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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 September 30, 2013

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**62-1413174**
(State of other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4505 Emperor Blvd., Suite 200 **Durham, North Carolina** **(Address of principal executive offices)**	**27703** **(Zip Code)**

(919) 859-1302
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

The number of shares of Common Stock, par value $0.01, of the Registrant outstanding as of October 31, 2013 was 59,091,393.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
September 30, 2013 and December 31, 2012
(In thousands, except per share data)

	2013 (Unaudited)	2012 (Note 1)
Assets		
Cash and cash equivalents	$ 26,050	$ 20,891
Restricted cash	150	308
Investments	16,541	14,708
Receivables	2,369	4,562
Prepaid expenses and other current assets	1,656	1,097
Deferred collaboration expense	73	412
Total current assets	46,839	41,978
Investments	680	1,151
Furniture and equipment, net	359	583
Deferred collaboration expense	252	5,033
Other assets	5,075	8,694
Total assets	$ 53,205	$ 57,439
Liabilities and Stockholders' Equity		
Accounts payable	$ 1,241	$ 3,974
Accrued expenses	7,668	9,860
Interest payable	2,734	1,998
Deferred collaboration revenue	1,539	1,392
Total current liabilities	13,182	17,224
Deferred collaboration revenue	5,032	5,920
Foreign currency derivative	1,581	4,749
Non-recourse notes payable	30,000	30,000
Stockholders' equity:		
Preferred stock, $0.001 par value; shares authorized— 5,000; no shares issued and outstanding	—	—
Common stock, $0.01 par value: shares authorized — 95,000; shares issued and outstanding — 59,091 in 2013 and 50,893 in 2012	591	509
Additional paid-in capital	420,097	391,611
Accumulated other comprehensive income	2	27
Accumulated deficit	(417,280)	(392,601)
Total stockholders' equity (deficit)	3,410	(454)
Total liabilities and stockholders' equity	$ 53,205	$ 57,439

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
Periods Ended September 30, 2013 and 2012
(In thousands, except per share data-Unaudited)

	Three Months		Nine Months	
	2013	2012	2013	2012
Revenues				
Royalty revenue	$ 8	$ 2,848	$ 2,042	$ 2,848
Collaborative and other research and development	2,381	2,913	4,722	19,344
Total revenues	2,389	5,761	6,764	22,192
Expenses				
Research and development	7,977	12,072	27,116	40,374
General and administrative	1,337	1,591	3,950	4,897
Royalty	—	114	81	114
Total operating expenses	9,314	13,777	31,147	45,385
Loss from operations	(6,925)	(8,016)	(24,383)	(23,193)
Interest and other income	18	54	72	182
Interest expense	(1,191)	(1,166)	(3,536)	(3,486)
Gain (loss) on foreign currency derivative	97	(572)	3,168	(1,531)
Net loss	$ (8,001)	$ (9,700)	$ (24,679)	$ (28,028)
Basic and diluted net loss per common share	$ (0.14)	$ (0.19)	$ (0.46)	$ (0.57)
Weighted average shares outstanding	57,124	50,661	53,910	49,001
Unrealized loss on investments	(4)	—	(25)	—
Comprehensive loss	$ (8,005)	$ (9,700)	$ (24,704)	$ (28,028)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended September 30, 2013 and 2012
(In thousands-Unaudited)

	2013	2012
Operating activities		
Net loss	$(24,679)	$(28,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	247	461
Gain on disposal of furniture and equipment	(47)	—
Stock-based compensation expense	3,479	3,345
Amortization of debt issuance costs	329	329
Change in fair value of foreign currency derivative	(3,168)	1,531
Changes in operating assets and liabilities:		
Receivables	2,193	2,063
Prepaid expenses and other assets	(559)	(393)
Deferred collaboration expense	5,120	2,200
Accounts payable and accrued expenses	(4,925)	(3,779)
Interest payable	736	(472)
Interest reserve	—	1,742
Deferred collaboration revenue	(741)	(9,366)
Net cash used in operating activities	**(22,015)**	**(30,367)**
Investing activities		
Acquisitions of furniture and equipment	(26)	(115)
Proceeds from sale of furniture and equipment	50	—
Change in restricted cash	158	325
Purchases of investments	(15,232)	(14,487)
Sales and maturities of investments	13,845	35,515
Net cash (used in) provided by investing activities	**(1,205)**	**21,238**
Financing activities		
Sale of common stock, net	23,648	17,811
Exercise of stock options	1,317	522
Employee stock purchase plan sales	124	321
Receipt (payment) of foreign currency derivative collateral	3,290	(2,010)
Net cash provided by financing activities	**28,379**	**16,644**
Increase in cash and cash equivalents	5,159	7,515
Cash and cash equivalents at beginning of period	20,891	16,444
Cash and cash equivalents at end of period	**$ 26,050**	**$ 23,959**

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)
(In thousands, except per share amounts)

Note 1 — Significant Accounting Policies

The Company

BioCryst Pharmaceuticals, Inc. (the "Company") is a biotechnology company that designs, optimizes and develops novel drugs that block key enzymes involved in the pathogenesis of disease related to therapeutic areas with unmet medical needs aligned with its capabilities and expertise. The Company was incorporated in Delaware in 1986 and its headquarters is located in Durham, North Carolina. The Company integrates the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design. BioCryst has incurred losses and negative cash flows from operations since inception.

In the fourth quarter of 2012, the Company implemented a restructuring plan to significantly reduce its cost structure. Based on its current operating plans, the Company expects that it has sufficient liquidity, with its existing cash and investments of $43,421, to continue its planned operations through 2014. The Company's liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events in the future. In order to continue its operations substantially beyond 2014 it will need to: (1) successfully secure or increase U.S. Government funding of its programs; (2) out-license rights to certain of its product candidates, pursuant to which the Company would receive cash milestone payments; (3) raise additional capital through equity or debt financings or from other sources; (4) obtain product candidate regulatory approvals, which would generate revenue and cash flow; (5) reduce spending on one or more research and development programs; and/or (6) restructure operations. The Company will continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, JPR Royalty Sub LLC ("Royalty Sub"). Royalty Sub was formed in connection with a $30,000 financing transaction the Company completed on March 9, 2011. See Note 4, Royalty Monetization, for a further description of this transaction. All intercompany transactions and balances have been eliminated.

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's consolidated financial position, results of operations, and cash flows.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2012 and the notes thereto included in the Company's 2012 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, 2012 has been derived from the audited consolidated 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 commercial checking accounts, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Restricted Cash

Restricted cash as of September 30, 2013 includes $150 the Company is required to maintain in an interest bearing money market account to serve as collateral for a corporate credit card program.

