2006, and the statements of cash flows for the six months ended June 30, 2007 and 2006 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, 2007, the results of operations for the three and six months ended June 30, 2007 and 2006, and cash flows for the six months ended June 30, 2007 and 2006. 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, 2006 and the notes thereto included in the Company's 2006 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, 2006 has been derived from the audited financial statements included in the Company's most recent Annual Report on Form 10-K.

***Cash and Cash Equivalents***

The Company generally considers cash equivalents to be all cash held in 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. At June 30, 2007, the Company had approximately \$35.3 million of marketable securities of which \$19.7 million is classified as available-for-sale and \$15.6 million is classified as held-to-maturity.

Securities available-for-sale consisted of U.S. Agency securities carried at fair value based on independent quoted market prices. At June 30, 2007, the amortized cost of securities available-for-sale approximated fair value. 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 carried at amortized cost. The estimated fair value of these securities, both individually and in the aggregate, approximated amortized cost at June 30, 2007. Fair value was based on independent quoted market prices.

***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. To date, the Company has not established a reserve and has never had any default of amounts due from third parties. At June 30, 2007, the Company had the following receivables from collaborations. Note that amounts are in thousands.

	<u>Billed</u>	<u>Unbilled</u>
U.S. Department of Health and Human Services	\$ 3,094	\$ 14,234
Mundipharma International Holdings Limited	212	579
Shionogi & Co., Ltd.	154	—
Total	<u>\$ 3,460</u>	<u>\$ 14,813</u>

### **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* ("Statement No. 144"), 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**

Patents and licenses are recorded at cost and amortized on a straight-line basis over their estimated useful lives or 20 years, whichever is less. The Company periodically reviews its patents and licenses for impairment in accordance with Statement No. 144 to determine any impairment that needs to be recognized.

### **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, 2007 and 2006 consisted primarily of development and clinical trial expenses payable to contract research organizations in connection with the Company's research and development programs.

### **Accumulated Other Comprehensive (Loss) Income**

Accumulated other comprehensive (loss) 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 \$4,391 of unrealized losses on its securities that are included in accumulated other comprehensive (loss) income at June 30, 2007. Other comprehensive loss for the periods ended June 30, 2007 and 2006 appear in the following table. Note that amounts are in thousands.

	<b>Three Months</b>		<b>Six Months</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (6,963)	\$ (10,083)	\$ (15,788)	\$ (17,965)
Unrealized loss (gain) on securities available-for-sale	(30)	9	(37)	9
Other comprehensive loss	<u>\$ (6,993)</u>	<u>\$ (10,074)</u>	<u>\$ (15,825)</u>	<u>\$ (17,956)</u>

### **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 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.

### **Research and Development Expenses**

In accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs* (“Statement No. 2”), the Company expenses research and development costs as incurred. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by contract research organizations (“CRO’s”), 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 CRO’s. Costs for studies performed by CRO’s 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 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 are deferred and recognized over the related revenue recognition period.

### **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. Statement No. 123R was adopted by the Company on January 1, 2006 using the “modified prospective” transition method. 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, 2007, the Company had two stock-based employee compensation plans, the Stock Incentive Plan (“Incentive Plan”) and the Employee Stock Purchase Plan (“ESPP”). In addition, 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. Prior to January 1, 2006, the Company accounted for all share-based payments under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB Opinion No. 25”), and other related interpretations, as permitted by Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (“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. Stock-based compensation expense of \$2,809,692 (\$2,703,879 of expense related to the Incentive Plan, \$68,387 of expense related to the ESPP, and \$37,426 of expense related to the inducement grant) was recognized during the first six months of 2007, while \$1,176,673 (\$1,131,138 of expense related to the Plan and \$45,535 of expense related to the ESPP) was recognized during the first six months of 2006.

As of June 30, 2007, there was approximately \$15,305,154 of total unrecognized compensation cost related to non-vested employee stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: \$2,900,435 in the remainder of 2007, \$4,933,536 in 2008, \$4,210,206 in 2009, \$2,941,687 in 2010, and \$319,290 in 2011.

## 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.

## 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 employees, directors, and consultants of the Company under the Stock Incentive Plan ("Incentive Plan"), as amended and restated in March 2007. The Incentive Plan was approved by the Company's stockholders on May 16, 2007 and permits the Company to issue awards for approximately 5.9 million shares of common stock over the term of the Incentive Plan as amended and restated. 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 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. 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.

For each stock option award granted under the Incentive Plan during the first six months of 2007 and 2006, 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 the stock option awards granted under the Incentive Plan during the first six months of 2007 and 2006 was \$6.08 and \$8.88, 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 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 valuation date 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.

### Weighted Average Assumptions for Stock Option Awards Granted under the Incentive Plan

	2007	2006
Expected Life in Years	5.7	5.9
Expected Volatility	74.7%	82.5%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	4.7%	5.0%

Related activity under the Incentive Plan is as follows:

	<u>Awards Available</u>	<u>Awards Outstanding</u>	<u>Weighted Average Exercise Price</u>
Balance December 31, 2006	820,754	3,952,568	\$ 8.94
Incentive Plan amended	1,200,000	—	—
Stock option awards granted	(1,380,706)	1,380,706	9.36
Restricted stock awards granted	(50,000)	50,000	—
Stock option awards exercised	—	(201,774)	5.33
Stock option awards canceled	197,156	(197,156)	13.84
Balance June 30, 2007	<u>787,204</u>	<u>4,984,344</u>	8.92

The grant date fair value of the restricted stock awards granted under the Incentive Plan during the first six months of 2007 was \$11.81.

#### ***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 84,656 shares remain available for purchase at June 30, 2007. 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 14,957 shares during the first six months of 2007 under the ESPP. The fair value expense of options granted under the ESPP was 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. These 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.

For the stock option awards granted under the inducement grant, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the following assumptions: expected life of 5.7 years, expected volatility of 72.9%, expected dividend yield of 0.0%, and risk-free interest rate of 4.7%. The weighted average grant date fair value of these stock option awards was \$5.25. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. 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 valuation date 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.

The exercise price of the stock option awards and the grant date fair value of the restricted stock granted under the inducement grant was \$8.20.

### Note 3 — Collaborative Agreements

In November 2005, the Company announced a collaborative relationship with F.Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (“Roche”) for the development and commercialization of BCX-4208. In February 2006, the Company announced a collaborative relationship with Mundipharma International Holdings Limited (“Mundipharma”) for the development and commercialization of Fodosine™. For these license agreements, the Company deferred the upfront payments received in these collaborations 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 AECOM and 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 October 2006 for the Roche agreement, the Company will also recognize the proportionate amount of expense related to the deferred assets.

In June 2006 and in February 2007, the Company entered into collaborative relationships with Green Cross Corporation (“Green Cross”) and Shionogi & Co., Ltd. (“Shionogi”), respectively, for the development and commercialization of peramivir. Consistent with the accounting treatment in the Roche and Mundipharma license arrangements, the Company has deferred the upfront payments made by Green Cross and Shionogi and the sublicense fees payable by the Company to UAB. The recognition of the revenue and the expense from the Green Cross agreement began in August 2006 and will continue through November 2009. The recognition of the revenue and the expense from the Shionogi agreement began in April 2007 and will continue through December 2017.

In January 2007, the Company announced that it had been awarded a four-year contract from the U.S. Department of Health and Human Services (“HHS”) for the development of peramivir. The contract commits \$102.6 million to support the development of both intravenous and intramuscular formulations of peramivir. In addition, the contract also funds the validation of U.S. based manufacturing facilities. The contract with HHS is defined as a cost-plus-fixed-fee contract. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of peramivir plus a fixed fee, or profit.

### Note 4 — Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board (“FASB”) 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 FASB Statement 109, “*Accounting for Income Taxes,*” 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.

Upon adoption, the Company has concluded that there were no significant uncertain tax positions requiring recognition in its financial statements. As of June 30, 2007, all of the Company’s deferred tax assets were fully reserved by a valuation allowance equal to 100% of the net deferred tax assets. The Company has never been profitable and has not paid any income taxes. Tax years 2003-2006 remain open to examination by the major taxing jurisdictions to which the Company is subject. Additionally, years prior to 2003 are also open to examination to the extent of loss and credit carryforwards from those years.

The Company has significant net operating loss and business credit carryovers which are subject to a valuation allowance due to the uncertain nature of the realization of the losses. The Internal Revenue Code imposes certain limitations on the utilization of net operating loss carryovers and other tax attributes after a change in control. The Company has encountered ownership changes which could significantly limit the possible utilization of such carryovers. The Company has not performed a detailed analysis to determine the effect of such ownership changes on its ability to use these net operating loss and credit carryforwards. However, it is not anticipated that limitations, if any, would have a material impact on the balance sheet as a result of offsetting changes in the deferred tax valuation allowance.

The Company will recognize interest and penalties accrued related to unrecognized tax benefits as components of its income tax provision. The Company did not have any interest and penalties accrued upon the adoption of FIN No. 48 and as of June 30, 2007, the Company does not have any interest and penalties accrued related to unrecognized tax benefits.

## **Note 5 — Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board 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.

In June 2007, the Emerging Issues Task Force (“EITF”) reached a final consensus on Emerging Issues Task Force Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (“EITF Issue 07-3”). The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If a company’s expectations change, such that it does not expect the goods will be delivered or the services rendered, the capitalized nonrefundable advance payments should be charged to expense. EITF Issue 07-3 is effective for new contracts entered into during the fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. This consensus may not be applied to earlier periods and early adoption is not permitted. Currently, the Company charges nonrefundable advance payments for future research and development activities to expense as payments are made. Therefore, the adoption of this standard will have an impact on the Company’s financial statements when adopted.

## **Note 6 — Subsequent Event**

On August 6, 2007, the Company entered into a Stock and Warrant Purchase Agreement with a group of existing stockholders for the private placement of 8,315,513 shares of the Company’s common stock at a purchase price of \$7.80 per share and warrants to purchase 3,159,895 shares of the Company’s common stock at a purchase price of \$0.125 per warrant. The aggregate purchase price of the transaction was approximately \$65.3 million. The exercise price of the warrants is \$10.25 per share. The participants in the transaction include funds managed by Baker Brothers Investments, Kleiner Perkins Caufield & Byers, EHS Holdings, OrbiMed Advisors, Texas Pacific Group Ventures, and Stephens Investment Management, all of whom are current shareholders in the Company.

The shares and warrants included in the private placement have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. The Company has agreed to register the shares, the warrants, and the shares of common stock issuable upon exercise of the warrants for resale. If registration is not completed within the period specified in the Stock and Warrant Purchase Agreement, the Company will be subject to pay liquidated damages to the group of institutional investors up to a maximum of 12% of the transaction value related to the common stock only. The Company expects the transaction to be closed on or about August 9, 2007.

## **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, event payments, research and development fees, government contracts, and interest income. Revenue is recognized in accordance with SAB No. 104 and EITF Issue 00-21. License fees, 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, Mundipharma and Shionogi license agreements, we deferred the upfront payments over the remaining life of the patents which are through 2023, 2017 and 2017, respectively. 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.

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. For example, the amounts received from Mundipharma and HHS for the reimbursement of development costs will be recorded as revenue in the period the related costs are incurred.

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 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 June 30, 2007 was \$211.3 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, 2006, we spent 66.0% 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;
- payments of amounts to academic institutions and others as a result of our recent collaborations;
- engaging investigators to conduct clinical trials;
- hiring CRO's 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, during the first six months of 2007, we incurred significant costs related to the Phase II trials with peramivir and the ongoing manufacturing of drug substance for both peramivir and Fodosine™. As these trials progress and additional trials are started in other indications, our costs for clinical studies will increase significantly. In addition, the costs associated with the manufacturing of Fodosine™ and peramivir will increase as we continue scaling up to the larger production runs required for clinical development, manufacturing validation and additional toxicology studies for these programs.

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 January 2007, we announced a \$102.6 million contract with HHS for the funding of the development, manufacturing and clinical trials required for licensure of peramivir with both the intravenous ("i.v.") and intramuscular ("i.m.") formulations. In March 2007, we announced a license agreement with Shionogi for the development and commercialization of peramivir in Japan for an upfront payment of \$14 million. 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 manufacturing we performed, Roche has taken over the development and is paying all 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 is paying 50% of the clinical development costs we incur for Fodosine™ on existing and planned clinical trials up to a maximum of \$10 million. Mundipharma's portion of these reimbursable costs from the inception of the contract through June 30, 2007 has been approximately \$5.6 million, of which approximately \$0.8 million has not been paid and is reflected on our balance sheet in accounts receivable.

The contract with HHS is a standard cost-plus-fixed-fee contract which provides for the reimbursement of allowable costs plus an element of overhead and profit. This is expected to have a significant positive revenue impact on our financial statements. As the costs of our peramivir program increase for the clinical trials, manufacturing and other expenses we will submit invoices to HHS for reimbursement of expenses allowable under the contract. The expenses are recorded as R&D expenses and reimbursements are recorded as revenue. In the same way, as we incur R&D costs for our Fodosine™ program that are reimbursable under the Mundipharma contract or R&D expenses for peramivir that are related to the Shionogi contract, we will invoice the respective company for those costs. The amounts reimbursable will be recorded as revenue in the same period the costs are incurred.

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 Shionogi and Green Cross collaborations, we will owe sublicense payments to UAB. 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, IRL and UAB 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 partners. The revenues expected from the Mundipharma agreement in 2007 will primarily consist of continuing reimbursement of R&D expenses in accordance with the contract and the amortization of the upfront and event payments. The primary revenue expected from our other agreements for 2007 is the continuing amortization of the upfront payment received.

In March 2007 we submitted a proposed pivotal trial of oral Fodosine™ in CTCL to the FDA and requested a special protocol assessment (“SPA”) which is a request for feedback from the FDA that allows a company to receive official evaluation and guidance on the design of pivotal trial protocols. In July 2007, we announced the Company had received an SPA for a pivotal trial of Fodosine™ in CTCL patients. The trial is planned to be a multicenter, multinational, open-label, single-arm, repeat dose pivotal trial which is expected to begin enrollment during the third quarter of 2007. During January 2007, we initiated a pivotal clinical trial with Fodosine™ in T-ALL, which triggered a \$5 million event payment from Mundipharma. Subsequently, in March 2007, the Company made a decision to put this trial on voluntary hold to investigate particulates that were found in some batches of i.v. formulation. We are working closely with Mundipharma to determine a mutually agreeable course of future action with regard to the clinical evaluation of Fodosine™ in T-ALL.

Although we may, in some cases, be able to control the timing of development expenses, in part by accelerating or decelerating certain costs, many of these costs will be incurred irrespective of whether we are able to discover drug candidates or obtain collaborative partners for commercialization. In addition, the achievement of milestones in our collaboration agreements is uncertain and unpredictable and would most likely have a significant impact on our operating results in the periods they are achieved. As a result, we believe that quarter-to-quarter comparisons of our financial results and cash flows 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 June 30, 2007 compared to the three months ended June 30, 2006)**

Collaborative and other research and development revenues increased to \$13,444,000 for the three months ended June 30, 2007 as compared to \$1,558,000 for the three months ended June 30, 2006, primarily due to revenue from HHS related to our contract for the development of peramivir and the amortization of deferred revenue from our collaborations.

Research and development (“R&D”) expenses increased 69.9% to \$19,013,000 for the second quarter of 2007 from \$11,190,000 for the second quarter of 2006, while general and administrative (“G&A”) expenses increased 45.4% to \$2,013,000 for the second quarter of 2007 from \$1,384,000 for the second quarter of 2006. The variance in R&D expenses is mainly attributable to an increase in expenses related to manufacturing costs for our lead drug candidates, Fodosine™ and peramivir, animal studies related to our preclinical compounds and costs related to our increase in personnel required to support the advanced development of our drug candidates. The increase in G&A expenses is primarily due to an increase in personnel related costs as a result of increased headcount, and an increase of \$379,000 in share-based compensation expense.

Interest income for the three months ended June 30, 2007 was \$619,000 as compared to \$933,000 for the three months ended June 30, 2006. This decrease was due to a lower average balance of interest-bearing assets for the second quarter of 2007 versus the second quarter of 2006.