Investments

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. The objective of the Company's investment policy is to ensure the safety and preservation of

invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of its credit exposure. Per its policy, the Company is able to invest in marketable debt securities that may consist of U.S. Government and government agency securities, money market and mutual fund investments, municipal and corporate notes and bonds, commercial paper and asset or mortgage-backed securities, among others. The Company's investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of three years and requires an average portfolio maturity of no more than 18 months. Some of the securities the Company invests in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. Generally, the Company's investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At September 30, 2013, the Company believes that the costs of its investments are recoverable in all material respects.

The following tables summarize the fair value of the Company's investments by type. The estimated fair value of the Company's fixed income investments are classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs.

	September 30, 2013				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 9,075	$ 62	$ 2	$ (2)	$ 9,137
Commercial paper	7,330	—	1	—	7,331
Municipal obligations	750	3	—	—	753
Total investments	$ 17,155	$ 65	$ 3	$ (2)	$ 17,221

	December 31, 2012				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 999	$ 2	$ 2	$ —	$ 1,003
Obligations of U.S. Government and its agencies	3,505	6	2	—	3,513
Corporate debt securities	4,035	22	6	—	4,063
Commercial paper	1,695	—	1	—	1,696
Municipal obligations	5,541	27	16	—	5,584
Total investments	$ 15,775	$ 57	$ 27	$ —	$ 15,859

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2013.

Maturing in one year or less	$16,541
Maturing after one year through two years	680
Total investments	$17,221

Receivables from Collaborations

Receivables are recorded for amounts due to the Company related to reimbursable research and development costs from the U.S. Department of Health and Human Services and the National Institute of Allergy and Infectious Diseases ("NIAID") or royalty receivables from Shionogi & Co., Ltd. ("Shionogi"). These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At September 30, 2013 and December 31, 2012, the Company had the following receivables.

	September 30, 2013		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$544	$1,803	$2,347
National Institute of Allergy and Infectious Diseases	—	22	22
Total receivables	$544	$1,825	$2,369

	December 31, 2012		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$150	$3,888	$4,038
Shionogi & Co. Ltd.	524	—	524
Total receivables	$674	$3,888	$4,562

Monthly invoices are submitted to the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority ("BARDA/HHS") and NIAID related to reimbursable research and development costs. The Company is also entitled to monthly reimbursement of indirect costs based on rates stipulated in the underlying contracts. The Company's calculations of its indirect cost rates are subject to audit by the federal government.

Patents and Licenses

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

Accrued Expenses

The Company enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under

these contractual commitments when the Company determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with its applicable personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organization (“CROs”) 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 fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company’s 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, the Company estimates the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Accrued expenses as of September 30, 2013 and December 31, 2012 included $2,846 and $6,573, respectively, of research and development costs.

Income Taxes

The liability method is used in the Company’s accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Accumulated Other Comprehensive (Loss) Income

Accumulated other comprehensive (loss) income is comprised of unrealized gains and losses on investments available-for-sale and is disclosed as a separate component of stockholders’ equity. No reclassifications out of accumulated other comprehensive (loss) income were recorded during the three months and nine months ended September 30, 2013 and 2012.

Revenue Recognition

The Company recognizes revenues from collaborative and other research and development arrangements and product sales. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller’s price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees is recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. In the event a license agreement contains multiple deliverables, the Company evaluates whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of our license agreements, the Company receives royalty payments based upon our licensees’ net sales of covered products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured.

Royalty revenue paid by Shionogi on their product sales is subject to returns. Prior to the third quarter of 2012, the Company did not have sufficient historical experience to reasonably estimate product returns and therefore could not reasonably record the underlying revenue. During the third quarter of 2012, and after the completion of the 2011/2012 flu season in Japan, the Company obtained sufficient historical information to reasonably estimate product returns and recognized royalty revenue of $2,848, net of an allowance for estimated returns. During the nine months of 2013, the Company recognized royalty revenue of $2,042.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue. Under the Company's contracts with BARDA/HHS and NIAID, revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

Sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates.

The Company recorded the following revenues for the three and nine months ended September 30, 2013 and 2012:

	Three Months		Nine Months	
	2013	2012	2013	2012
Royalty revenue	$ 8	$2,848	$2,042	$ 2,848
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	2,063	2,618	3,812	10,690
National Institute of Allergy and Infectious Diseases	22	—	22	—
Shionogi (Japan)	296	295	888	888
Mundipharma (United Kingdom)	—	—	—	7,766
Total revenues	$2,389	$5,761	$6,764	$22,192

Research and Development Expenses

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

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

Deferred collaboration expenses represent sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners, and other consideration paid to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock awards, are recognized in the Company's Consolidated Statements of Comprehensive Loss based on their fair values. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock awards is based on the grant date closing price of the common stock. Stock-based compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award.

Interest Expense and Deferred Financing Costs

Interest expense for the three months ended September 30, 2013 and 2012 was $1,191 and $1,166, respectively, and $3,536 and $3,486 for the nine months ended September 30, 2013 and 2012, respectively, and relates to the issuance of the PhaRMA Notes (defined in Note 4). Costs directly associated with the issuance of the PhaRMA Notes have been capitalized and are included in other non-current assets on the Consolidated Balance Sheets. These costs are being amortized to interest expense over the term of the PhaRMA Notes using the effective interest rate method. Amortization of deferred financing costs included in interest expense was $110 for each of the three months ended September 30, 2013 and 2012, and $329 for each of the nine months ended September 30, 2013 and 2012.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement (defined in Note 4) to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore mark-to-market adjustments are recognized in the Company's Consolidated Statements of Comprehensive Loss. Cumulative mark-to-market adjustments resulted in a gain of $97 and a loss of $572 for the three months ended September 30, 2013 and 2012, respectively, and a gain of $3,168 and a loss of $1,531 for the nine months ended September 30, 2013 and 2012, respectively. Mark-to-market adjustments are determined by a third party pricing model which uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on thresholds defined in the Currency Hedge Agreement. As of September 30, 2013 and December 31, 2012, $1,890 and $5,180 of hedge collateral was posted under the agreement, respectively.

Restructuring Activities

During the fourth quarter of 2012, the Company announced a corporate restructuring plan to significantly reduce its cost structure in response to setbacks in several of its development programs. In connection with this plan, the Company recognized restructuring costs of $1,759, consisting of one-time termination benefits and charges related to vacant office space.

The following table sets forth activity in the restructuring liability for the nine months ended September 30, 2013.

	Employee separation costs	Facilities related charges	Total
Balance at December 31, 2012	$ 1,604	$ 97	$ 1,701
Accruals	—	(34)	(34)
Payments	(1,509)	—	(1,509)
Balance at September 30, 2013	$ 95	$ 63	$ 158

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein because common equivalent shares from unexercised stock options and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. The calculation of diluted earnings per share for the three months ended September 30, 2013 and 2012 does not include 2,783 and 1,207, respectively, of such potential common shares, as their impact would be anti-dilutive. The calculation of diluted earnings per share for the nine months ended September 30, 2013 and 2012 does not include 1,731 and 1,158, respectively, of such potential common shares, as their impact would be anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Concentration of Market Risk

A significant source of revenue for the Company is reimbursement of peramivir development expenses, which is earned under the cost-plus-fixed-fee contract with BARDA/HHS. The Company relies on BARDA/HHS to reimburse substantially all of the development costs for its peramivir program. Accordingly, reimbursement of these expenses represents a significant portion of the Company's collaborative and other research and development revenues; however, this revenue has been decreasing recently due to a reduction in development activity. The completion or termination of this program/collaboration could negatively impact the Company's future Consolidated Statements of Comprehensive Loss and Cash Flows. Another significant source of revenue is royalty revenue from the net sales of RAPIACTA®. The underlying cash flow from these royalty payments goes directly to pay the interest, and then the principal, on the Company's non-recourse notes payable. Payment of the interest and the ultimate repayment of principal of these notes will be entirely funded by future royalty payments derived from net sales of RAPIACTA®. The Company's drug development activities are performed by a limited group of third party vendors. If any of these vendors were unable to perform their services, this could significantly impact the Company's ability to complete its drug development activities.

Credit Risk

Cash equivalents and investments are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the Consolidated Balance Sheets. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of no more than 18 months. A significant amount of the Company's receivables are due from BARDA/HHS, for which there is no assumed credit risk, or from Shionogi, for which a single royalty payment is remitted within two months of quarterly sales underlying the royalty payment. Accordingly, credit risk for these receivables is considered minimal based upon the nature of the underlying receivable and their timely remittance.

Recent Accounting Pronouncements

On February 5, 2013, the Financial Accounting Standards Board issued an amendment to ASU 2013-02, "Comprehensive Income (Topic 220)" ("ASU 2013-02") to the disclosure requirements for reporting reclassifications out of accumulated other comprehensive income. ASU 2013-02 was effective for the first interim or annual period beginning after December 15, 2012. The amendment requires companies to present information about reclassification adjustments from accumulated other comprehensive income to the income statement, including the income statement line items affected by the reclassification. The information must be presented in the financial statements in a single note or on the face of the financial statements. The new accounting guidance also requires the disclosure to be cross referenced to other financial statement disclosures for reclassification items that are not reclassified to net income in their entirety in the same reporting period. The Company adopted ASU 2013-02 in the first quarter of 2013. The adoption did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

Note 2 — Stock-Based Compensation

As of September 30, 2013, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ("Incentive Plan") and the Employee Stock Purchase Plan ("ESPP"), both of which were amended and restated in March 2012 and approved by the Company's stockholders in May 2012. Stock-based compensation expense of $3,479 ($3,404 of expense related to the Incentive Plan and $75 of expense related to the ESPP) was recognized during the first nine months of 2013, while $3,345 ($3,233 of expense related to the Incentive Plan and $112 of expense related to the ESPP) was recognized during the first nine months of 2012.

There was approximately $6,383 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock awards granted by the Company as of September 30, 2013. That cost is expected to be recognized as follows: $1,819 during the remainder of 2013, $2,561 in 2014, $1,398 in 2015, $533 in 2016 and $72 in 2017.

Stock Incentive Plan

The Company grants stock option awards and restricted stock awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Prior to March 1, 2011, stock option awards granted to employees generally vest

25% after one year and monthly thereafter on a pro rata basis over the next three years until fully vested after four years. Commencing March 1, 2011, stock option awards granted to employees generally vest 25% each year until fully vested after four years. In January 2013, the Company made retention grants of stock option awards and restricted stock. These awards vest 50% each year until fully vested after two years. In August 2013, the Company issued 1,032 performance-based stock options. These awards vest upon successful completion of specific development milestones. As of September 30, 2013 and based on the information available at that time, it is not considered probable that any of the specific development milestones will be met and, accordingly, no compensation expense has been recognized for options under this performance based grant award. Stock option awards granted to non-employee directors of the Company generally vest monthly over one year. All stock option awards have contractual terms of 5 to 10 years. The vesting exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2012	2,815	8,073	$ 6.09
Restricted stock awards granted	(310)	—	—
Restricted stock awards cancelled	53	—	—
Stock option awards granted	(3,237)	3,237	3.02
Stock option awards exercised	—	(562)	2.37
Stock option awards cancelled	1,624	(1,624)	6.96
Balance September 30, 2013	945	9,124	$ 5.07

For stock option awards granted under the Incentive Plan during the first nine months of 2013 and 2012, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the nine months of 2013 and 2012 was $2.10 and $3.24, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following table summarizes the key assumptions used by the Company to value the stock option awards granted during the first nine months of 2013 and 2012. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents the historical volatility on the Company's publicly traded common stock. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

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

	2013	2012
Expected Life in Years	5.0	5.4
Expected Volatility	85%	87%
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	0.90%	0.86%

Employee Stock Purchase Plan

The Company has reserved a total of 975 shares of common stock to be purchased under the ESPP, of which 88 shares remain available for purchase at September 30, 2013. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning price or 85% of the ending price during each six-month purchase interval. No more than 3 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 or more in any one calendar year. The Company issued 89 shares during the first nine months of 2013 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model.

Note 3 — Collaborative and Other Research and Development Contracts

U.S. Department of Health and Human Services ("BARDA/HHS"). In January 2007, BARDA/HHS awarded the Company a $102,661, four-year contract for the advanced development of peramivir for the treatment of influenza. During 2009, peramivir clinical development shifted to focus on intravenous delivery and the treatment of hospitalized patients. To support this focus, a September 2009 contract modification was awarded to extend the intravenous ("i.v.") peramivir program

by 12 months and to increase funding by $77,191. On February 24, 2011, the Company announced that BARDA/HHS had awarded it a $55,000 contract modification, intended to fund completion of the Phase 3 development of i.v. peramivir for the treatment of patients hospitalized with influenza. This contract modification brings the total award from BARDA/HHS to $234,852 and extends the contract term by 24 months through December 31, 2013, providing funding through completion of Phase 3 and to support the filing of a New Drug Application ("NDA") to seek regulatory approval for i.v. peramivir in the U.S.