#### **Results of Operations (six months ended June 30, 2007 compared to the six months ended June 30, 2006)**

Collaborative and other research and development revenues increased to \$22,603,000 for the six months ended June 30, 2007 compared to \$2,330,000 for the six months ended June 30, 2006, primarily due to revenue from HHS related to our contract for the development of peramivir, which included approximately \$2 million of pre-contract costs from 2006 that had been deferred on the Company’s balance sheet as of December 31, 2006. In addition, the amortization of deferred revenue from our collaborations was \$1.5 million greater for the six months in 2007 primarily due to the amortization of the deferred revenue from the Roche and Shionogi collaborations.

R&D expenses increased 83.1% to \$35,208,000 for the six months ended June 30, 2007 from \$19,234,000 for the six months ended June 30, 2006. The increase is primarily attributable to an increase in expenses related to manufacturing costs for our lead drug candidates, Fodosine™ and peramivir, costs related to advanced clinical trials for these drug candidates, an increase in personnel related costs supporting the personnel required for the advanced development of our drug candidates and an increase in animal studies related to our preclinical compounds. Also recognized in R&D expenses during 2007 was approximately \$2 million of pre-contract costs that were actually incurred during 2006. These costs were directly related to the Phase 2 trials for peramivir and were deferred at December 31, 2006 in anticipation of reimbursement under a contract award from HHS.

General and administrative expenses for the six months ended June 30, 2007 increased 52.3% to \$4,385,000 as compared to \$2,879,000 for the same period in 2006, primarily due to \$940,000 of additional share-based compensation expense compared to 2006, additional compensation expense related to an increase in personnel, and an increase in professional fees.

Interest income for the six months ended June 30, 2007 was \$1,202,000, a 33.9% decrease as compared to the same period in 2006. This increase was due to a lower average cash balance during the second quarter of 2007.

### **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 and cash from collaborative and other research and development agreements, including government contracts, and to a lesser extent interest. For example, during the first six months of 2007, we received cash from collaborative and other research and development agreements and government contracts (primarily Shionogi, Mundipharma and HHS) of approximately \$24.8 million net of sublicense fees and on August 6, 2007 we announced a \$65.3 million private placement of common stock to certain existing stockholders, which we expect to close on or about August 9, 2007. Assuming the private placement closes, our outstanding common stock will increase by approximately 8.3 million shares and our fully-diluted outstanding shares will increase by an additional approximately 3.2 million shares pursuant to warrants exercisable at \$10.25 per share. Other sources of funding have included the following:

- other collaborative and other research and development agreements;
- government grants and contracts;
- 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 increase the manufacturing of our compounds for clinical trials and for the continuation of the validation process. 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.

On August 7, 2007, we amended our lease for our current Birmingham facilities through June 30, 2015. We have an option to renew the lease for an additional five years at the current market rate in effect on June 30, 2015. The lease requires us to pay monthly rent currently at \$39,100 per month in July 2007 and escalating annually to a minimum of \$48,072 per month in the final year, plus our pro rata share of operating expenses and real estate taxes in excess of base year amounts. In addition, the lease amendment provides an allowance of \$300,000 for our use in making certain improvements to the premises.

In August 2006, we opened an office in Cary, North Carolina for the establishment of our clinical and regulatory operation. We currently have 5,375 square feet under lease through February 2010. This lease requires us to pay \$7,391 per month and escalates annually to \$7,841 per month in the final year.

We have not incurred any significant charges related to building renovations since 2001. Our capital costs during 2006 were approximately \$1.4 million and we anticipate capital costs of approximately \$2.0 million in 2007, which will be partially funded by the \$300,000 tenant allowance in our lease amendment.

At December 31, 2006, we had long-term operating lease obligations, which provide for aggregate minimum payments of \$549,758 in 2007, \$565,257 in 2008 and \$538,351 in 2009. These obligations include the future rental of our operating facilities.

We plan to finance our needs principally from the following:

- payments under our contract with HHS;
- our existing capital resources 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.

In March 2007, we announced a collaborative agreement with Shionogi for rights to peramivir in Japan. This agreement required an upfront payment of \$14 million that was received in April 2007.

In January 2007, we announced that HHS had awarded the Company a \$102.6 million, four-year contract for the advanced development of peramivir. Funding from the contract will support manufacturing, process validation, clinical studies and other product approval requirements for peramivir. The contract is a standard cost plus fixed fee contract, which we expect will continue to have a significant positive impact on our financial position and cash flow. We bill our incurred costs to HHS on a monthly basis. Any significant delays in payment or cancellation of this contract by HHS would have a significant negative effect on our financial position.

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 is paying 50% of the clinical development costs we are incurring 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. In January 2007, we initiated our pivotal study with Fodosine™ in T-cell leukemia patients under an SPA negotiated with the FDA, which triggered a \$5 million event payment from Mundipharma. Subsequently, in March 2007, the Company made a decision to put this trial on voluntary hold to investigate particulates that were found in some batches of i.v. formulation. We are working closely with Mundipharma to determine a mutually agreeable course of future action with regard to the clinical evaluation of Fodosine™ in T-ALL. In March 2007 we submitted a proposed pivotal trial of oral Fodosine™ in CTCL to the FDA and requested a special protocol assessment ("SPA") which is a request for feedback from the FDA that allows a company to receive official evaluation and guidance on the design of pivotal trial protocols. In July 2007, we announced the Company had received an SPA for a pivotal trial of Fodosine™ in CTCL patients. The trial is planned to be a multicenter, multinational, open-label, single-arm, repeat dose pivotal trial which is expected to begin enrollment during the third quarter of 2007.

The collaboration with Roche for the worldwide development and commercialization of BCX-4208 in November 2005 provided an upfront payment of \$30 million, which was received in 2006. Roche has taken over the development and is paying 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.

For the year, our cash, cash equivalents and marketable securities balance has decreased from \$46.2 million as of December 31, 2006 to \$42.5 million as of June 30, 2007, primarily due to the monthly cash burn from operations less the cash received from collaborations. Our gross cash burn for the first six months of 2007 was significantly offset by the reimbursement from Mundipharma for the clinical expenses incurred in 2006 and 2007, plus the event payment and upfront payment received from Mundipharma and Shionogi, respectively which totaled approximately \$24 million. We are continuing to project our net cash burn rate to average approximately \$3.0 million per month in 2007. We caution that our revenues, our expenses and our cash flows will vary significantly from quarter to quarter due to the nature of the trials in influenza and the reimbursement from HHS. Given that our average monthly burn rate in the first six months of this year was much lower than \$3 million, we expect the average monthly burn rate for the remaining six months will be correspondingly higher.

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

As of June 30, 2007, we had \$42.5 million in cash, cash equivalents and marketable securities. On August 6, 2007, we announced a \$65.3 million private placement of unregistered common stock and warrants to certain existing stockholders, which we expect to close on or about August 9, 2007. With our currently available funds, the amounts to be received from HHS, Shionogi and our other collaborators, and assuming we receive the funds from the private placement, we believe these resources 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. For example, our recently announced private placement has registration provisions that would cause the Company to pay 1.5% per month up to a maximum of 12.0% of the stock proceeds if the shares are not registered in the time designated by the stock purchase agreement.

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

- our ability to perform under the contract with HHS and receive reimbursement;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;
- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;
- the extent to which our partners, including governmental agencies will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for certain drug candidates; or a decision to build or expand internal development and commercial capabilities;

- Successful commercialization of marketed products by either us or a partner;
- the scope and results of preclinical studies and clinical trials to identify and evaluate drug candidates;
- our ability to enroll sites and patients in our clinical trials;
- the scope of manufacturing of our drug candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development of our drug candidates;
- the scope of manufacturing of our drug substance and drug products required for future NDA filings;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals; and
- the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

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 HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

#### **Off-Balance Sheet Arrangements**

As 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 June 30, 2007, we are not involved in any material unconsolidated entities or off-balance sheet arrangements.

#### **Contractual Obligations**

Our contractual obligations as of December 31, 2006 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, 2006.

#### **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, 2006, and Note 1 to our financial statements included in Part I, Item I of this report, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

### ***Revenue Recognition***

Our 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 SAB No. 104 and EITF Issue 00-21. License fees, 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, we deferred the upfront payments over the remaining life of the patents which are through 2023 and 2017, respectively. 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.

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. For example, the amounts received from Mundipharma and HHS for the reimbursement of development costs will be recorded as revenue in the period the related costs are incurred.

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 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 CRO's, 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 No. 2. 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 CRO's. We accrue costs for studies performed by CRO's 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.

Additionally, we have license agreements with third parties, such as AECOM, IRL, and UAB 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.

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

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Direct external R&amp;D expenses by program:</b>				
PNP Inhibitor (Fodosine™)	\$ 3,155	\$ 4,272	\$ 6,522	\$ 7,650
Neuraminidase Inhibitor (peramivir)	9,633	2,819	14,987	4,441
Hepatitis C Polymerase Inhibitor	150	426	595	669
Other	1,092	237	1,301	300
<b>All other R&amp;D expenses:</b>				
Compensation and fringe benefits	2,664	1,498	5,117	2,716
Supplies and services	400	535	2,981	707
Maintenance, depreciation, and amortization	318	283	624	521
Overhead allocation and other	1,601	1,120	3,081	2,230
<b>Total R&amp;D expenses</b>	<b>\$ 19,013</b>	<b>\$ 11,190</b>	<b>\$ 35,208</b>	<b>\$ 19,234</b>

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

The successful development of our drug candidates is uncertain and subject to a number of risks. We cannot be certain that any of our drug candidates will prove to be safe and effective or will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory clearance. We, the FDA or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our products under development. Delays or rejections may be encountered based on additional governmental regulation, legislation, administrative action or changes in FDA or other regulatory policy during development or the review process. Other risks associated with our product development programs are described in Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K, as updated by Part II, Item IA of this report and as updated from time to time in our subsequent periodic reports and current reports filed with the SEC. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of completion of any of our product development programs and the period in which material net cash inflows from any of our product development programs will commence are unavailable.

#### **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 CRO's 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 incur costs that we previously failed to identify, 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***

In accordance with Statement No. 123R, all share-based payments, including grants of stock option awards and restricted stock awards, are recognized in our income statement based on their fair values. We adopted Statement No. 123R on January 1, 2006 using the “modified prospective” transition method. 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. 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.

As of June 30, 2007, we had two stock-based employee compensation plans, the Incentive Plan and the ESPP. In addition, we made an inducement grant outside of the Incentive Plan and ESPP to recruit a new employee to a key position within the Company. Prior to January 1, 2006, we accounted for all share-based payments under the recognition and measurement provisions of APB Opinion 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. Stock-based compensation expense of \$2,809,692 (\$2,703,879 of expense related to the Incentive Plan, \$68,387 of expense related to the ESPP, and \$37,426 of expense related to the inducement grant) was recognized during the first six months of 2007, while \$1,176,673 (\$1,131,138 of expense related to the Plan and \$45,535 of expense related to the ESPP) was recognized during the first six months of 2006.

As of June 30, 2007, there was approximately \$15,305,154 of total unrecognized compensation cost related to non-vested employee stock option awards and stock awards granted by the Company. That cost is expected to be recognized as follows: \$2,900,435 in the remainder of 2007, \$4,933,536 in 2008, \$4,210,206 in 2009, \$2,941,687 in 2010, and \$319,290 in 2011.

#### **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 negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and clinical trials, research and development programs;
- the potential funding from HHS for the development of peramivir our contract;
- 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” in our Annual Report on Form 10-K, as updated by Part II, Item 1A of this report.

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 June 30, 2007, 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 June 30, 2007 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 2006 Annual Report on Form 10-K includes a detailed discussion of our risk factors. The information below updates our risk factors as of June 30, 2007. These risk factors should be read in conjunction with all risk factors and information disclosed in that Form 10-K.

#### **Risks Relating to Our Business**

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

Since our inception in 1986, we have not been profitable. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. As of June 30, 2007, our accumulated deficit was approximately \$211.3 million. To become profitable, we must successfully manufacture and develop drug product candidates, receive regulatory approval, and successfully commercialize or enter into profitable agreements with other parties. It could be several years, if ever, before we receive royalties from any current or future license agreements or revenues directly from product sales.

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

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

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability.

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

- our ability to find suitable clinical sites and investigators to enroll patients;
- the availability of and willingness of patients to participate in our clinical trials;
- difficulty in maintaining contact with patients to provide complete data after treatment;
- our product candidates may not prove to be either safe or effective;
- manufacturing or quality problems could affect the supply of drug product for our trials; and
- delays or changes in requirements by governmental agencies.

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

***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 collaborative and other research and development agreements including government contracts, and, to a lesser extent, interest. For the year, our cash, cash equivalents and marketable securities balance has decreased from \$46.2 million as of December 31, 2006 to \$42.5 million as of June 30, 2007, primarily due to the monthly cash burn from operations less the cash received from collaborations. Our gross cash burn for the first six months of 2007 was significantly offset by the reimbursement from Mundipharma for the clinical expenses incurred in 2006 and 2007, plus the event payment and upfront payment received from Mundipharma and Shionogi, respectively. We are continuing to project our net cash burn rate to average approximately \$3.0 million per month in 2007. We caution that our revenues, our expenses and our cash flows will vary significantly from quarter to quarter due to the nature of the trials in influenza and the reimbursement from HHS. Given that our average monthly burn rate in the first six months of 2007 was much lower than \$3 million, we expect the average monthly burn rate for the remaining six months of 2007 will be correspondingly higher.

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

As of June 30, 2007, we had \$42.5 million in cash, cash equivalents and marketable securities. On August 6, 2007, we announced a \$65.3 million private placement of unregistered common stock and warrants to certain institutional investors, which we expect to close on or about August 9, 2007. Assuming the private placement closes, our outstanding common stock will increase by approximately 8.3 million shares and our fully-diluted outstanding shares will increase by an additional approximately 3.2 million shares pursuant to warrants exercisable at \$10.25 per share. Upon this sale of stock the Company is required to register the shares within 90 days, or 120 if reviewed by the SEC. Failure to have the shares registered in this timeframe would trigger liquidated damages of 1.5% per month on the stock cost, up to a maximum of 12%, which could have a significant impact on our cash. With our currently available funds, the amounts to be received from HHS, Shionogi and our other collaborators, and assuming we receive the funds from the private placement, we believe these resources 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, but not limited to:

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

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 HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale-back or eliminate certain of our research and development programs.

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

Our projections of revenues and incoming cash flows for 2007 are substantially dependant upon HHS reimbursement for the costs related to our peramivir program. If HHS were to eliminate or reduce the funding for this program or disallow some of our incurred costs, we would have to obtain additional funding for development of this drug candidate or significantly reduce or stop the development effort.

In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion. The U.S. government may terminate its contract with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms, which would have a significant negative impact on our cash flows and operations.

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

We have entered into a contract with HHS for the advanced development of our neuraminidase inhibitor, peramivir. In contracting with HHS, we are subject to various U.S. government contract requirements, including general clauses for a cost-reimbursement research and development contract. U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which subjects us to additional risks. These risks include the ability of the U.S. government to unilaterally:

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

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

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

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

Our business strategy is to maximize asset value. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third party alliances could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our drug product candidates. Our general strategy is to focus development and commercialization capabilities in specialty markets.

Currently, we have established collaborative relationships with four pharmaceutical companies, Roche, Mundipharma, Shionogi and Green Cross for development and commercialization of BCX-4208, Fodosine™ and peramivir, respectively. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including but not limited to:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day to day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our drug candidates, obtain regulatory approvals and achieve market acceptance of products developed from our drug candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our product candidates; and
- our partners may not comply with applicable government regulatory requirements.

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

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

Since we have never commercialized a product, our ability to receive revenue from products we commercialize presents several risks, which include:

- we have not yet commercialized any products or technologies, and we may never be able to do so;
- many competitors are more experienced and have significantly more resources;
- we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products are affected by the competitive landscape, which cannot be fully known at this time;
- reimbursement is constantly changing which could greatly affect usage of our products; and
- any future revenue directly from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, manufacture, market and commercialize any approved drugs.

***If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed.***

We depend on contract research organizations, third-party vendors and investigators for preclinical testing and clinical trials related to our drug discovery and development efforts, including the HHS contract. We intend to depend on them to assist in our future discovery and development efforts. These parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the approval of our products. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our products. Moreover, these parties may also have relationships with other commercial entities, some of which may compete with us. If they assist our competitors it could harm our competitive position.

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

***If our development collaborations with other parties fail, the development of our drug product candidates will be delayed or stopped.***

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

- discovery of proteins that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;
- licensing or design of enzyme inhibitors for development as drug product candidates;
- execution of some preclinical studies and late-stage development for our compounds and product candidates;
- management of our clinical trials, including medical monitoring and data management;
- execution of additional toxicology studies that may be required to obtain approval for our product candidates;
- manufacturing the starting materials and drug substance required to formulate our drug products and the drug products to be used in both our clinical trials and toxicology studies; and
- management of our regulatory function.

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

***Our development of both intravenous and intramuscular dosing of peramivir for avian flu is subject to all disclosed drug development and potential commercialization risks and numerous additional risks. Any potential revenue benefits to us are highly speculative.***

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

- the injectable versions of peramivir are at an early stage of development and have been tested in a limited number of humans, primarily healthy volunteers, and may not be safe or effective;
- necessary government or other third party funding and clinical testing for further development of peramivir may not be available timely, at all, or in sufficient amounts;
- the avian flu prevention or treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines could substantially replace potential demand for an antiviral such as peramivir;
- any substantial demand for avian flu treatments may occur before peramivir can be adequately developed and tested in clinical trials;
- numerous large and well-established pharmaceutical and biotech companies will be competing to meet the market demand for avian flu drugs and vaccines;
- regulatory authorities may not make needed accommodations to accelerate the drug testing and approval process for peramivir; and
- in the next few years, it is expected that a limited number of governmental entities will be the primary potential customers for peramivir and if we are not successful at marketing peramivir to these entities for any reason, we will not receive substantial revenues.

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

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

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

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

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

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

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

***If the clinical trials of our drug product candidates fail, our product candidates will not be marketed, and we will not realize product related revenue.***

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. If we or other third party partners are unable to demonstrate that our product candidates are safe and effective, our product candidates will not receive regulatory approval and will not be marketed, and we will not realize product related revenue. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. Positive results from preclinical studies and early clinical trials do not ensure positive results in clinical trials designed to permit application for regulatory approval, called pivotal clinical trials. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective.

We negotiated a special protocol assessment, or SPA, with the FDA for the recently initiated pivotal clinical trial of our lead anti-cancer compound, Fodosine<sup>TM</sup>. 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<sup>TM</sup> will receive FDA approval or that the process will be accelerated.

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

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

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

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

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

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

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

***If our drug product candidates do not achieve broad market acceptance, our business may never become profitable.***

Our drug product candidates may not gain the market acceptance required for us to be profitable even if they successfully complete initial and final clinical trials and receive approval for sale by the FDA or foreign regulatory agencies. The degree of market acceptance of any product candidates that we or our partners develop will depend on a number of factors, including but not limited to:

- our clinical evidence of safety and efficacy;
- cost-effectiveness, convenience and ease of use of our product candidates;

- their safety, availability and effectiveness relative to alternative treatments;
- the actual and potential side effects or other reactions;
- reimbursement policies of government and third-party payers; and
- the effectiveness of marketing and distribution support for our product candidates.

Physicians, patients, payers or the medical community in general may not accept or use our product candidates even after the FDA or foreign regulatory agencies approve the drug candidates. If our product candidates do not achieve significant market acceptance, we will not have enough revenues to become profitable.

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

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

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

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

We and our partners are performing research on or developing products for the treatment of several disorders including T-cell mediated disorders (T-cell cancers, psoriasis, transplant rejection, and rheumatoid arthritis), oncology, influenza, hepatitis C and cardiovascular disorders. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai's Targretin for CTCL and the current neuraminidase inhibitors marketed by GSK and Roche for influenza. In addition, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and in the fields of PNP, influenza, hepatitis C, and in other therapeutic areas where we have discovery efforts ongoing. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

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

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

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

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

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

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

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

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

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

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

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

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

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

We are highly dependent upon our senior management and scientific team, the loss of whose services might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, operational and scientific personnel, will harm our business because we rely upon these personnel for many critical functions of our business. In addition, we rely on members of our scientific advisory board and consultants to assist us in formulating our research and development strategy. All of the members of the scientific advisory board and all of our consultants are otherwise employed and each such member or consultant may have commitments to other entities that may limit their availability to us.

***We may be unable to establish sales, marketing and distribution capabilities necessary to successfully commercialize products we may develop.***

We currently have no marketing capability and no direct or third-party sales or distribution capabilities. If we successfully develop a drug product candidate and decide to commercialize it ourselves rather than relying on third parties, as we are considering doing in the United States for Fodosine™, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for that product.

***If users of our drug products are not reimbursed for use, future sales of our drug products will decline.***

The lack of reimbursement for the use of our product candidates by hospitals, clinics, patients or doctors will harm our business. Medicare, Medicaid, health maintenance organizations and other third-party payers may not authorize or otherwise budget for the reimbursement of our products. Governmental and third-party payers are increasingly challenging the prices charged for medical products and services. We cannot be sure that third-party payers would view our product candidates as cost-effective, that reimbursement will be available to consumers or that reimbursement will be sufficient to allow our product candidates to be marketed on a competitive basis. Changes in reimbursement policies, or attempts to contain costs in the health care industry could limit or restrict reimbursement for our product candidates and would materially and adversely affect our business, because future product sales would decline and we would receive less product or royalty revenue.

***The Medicare prescription drug coverage legislation and future legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In the United States, there have been a number of legislative and regulatory proposals, at both the federal and state government levels, to change the healthcare system in ways that could affect our ability to sell our products profitably, if approved. For example, the Medicare Prescription Drug and Modernization Act of 2003 (“MMA”), went into effect in 2006 and has changed the types of drugs covered by Medicare, and the methodology used to determine the price for such drugs. Further federal and state proposals and healthcare reforms are likely. Our business could be harmed by the MMA, by the possible effect of this legislation on amounts that private payors will pay and by other healthcare reforms that may be enacted or adopted in the future.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our clinical trials in the amount of \$10 million. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- the diversion of management's attention from managing our business.

***If our computer systems fail or our facility incurs damage, our business will suffer.***

Our drug development activities depend on the security, integrity and performance of the computer systems supporting them, and the failure of our computer systems could delay our drug development efforts. We currently store most of our preclinical and clinical data at our facility. Duplicate copies of most critical data are stored off-site in a bank vault. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

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

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

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

## Risks Relating to Our Common Stock

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

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended June 30, 2007, the 52-week range of the market price of our stock was from \$6.57 to \$14.94 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales of our common stock or other derivative securities;
- status of new or existing licensing or collaborative agreements and government contracts;
- we or our partners achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel or members of our board of directors;
- purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

***Because stock ownership is concentrated, you and other investors will have limited influence on stockholder decisions.***

As of July 31, 2007, our directors, executive officers and our stockholders who held 5% or greater of our outstanding common stock beneficially owned approximately 36.3% of our outstanding common stock and common stock equivalents. Assuming our private placement of common stock announced August 6, 2007 closes, that stock ownership concentration would increase to approximately 54.3%. As a result, these holders, if acting together, are able to significantly influence matters requiring stockholder approval, including the election of directors. This concentration of ownership may delay, defer or prevent a change in our control.

***We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.***

Our board of directors has the authority to issue up to 4,955,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and supermajority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

In June 2002, our board of directors adopted a stockholder rights plan and, pursuant thereto, issued preferred stock purchase rights ("Rights") to the holders of our common stock. The Rights have certain anti-takeover effects. If triggered, the Rights would cause substantial dilution to a person or group of persons who acquires more than 15% (19.9% for William W. Featheringill, a Director who owned approximately 9.64% as of August 6, 2007, but owned more than 15% at the time the Rights were put in place) of our common stock on terms not approved by the board of directors. In August 2007, this plan was amended for a transaction involving funds managed by or affiliated with Baker Bros. Advisors, LLC such that they could purchase up to 25% without triggering the Rights. Assuming closing of the private placement announced August 6, 2007, such group would own approximately 19.0% of our fully-diluted stock.

***We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.***

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

**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:**

- (a) The Company's annual meeting of stockholders was held on May 16, 2007.
- (b) Nominees Higgins and Seidenberg were elected as directors for three-year terms expiring in 2010. Messrs., Bennett, Biggar, Featheringill, Horovitz, Sherrill, Spencer, Stonehouse and Steer continue as directors.
- (c) Motion before stockholders:

1. Election of two directors as follows -

<b>Name</b>	<b>Votes For</b>	<b>Abstentions/ Withheld</b>
John L. Higgins	26,120,421	428,735
Beth C. Seidenberg, M.D.	25,527,035	1,022,121

2. Approval of the Stock Incentive Plan

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
16,422,029	1,247,175	53,724

3. Approval of Amendment of Certificate of Incorporation

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
25,455,349	1,037,284	56,522

4. Ratification of Ernst & Young, LLP

<b>Votes For</b>	<b>Votes Against</b>	<b>Abstentions/ Withheld</b>
26,386,608	110,543	52,004

**Item 5. Other Information:**

On August 5, 2007, in connection with the private placement transaction announced by the Company on August 6, 2007, the Company amended the definition in clause (2) of "Acquiring Person" in the Rights Agreement dated June 17, 2002, by and between the Company and American Stock Transfer & Trust Company (the "Rights Agreement") to increase the ownership percentage that will trigger the rights from 15% to 25.0% for Baker Bros. Advisors, LLC or any of its affiliates or associates, or any entities that it manages. The beneficial ownership of the Company's common stock by Baker Bros. Advisors, LLC and its affiliates will exceed 15% as a result of the private placement transaction.

**Item 6. Exhibits:**

a. Exhibits:

<b>Number</b>	<b>Description</b>
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	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.
4.2	Amendment to Rights Agreement, dated as of August 5, 2007.
10.1	Stock Incentive Plan, as amended and restated effective March 2007.
10.2	Employment Letter Agreement dated April 2, 2007, by and between the Company and David McCullough. Incorporated by reference to Exhibit 10.5 to the Company's Form 10-Q dated May 10, 2007.
10.3	Agreement dated January 3, 2007, between BioCryst Pharmaceuticals, Inc. and the Dept. of Health and Human Services, as amended by Amendment number 1 dated January 3, 2007 and Amendment number 2 dated May 11, 2007. (Portions omitted pursuant to request for confidential treatment and filed separately with the Commission.)
10.4	Third Amendment to Lease Agreement dated August 7, 2007, by and between Riverchase Capital LLC, a Florida limited liability company, Stow Riverchase, LLC, a Florida limited liability company, as successor landlord to RBP, LLC and the Company.
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 August 2007.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse

Jon P. Stonehouse  
*Chief Executive Officer*

/s/ Michael A. Darwin

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

## Exhibit Index

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**AMENDMENT OF BIOCRYST**

**RIGHTS AGREEMENT**

1. Clause (2) of the definition of “Acquiring Person” in the Company’s Rights Agreement dated June 17, 2002 (the “Rights Agreement”), is hereby amended to read in full as follows:

“(2) William W. Featheringill (the “Permitted Investor”) or any of his Affiliates or Associates (collectively with the Permitted Investor, the “Investor Group”) to the extent that the members of the Investor Group shall become the Beneficial Owner of, in the aggregate, up to, but not exceeding, 19.9% of the shares of Common Stock of the Company then outstanding, or (3) Baker Bros. Advisors, LLC (the “Baker Permitted Investor”) or any of its Affiliates or Associates, or any entities managed by Baker Bros. Advisors, LLC, including, but not limited to, Baker Bros. Investments, L.P., Baker Bros. Investments II, L.P., Baker/Tisch Investments, L.P., Baker Biotech Fund I, L.P., 14159, L.P. and Baker Brothers Life Sciences, L.P. (collectively with the Baker Permitted Investor, the “Baker Investor Group”) to the extent that the members of the Baker Investor Group shall become the Beneficial Owner of, in the aggregate, up to, but not exceeding, 25.0% of the shares of Common Stock of the Company then outstanding.”

2. In the two places where the following parenthetical appears in clause (i) of the definition of “Acquiring Person” in the Rights Agreement:

“(or, in the case of the Investor Group, more than 19.9% of the shares of Common Stock of the Company then outstanding)”

it shall be amended to read in full as follows:

“(or, in the case of the Investor Group or the Baker Investor Group, respectively, more than 19.9% or 25%, respectively, of the shares of Common Stock of the Company then outstanding)”.

3. References to the “Rights Agreement between BioCryst Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, dated as of June 14, 2002” shall be amended to refer to the “Rights Agreement between BioCryst Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, dated as of June 14, 2002, as amended to date.”

**BIOCRYSST PHARMACEUTICALS, INC.  
STOCK INCENTIVE PLAN  
(formerly the “BioCryst Pharmaceuticals, Inc. 1991 Stock Option Plan”)  
(AS AMENDED AND RESTATED IN MARCH OF 2007)**

**ARTICLE ONE  
GENERAL PROVISIONS**

**I. PURPOSES OF THE PLAN**

A. This Stock Incentive Plan (the “Plan”), formerly the “BioCryst Pharmaceuticals, Inc. 1991 Stock Option Plan,” is intended to promote the interests of BioCryst Pharmaceuticals, Inc., a Delaware corporation (the “Company”), by providing a method whereby (i) key employees (including officers and directors) of the Company (or its parent or subsidiary corporations) who are responsible for the management, growth and financial success of the Company (or any parent or subsidiary corporations), (ii) non-employee members of the board of directors of the Company (the “Board”) (or of any parent or subsidiary corporations) and (iii) consultants and other independent contractors who provide valuable services to the Company (or any parent or subsidiary corporations) may be offered the opportunity to acquire a proprietary interest, or otherwise increase their proprietary interest, in the Company as an incentive for them to remain in the service of the Company (or any parent or subsidiary corporations).

B. For purposes of the Plan, the following provisions shall be applicable in determining the parent and subsidiary corporations of the Company:

- Any corporation (other than the Company) in an unbroken chain of corporations ending with the Company shall be considered to be a **parent** corporation of the Company, provided each such corporation in the unbroken chain (other than the Company) owns, at the time of the determination, stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

- Each corporation (other than the Company) in an unbroken chain of corporations beginning with the Company shall be considered to be a **subsidiary** of the Company, provided each such corporation (other than the last corporation) in the unbroken chain owns, at the time of the determination, stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

C. The Plan, as hereby amended and restated, was approved and adopted by the Board in March of 2007 in order to increase by 1,200,000 the number of shares of the Company’s common stock, par value \$.01 per share (the “Common Stock”), that may be issued pursuant to the Plan. The Board’s adoption of the share increase is subject to approval by the Company’s stockholders at the Company’s 2007 Annual Stockholders Meeting.

**II. STRUCTURE OF THE PLAN**

A. The Plan shall be divided into three separate equity programs:

- the Discretionary Option Grant Program specified in Article Two, pursuant to which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of Common Stock,

- the Stock Issuance Program specified in Article Three, pursuant to which eligible persons may, at the discretion of the Plan Administrator, be issued shares of Common Stock directly, either through immediate purchase of such shares or as compensation for services rendered to the Company (or any parent or subsidiary), and

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- the Automatic Option Grant Program specified in Article Four, pursuant to which non-employee members of the Board will automatically receive option grants to purchase shares of Common Stock.

B. Unless the context clearly indicates otherwise, the provisions of Articles One and Five of the Plan shall apply to all equity programs under the Plan and shall accordingly govern the interests of all individuals under the Plan.

### **III. ADMINISTRATION OF THE PLAN**

A. A committee of two (2) or more non-employee Board members appointed by the Board (the “Primary Committee”) shall have sole and exclusive authority to administer the Discretionary Option Grant and Stock Issuance Programs with respect to Section 16 Insiders. For purposes of this Section, a Section 16 Insider shall mean an officer or director of the Company subject to the short-swing profit liabilities of Section 16 of the Securities Exchange Act of 1934 (the “1934 Act”).