The contract with BARDA/HHS is 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. BARDA/HHS will make periodic assessments of progress and the continuation of the contract is based on the Company's performance, the timeliness and quality of deliverables, and other factors. BARDA/HHS has rights under certain contract clauses to terminate this contract. The contract is terminable by BARDA/HHS at any time for breach or without cause.

In March 2013, BioCryst received written notification from BARDA/HHS in the form of a Stop-Work Order directing the Company to cease work on peramivir under its U.S. Government contract, except for certain activities primarily related to BioCryst's U.S. Food & Drug Administration ("FDA") Type C meeting that was completed in April 2013. The notification confirmed that BARDA/HHS would continue to support and fund certain activities necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests.

On July 11, 2013, BARDA/HHS released funding under the contract to enable completion of an NDA filing. The decision by BARDA/HHS was the result of an In-Process Review ("IPR") meeting that occurred in the second quarter of 2013. Based on the results of the IPR, BARDA/HHS decided to modify the March 2013 stop-work order to support activities directly associated with the filing of an NDA and to allow no more than $12,800 of funding already obligated under the contract to be used for that purpose.

Shionogi & Co., Ltd. ("Shionogi"). In March 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. The Company developed peramivir under a license from UAB and will owe sublicense payments to UAB on any future milestone payments and/or royalties received by the Company from Shionogi. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan and to provide rights for Shionogi to perform a Phase 3 clinical trial in Hong Kong. Shionogi has commercially launched peramivir under the commercial name RAPIACTA® in Japan.

Green Cross Corporation ("Green Cross"). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The Company received a one-time license fee of $250. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea.

National Institute of Allergy and Infectious Diseases ("NIAID"). In September 2013, NIAID contracted with the Company for the development of BCX4430 as a treatment for Marburg virus disease. NIAID, part of the National Institutes of Health, made an initial award of $5,000 to BioCryst. The total funding under this contract could be up to $22,000, if all contract options are exercised by NIAID.

The goals of this contract are to file investigational new drug ("IND") applications for intravenous ("i.v.") and intramuscular ("i.m.") BCX4430 for the treatment of Marburg virus disease, and to conduct an initial Phase 1 human clinical trial. The aggregate $22,000 contract and option funding supports the appropriate IND-enabling program and the initial clinical trial.

Mundipharma International Holdings Limited ("Mundipharma"). In February 2006, the Company entered into an exclusive, royalty bearing right and license agreement with Mundipharma for the development and commercialization of forodesine, a purine nucleoside phosphorylase ("PNP") inhibitor, for use in oncology (the "Original Agreement"). Under the terms of the Original Agreement, Mundipharma obtained rights to forodesine in markets across Europe, Asia, and Australasia in exchange for a $10,000 up-front payment.

The Company deferred revenue recognition of the $10,000 up-front payment that was received from Mundipharma in February 2006 because the Company was involved in the continued development of forodesine. Amortization of this revenue commenced in February 2006 and was initially scheduled to end in October 2017, which is the date of expiration for the last-to-expire patent covered by the agreement. The Company also deferred revenue recognition of a $5,000 payment

received from Mundipharma in connection with the initiation of a clinical trial in 2007. Amortization of this deferred revenue commenced in 2007 and was initially scheduled to end in October 2017. Under its agreement with AECOM/IRL, the Company paid sublicense payments related to these upfront cash payments received from Mundipharma. Expense recognition of these sublicense payments was deferred and recognized under the same term as the related deferred revenue.

On November 11, 2011, the Company entered into the Amended and Restated License and Development Agreement (the "Amended and Restated Agreement") with Mundipharma, amending and restating the Original Agreement. Under the terms of the Amended and Restated Agreement, Mundipharma obtained worldwide rights to forodesine. Commencing on November 11, 2011, Mundipharma controls the development and commercialization of forodesine and assumes all future development and commercialization costs. The Amended and Restated Agreement provides for the possibility of future event payments totaling $15,000 for achieving specified regulatory events for certain indications and tiered royalties ranging from mid to high single-digit percentages of net product sales in each country where forodesine is sold by Mundipharma. These royalties are subject to downward adjustments based on the then-existing patent coverage and/or the availability of generic compounds in each country.

The Amended and Restated Agreement is a multiple element arrangement for accounting purposes, in which the Company is required to deliver to Mundipharma both the worldwide rights to forodesine in the field of oncology and the transfer of product data and know-how to permit Mundipharma to develop and commercialize forodesine (the "Knowledge Transfer"). The Company accounted for these elements as a combined unit of accounting as they do not have stand-alone value to Mundipharma. The worldwide license rights were granted to Mundipharma on November 11, 2011. The Knowledge Transfer commenced in 2011 and was completed during the first quarter of 2012. Completion of the Knowledge Transfer concluded the Company's obligations under the Amended and Restated Agreement and resulted in the recognition of the unamortized deferred revenue and expense of $7,766 and $1,864, respectively, in the Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012. Recognition of these deferred amounts resulted in a $2,337 decrease in the Company's deferred tax assets, with an equal reduction to the valuation allowance, resulting in no impact to net deferred tax assets.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. ("AECOM" and "IRL", respectively). In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL (collectively, the "Licensors"). The lead product candidates from this collaboration are forodesine and BCX4208. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, product candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or employees of the Licensors. The Company agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from $1,400 to almost $4,000 per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from $150 to $500, that are creditable against actual royalties and other payments due to the Licensors. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In May 2010, the Company amended the license agreement through which the Company obtained worldwide exclusive rights to develop and ultimately distribute any product candidates that might arise from research on a series of PNP inhibitors, including forodesine and BCX4208. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sublicensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone payments the Company may receive in the future under its license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from its sublicensees in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by the Company remains unchanged.

In consideration for these modifications in 2010, the Company issued to the Licensors shares of its common stock with an aggregate value of $5,911 and paid the Licensors $90 in cash. Additionally, at the Company's sole option and subject to certain agreed upon conditions, any future non-royalty payments due to be paid by it to the Licensors under the license agreement may be made either in cash, in shares of its common stock, or in a combination of cash and shares. At June 30, 2013, the Company, during its routine evaluation, assessed the carrying value of its deferred collaboration costs associated with this agreement and determined a $4,995 write-off of the underlying asset was necessary. The determination of the write-off was based upon management's estimate of the future cash flows associated with out-licensing the PNP technology as compared to the carrying value of the deferred collaboration costs.