B. Administration of the Discretionary Option Grant and Stock Issuance Programs with respect to all other persons eligible to participate in the programs may, at the Board’s discretion, be vested in the Primary Committee, another committee of one (1) or more Board members appointed by the Board (the “Secondary Committee”), or the Board may retain the power to administer those programs with respect to all such persons.

C. Members of the Primary Committee and any Secondary Committee shall serve for such period of time as the Board may determine and shall be subject to removal by the Board at any time.

D. Each Plan Administrator (whether the Primary Committee, the Board or the Secondary Committee) shall, within the scope of its administrative functions under the Plan, have full power and authority (subject to the express provisions of the Plan) to establish such rules and regulations as it may deem appropriate for the proper administration of the Discretionary Option Grant and Stock Issuance Programs and to make such determinations under, and issue interpretations of, the provisions of such programs and any outstanding options or stock issuances thereunder as it may deem necessary or advisable. Decisions of the Plan Administrator within the scope of its administrative authority under the Plan shall be final and binding on all parties.

E. Service on the Primary Committee or the Secondary Committee shall constitute service as a Board member, and members of each such committee shall accordingly be entitled to full indemnification and reimbursement as Board members for their service on such committee. No member of the Primary Committee or Secondary Committee shall be liable for any act of omission made in good faith with respect to the Plan or any option grants or stock issuances under the Plan.

F. Administration of the Automatic Option Grant Program shall be self-executing in accordance with the express terms and conditions of Article Four, and no Plan Administrator shall exercise any discretionary functions under that program.

### **IV. ELIGIBILITY**

A. The persons eligible to participate in the Discretionary Option Grant and Stock Issuance Programs shall be limited to the following:

(i) officers and other key employees of the Company (or its parent or subsidiary corporations) who render services which contribute to the management, growth and financial success of the Company (or its parent or subsidiary corporations);

(ii) individuals who are consultants or independent advisors and who provide valuable services to the Company (or its parent or subsidiary corporations); and

(iii) non-employee members of the Board (or of the board of directors of parent or subsidiary corporations).

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B. Only Board members who are not employees of the Company (or any parent or subsidiary) shall be eligible to receive automatic option grants pursuant to the Automatic Option Grant Program specified in Article Four.

C. The Plan Administrator shall, within the scope of its administrative jurisdiction under the Plan, have full power and authority to determine (i) whether to grant options in accordance with the Discretionary Option Grant Program or to effect stock issuances in accordance with the Stock Issuance Program, (ii) which eligible persons are to receive option grants under the Discretionary Option Grant Program, the time or times when such option grants are to be made, the number of shares to be covered by each such grant, the status of the granted option as either an incentive stock option ("Incentive Option") which satisfies the requirements of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") or a non-statutory option not intended to meet such requirements, the time or times when each such option is to become exercisable, the vesting schedule (if any) applicable to the option shares and the maximum term for which such option is to remain outstanding, and (iii) which eligible persons are to receive stock issuances under the Stock Issuance Program, the time or times when such issuances are to be made, the number of shares to be issued to each participant, the vesting schedule (if any) applicable to the shares and the consideration for such shares.

## **V. STOCK SUBJECT TO THE PLAN**

A. Shares of the Company's Common Stock shall be available for issuance under the Plan and shall be drawn from either the Company's authorized but unissued shares of Common Stock or from reacquired shares of Common Stock, including shares repurchased by the Company on the open market. The maximum number of shares of Common Stock which may be issued over the term of the Plan, as amended and restated, shall not exceed 5,944,274 shares, subject to adjustment from time to time in accordance with the provisions of this Section V. Such authorized share reserve includes (i) the 4,744,274 shares of Common Stock reserved and available for issuance under the Plan as of March 20, 2007; and (ii) the increase of 1,200,000 shares of Common Stock authorized by the Board subject to shareholder approval at the 2007 Annual Stockholders Meeting.

B. In no event shall the number of shares of Common Stock for which any one individual participating in the Plan may receive options, separately exercisable stock appreciation rights and direct stock issuances exceed 1,500,000 shares of Common Stock in the aggregate. For purposes of such limitation, however, no stock options granted prior to the date the Common Stock was first registered under Section 12 of the 1934 Act (the "Section 12(g) Registration Date") shall be taken into account.

C. Should an outstanding option under this Plan expire or terminate for any reason prior to exercise in full, the shares subject to the portion of the option not so exercised shall be available for subsequent option grant or direct stock issuances under the Plan. Unvested shares issued under the Plan and subsequently repurchased by the Corporation, at the original issue price paid per share, pursuant to the Corporation's repurchase rights under the Plan, or shares underlying terminated share right awards, shall be added back to the number of shares of Common Stock reserved for issuance under the Plan and shall accordingly be available for reissuance through one or more subsequent option grants or direct stock issuances under the Plan. However, should the exercise price of an outstanding option under the Plan be paid with shares of Common Stock or should shares of Common Stock otherwise issuable under the Plan be withheld by the Company in satisfaction of the withholding taxes incurred in connection with the exercise of an outstanding option or the vesting of a direct stock issuance under the Plan, then the number of shares of Common Stock available for issuance under the Plan shall be reduced by the gross number of shares for which the option is exercised or which vest under the direct stock issuance, and not by the net number of shares of Common Stock actually issued to the holder of such option or stock issuance. Shares of Common Stock subject to any option surrendered for an appreciation distribution under Section IV of Article Two or Section III of Article Four shall not be available for subsequent issuance under the Plan.

D. In the event any change is made to the Common Stock issuable under the Plan by reason of any stock split, stock dividend, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Common Stock as a class without receipt of consideration, then appropriate adjustments shall be made to (i) the maximum number and/or class of securities issuable under the Plan, (ii) the maximum number and/or class of securities for which any one individual participating in the Plan may be granted stock options, separately exercisable stock appreciation rights, and direct stock issuances under the Plan from and after the Section 12(g) Registration Date, (iii) the number and/or class of securities and price per share in effect under each outstanding option under the Plan, (iv) the number and/or class of securities in effect under each outstanding direct stock issuance under the Plan, and (v) the number and/or class of securities for which automatic option grants are subsequently to be made per non-employee Board member under the Automatic Option Grant Program. The purpose of such adjustments shall be to preclude the enlargement or dilution of rights and benefits under the Plan.

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E. The fair market value per share of Common Stock on any relevant date under the Plan shall be determined in accordance with the following provisions:

(i) If the Common Stock is not at the time listed or admitted to trading on any national securities exchange but is traded in the over-the-counter market, the fair market value shall be the mean between the highest bid and lowest asked prices (or, if such information is available, the closing selling price) per share of Common Stock on the date in question in the over-the-counter market, as such prices are reported by the National Association of Securities Dealers through the Nasdaq National Market or any successor system. If there are no reported bid and asked prices (or closing selling price) for the Common Stock on the date in question, then the mean between the highest bid price and lowest asked price (or the closing selling price) on the last preceding date for which such quotations exist shall be determinative of fair market value.

(ii) If the Common Stock is at the time listed or admitted to trading on any national securities exchange, then the fair market value shall be the closing selling price per share of Common Stock on the date in question on the securities exchange determined by the Plan Administrator to be the primary market for the Common Stock, as such price is officially quoted in the composite tape of transactions on such exchange. If there is no reported sale of Common Stock on the exchange on the date in question, then the fair market value shall be the closing selling price on the exchange on the last preceding date for which such quotation exists.

(iii) If the Common Stock is at the time neither listed nor admitted to trading on any securities exchange nor traded in the over-the-counter market, then the fair market value shall be determined by the Plan Administrator after taking into account such factors as the Plan Administrator shall deem appropriate.

## **ARTICLE TWO**

### **DISCRETIONARY OPTION GRANT PROGRAM**

#### **I. TERMS AND CONDITIONS OF OPTIONS**

Options granted pursuant to this Article Two shall be authorized by action of the Plan Administrator and may, at the Plan Administrator's discretion, be either Incentive Options or non-statutory options. Individuals who are not Employees may only be granted non-statutory options under this Article Two. Each option granted shall be evidenced by one or more instruments in the form approved by the Plan Administrator. Each such instrument shall, however, comply with the terms and conditions specified below, and each instrument evidencing an Incentive Option shall, in addition, be subject to the applicable provisions of Section II of this Article Two.

##### **A. Option Price.**

1. The option price per share shall be fixed by the Plan Administrator. In no event, however, shall the option price per share be less than one hundred percent (100%) of the fair market value per share of Common Stock on the date of the option grant.

2. The option price shall become immediately due upon exercise of the option and shall, subject to the provisions of Section V of this Article Two and the instrument evidencing the grant, be payable as follows:

- full payment in cash or check drawn to the Company's order;

- full payment in shares of Common Stock held by the optionee for the requisite period necessary to avoid a charge to the Company's earnings for financial reporting purposes and valued at fair market value on the Exercise Date (as such term is defined below);

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- full payment through a combination of shares of Common Stock held by the optionee for the requisite period necessary to avoid a charge to the Company's earnings for financial reporting purposes and valued at fair market value on the Exercise Date and cash or cash equivalent; or

- full payment through a broker-dealer sale and remittance procedure pursuant to which the optionee (I) shall provide irrevocable written instructions to a designated brokerage firm to effect the immediate sale of the purchased shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate option price payable for the purchased shares plus all applicable Federal and State income and employment taxes required to be withheld by the Company in connection with such purchase and (II) shall provide written directives to the Company to deliver the certificates for the purchased shares directly to such brokerage firm in order to complete the sale transaction.

For purposes of this subparagraph 2, the Exercise Date shall be the date on which written notice of the option exercise is delivered to the Corporation. Except to the extent the sale and remittance procedure is utilized in connection with the exercise of the option, payment of the option price for the purchased shares must accompany such notice.

#### **B. Term and Exercise of Options.**

Each option granted under this Article Two shall be exercisable at such time or times, during such period, and for such number of shares as shall be determined by the Plan Administrator and set forth in the instrument evidencing the option grant. No such option, however, shall have a maximum term in excess of ten (10) years from the grant date. During the lifetime of the optionee, the option, together with any stock appreciation rights pertaining to such option, shall be exercisable only by the optionee and shall not be assignable or transferable by the optionee except for a transfer of the option by will or by the laws of descent and distribution following the optionee's death. However, the Plan Administrator shall have the discretion to provide that a non-statutory option may, in connection with the optionee's estate plan, be assigned in whole or in part during the optionee's lifetime either as (i) as a gift to one or more members of optionee's immediate family, to a trust in which optionee and/or one or more such family members hold more than fifty percent (50%) of the beneficial interest or an entity in which more than fifty percent (50%) of the voting interests are owned by optionee and/or one or more such family members, or (ii) pursuant to a domestic relations order. The assigned portion shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment and shall be set forth in such documents issued to the assignee as the Plan Administrator may deem appropriate.

#### **C. Termination of Service.**

1. Except to the extent otherwise provided pursuant to Section V of this Article Two, the following provisions shall govern the exercise period applicable to any options held by the optionee at the time of cessation of Service or death.

- Should the optionee cease to remain in Service for any reason other than death or permanent disability, then the period for which each outstanding option held by such optionee is to remain exercisable shall be limited to the three (3)-month period following the date of such cessation of Service. However, should optionee die during the three (3)-month period following his or her cessation of service, the personal representative of the optionee's estate or the person or persons to whom the option is transferred pursuant to the optionee's will or in accordance with the laws of descent and distribution shall have a twelve (12)-month period following the date of the optionee's death during which to exercise such option.

- In the event such Service terminates by reason of permanent disability (as defined in Section 22(e)(3) of the Internal Revenue Code), then the period for which each outstanding option held by the optionee is to remain exercisable shall be limited to the twelve (12)-month period following the date of such cessation of Service.

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- Should the optionee, after completing five (5) full years of service, die while in Service, then the exercisability of each of his or her outstanding options shall automatically accelerate so that each such option shall become fully exercisable with respect to the total number of shares of Common Stock at the time subject to such option and may be exercised for all or any portion of such shares. The personal representative of the optionee's estate or the person or persons to whom the option is transferred pursuant to the optionee's will or in accordance with the laws of descent and distribution shall have a twelve (12)-month period following the date of the optionee's death during which to exercise such option.

- In the event such service terminates by reason of death prior to the optionee obtaining five (5) full years of service, then the period for which each outstanding vested option held by the optionee at the time of death shall be exercisable by the optionee's estate or the person or persons to whom the option is transferred pursuant to the optionee's will shall be limited to the twelve (12)-month period following the date of the optionee's death.

- Under no circumstances, however, shall any such option be exercisable after the specified expiration date of the option term.

- Each such option shall, during such limited exercise period, be exercisable for any or all of the shares for which the option is exercisable on the date of the optionee's cessation of Service. Upon the expiration of such limited exercise period or (if earlier) upon the expiration of the option term, the option shall terminate and cease to be exercisable. However, each outstanding option shall immediately terminate and cease to remain outstanding, at the time of the optionee's cessation of Service, with respect to any shares for which the option is not otherwise at that time exercisable or in which the optionee is not otherwise vested.

- Should (i) the optionee's Service be terminated for misconduct (including, but not limited to, any act of dishonesty, willful misconduct, fraud or embezzlement) or (ii) the optionee make any unauthorized use or disclosure of confidential information or trade secrets of the Company or its parent or subsidiary corporations, then in any such event all outstanding options held by the optionee under this Article Two shall terminate immediately and cease to be exercisable.

2. The Plan Administrator shall have complete discretion, exercisable either at the time the option is granted or at any time while the option remains outstanding, to permit one or more options held by the optionee under this Article Two to be exercised, during the limited period of exercisability provided under subparagraph 1 above, not only with respect to the number of shares for which each such option is exercisable at the time of the optionee's cessation of Service but also with respect to one or more subsequent installments of purchasable shares for which the option would otherwise have become exercisable had such cessation of Service not occurred.

3. For purposes of the foregoing provisions of this Section I.C (and for all other purposes under the Plan):

- The optionee shall be deemed to remain in the **Service** of the Company for so long as such individual renders services on a periodic basis to the Company (or any parent or subsidiary corporation) in the capacity of an Employee, a non-employee member of the board of directors or an independent consultant or advisor, unless the agreement evidencing the applicable option grant specifically states otherwise.

- The optionee shall be considered to be an **Employee** for so long as such individual remains in the employ of the Company or one or more of its parent or subsidiary corporations, subject to the control and direction of the employer entity not only as to the work to be performed but also as to the manner and method of performance.

#### **D. Stockholder Rights.**

An optionee shall have no stockholder rights with respect to any shares covered by the option until such individual shall have exercised the option and paid the option price for the purchased shares.

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#### **E. Repurchase Rights.**

The shares of Common Stock acquired upon the exercise of options granted under this Article Two may be subject to repurchase by the Company in accordance with the following provisions:

(a) The Plan Administrator shall have the discretion to grant options which are exercisable for unvested shares of Common Stock under this Article Two. Should the optionee cease Service while holding such unvested shares, the Company shall have the right to repurchase any or all those unvested shares at the option price paid per share. The terms and conditions upon which such repurchase right shall be exercisable (including the period and procedure for exercise and the appropriate vesting schedule for the purchased shares) shall be established by the Plan Administrator and set forth in the instrument evidencing such repurchase right.

(b) All of the Company's outstanding repurchase rights shall automatically terminate, and all shares subject to such terminated rights shall immediately vest in full, upon the occurrence of any Corporate Transaction under Section III of this Article Two, except to the extent: (i) any such repurchase right is expressly assigned to the successor corporation (or parent thereof) in connection with the Corporate Transaction or (ii) such termination is precluded by other limitations imposed by the Plan Administrator at the time the repurchase right is issued.

(c) The Plan Administrator shall have the discretionary authority, exercisable either before or after the optionee's cessation of Service, to cancel the Corporation's outstanding repurchase rights with respect to one or more shares purchased or purchasable by the optionee under this Discretionary Option Grant Program and thereby accelerate the vesting of such shares in whole or in part at any time.

#### **II. INCENTIVE OPTIONS**

The terms and conditions specified below shall be applicable to all Incentive Options granted under this Article Two. Incentive Options may only be granted to individuals who are Employees of the Company. Options which are specifically designated as "non-statutory" options when issued under the Plan shall not be subject to such terms and conditions.

A. **Dollar Limitation.** The aggregate fair market value (determined as of the respective date or dates of grant) of the Common Stock for which one or more options granted to any Employee under this Plan (or any other option plan of the Company or its parent or subsidiary corporations) may for the first time become exercisable as incentive stock options under the Federal tax laws during any one calendar year shall not exceed the sum of One Hundred Thousand Dollars (\$100,000). To the extent the Employee holds two or more such options which become exercisable for the first time in the same calendar year, the foregoing limitation on the exercisability of such options as incentive stock options under the Federal tax laws shall be applied on the basis of the order in which such options are granted. Should the number of shares of Common Stock for which any Incentive Option first becomes exercisable in any calendar year exceed the applicable One Hundred Thousand Dollar (\$100,000) limitation, then that option may nevertheless be exercised in such calendar year for the excess number of shares as a non-statutory option under the Federal tax laws.

B. **10% Stockholder.** If any individual to whom an Incentive Option is granted is the owner of stock (as determined under Section 424(d) of the Internal Revenue Code) possessing 10% or more of the total combined voting power of all classes of stock of the Company or any one of its parent or subsidiary corporations, then the option price per share shall not be less than one hundred and ten percent (110%) of the fair market value per share of Common Stock on the grant date, and the option term shall not exceed five (5) years, measured from the grant date.

C. **Termination of Employment.** Any portion of an Incentive Option that remains outstanding (by reason of the optionee remaining in the Service of the Company, pursuant to the Plan Administrator's exercise of discretion under Section V of this Article Two, or otherwise) more than 3 months following the date an optionee ceases to be an Employee of the Company shall thereafter be exercisable as a non-statutory option under federal tax laws.

Except as modified by the preceding provisions of this Section II, the provisions of Articles One, Two and Five of the Plan shall apply to all Incentive Options granted hereunder.

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### III. CORPORATE TRANSACTIONS/CHANGES IN CONTROL

A. In the event of any of the following stockholder-approved transactions (a "Corporate Transaction"):

(i) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the State of the Company's incorporation,

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company in liquidation or dissolution of the Company, or

(iii) any reverse merger in which the Company is the surviving entity but in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from the persons holding those securities immediately prior to such merger,

then the exercisability of each option outstanding under this Article Two shall automatically accelerate so that each such option shall, immediately prior to the specified effective date for the Corporate Transaction, become fully exercisable with respect to the total number of shares of Common Stock at the time subject to such option and may be exercised for all or any portion of such shares. However, an outstanding option under this Article Two shall **not** so accelerate if and to the extent the acceleration of such option is subject to other limitations imposed by the Plan Administrator at the time of grant, unless the Plan Administrator, in its discretion, later determines to waive such limitations.

B. Immediately after the consummation of the Corporate Transaction, all outstanding options under this Article Two shall terminate and cease to be outstanding, except to the extent assumed by the successor corporation or its parent company. The Plan Administrator shall have complete discretion to provide, on such terms and conditions as it sees fit, for a cash payment to be made to any optionee on account of any option terminated in accordance with this paragraph, in an amount equal to the excess (if any) of (A) the fair market value of the shares subject to the option as of the date of the Corporate Transaction, over (B) the aggregate exercise price of the option.

C. Each outstanding option under this Article Two which is assumed in connection with the Corporate Transaction or is otherwise to continue in effect shall be appropriately adjusted, immediately after such Corporate Transaction, to apply and pertain to the number and class of securities which would have been issued to the option holder, in consummation of such Corporate Transaction, had such person exercised the option immediately prior to such Corporate Transaction. Appropriate adjustments shall also be made to the option price payable per share, provided the aggregate option price payable for such securities shall remain the same. In addition, the class and number of securities available for issuance under the Plan following the consummation of the Corporate Transaction shall be appropriately adjusted.

D. The grant of options under this Article Two shall in no way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

E. The exercisability of each outstanding option under this Article Two shall automatically accelerate, and the Company's outstanding repurchase rights under this Article Two shall immediately terminate upon the occurrence of a Change in Control.

F. For purposes of this Section III (and for all other purposes under the Plan), a Change in Control shall be deemed to occur in the event:

(i) any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders; or

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(ii) there is a change in the composition of the Board over a period of twenty-four (24) consecutive months or less such that a majority of the Board members (rounded up to the next whole number) ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who either (A) have been Board members continuously since the beginning of such period or (B) have been elected or nominated for election as Board members during such period by at least two-thirds of the Board members described in clause (A) who were still in office at the time such election or nomination was approved by the Board.

G. All options accelerated in connection with the Change in Control shall remain fully exercisable until the expiration or sooner termination of the option term.

H. The portion of any Incentive Option accelerated under this Section III in connection with a Corporate Transaction or Change in Control shall remain exercisable as an incentive stock option under the Federal tax laws only to the extent the dollar limitation of Section II of this Article Two is not exceeded. To the extent such dollar limitation is exceeded, the accelerated portion of such option shall be exercisable as a non-statutory option under the Federal tax laws.

#### **IV. STOCK APPRECIATION RIGHTS**

A. Provided and only if the Plan Administrator determines in its discretion to implement the stock appreciation right provisions of this Section IV, one or more optionees may be granted the right, exercisable upon such terms and conditions as the Plan Administrator may establish, to surrender all or part of an unexercised option granted under this Article Two in exchange for a distribution from the Company in an amount equal to the excess of (i) the fair market value (on the option surrender date) of the number of shares in which the optionee is at the time vested under the surrendered option (or surrendered portion thereof) over (ii) the aggregate option price payable for such vested shares. The distribution may be made in shares of Common Stock valued at fair market value on the option surrender date, in cash, or partly in shares and partly in cash, as the Plan Administrator shall determine in its sole discretion.

B. The shares of Common Stock subject to any option surrendered for an appreciation distribution pursuant to this Section IV shall **not** be available for subsequent option grant under the Plan.

#### **V. EXTENSION OF EXERCISE PERIOD**

The Plan Administrator shall have full power and authority, exercisable either at the time the option is granted or at any time while the option remains outstanding, to extend the period of time for which any option granted under this Article Two is to remain exercisable following the optionee's cessation of Service or death from the limited period in effect under Section I.C.1 of Article Two to such greater period of time as the Plan Administrator shall deem appropriate; provided, however, that in no event shall such option be exercisable after the specified expiration date of the option term.

### **ARTICLE THREE**

#### **STOCK ISSUANCE PROGRAM**

##### **I. STOCK ISSUANCE TERMS**

Shares of Common Stock may be issued under the Stock Issuance Program through direct and immediate issuances without any intervening option grants. Each such stock issuance shall be evidenced by a Stock Issuance Agreement which complies with the terms specified below. Shares of Common Stock may also be issued under the Stock Issuance Program pursuant to share right awards which entitle the recipients to receive shares upon the attainment of designated Service and/or performance goals.

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**A. Purchase Price.**

1. The purchase price per share shall be fixed by the Plan Administrator, but shall not be less than one hundred percent (100%) of the fair market value per share of Common Stock on the issuance date.

2. Shares of Common Stock may be issued under the Stock Issuance Program for any of the following items of consideration which the Plan Administrator may deem appropriate in each individual instance:

- cash or check made payable to the Company, or
- services rendered to the Company (or any parent or subsidiary).

**B. Vesting Provisions.**

1. The Plan Administrator may issue shares of Common Stock under the Stock Issuance Program which are fully and immediately vested upon issuance or which are to vest in one or more installments over the participant's period of Service or upon attainment of specified performance objectives. Alternatively, the Plan Administrator may issue share right awards under the Stock Issuance Program which shall entitle the recipient to receive a specified number of shares of Common Stock upon the attainment of one or more Service and/or performance goals established by the Plan Administrator. Upon the attainment of such Service and/or performance goals, fully-vested shares of Common Stock shall be issued in satisfaction of those share right awards.

2. Any new, substituted or additional securities or other property (including money paid other than as a regular cash dividend) issued by reason of any stock dividend, stock split, recapitalization, combination of shares, exchange of shares or other change affecting the outstanding Common Stock as a class without the Company's receipt of consideration, shall be issued or set aside with respect to the shares of unvested Common Stock granted to a participant or subject to a participant's share right award, subject to (i) the same vesting requirements applicable to the participant's unvested shares of Common Stock or share rights award, and (ii) such escrow arrangements as the Plan Administrator shall deem appropriate.

3. The participant shall have full stockholder rights with respect to any shares of Common Stock issued to the participant under the Stock Issuance Program, whether or not the participant's interest in those shares is vested. Accordingly, the participant shall have the right to vote such shares and to receive any regular cash dividends paid on such shares.

4. The participant shall not have any stockholders rights with respect to any shares of Common Stock subject to a share right award. However, the Plan Administrator may provide for a participant to receive one or more dividend equivalents with respect to such shares, entitling the participant to all regular cash dividends payable on the shares of Common Stock underlying the share right award, which amounts shall be (i) subject to the same vesting requirements applicable to the shares of Common Stock underlying the share rights award, and (ii) payable upon issuance of the shares to which such dividend equivalents relate.

5. Should the participant cease to remain in Service while holding one or more unvested shares of Common Stock issued under the Stock Issuance Program or should the performance objectives not be attained with respect to one or more such unvested shares of Common Stock, then those shares shall be immediately surrendered to the Company for cancellation, and the participant shall have no further stockholder rights with respect to those shares. To the extent the surrendered shares were previously issued to the participant for consideration paid in cash, the Company shall repay to the participant the cash consideration paid for the surrendered shares.

6. The Plan Administrator may in its discretion waive the surrender and cancellation of one or more unvested shares of Common Stock which would otherwise occur upon the cessation of the Participant's Service or the non-attainment of the performance objectives applicable to those shares. Such waiver shall result in the immediate vesting of the participant's interest in the shares of Common Stock as to which the waiver applies. Such waiver may be effected at any time, whether before or after the participant's cessation of Service or the attainment or non-attainment of the applicable performance objectives.

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7. Outstanding share right awards under the Stock Issuance Program shall automatically terminate, and no shares of Common Stock shall actually be issued in satisfaction of those awards, if the Service and/or performance goals established for such awards are not attained. The Plan Administrator, however, shall have the discretionary authority to issue shares of Common Stock in satisfaction of one or more outstanding share right awards as to which the designated Service and/or performance goals are not attained. Such authority may be exercised at any time, whether before or after the participant's cessation of Service or the attainment or non-attainment of the applicable performance objectives.

## **II. CORPORATE TRANSACTION/CHANGE IN CONTROL**

A. All of the Company's outstanding repurchase rights under the Stock Issuance Program shall terminate automatically, and all the shares of Common Stock subject to those terminated rights shall immediately vest in full, in the event of any Corporate Transaction, except to the extent (i) those repurchase rights are to be assigned to the successor corporation (or parent thereof) in connection with the such Corporate Transaction, or (ii) such accelerated vesting is precluded by other limitations imposed in the Stock Issuance Agreement, unless the Plan Administrator determines to waive such limitations.

B. Each repurchase right which is assigned in connection with (or is otherwise to continue in effect after) a Corporate Transaction shall be appropriately adjusted such that it shall apply and pertain to the number and class of securities issued to the participant in consummation of the Corporate Transaction with respect to the shares granted to participant under this Article III.

C. All of the Company's outstanding repurchase rights under the Stock Issuance Program shall automatically terminate, and all shares of Common Stock subject to those terminated rights shall immediately vest, in the event of any Change in Control.

D. All shares of Common Stock underlying outstanding share right awards issued under the Stock Issuance Program shall vest, and all of the shares of Common Stock subject to such share right awards shall be issued to participants, immediately prior to the consummation of any Corporate Transaction or Change in Control.

## **III. SHARE ESCROW/LEGENDS**

Unvested shares may, in the Plan Administrator's discretion, be held in escrow by the Company until the participant's interest in such shares vests or may be issued directly to the participant with restrictive legends on the certificates evidencing those unvested shares.

## **ARTICLE FOUR AUTOMATIC OPTION GRANT PROGRAM**

### **I. ELIGIBILITY.**

The individuals eligible to receive automatic option grants pursuant to the provisions of this Article Four shall be (i) those individuals who, after the effective date of this amendment and restatement, first become non-employee Board members, whether through appointment by the Board, election by the Company's stockholders, or by continuing to serve as a Board member after ceasing to be employed by the Company, and (ii) those individuals already serving as non-employee Board members on the effective date of this amendment and restatement. As used herein, a "non-employee" Board member is any Board member who is not employed by the Company on the date in question.

### **II. TERMS AND CONDITIONS OF AUTOMATIC OPTION GRANTS**

A. **Grants.** Option grants shall be made under this Article Three as follows:

1. Each individual who first becomes a non-employee Board member on or after the effective date of this amendment and restatement shall automatically be granted at such time a non-statutory stock option under the terms and conditions of this Article Four, to purchase a number shares of Common Stock equal to the product of (i) 20,000, and (ii) a fraction, the numerator of which is the number of months (rounded to the nearest whole number) remaining between the date such Board member first became a non-employee Board member and the Company's next scheduled Annual Stockholders Meeting, and the denominator of which is 12.

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2. Immediately following each Annual Stockholders Meeting of the Company, each individual who is then serving as a non-employee Board member (except for those individuals first elected to serve as non-employee Board members at such meeting), shall automatically be granted a non-statutory stock option under this Article Four to acquire 15,000 shares of Common Stock.

**B. Exercise Price.** The exercise price per share of each automatic option grant made under this Article Four shall be equal to one hundred percent (100%) of the fair market value per share of Common Stock on the automatic grant date.

**C. Payment.** The exercise price shall be payable in one of the alternative forms specified below:

(i) full payment in cash or check made payable to the Company's order; or

(ii) full payment in shares of Common Stock held for the requisite period necessary to avoid a charge to the Company's reported earnings and valued at fair market value on the Exercise Date (as such term is defined below); or

(iii) full payment in a combination of shares of Common Stock held for the requisite period necessary to avoid a charge to the Company's reported earnings and valued at fair market value on the Exercise Date and cash or check payable to the Company's order; or

(iv) full payment through a sale and remittance procedure pursuant to which the non-employee Board member (I) shall provide irrevocable written instructions to a designated brokerage firm to effect the immediate sale of the purchased shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate exercise price payable for the purchased shares and shall (II) concurrently provide written directives to the Company to deliver the certificates for the purchased shares directly to such brokerage firm in order to complete the sale transaction.

For purposes of this subparagraph C, the Exercise Date shall be the date on which written notice of the option exercise is delivered to the Company. Except to the extent the sale and remittance procedure specified above is utilized for the exercise of the option, payment of the option price for the purchased shares must accompany the exercise notice.

**D. Option Term.** Each automatic grant under this Article Four shall have a term of ten (10) years measured from the automatic grant date.

**E. Exercisability.**

1. Each initial automatic grant made pursuant to Section II.A.1 of this Article Four shall vest and become exercisable over the period extending from the date of grant to the scheduled date of the next Annual Stockholders Meeting following the grant. A pro rata portion of such automatic grant shall vest on the last day of each calendar month following the date of grant, with the final portion vesting on the scheduled date of such Annual Stockholders Meeting.

2. Each 15,000 share automatic grant made pursuant to Section II.A.2 of this Article Four shall vest and become exercisable for 1/12th of the option shares upon the optionee's completion of each month of Board service over the twelve (12)-month period measured from the automatic grant date.

**F. Non-Transferability.** During the lifetime of the optionee, each automatic option, together with the limited stock appreciation right pertaining to such option, shall be exercisable only by the optionee, except to the extent such option or the limited stock appreciation right is assigned or transferred (i) by will or by the laws of descent and distribution following the optionee's death, or (ii) during optionee's lifetime either (A) as a gift in connection with the optionee's estate plan to one or more members of optionee's immediate family, to a trust in which optionee and/or one or more such family members hold more than fifty percent (50%) of the beneficial interest or to an entity in which more than fifty percent (50%) of the voting interests are owned by optionee and/or one or more such family members, or (B) pursuant to a domestic relations order. The portion of any option assigned or transferred during optionee's lifetime shall be exercisable only by the person or persons who acquire a proprietary interest in the option pursuant to such assignment. The terms applicable to the assigned portion shall be the same as those in effect for this option immediately prior to such assignment and shall be set forth in such documents issued to the assignee as the Plan Administrator may deem appropriate.