On November 17, 2011, the Company further amended its agreements with the Licensors whereby the Licensors agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined in the license agreement) received by the Company under its Amended and Restated Agreement with Mundipharma that will be paid to AECOM/IRL.

On June 19, 2012, the Company further amended its agreement with the Licensors whereby the Licensors changed the definition of the term "Field" to exclude certain compounds from the definition and also to include within the definition of the term "Field" the antiviral use of BCX4430. As of September 30, 2013, the Company is in the process of renegotiating the terms of this agreement.

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

Emory University ("Emory"). In June 2000, the Company licensed intellectual property from Emory related to the hepatitis C polymerase target associated with hepatitis C viral infections. In accordance with termination provision under the license agreement, the Company provided ninety (90) days written notice of termination in April, 2013 following the termination of its antiviral development program for treatment of hepatitis C as announced in January 2013. The license agreement was terminated on July 28, 2013.

Note 4— Royalty Monetization

Overview

On March 9, 2011, the Company completed a $30,000 financing transaction to monetize certain future royalty and milestone payments under its license agreement with Shionogi (the "Shionogi Agreement"), pursuant to which Shionogi licensed from the Company the rights to market peramivir in Japan and, if approved for commercial sale, Taiwan. The Company received net proceeds of $22,691 from the transaction after transaction costs of $4,309 and the establishment of a $3,000 interest reserve account by Royalty Sub, which will be available to help cover interest shortfalls in the future.

As part of the transaction, the Company entered into a purchase and sale agreement dated as of March 9, 2011 with Royalty Sub, whereby the Company transferred to Royalty Sub, among other things, (i) its rights to receive certain royalty and milestone payments from Shionogi arising under the Shionogi Agreement, and (ii) the right to receive payments under a Japanese yen/US dollar foreign currency hedge arrangement (as further described below, the "Currency Hedge Agreement"), put into place by the Company in connection with the transaction. Royalty payments will be paid by Shionogi in Japanese yen and milestone payments will paid in U.S. dollars. The Company's collaboration with Shionogi was not impacted as a result of this transaction.

Non-Recourse Notes Payable

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of $30,000 in aggregate principal amount of its PhaRMA Senior Secured 14% Notes due 2020 (the "PhaRMA Notes"). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the "Indenture"), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes issued are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. The PhaRMA Notes bear interest at 14% per annum, payable annually in arrears on September 1st of each year, beginning on September 1, 2011 (the "Payment Date"). The Company remains entitled to receive any royalties and milestone payments related to sales of peramivir by Shionogi following repayment of the PhaRMA Notes.

Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of the Company's pledge of its equity interests in Royalty Sub in support of the PhaRMA Notes. The Company may, but is not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhaRMA Notes.

In September 2013, Royalty Sub paid $1,844 of interest on the PhaRMA Notes from royalty payments received from RAPIACTA® sales from the preceding four calendar quarters. This payment resulted in an obligation shortfall of approximately $2,356 associated with accrued interest due September 3, 2013. As stipulated under the PhaRMA Notes Indenture, if the amount available for payment on any Payment Date is insufficient to pay all of the interest due on a Payment Date, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Accordingly, commencing in September 2013, the Company began accruing interest at 14% per annum on the interest shortfall of $2,356. Under the terms of the Indenture, Royalty Sub's inability to pay the full amount of interest payable in September 2013 did not constitute an event of default under the PhaRMA Notes unless the shortfall, plus interest thereon, is not satisfied on the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2014.

The Indenture does not contain any financial covenants. The Indenture includes customary representations and warranties of Royalty Sub, affirmative and negative covenants of Royalty Sub, Events of Default and related remedies, and provisions regarding the duties of the Trustee, indemnification of the Trustee, and other matters typical for indentures used in structured financings of this type.

As of September 30, 2013, the aggregate fair value of the PhaRMA Notes approximate the carrying value of $30,000 since the stated rate and terms are representative of current rates and terms available to the Company. The fair value was determined by a quoted price in a not actively traded market representing Level 2 in the fair value hierarchy as defined by U.S. GAAP.

Beginning on March 9, 2012, the PhaRMA Notes became redeemable by Royalty Sub. Accordingly, the PhaRMA Notes are redeemable at the option of Royalty Sub at any time at a redemption price equal to the percentage of the outstanding principal balance of the PhaRMA Notes being redeemed specified below for the period in which the redemption occurs, plus accrued and unpaid interest through the redemption date on the PhaRMA Notes being redeemed:

Payment Dates (Between Indicated Dates)	Redemption Percentage
From and including March 9, 2013 to and including March 8, 2014	103.5%
From and including March 9, 2014 and thereafter	100.0%

Foreign Currency Hedge

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, the Company has the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which the Company may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of $1,950 will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement.

The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments resulted in a gain of $97 and a loss of $572 for the three months ended September 30, 2013 and 2012, respectively, and a gain of $3,168 and a loss of $1,531 for the nine months ended September 30, 2013 and 2012, respectively. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds. As of September 30, 2013, $1,890 was posted under the Currency Hedge Agreement. The Company will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. Subject to certain obligations the Company has in connection with the PhaRMA Notes, the Company has the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and payment of a $1,950 termination fee. If the Company terminates the hedge agreement with respect to currency hedges for 2016 through 2020, the maximum obligation under the currency hedge is $5,850, including the $1,950 termination fee.

Note 5 — Stockholders' Equity

In June 2011, the Company entered into an At Market Issuance Sales Agreement (the "ATM") with McNicoll, Lewis & Valak ("MLV") pursuant to which the Company may issue and sell $70,000 in shares of its common stock at current market prices under a Form S-3 registration statement with MLV acting as the sales agent. Subject to the terms and conditions of the ATM, MLV will use commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instruction, including any price, time or size limits or other customary parameters or conditions the Company may impose. The Company will pay MLV an aggregate commission rate of 2% of the gross proceeds of the sales price per share of any common stock sold under the ATM. On June 28, 2011, the Company filed a Registration Statement on Form S-3, which became effective on July 13, 2011, for the issuance and sale of up to $70,000 of equity or other securities. During the nine months ended September 30, 2013, the Company sold an aggregate of 2,883 shares of common stock at an average per share price of $1.85 pursuant to the Agreement for net proceeds of $5,218.

On August 6, 2013, the Company completed a public offering of 4,600 shares of common stock at a price of $4.40 per share. Net proceeds available to the Company from the offering, after deducting costs, were approximately $18,500.