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### **G. Cessation of Board Service.**

1. Should the optionee cease to serve as a Board member for any reason while holding one or more automatic option grants under this Article Four, then such optionee shall have the remainder of the ten (10) year term of each such option in which to exercise each such option for any or all of the shares of Common Stock for which the option is exercisable at the time of such cessation of Board service. Each such option shall immediately terminate and cease to be outstanding, at the time of such cessation of Board service, with respect to any shares for which the option is not otherwise at that time exercisable. Upon the expiration of the ten (10)-year option term, the automatic grant shall terminate and cease to be outstanding in its entirety. Upon the death of the optionee, whether before or after cessation of Board service, any option held by optionee at the time of optionee's death may be exercised, for any or all of the shares of Common Stock for which the option was exercisable at the time of cessation of Board service by the optionee and which have not been theretofore exercised by the optionee, by the personal representative of the optionee's estate or by the person or persons to whom the option is transferred pursuant to the optionee's will or in accordance with the laws of descent and distribution. Any such exercise must occur during the remainder of the ten (10) year term of such option.

H. **Stockholder Rights.** The holder of an automatic option grant under this Article Four shall have none of the rights of a stockholder with respect to any shares subject to such option until such individual shall have exercised the option and paid the exercise price for the purchased shares.

### **III. CORPORATE TRANSACTIONS/CHANGES IN CONTROL**

A. In the event of a Corporate Transaction, the exercisability of each option outstanding under this Article Four shall automatically accelerate so that each such option shall, immediately prior to the specified effective date for the Corporate Transaction, become fully exercisable with respect to the total number of shares of Common Stock at the time subject to such option and may be exercised for all or any portion of such shares.

B. Immediately after the consummation of the Corporate Transaction, all outstanding options under this Article Four shall terminate and cease to be outstanding, except to the extent assumed by the successor corporation or its parent company. If so provided by the terms of the Corporate Transaction, the optionee shall receive a cash payment on account of any option terminated in accordance with this paragraph, in an amount equal to the excess (if any) of (A) the fair market value of the shares subject to the option as valued pursuant to the Corporate Transaction over (B) the aggregate exercise price of the option.

C. Each outstanding option under this Article Four which is assumed in connection with the Corporate Transaction or is otherwise to continue in effect shall be appropriately adjusted, immediately after such Corporate Transaction, to apply and pertain to the number and class of securities which would have been issued to the option holder, in consummation of such Corporate Transaction, had such person exercised the option immediately prior to such Corporate Transaction. Appropriate adjustments shall also be made to the option price payable per share, provided the aggregate option price payable for such securities shall remain the same.

D. In connection with any Change in Control, the exercisability of each option grant outstanding at the time under this Article Four shall automatically accelerate so that each such option shall, immediately prior to the specified effective date for the Change in Control, become fully exercisable with respect to the total number of shares of Common Stock at the time subject to such option and may be exercised for all or any portion of such shares.

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E. The automatic grant of options under this Article Four shall in no way affect the right of the Company to adjust, reclassify, reorganize or otherwise change its capital or business structure or to merge, consolidate, dissolve, liquidate or sell or transfer all or any part of its business or assets.

#### **IV. STOCK APPRECIATION RIGHTS**

A. With respect to options granted under the Automatic Option Grant Program prior to March 7, 2006:

1. Upon the occurrence of a Hostile Take-Over, the optionee shall have a thirty (30)-day period in which to surrender to the Company each option held by him or her under this Article Four. The optionee shall in return be entitled to a cash distribution from the Company in an amount equal to the excess of (i) the Take-Over Price of the shares of Common Stock at the time subject to each surrendered option (whether or not the option is then exercisable for those shares) over (ii) the aggregate exercise price payable for such shares. The cash distribution shall be made within five (5) days following the date the option is surrendered to the Company, and neither the approval of the Plan Administrator nor the consent of the Board shall be required in connection with the option surrender and cash distribution. Any unsurrendered portion of the option shall continue to remain outstanding and become exercisable in accordance with the terms of the instrument evidencing such grant. This limited stock appreciation right shall in all events terminate upon the expiration or sooner termination of the option term and may not be assigned or transferred by the optionee.

2. For purposes of Article Four, the following definitions shall be in effect:

- A **Hostile Take-Over** shall be deemed to occur in the event any person or related group of persons (other than the Company or a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 of the 1934 Act, as amended) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which the Board does not recommend such stockholders to accept.

- The **Take-Over Price** per share shall be deemed to be equal to the fair market value per share on the option surrender date.

B. With respect to each option granted under the Automatic Option Grant Program on and after March 7, 2006, each optionee shall have the right to surrender all or part of the option (to the extent not then exercised) in exchange for a distribution from the Company in an amount equal to the excess of (i) the fair market value (on the option surrender date) of the number of shares in which the optionee is at the time vested under the surrendered option (or surrendered portion thereof) over (ii) the aggregate option price payable for such vested shares. The distribution shall be made in shares of Common Stock valued at fair market value on the option surrender date.

C. The shares of Common Stock subject to any option surrendered for an appreciation distribution pursuant to this Section IV shall **not** be available for subsequent option grant under the Plan.

#### **ARTICLE FIVE MISCELLANEOUS**

##### **I. AMENDMENT OF THE PLAN**

The Board shall have complete and exclusive power and authority to amend or modify the Plan in any or all respects whatsoever. However, no such amendment or modification shall, without the consent of the holders, adversely affect rights and obligations with respect to options at the time outstanding under the Plan. In addition, certain amendments may require stockholder approval pursuant to applicable laws or regulations.

##### **II. TAX WITHHOLDING**

A. The Company's obligation to deliver shares or cash upon the exercise of stock options or stock appreciation rights or upon the grant or vesting of direct stock issuances under the Plan shall be subject to the satisfaction of all applicable Federal, State and local income and employment tax withholding requirements.

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B. The Plan Administrator may, in its discretion and upon such terms and conditions as it may deem appropriate, provide any or all holders of outstanding options or stock issuances under the Plan (other than the automatic option grants under Article Four) with the election to have the Company withhold, from the shares of Common Stock otherwise issuable upon the exercise or vesting of such awards, a whole number of such shares with an aggregate fair market value equal to the minimum amount necessary to satisfy the Federal, State and local income and employment tax withholdings (the "Taxes") incurred in connection with the acquisition or vesting of such shares. In lieu of such direct withholding, one or more participants may also be granted the right to deliver whole shares of Common Stock to the Company in satisfaction of such Taxes. Any withheld or delivered shares shall be valued at their fair market value on the applicable determination date for such Taxes.

### **III. EFFECTIVE DATE AND TERM OF PLAN**

A. The Plan, as amended and restated, shall be effective on the date specified in the Board of Directors resolution adopting the Plan. Except as provided below, each option issued and outstanding under the Plan immediately prior to such effective date shall continue to be governed solely by the terms and conditions of the agreement evidencing such grant, and nothing in this restatement of the Plan shall be deemed to affect or otherwise modify the rights or obligations of the holders of such options with respect to their acquisition of shares of Common Stock thereunder. The Plan Administrator shall, however, have full power and authority, under such circumstances as the Plan Administrator may deem appropriate (but in accordance with Article I of this Section Five), to extend one or more features of this amendment and restatement to any options outstanding on the effective date.

B. Unless sooner terminated in accordance with the other provisions of this Plan, the Plan shall terminate upon the earlier of (i) March 6, 2016 or (ii) the date on which all shares available for issuance under the Plan shall have been issued or cancelled pursuant to the exercise, surrender or cash-out of the options granted hereunder. If the date of termination is determined under clause (i) above, then any options or stock issuances outstanding on such date shall continue to have force and effect in accordance with the provisions of the agreements evidencing those awards.

C. Options may be granted with respect to a number of shares of Common Stock in excess of the number of shares at the time available for issuance under the Plan, provided each granted option is not to become exercisable, in whole or in part, at any time prior to stockholder approval of an amendment authorizing a sufficient increase in the number of shares issuable under the Plan.

### **IV. USE OF PROCEEDS**

Any cash proceeds received by the Company from the sale of shares pursuant to options or stock issuances granted under the Plan shall be used for general corporate purposes.

### **V. REGULATORY APPROVALS**

A. The implementation of the Plan, the granting of any option hereunder, and the issuance of stock (i) upon the exercise or surrender of any option or (ii) under the Stock Issuance Program shall be subject to the procurement by the Company of all approvals and permits required by regulatory authorities having jurisdiction over the Plan, the options granted under it and the stock issued pursuant to it.

B. No shares of Common Stock or other assets shall be issued or delivered under the Plan unless and until there shall have been compliance with all applicable requirements of Federal and state securities laws, including (to the extent required) the filing and effectiveness of the Form S-8 registration statement for the shares of Common Stock issuable under the Plan, and all applicable listing requirements of any stock exchange (or the Nasdaq National Market, if applicable) on which Common Stock is then trading.

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## **VI. NO EMPLOYMENT/SERVICE RIGHTS**

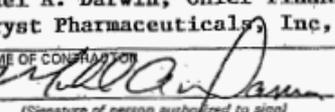
Neither the action of the Company in establishing or restating the Plan, nor any action taken by the Plan Administrator hereunder, nor any provision of the Plan shall be construed so as to grant any individual the right to remain in the employ or service of the Company (or any parent or subsidiary corporation) for any period of specific duration, and the Company (or any parent or subsidiary corporation retaining the services of such individual) may terminate such individual's employment or service at any time and for any reason, with or without cause.

## **VII. MISCELLANEOUS PROVISIONS**

A. Except to the extent otherwise expressly provided in the Plan, the right to acquire Common Stock or other assets under the Plan may not be assigned, encumbered or otherwise transferred by any participant.

B. The provisions of the Plan relating to the exercise of options and the issuance and/or vesting of shares shall be governed by the laws of the State of Alabama without resort to that state's conflict-of-laws provisions, as such laws are applied to contracts entered into and performed in such State.

NOTE: THIS DOCUMENT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST PURSUANT TO RULE 24B-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934. PORTIONS OF THIS DOCUMENT FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED HAVE BEEN REDACTED AND ARE MARKED HEREIN BY "\_\_\_\_". SUCH REDACTED INFORMATION HAS BEEN FILED SEPARATELY WITH THE COMMISSION PURSUANT TO THE CONFIDENTIAL TREATMENT REQUEST.

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) <input checked="" type="checkbox"/>		RATING	PAGE OF PAGES 1 28		
2. CONTRACT (Proc. Inst. Ident.) NO. HHS0100200700032C		3. EFFECTIVE DATE		4. REQUISITION/PURCHASE REQUEST/PROJECT NO.			
5. ISSUED BY HHS/OS/OPHEP/OPHEMC 330 Independence Ave, SW, Rm G640 Washington, DC 20201		CODE	6. ADMINISTERED BY (If other than item 5)		CODE		
7. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) BioCryst Pharmaceuticals Inc. 2190 Parkway Lake Drive Birmingham, AL 35244  [REDACTED]				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT N/A			
CODE				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN		ITEM 5	
11. SHIP TO/MARK FOR See Paragraph D.1.		CODE	12. PAYMENT WILL BE MADE BY See Article G.4.		CODE		
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) ( ) <input type="checkbox"/> 41 U.S.C. 253(c) ( )				14. ACCOUNTING AND APPROPRIATION DATA			
15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
	SEE SECTION B						
<b>15G. TOTAL AMOUNT OF CONTRACT</b>					<b>\$102,661,429</b>		
<b>18. TABLE OF CONTENTS</b>							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	20
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	4	X	J	LIST OF ATTACHMENTS	27
X	D	PACKAGING AND MARKING	8	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	9	X	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	28
X	F	DELIVERIES OR PERFORMANCE	10		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	12		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	15				
<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE</b>							
17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 2 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any condition sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.			
19A. NAME AND TITLE OF SIGNER (Type or print) Michael A. Darwin, Chief Financial Officer BioCryst Pharmaceuticals, Inc.				20A. NAME OF CONTRACTING OFFICER [REDACTED]			
19B. NAME OF CONTRACTOR BY  (Signature of person authorized to sign)			19C. DATE SIGNED 12-08-06				
AUTHORIZED FOR LOCAL REPRODUCTION Previous edition is usable				STANDARD FORM 26 (REV. 10-2002) Prescribed by GSA - FAR 148 CFR 101.114(a)			

**SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS**

**B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This project from the Department of Health and Human Services (HHS) through the Office of Public Health Emergency Medical Countermeasures (OPHEMC) within the Office of Public Health Emergency Preparedness (OPHEP) provides incremental multi-year funding for cost-reimbursable contracts for the advanced development of prophylactic and therapeutic drugs against pandemic and seasonal influenza viral pathogens leading towards U.S.-licensure. The antiviral drugs of interest may include any compound or drug providing anti-influenza. These may include synthetic chemical compounds, snRNAi, polyclonal/monoclonal antibody cocktails or other drugs, which could be used in the treatment and/or prophylaxis to decrease the morbidity and mortality associated with seasonal and pandemic influenza. The objective of this project is to facilitate the development and U.S.-licensure of antiviral drugs effective as prophylactic/therapeutic agents against influenza virus infection.

**B.2. HHSAR 352.232-74 Estimated Cost and Fixed Fee — Incrementally Funded Contract (Apr 1984)**

(a) It is estimated that the total cost to the Government for full performance of this contract will be \$102,661,429, of which the sum of \_\_\_\_\_ represents the estimated reimbursable costs and \_\_\_\_\_ represents the fixed fee.

(b) Total funds currently available for payment and allotted to this contract are \_\_\_\_\_, of which \_\_\_\_\_ represents the estimated reimbursable costs and \_\_\_\_\_ represents the fixed-fee. For further provisions on funding, see the Limitation of Funds clause.

(c) It is estimated that the amount currently allotted will cover performance through \_\_\_\_\_.

(d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor

**B3. Cancellation Ceiling**

(a) This clause does not apply when the contract is fully funded.

(b) The total funding in B.2 (c) includes an amount that covers the cancellation charge described in FAR 52.217-2, Cancellation Under Multi-year Contracts. The cancellation charge shall not exceed \$\_\_\_\_\_ (insert dollar amount or express as a percentage of total funding under B.2 (b)).

**B.4. CONTRACT LINE ITEM NUMBERS (CLINS)**

<u>ITEM</u>	<u>SUPPLIES / SERVICES</u>	<u>QTY/UNIT</u>	<u>EST. COST</u>	<u>FIXED FEE</u>	<u>TOTAL EST. CPF</u>
0001	Product Development Plan (milestone 1)	1 Job			
0002	Clinical Development, and Regulatory Licensure Plans (milestone 2)	1 Job			
0003	Feasibility Plan (milestone 3)	1 Job			
0004	Contractor Defined Milestones (milestone 4); See milestone 4 of the Statement of Work for key elements	1 Job			
0005	Technical Progress Reports and Executive Summary	12 reports per year			
0006	Security of Contract Operations and Information Technology Security	Not Separately Priced (NSP)	NSP	NSP	NSP
0007	Final Report	1 report			

**Note:** For the purposes of this contract, “United States” and “U.S.” are defined to include the 50 states, the District of Columbia, Puerto Rico.

## SECTION C — DESCRIPTION/SPECIFICATIONS

### C.1 STATEMENT OF WORK

#### Purpose

The purpose of this contract is to support advanced stage development of new antiviral compounds for the treatment and prophylaxis of pandemic and seasonal influenza leading toward submission of a U.S. licensure application and development of required industrial capacity to support implementation of the influenza antivirals at full production capacity at or before the onset of a pandemic. Influenza antivirals shall be produced at one or more Food and Drug Administration (FDA)-licensed manufacturing facilities and shall provide sufficient surge capacity to contribute substantially to U.S. and ideally global antiviral needs during an influenza pandemic.

This advanced development contract is milestone-driven and funding is expected to occur in phases. Periodic assessments of progress will be conducted by DHHS. Continuation of effort on initial and subsequent milestones and associated funding will be based on contractor performance, timeliness and quality of deliverables, availability of other antiviral drugs and products deemed more advantageous to the USG, and consultations between the contractor, HHS, and interagency working group members. This paragraph does not limit the Government's rights under contract clauses that include, but are not limited to, FAR 52.217-2, Cancellation Under Multi-year contracts, and 52.249-6, Termination (Cost-Reimbursement).

#### STATEMENT OF WORK

Independently and not as an agent of the government, the contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities not otherwise provided by the government as needed to perform the work described below.

The proposal will include a Contractor Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget. The level of detail contained in the CWP and the corresponding Gantt chart will be sufficient to facilitate management and execution of the contract.

#### Milestones

- I. Milestone 1: Within three (3) months of contract award, the Contractor shall provide to the HHS for review and acceptance a milestone-driven **Product Development Plan** for development of influenza antiviral drugs. This plan shall include: a) *in vitro* and *in vivo* antiviral testing, b) pre-clinical studies (already completed) to support clinical evaluation; c) process development and scale up manufacturing of antiviral compounds; d) clinical and consistency lot manufacturing for FDA product licensure, e) general clinical development plan including development and validation of clinical sample assays; f) product lot release assay development and validation, and g) regulatory master plan for product licensure. Antiviral agents used in these studies may be produced by the Contractor or a corporate partner.
- II. Milestone 2: Within six (6) months of contract award, the Contractor shall submit to HHS for review and acceptance complete milestone-driven **Clinical Development and Regulatory Licensure Plans** to initiate new antiviral development, clinical studies, as appropriate based on the current stage of development and as outlined in the development, testing, and manufacturing plan.
  - A. A pre-clinical testing plan and results that are integrated with the clinical testing and manufacturing plans using the most current and available information including consultation with Center for Drug Evaluation and Research (CDER) at FDA. As this stage of product development should be completed, and then a detailed summary of the studies and results should be incorporated as an appendix in the preliminary results section of the technical proposal.

- B. A clinical testing plan that is integrated with the pre-clinical testing and manufacturing plans using the most current and available information including consultation with FDA CDER. Clinical trials performed as a result of this solicitation shall include any of Phase I and Phase 2, trials, as needed to achieve U.S. licensure. Trials should include children, adults, and the elderly, as needed, to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the schedule for each clinical trial should clearly indicate key outcomes, populations, study sites and collaborators, analytic strategy, sample size, timelines, and other key components. If one or more these stages of product development have been completed, then a detailed summary of the studies and results should be incorporated as an appendix in the preliminary results section of the technical proposal.
- C. A regulatory plan that is integrated with all products and clinical testing and manufacturing activities using the most current and available information including consultation with FDA CDER.
- III. Milestone 3: Within twelve (12) months of contract award the Contractor shall provide the USG with the following, as appropriate for the antiviral drug(s) being developed. **A feasibility plan** comprehensive of all antiviral drug descriptions and studies for U.S. licensure as follows:
- (a) Mechanism of action, antiviral activity *in vitro*, and resistance studies such as drug resistance and cross resistance, immune response.
  - (b) Pharmacokinetics studies like drug absorption and bioavailability, distribution, metabolism, elimination,
  - (c) Animal toxicology studies.
  - (d) Drug interactions, carcinogenesis, mutagenesis and fertility impairment studies.
  - (e) Special population studies including pediatric, geriatric groups and groups with impaired organ functions.
  - (f) Treatment, prophylaxis, dosage, administration routes, adverse events.
  - (g) Safety studies in different age group of people.
  - (h) Seasonal influenza challenge studies
- IV. Milestone 4: Contractor defined milestones
- The Contractor shall provide a work breakdown structure including comprehensive and integrated timelines (Gantt chart) and major milestones to complete the remaining the scope of work as relevant given the stage of antiviral development and evaluation toward product licensure. The Contractor shall propose milestones at which time data will be presented summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential milestones may include FDA acceptance of an IND application, production of investigational lots of antiviral drugs validation of QC lot release product methods, validation of manufacturing processes, stability study programs, consistency lot manufacturing, completion of clinical trials and progress to a new phase of antiviral drug evaluation, submission of a licensure application.

## **Security of Contract Operations and Information Technology**

The work performed for development, manufacture, transport, storage and distribution will be performed under a detailed security plan that ensures against theft, tampering or destruction of the specific pertinent product-related material, equipment, documents, information, and data. The Contractor shall develop a written **Draft** Security Plan, for the protection of physical facilities, using, for example, fencing, controlled access, surveillance equipment, 2-person integrity rule, tamper evident packaging, and armed guards. The Contractor shall submit the Draft Security Plan to the Contracting Officer and Project Officer with the technical proposal. The Draft Security Plan shall describe the procedures to be utilized to manage and monitor the general internal operations of the firm and a description of the Contractor's facility(ies) in which the work will be performed and related activity conducted, including work by any subcontractors and consultants. The Draft Security Plan shall also include the Contractor's procedures for screening and background investigations of all employees, subcontractors and consultants who have access to the development, manufacturing, transport, storage, and distribution of the product. Such background inquiries and screening should include, but not be limited to, education, previous employment, fingerprints and complete criminal history (FBI, state, and local), credit reports, civil actions, DMV, social security account number verification, drug testing, and references. Screening data should include the employee's full name, any aliases, date(s) of birth, and Social Security numbers and other identifying numbers as appropriate, e.g., Passport number. (At time of award) The US Government can audit and review at its discretion the Contractor's personnel records in order to confirm compliance with personnel screening and background investigation requirements. Such access will also include interviews with relevant Contractor human resources supervisory and hiring personnel.

This plan shall ensure confidentiality, integrity of, and timely access by authorized individuals to data, information and information technology systems, consistent with OMB Circular A-130, Appendix III. This plan should also address the Contractor's security-related due diligence on public information, marketing, advertising, including use of web site[s] impacting product and supply chain security.

This plan shall also include the security measures to be used to protect the medical countermeasure to be stored at the Contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc.

The Project Officer and the Information Protection and Systems Security (IPASS) Coordinator will review the plan and submit comments to the Contractor within \_\_\_\_\_after receipt. The Contractor shall revise the Security Plan, if required, and submit a Final Security Plan to the Government within \_\_\_\_\_. Upon completion of all the required security measures, the Contractor shall supply to the Project Officer a letter certifying compliance. Performance of work under this contract shall be in accordance with this written Security Plan.

**[END OF STATEMENT OF WORK]**

### **Meetings and conferences:**

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Project Officer. Such meetings may include, but are not limited to, meetings of all Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues,; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences with the Contractor and subcontractors with HHS officials will be held at times and dates to be determined to review technical and product development progress.

## C.2. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the Contracting Officer and the Project Officer technical progress reports covering the work accomplished during each reporting period on a periodical basis as established by the Project Officer. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the following format:

- I. Technical Progress Reports: On the fifteenth of each month for the previous calendar month or within fifteen days past the achievement of prescribed project milestones, the Contractor shall submit to the Project Officer and the Contracting Officer. The frequency of Technical Progress Reporting will be determined by the Contracting Officer and Project Officer after contract award. The format and type of Technical Progress Report and Executive Summary will be provided by the Project Officer. Technical Progress Reports will include project timelines and milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or Word Perfect, Microsoft Excel, Microsoft Project Manger, and/or Adobe Acrobat PDF files. Such reports shall include the following specific information:
  - A. Title page containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission;
  - B. Introduction/Background — An introduction covering the purpose and scope of the contract effort;
  - C. Progress — The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period;
  - D. Issues — Issues resolved, new issues, and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines are provided.
  - E. Invoices — Summary of any invoices submitted during the reporting period.
  - F. Action Items — Summary table of activities or tasks to be accomplished by a certain date and by whom.
  - G. Distribution List — A list of persons receiving the Technical Progress report
  - H. Attachments — Results on the project are provided as attachments
- II. The Executive Summary, which shall accompany each Technical Progress Report, will be formatted in Microsoft Power Point presentations and include the following:
  - A. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission;
  - B. Project Progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets;
  - C. Project Issues presented headings and each item as a talking point bullet.
- III. Final Reports — By the expiration date of the contract, the Contractor shall submit a comprehensive Final Report that shall detail, document, and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the Project Officer for review and revision, then the original, four copies, and an electronic file containing the Final Report with revisions shall be submitted to the Project Officer for distribution to the Contracting Officer and the Program.

**SECTION D—PACKAGING, MARKING AND SHIPPING**

**D.1. SHIPPING**

**I. Method of Delivery**

Unless otherwise specified by the Contracting Officer or the Contracting Officer's representative, delivery of items, to be furnished to the government under this contract (including invoices), shall be made by first class mail.

**II. Addressees — For all contract deliverables.**

Project Officer  
HHS/OPHEP/OPHEMC  
330 Independence Avenue SW  
Room G640  
Washington, D.C. 20201

Contracting Officer  
HHS/OPHEP/OPHEMC  
330 Independence Avenue SW  
Room G640  
Washington, D.C. 20201

**SECTION E—INSPECTION AND ACCEPTANCE**

The Contracting Officer or the duly authorized representative will inspect and accept materials and services to be delivered under the contract. Contractor inspector is hereby noted, as the Project Officer and place of inspection will be the contractor's facilities. In addition, the following clause is incorporated by reference:

FAR Clause No.52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APR 1984)

**SECTION F—DELIVERIES OR PERFORMANCE**

**F.1. PERIOD OF PERFORMANCE**

The period of performance of this contract is from the date of contract award to \_\_\_\_\_ after contract award.

Delivery will be required F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEE’S PREMISES (APR 1984).

**F.2. Technical Report Requirements**

<b>Item</b>	<b>Deliverable</b>	<b>Quantity</b>	<b>Due Date</b>
1.	<b>Technical Progress Report</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	1 <sup>st</sup> Report due on/before _____; thereafter, due on/before the 15 <sup>th</sup> of the month or milestone following each reporting period. Not due when Final is due.
2.	<b>Executive Summary</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	1 <sup>st</sup> Report due on/before _____; thereafter, due on/before the 15 <sup>th</sup> of the month following each anniversary date of the contract. Not due when Final is due.
3.	<b>Final Report</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	Due on/before the completion date of the contract.

**F.3. Contract Deliverables**

<b>Milestones</b>	<b>Deliverable</b>	<b>Quantity</b>	<b>Due Date</b>
1.	<b>Product Development Plan</b> (milestone 1)	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	.
2.	<b>Clinical Development, and Regulatory Licensure Plans</b> (milestone 2)	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	
3.	<b>Feasibility Plan</b> (milestone 3)	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	
4.	<b>Contractor Defined Milestones</b> (milestone 4)	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	
5.	<b>Final Security Plan</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	_____ after Governments Final Comments
6.	<b>Technical Progress Reports and Executive Summary</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	See section C.2.Reporting requirements.
7.	<b>Final Report</b>	Original — C.O. 2 Copies — P.O. 1 Electronic Copy — P.O.	See section C.2.Reporting requirements.

**F.4. STOP WORK ORDER**

The following clause is incorporated by reference:

FAR CLAUSE 52.242-15, STOP WORK ORDER (AUG 1989) with ALTERNATE I (APR 1984)

**SECTION G.—CONTRACT ADMINISTRATION DATA**

**G.1. CONTRACTING OFFICER**

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

2) The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

3) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

**G.2. PROJECT OFFICER**

The Government’s Project Officer(s) will be identified by modification upon contract execution.

The Project Officer is responsible for: (1) monitoring the Contractor’s technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

**G.3. KEY PERSONNEL**

Pursuant to HHSAR Clause 352.270-5, Key Personnel, incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title

Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate

#### **G. 4. INVOICE SUBMISSION**

Invoices will be submitted in accordance with “Invoice/Financing Request Instructions” attached to this contract.

#### **G. 5. CONTRACT FINANCIAL REPORT**

Financial reports will be submitted to the address specified in Block 7 of face page of the contract. Normally, reports are due quarterly. Examples of the cost elements to be reported include the following:

Expenditure Category

1. Direct Labor
  - a. Principal Investigator
  - b. Co-Principal Investigator
2. Personnel — Other
3. Fringe Benefits
4. Materials/Supplies
5. Travel
6. Consultant Costs
7. Subcontract Costs
8. Other Direct Costs
9. Clinical Trials Costs
10. Indirect Cost
11. Fee
12. Total Cost

#### **G. 6. INDIRECT COST RATES**

**Profit making organizations will negotiate provisional and/or final indirect cost rates with their cognizant Government Audit Agency.**

#### **G. 7. POST AWARD EVALUATION OF PAST PERFORMANCE**

Interim and final evaluations of contractor performance shall be conducted on this contract in accordance with FAR 42.15. The final performance evaluation shall be completed at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement.

#### **G.8. GOVERNMENT PROPERTY**

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at: <http://www.knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contracts Property Administrator.
- b. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph a. above, the contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for performing annual inventories required under this contract. This form is included as an attachment in SECTION J of this contract.

## **SECTION H—SPECIAL CONTRACT REQUIREMENTS**

### **H. 1. HUMAN SUBJECTS**

Research involving human subjects shall not be conducted under this contract until the protocol developed in \_\_\_\_\_ has been approved by DHHS, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying Internal Review Board (IRB) review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

### **H. 2. HUMAN MATERIALS**

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

### **H. 3. ANIMAL WELFARE ASSURANCE**

The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

### **H. 4. CONFIDENTIALITY OF INFORMATION**

The following information is covered by HHSAR 352.224-70, confidentiality of Information (APR 1984):

[redacted]

### **H. 5. REVIEW AND APPROVAL**

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written approval in advance from the Government.

### **H. 6. IDENTIFICATION AND DISPOSITION OF DATA**

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

### **H. 7. EPA ENERGY STAR REQUIREMENTS**

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

#### **H.8. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in DHHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov.

Office of Inspector General  
Department of Health and Human Services  
TIPS HOTLINE  
P.O. Box 23489  
Washington, DC 20026

#### **H.9. ACKNOWLEDGMENT OF FEDERAL FUNDING**

- A. Section 507 of P.L. 104-208 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

- B. Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of Public Health Emergency Preparedness, Office of Research and Development Coordination whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of Public Health Emergency Preparedness, Office of Public Health Emergency Medical Countermeasures, under Contract No. HHSO100200700032C.

- C. Press Releases

Pursuant to Section 508 of Public Law 109-49, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

#### **H.10. NEEDLE EXCHANGE**

Pursuant to Section 505 of Public Law 109-49, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

#### **H.11 PRESS RELEASES**

Pursuant to Section 508 of Public Law 109-49, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

#### **H.12. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provisions of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

#### **H.13. MANUFACTURING STANDARDS**

**The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.**

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

#### **H.14. ANTI-LOBBYING PROVISIONS**

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant;

the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or and State or Local legislature.

#### **H.15. POSSESSION, USE AND TRANSFER OF SELECTED BIOLOGICAL AGENTS OR TOXINS**

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to *domestic institutions* that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 ([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)), as required, before using DHHS funds for research involving Select Agents. No DHHS funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to *foreign institutions* that possess, use, and/or transfer Select Agents under this contract, before using DHHS funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the DHHS that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: ([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)) are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an HHS representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An DHHS-chaired committee of U.S. federal employees (including representatives of select DHHS grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 ([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)). The committee will provide recommendations to the OPHEMC Director, DHHS. The Director (or designee) will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No DHHS funds can be used for research involving Select Agents at a foreign institution until DHHS grants this approval.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/> and <http://www.cdc.gov/od/sap/docs/salist.pdf>. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/index.html](http://www.aphis.usda.gov/programs/ag_selectagent/index.html) and [http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_forms.html](http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html).