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 and elsewhere in this report, as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K , Quarterly Reports on Form 10-Q and Current Reports on Form 8-K . See "Information Regarding Forward-Looking Statements."

Cautionary Statement

The discussion herein contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created in Section 21E. Forward-looking statements regarding our financial condition and our results of operations are based upon our consolidated financial statements, which have been prepared in accordance with U.S. GAAP, as well as projections for the future. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to biotechnology and biopharmaceutical companies, including risks inherent in our drug discovery, drug development and commercialization efforts, clinical trials, uncertainty of regulatory actions and marketing approvals, reliance on collaborative partners, enforcement of patent and proprietary rights, the need for future capital, competition associated with products, potential competition associated with our product candidates and retention of key employees. In order for any of our product candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the product candidate to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, and obtain market acceptance and adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements. Statements contained in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report which are not historical facts are, or may constitute, forward-looking statements. Forward-looking statements involve known and unknown risks that could cause our actual results to differ materially from expected results. The most significant known risks are discussed in the section entitled "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on any forward-looking statements.

Our revenues are difficult to predict and depend on numerous factors, including the prevalence and severity of influenza in regions for which peramivir has received regulatory approval, seasonality of influenza, ongoing discussions with government agencies regarding future peramivir and/or BCX4430 development, as well as entering into, or modifying, licensing agreements for our product candidates. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward and the achievement of developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend on several factors, including research and development expenses (and whether these expenses are reimbursable under government contracts), drug manufacturing, and clinical research activities, the ongoing requirements of our development programs, and the availability of capital and direction from regulatory agencies, which are difficult to predict. Management may be able to control the timing and level of research and development and general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Overview

We are a biotechnology company that designs, optimizes and develops novel drugs that block key enzymes involved in the pathogenesis of diseases. We focus on therapeutic areas with unmet medical needs that are of interest to us and aligned with our capabilities and expertise. We integrate the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design. Our strategy is to create a sustainable portfolio of commercial products and product candidates whereby we out-license rights to product candidates in geographies or therapeutic areas where we do not intend to and/or do not have the ability to commercialize them. We currently have commercial partnerships with Shionogi and Green Cross and a development partnership with Mundipharma.

Critical Accounting Policies and Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change and regularly discuss financial events, policies, and issues with members of our audit committee and our independent registered public accounting firm. We routinely evaluate our estimates and policies regarding revenue recognition, administration, inventory and manufacturing, taxes, stock-based compensation, research and development, consulting and other expenses and any associated liabilities.

Recent Corporate Highlights

Peramivir

Peramivir is a potent, intravenously administered investigational antiviral agent that rapidly delivers high plasma concentrations to the sites of influenza infection. Discovered by BioCryst, peramivir inhibits the interactions of influenza neuraminidase, an enzyme that is critical to the spread of influenza within the host. In laboratory tests, peramivir has shown activity against multiple influenza strains, including H7N9, H5N1 and pandemic H1N1 swine flu viral strains. We are developing peramivir under a $234.8 million contract with BARDA/HHS. We are seeking an indication for the treatment of acute uncomplicated influenza and expect to submit the peramivir NDA by the end of 2013.

In March 2013, we received written notification from BARDA/HHS in the form of a Stop-Work Order directing us to cease work on peramivir under our U.S. Government contract, except for certain activities primarily related to our FDA Type C meeting. The notification confirmed that BARDA/HHS would continue to support and fund certain activities necessary to achieve immediate milestones, as well as activities deemed essential to maintain compliance with FDA regulations or to fulfill pending FDA requests.

On April 15, 2013, we announced that we had received final meeting minutes from our Type C meeting regarding i.v peramivir with the FDA. The meeting minutes confirmed that our proposed peramivir NDA content supports a reviewable NDA submission for the indication of acute uncomplicated influenza. In addition, we have completed a pre-NDA meeting with the FDA, and in this meeting, we reached agreement with the FDA regarding all requirements for a complete NDA submission.

On July 11, 2013, we announced that BARDA/HHS released funding of up to $12.8 million under the current $234.8 million contract to fund predominantly all activities necessary to file a New Drug Application (“NDA”) for intravenous peramivir. The decision by BARDA/HHS was a result of an In-Process Review (“IPR”) meeting that occurred in the second quarter of 2013. Based on the results of the IPR, BARDA/HHS decided to modify the March 2013 stop-work order to support activities directly associated with the filing of an NDA. In light of this funding decision, substantially all activities to file the peramivir NDA will be covered by this funding; however, we do expect to incur some modest unreimbursed costs in 2013 for the peramivir program.

BCX4161 & 2nd generation HAE compound

Discovered by BioCryst, BCX4161 is a novel, selective inhibitor of plasma kallikrein in development as an orally administered treatment for the prevention of attacks in patients with hereditary angioedema (“HAE”). By inhibiting plasma kallikrein, BCX4161 suppresses bradykinin production. Bradykinin is the mediator of acute swelling attacks in HAE patients. HAE is a rare, severely debilitating and potentially fatal genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people. HAE symptoms include recurrent episodes of edema in various locations, including the hands, feet, face, genitalia and airway. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation.

In March 2013, we announced initialization of a BCX4161 Phase 1 clinical trial to support the product candidate's development as a treatment for HAE. The main objectives for the BCX4161 Phase 1 clinical trial were to demonstrate safety, adequate and consistent drug exposure, and pharmacodynamic effects after oral administration. On July 22, 2013, we announced that the Phase 1 clinical trial of orally-administered BCX4161 in healthy volunteers successfully met all of its objectives. The safety, tolerability, drug exposure and on-target kallikrein inhibition results of the Phase 1 trial strongly support advancing the development program into a Phase 2a study in HAE patients.

Overall, 87 healthy volunteers completed the study: 30 received a single dose of BCX4161 from 50 mg up to 1000 mg, 40 subjects were dosed with 100 mg, 200 mg, 400 mg, or 800 mg BCX4161 every eight hours for seven days and 17 received placebo. Oral administration of BCX4161 was generally safe and well tolerated. There were no serious adverse events and no dose limiting adverse events. Laboratory tests of coagulation remained normal. Drug exposure was dose proportional through 400 mg three times a day. Steady state (day seven) blood levels were 30% higher compared to the first day of dosing. At 400 mg three times a day, pre-dose geometric mean (coefficient of variance, CV) drug levels on day 7 were 28.6 ng/mL (CV 77%) and post-dose maximum drug levels were 152 ng/mL (CV 57%). Kallikrein inhibition was observed throughout the dosing interval, $p<0.0001$ compared to placebo.