For foreign institutions, see the NIAID Select Agent Award information: [http://www.niaid.nih.gov/ncn/clinical/default\\_biodefense.htm](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm)

## PART II — CONTRACT CLAUSES

### SECTION I — CONTRACT CLAUSES

#### ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT — FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>.

#### I.1. GENERAL CLAUSES

##### General Clauses for a Cost-Reimbursement Research and Development Contract

FAR	52.202-1	Jul 2004	Definitions
FAR	52.203-3	Apr 1984	Gratuities (Over \$100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over \$100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
FAR	52.203-12	Sep 2003	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over \$100,000)
FAR	52.204-7	Oct 2003	Central Contractor Registration
FAR	52.209-6	Sep 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
FAR	52.215-2	Jun 1999	Audit and Records — Negotiation (Over \$100,000)
FAR	52.215-8	Oct 1997	Order of Precedence — Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)

FAR	52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data — Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.217-2	Oct 1997	Cancellation Under Multi-Year Contracts
FAR	52.219-8	May 2004	Utilization of Small Business Concerns (Over \$100,000)
FAR	52.219-9	Sep 2006	Small Business Subcontracting Plan (Over \$500,000)
FAR	52.219-16	Jan 1999	Liquidated Damages — Subcontracting Plan (Over \$500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Sep 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Sep 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over \$100,000)
FAR	52.225-1	Jun 2003	Buy American Act — Supplies
FAR	52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
FAR	52.227-11	Jan 1997	Patent Rights — Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.

FAR	52.227-14	Jun 1987	Rights in Data — General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest (Over \$100,000)
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost (applies when contract is fully funded)
FAR	52.232-22	Apr 1984	Limitation of Funds (applies when contract is incrementally funded)
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer—Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs (Over \$650,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
FAR	52.243-2	Aug 1987	Changes — Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
FAR	52.244-6	Sep 2006	Subcontracts for Commercial Items
FAR	52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays

FAR	52.253-1	Jan 1991	Computer Generated Forms
HHSAR	352.202-1	Jan 2001	Definitions — with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance — Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

## I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

**ARTICLE I.1.** of this SECTION is hereby modified as follows:

FAR Clauses **52.219-9, Small Business Subcontracting Plan** (September 2006), and **52.219-16, Liquidated Damages—Subcontracting Plan** (January 1999) are deleted in their entirety.

FAR Clause **52.232-20, Limitation of Cost**, is deleted in its entirety and FAR Clause **52.232-22, Limitation of Funds** (APRIL 1984) is substituted therefore. [Note: When this contract is fully funded, FAR Clause **52.232-22, Limitation of Funds** will no longer apply and FAR Clause **52.232-20, Limitation of Cost** will become applicable.]

## I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the contracting officer will make their full text available.

**52.215-17 Waiver of Facilities Capital Cost of Money (October 1997)**

**52.243-2, Changes—Cost Reimbursement (August 1987)**

#### **I.4 Additional Contract Clauses of SECTION I — Added in full text**

##### **52.222-39 Notification of Employee Rights Concerning Payment of Union Dues or Fees.**

Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004)

(a) Definition. As used in this clause— “United States” means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

##### Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board  
Division of Information  
1099 14th Street, N.W.  
Washington, DC 20570  
1-866-667-6572  
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB’s website at <http://www.nlr.gov>.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR Part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR Part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR Part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to—

- (1) Contractors and subcontractors that employ fewer than 15 persons;
- (2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor’s employees;
- (3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;
- (4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor’s facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that—
  - (i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
  - (ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or
- (5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall—

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR Part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

#### 52.227-14, Rights in Data Alternate II (June 1987)

(g)(2) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be withholdable. If delivery of such data is so required, the Contractor may affix the following "Limited Rights Notice" to the data and the Government will thereafter treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with such Notice:

##### LIMITED RIGHTS NOTICE (JUNE 1987)

(a) These data are submitted with limited rights under Government Contract No. **HHSO10020070032C** and subcontracts. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

##### **(i) Use (except for manufacture) by support service contractors.**

(b) This Notice shall be marked on any reproduction of these data, in whole or in part.

(End of Clause)

## **I. 5. Department of Health and Human Services Acquisition Regulations (HHSAR)**

(48 CFR Chapter 3) Clauses: Full text of these clauses can be found at  
<http://www.dhhs.gov/oamp/dap/hhsar.html/>

352.223-70, Safety and Health (January 2001)

352.224-70, Confidentiality of Information (April 1984)

352.270-5, Key Personnel (April 1984)

352.270-8, Protection of Human Subjects (January 2001)

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human Subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

352.270-9, Care of Live Vertebrate Animals (January 2001)

PART III — LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

**SECTION J — LIST OF ATTACHMENTS**

Invoice/Financing Request Instructions (1 page)

Report of Government owned Contractor held property (1 page)

Contractor defined milestones (December 11, 2006, 7 pages)

**SECTION K — REPRESENTATIONS AND CERTIFICATIONS**

The following documents are incorporated by reference in this contract:

Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website. [This includes the changes if any identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the contractor's proposal.]

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT** 1. CONTRACT ID CODE PAGE OF PAGES  
1 | 2

2. AMENDMENT/MODIFICATION NO: One (1) 3. EFFECTIVE DATE See 6166R16C 4. REQUISITION/PURC N/A 5. PROJECT NO. (If applicable) N/A

6. ISSUED BY CODE Office of Preparedness and Response  
Office of Medical Countermeasures  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW Room G640  
Washington, DC 20201 7. ADMINISTERED BY (If other than Item 6) CODE

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) (X) 9A. AMENDMENT OF SOLICITATION NO.  
9B. DATED (SEE ITEM 11)  
X 10A. MODIFICATION OF CONTRACT/ ORDER  
HHSO100200700032C  
10B. DATED (SEE ITEM 13)  
12-29-06

CODE FACILITY CODE 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended,  is not extended.  
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
ICC: DOC# TIN# LOC# CAN#1993162 \$24,811,973

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS; IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

- A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
- B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
- C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
- X D. OTHER (Specify type of modification and authority)  
FAR 52.232-22, Limitation of Funds Clause

E. IMPORTANT: Contractor [X] is not, [ ] is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible)

PURPOSE: The purpose of this modification is to provide incremental funding: To Modify B.2. Estimated Cost and Fixed Fee as reflected on page 2.

The contract allotted amount is \$24,811,973  
The total contract amount remains unchanged. (\$102,661,429)  
The contract completion date remains unchanged. (December 31, 2010)

15A. NAME AND TITLE OF SIGNER (Type or print) Michael A. Dany CFO 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)  
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign) 15C. DATE SIGNED 16B. UNITED STATES OF AMERICA BY (Signature of Contracting Officer) 16C. DATE SIGNED 01-03-07

ARTICLE B.2. ESTIMATED COST and FIXED FEE- paragraphs b., c., and d. are hereby revised as follows:

- b. Total funds currently available for payment and allotted to this contract are increased by \$24,811,973 from \$77,849,456 to \$102,661,429 in order to fully fund the contract. For further provisions on funding, see the LIMITATION OF COST Clause referenced in part II, Contract Clauses.
  - c. Reserved.
  - d. Reserved.
-

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE	PAGE OF PAGES 1   2
2. AMENDMENT/MODIFICATION NO: Two (2)	3. EFFECTIVE DATE 5/11/07	4. REQUISITION/PURC N/A	5. PROJECT NO. (If applicable) N/A	
6. ISSUED BY Office of Preparedness and Response Office of Medical Countermeasures U.S. Department of Health and Human Services 330 Independence Avenue, SW Room G640 Washington, DC 20201	CODE	7. ADMINISTERED BY (If other than Item 6)		CODE
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)  BioCryst Pharmaceuticals, Inc 2190 Parkway Lake Drive Birmingham, AL 35244 ██████████ ██████████			00	9A. AMENDMENT OF SOLICITATION NO.
				9B. DATED (SEE ITEM 11)
			X	10A. MODIFICATION OF CONTRACT/ ORDER HHSO100200700032C
				10B. DATED (SEE ITEM 13) 01-03-07
CODE	FACILITY CODE			

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended,  is not extended.  
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)  
SOCC: DOC# TIN# LOC# CAN#

**13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS; IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

- A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
- B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
- x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:  
Far 1.602-1, FAR 52.243.2 Changes - Cost Reimbursement; HHSAR 352.270-5- Key Personnel
- D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor [X] is not, [ ] is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible)

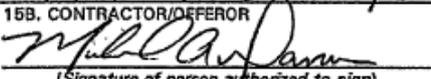
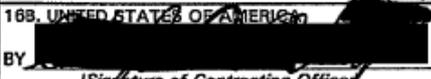
PURPOSE: The purpose of this modification is to

1. Modify Article F.3. Contract Deliverables to extend the delivery date of Milestone 1 Product Development Plan for six (6) months after contract award.
2. Modify Article G.3 Key Personnel

The total contract amount remains unchanged. (\$102,661,429)

The contract completion date remains unchanged. (December 31, 2010)

Except as provided herein, all terms and conditions referenced in item 9A or 10A, as heretofore changed, remains full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Michael A. Darwin, CFO		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) ██████████	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED 4/26/07	16B. UNITED STATES OF AMERICA BY  (Signature of Contracting Officer)	16C. DATE SIGNED 5/11/07

**Article F.3 Contract Deliverables, are hereby revised as follows**

Milestones	Deliverable	Quantity	Due Date
1	Product Development Plan (milestone 1)	Original - C.O. 2 Copies - P.O 1 Electronic Copy - P.O	Six (6) months after contract award

**Article G.3 Key Personnel, are hereby revised as follows:**

**Additional Key Personnel**

[REDACTED]	[REDACTED]

**Removal of Key Personnel**

[REDACTED]	[REDACTED]
------------	------------

STATE OF ALABAMA )  
SHELBY )  
COUNTY

**THIRD AMENDMENT TO LEASE AGREEMENT**

**THIS THIRD AMENDMENT TO LEASE AGREEMENT**, hereafter referred to as the "Agreement" is made and entered into on this 7th day of August, 2007, by and between **Riverchase Capital LLC**, a Florida limited liability company, and **Stow Riverchase, LLC**, a Florida limited liability company, as successor landlord to **RBP, LLC**, an Alabama limited liability company, hereafter referred to as collectively "**Landlord**" and **BioCryst Pharmaceuticals, Inc.** hereafter referred to as "**Tenant**".

**WITNESSETH:**

**WHEREAS**, Landlord and Tenant entered into a Lease Agreement dated July 13, 2000, and amended by the First Amendment to Lease Agreement dated May 15, 2001, and by the Second Amendment to Lease Agreement dated November 14, 2005, collectively referred to as the "Lease", for approximately 50,150 square feet of office/warehouse space consisting of Suites A, B and H of the 2190 wing and Suites A and C of the 2192 wing, the "Premises", at the building known as Riverchase Business Park, the "Building", located at 2190/2192 Parkway Lake Drive, Hoover, Alabama 35244.

**WHEREAS**, the parties hereto have reached additional agreements to amend the terms of the Lease in the manner hereinafter set forth.

**NOW, THEREFORE**, for and in consideration of the mutual covenants and agreements herein contained, and other good and valuable considerations, the receipt and sufficiency of which is hereby acknowledged, Landlord and Tenant understand and agree as follows:

1. The Lease Expiration Date is hereby changed to June 30, 2015.
2. The following is added to Section 1 (Fixed Minimum Rent Payment) of the Addendum attached as Exhibit D to the Lease:

July 1, 2010 — June 30, 2011	\$42,711.08/month
July 1, 2011 — June 30, 2012	\$43,992.42/month
July 1, 2012 — June 30, 2013	\$45,312.20/month
July 1, 2013 — June 30, 2014	\$46,671.56/month
July 1, 2014 — June 30, 2015	\$48,071.71/month

3. Section 5 (Early Termination) of the Addendum attached as Exhibit D to the Lease is hereby deleted, and Tenant waives its right to terminate the Lease prior to the Lease Expiration Date.
4. Commencing July 1, 2007, Common Area maintenance costs shall not include the 15% administrative and overhead charge.
5. Landlord hereby grants to Tenant one-time a right of first refusal to lease additional contiguous space in the Building on the following terms and conditions. In the event Landlord receives from a third party a bona fide offer to lease all or a portion of space in the Building that is contiguous to the Premises, which offer Landlord intends to accept (the "Third Party Offer"), Landlord shall provide Tenant with written notice of its intent to accept the Third Party Offer, which notice shall include the business terms of the Third Party Offer. Such notice shall constitute Landlord's offer to lease to Tenant the space described in the Third Party Offer upon the same terms and conditions as the Third Party Offer (the "Landlord Offer"). Tenant shall have five (5) business days after it receives the Landlord Offer to notify Landlord in writing of Tenant's acceptance thereof. Within ten (10) days after Tenant's acceptance of the Landlord Offer, Landlord and Tenant shall execute and deliver a lease agreement containing terms and conditions identical to those comprising the Third Party Offer. The failure of Tenant to accept the Landlord Offer within the five (5) business day period described above shall nullify and void the right of first refusal granted herein as it relates solely to the particular Third Party Offer of which Tenant received notice, and Landlord shall be free to lease such space to such third party upon the terms and conditions of the Third Party Offer.

6. Landlord shall provide Tenant with an allowance of \$300,000 for Tenant's use in making certain improvements to the Premises. Upon completion of such Tenant Improvements, Tenant shall submit to Landlord (i) a request for payment specifying Tenant's total actual costs of the Tenant Improvements (Landlord's contribution shall not exceed the lesser of \$300,000 or Tenant's total actual costs), (ii) copies of paid invoices for the Tenant Improvements, (iii) final, unconditional lien waivers and releases from all parties furnishing materials and/or services in connection with the Tenant Improvements, (iv) an estoppel certificate from Tenant in form and substance reasonably acceptable to Landlord, (v) evidence (including, without limitation, access to the Premises by Landlord, its lender and their respective agents) reasonably satisfactory to Landlord that the Tenant Improvements have been completed in a good and workmanlike manner and in accordance with the Lease, (vi) such additional documents, certificates and affidavits as Landlord may reasonably request evidencing completion of (and payment for) the Tenant Improvements. The Tenant Improvements shall be governed by Section 2 of the Addendum attached as Exhibit D to the Lease. Landlord must approve Tenant's plans and specifications for the Tenant Improvements and must approve Tenant's selection of the general contractor.
7. Section 3 (Expansion Option) of the Addendum attached as Exhibit D to the Lease is hereby deleted, and Tenant waives its rights in connection therewith.
8. Section 4 (Option to Renew) of the Addendum attached as Exhibit D to the Lease is hereby modified such that Tenant will have one (1) option to renew the Lease for an additional term of five (5) years upon giving written notice to Landlord at least nine (9) months prior to June 30, 2015, such renewal to be upon the existing terms and conditions contained in the Lease at a mutually agreed upon rental rate. If a mutually agreed upon rental rate is not agreed within six (6) months of the Lease expiration of June 30, 2015 the option to renew shall become null and void and the Lease shall terminate on June 30, 2015. In the event Tenant exercises such option, Landlord shall professionally clean the floors and repaint the walls with material equivalent in quality and quantity to those installed or used in the initial Tenant finish. At Tenant's option, Landlord shall reimburse Tenant the cost to professionally clean the floors and repaint the walls, in lieu of performance of such work on the Tenant's behalf.

IN WITNESS WHEREOF, the parties hereto have entered into this Agreement as of the day and year first above written.

**WITNESS:**

Signature: /s/ Stephen Butler

Name: Stephen Butler

**WITNESS:**

Signature: /s/ Stephen Butler

Name: Stephen Butler

**WITNESS:**

Signature: /s/ Stephen Butler

Name: Stephen Butler

**LANDLORD:**

**Riverchase Capital, LLC**  
**a Florida limited liability company**

By: /s/Bruce D. Burdge  
Bruce D. Burdge

Its: President

**Stow Riverchase, LLC**  
**a Florida limited liability company**

By: Arcis Realty, LLC, as its attorney-in-fact

By: /s/Bruce D. Burdge  
Bruce D. Burdge

Its: President

**TENANT: BioCryst Pharmaceuticals, Inc.**

By: /s/ Michael A. Darwin

Its: Vice President Finance, Treasurer, Secretary

**CERTIFICATIONS**

I, Jon P. Stonehouse, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2007

/s/ JON P. STONEHOUSE

Jon P. Stonehouse  
Chief Executive Officer

## CERTIFICATIONS

I, Michael A. Darwin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioCryst Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2007

/s/ MICHAEL A. DARWIN

Michael A. Darwin  
Chief Financial Officer and Chief Accounting Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jon P. Stonehouse, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Jon P. Stonehouse

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Jon P. Stonehouse

Chief Executive Officer

August 9, 2007

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BioCryst Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Darwin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Michael A. Darwin

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Michael A. Darwin  
Chief Financial Officer

August 9, 2007