In late October 2013, we initiated participant screening in a proof of concept Phase 2a clinical trial in patients with HAE (entitled "OPuS-1"). This trial will test 400 mg of BCX4161 administered three times daily for 28 days in a randomized, placebo-controlled, two-period cross-over design. Approximately 25 HAE patients who have a high frequency of attacks (more than one per week) will be enrolled. The main goals for this clinical trial are to evaluate the safety and tolerability of BCX4161 and to estimate the degree of efficacy in reducing the frequency of attacks. This study is designed to provide proof of concept for oral kallikrein inhibition as a treatment strategy for HAE. On July 31, 2013, we were notified by the FDA that it had removed the clinical hold placed on BCX4161. This notification provides us the ability to initiate BCX4161 clinical trials in the United States and/or include U.S. clinical sites in our BCX4161 clinical trials. To date, our BCX4161 clinical trials have not been conducted in the U.S.

In addition, we are finalizing our nonclinical evaluation of a number of potent and specific second generation oral kallikrein inhibitors with oral bioavailability between 20% and 60%. One or more compounds are expected to enter preclinical development before the end of 2013.

BCX4430

In September 2013, the National Institute of Allergy and Infectious Diseases ("NIAID") contracted with BioCryst for the development of BCX4430 as a treatment for Marburg virus disease. NIAID, part of the National Institutes of Health, made an initial award of $5.0 million to BioCryst. The total funding under the contract could be up to $22.0 million, if all contract options are exercised by NIAID. The goals of this contract are to file investigational new drug ("IND") applications for intravenous ("i.v.") and intramuscular ("i.m.") BCX4430 for the treatment of Marburg virus disease, and to conduct an initial Phase 1 human clinical trial. The aggregate $22.0 million contract and option funding supports the appropriate IND-enabling program and the initial clinical trial.

On November 12, 2012, we announced proof-of-principle data at the 2nd Antivirals Congress in Cambridge demonstrating that BCX4430 is efficacious and well-tolerated in a preclinical disease model for evaluating efficacy against yellow fever virus infection.

The objective of our broad spectrum antiviral ("BSAV") program is to develop a broad-spectrum therapeutic for viruses that pose a threat to national health and security. We are continuing our collaboration with U.S. Army Medical Research Institute of Infectious Diseases ("USAMRIID") regarding filoviruses, while seeking additional U.S. Government funding for the further development of BCX4430. The primary focus of the program is treatment of hemorrhagic fever viruses, such as Marburg virus and Ebola virus. BCX4430 is the lead compound in our BSAV research program.

Ulodesine

Ulodesine is a purine nucleoside phosphorylase ("PNP") inhibitor developed as a once-daily oral, chronic treatment for gout. It acts upstream of xanthine oxidase in the purine metabolism pathway to reduce the production of serum uric acid ("sUA"). Xanthine oxidase inhibitors, such as allopurinol and febuxostat, reduce uric acid production. In Phase 2 clinical trials, the combination of low doses of ulodesine and allopurinol resulted in a synergistic effect in reducing sUA.

In July 2012, we announced favorable 52-week safety results and sustained efficacy from the extension phase of the randomized Phase 2b clinical trial of ulodesine added to allopurinol in patients with gout who had failed to reach the sUA therapeutic goal of <6 mg/dL on allopurinol alone, as well as positive Phase 2 safety results in patients with mild to moderate

renal impairment. The approximate doubling of sUA response rates with ulodesine seen at 12 weeks was sustained through 52 weeks of treatment. After 52 weeks of treatment, ulodesine doses of 5 mg, 10 mg, and 20 mg/day showed response rates of 45%, 47% and 64%, respectively, compared to 19% for placebo. With the results of the 203 clinical trial, we have now concluded Phase 2 testing and are ready for Phase 3 development. We intend to out-license ulodesine on a worldwide basis prior to initiating Phase 3 development. Due to the cost of Phase 3 development and commercialization, we do not plan to initiate Phase 3 development without a partner. We cannot predict if, or when, we will be successful with an outlicensing transaction.

Forodesine

Discovered by BioCryst, forodesine is a PNP inhibitor in development by Mundipharma as a treatment for cancer under a world-wide license agreement. In January 2013, Mundipharma's Japanese subsidiary, Mundipharma K.K., initiated enrollment in a phase 1/2 clinical trial of forodesine in recurrent/refractory peripheral t-cell lymphoma patients. The objective of the Phase 1 portion is to confirm safety and tolerability in recurrent/refractory peripheral T-cell lymphoma patients during repeated oral administration of forodesine 300 mg twice daily for 28 days, to evaluate pharmacokinetics, and to determine the recommended dose for Phase 2. The goal of the Phase 2 portion is to evaluate the efficacy, safety, and pharmacokinetics of the recommended dosage regimen determined in the Phase 1 portion. The primary efficacy endpoint shall be objective response rate ("ORR") based on evaluation by an image assessment committee.

On November 11, 2011, we entered into the Amended and Restated License and Development Agreement with Mundipharma, amending and restating the February 1, 2006 exclusive, royalty-bearing Development and License Agreement for the development and commercialization of forodesine for use in the field of oncology. Under the terms of the Amended and Restated Agreement, Mundipharma obtained worldwide rights to forodesine, so they now control the worldwide development and commercialization of forodesine and assume all future development and commercialization costs. Additionally, on November 17, 2011, we further amended our agreements with AECOM/IRL whereby AECOM/IRL agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined in the Amended and Restated Agreement) received by us under our Amended and Restated Agreement with Mundipharma.

The Amended and Restated Agreement is a multiple element arrangement for accounting purposes in which we are required to deliver to Mundipharma both the worldwide rights to forodesine and the transfer of product data and know-how to permit Mundipharma to develop and commercialize forodesine (the "Knowledge Transfer"). The world-wide license rights were granted to Mundipharma upon execution of Amended and Restated Agreement and the Knowledge Transfer was completed in the first quarter of 2012. We have accounted for these elements as a combined unit of accounting as neither one has stand-alone value to Mundipharma. Upon completion of the Knowledge Transfer, the unamortized deferred revenue and deferred expense of $7.8 million and $1.9 million, respectively, was recognized in our Statements of Comprehensive Loss in the quarter ended March 31, 2012.

Results of Operations (three months ended September 30, 2013 compared to the three months ended September 30, 2012)

For the three months ended September 30, 2013, total revenues decreased to $2.4 million compared to $5.8 million for the three months ended September 30, 2012. This decrease resulted primarily from the recognition of $2.8 million of previously deferred RAPIACTA® royalty revenue in the third quarter of 2012 and approximately a $532,000 decline in reimbursable BARDA/HHS revenue associated with a decline in third quarter 2013 reimbursable peramivir development expenses, as compared to the third quarter of 2012. Revenues in the third quarter of 2013 included $2.1 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of i.v. peramivir and $0.3 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the third quarter of 2012 included $2.8 million of royalty revenue from Shionogi sales of RAPIACTA®, $2.7 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and $0.3 million associated with collaborative revenue amortization from other corporate partnerships.

Research and development expenses for the third quarter of 2013 decreased to $8.0 million from $12.1 million in the same quarter of 2012. The 2013 R&D expenses, compared with 2012, reflect decreased spending on our ulodesine and BCX5191 programs, reduced R&D infrastructure costs and the conclusion of the clinical development program for peramivir and its transition to NDA preparation. This decrease was partially offset by higher development expenses for BCX4161 associated with advancing our hereditary angioedema program.

General and administrative expenses decreased to $1.3 million for the third quarter of 2013 compared to $1.6 million in the same quarter of 2012. The decrease of $0.3 million is due primarily to the December 2012 corporate restructuring that reduced BioCryst's cost structure and operations.

Interest expense related to the non-recourse notes issued in conjunction with the non-dilutive peramivir royalty monetization transaction was $1.2 million for the third quarter of 2013 and 2012. In addition, a mark-to-market gain of $0.1 million was recognized in the third quarter of 2013 related to our foreign currency hedge, established in conjunction with the royalty monetization, as compared to a mark-to-market loss of $0.6 million in the same quarter in 2012. These gains/losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement.

Results of Operations (nine months ended September 30, 2013 compared to the nine months ended September 30, 2012)

For the nine months ended September 30, 2013, total revenues decreased to $6.8 million compared to $22.2 million for the nine months ended September 30, 2012. The decrease was primarily due to the recognition of $7.8 million of previously deferred forodesine-related revenue during the first quarter of 2012, as well as a $6.9 million decrease in BARDA/HHS revenue due to a decline in reimbursable peramivir expenses as compared to the first nine months of 2012. Revenues in the first nine months of 2013 included $2.0 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, $3.8 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of i.v. peramivir and $0.9 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the first nine months of 2012 included the recognition of $7.8 million of previously deferred revenue associated with the Amended and Restated License and Development Agreement with Mundipharma, $2.8 million of royalty revenue from Shionogi sales of RAPIACTA®, $10.7 million of reimbursement of collaborative expenses from BARDA/HHS related to the continued development of i.v. peramivir and $0.9 million associated with collaborative revenue amortization from other corporate partnerships.

Research and development (“R&D”) expenses decreased to $27.1 million for the nine months of 2013 from $40.4 million in the same nine months of the prior year. Lower 2013 development expenses were associated with spending decreases in the BCX5191 and peramivir programs as well as reduced R&D infrastructure costs, which were partially offset by higher BCX4161 costs. In addition, approximately $1.9 million of this decrease resulted from the recognition in the 2012 period of previously deferred expenses associated with the Amended and Restated License and Development Agreement with Mundipharma which was not repeated in the 2013 period.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
R&D expenses by program:				
BCX4161	$4,312	$ 2,306	$10,549	$ 6,593
Peramivir	2,187	2,373	4,479	10,001
BCX4430	623	286	3,173	946
Ulodesine	213	2,698	5,844	8,175
BCX5191	—	2,590	532	6,857
Forodesine	—	—	22	2,176
Other research, preclinical and development costs	642	1,819	2,517	5,626
Total R&D expenses	$7,977	$12,072	$27,116	$40,374

General and administrative expenses decreased to $4.0 million for the first nine months of 2013 compared to $4.9 million in the same period of the prior year. The decrease of $0.9 million is primarily due to the December 2012 restructuring that reduced BioCryst’s cost structure and operations.

Interest expense related to the non-recourse notes issued in conjunction with the non-dilutive peramivir royalty monetization transaction was $3.5 million for the first nine months of both 2013 and 2012. In addition, a mark-to-market gain of $3.2 million was recognized in the first nine months of 2013 related to our foreign currency hedge, established in conjunction with the royalty monetization, compared to a mark-to-market loss of $1.5 million in the same quarter in 2012, resulting from changes in the U.S. dollar/Japanese yen exchange rate. These gains/losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate and the related mark-to-market valuation of our underlying hedge arrangement.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception and we expect our 2013 operating expenses to exceed our 2013 revenue. Our operations have principally been funded through public offerings and private placements of equity

securities; cash from collaborative and other research and development agreements, including government contracts; and to a lesser extent, the PhaRMA Notes financing. In addition, we have funded our operations and specific development programs through government contracts. Currently, we have $234.8 million of funding through December 2013 under a BARDA/HHS contract for the development of peramivir and $5.0 million of committed funding under a $22.0 million contract with NIAID for the development of BCX4430. Our BARDA/HHS contract is subject to a March 2013 stop-work order, which was modified in July 2013 to support activities directly associated with a peramivir NDA filing and to allow up to $12.8 million of funding under the contract to be used for that purpose. However, the level of activity on the peramivir program has decreased as compared to previous quarters and fiscal years, and as a result, revenue associated with reimbursement of peramivir development expenses has become a smaller component of our total revenue and therefore has contributed less to our operating cash flows. On March 9, 2011, we completed a $30.0 million non-recourse debt financing transaction designed to monetize certain future royalty and milestone payments under our license agreement with Shionogi. We received net proceeds from this transaction of approximately $22.7 million. Other sources of funding have included the following:

- other collaborative and other research and development agreements;
- government grants;
- equipment lease financing;
- facility leases;
- research grants; and
- interest income.

As of September 30, 2013, we had net working capital of $33.7 million, an increase of approximately $8.9 million from $24.8 million at December 31, 2012. The increase in working capital was principally due to our normal operating expenses associated with the development of our product candidates, which offset approximately $18.5 million in net proceeds derived from the sale of 4.6 million shares of common stock through our August 2013 public offering, $5.2 million in net proceeds derived from the sale of approximately 2.9 million shares of common stock through our At-the-Market (“ATM”) financing facility and $3.3 million in cash collateral collected under our foreign currency hedge associated with changes in exchange rates. Our principal sources of liquidity at September 30, 2013 were approximately $26.2 million in cash and cash equivalents; approximately $17.2 million in investments considered available-for-sale; and approximately $2.4 million in BARDA/HHS and NIAID receivables. As of September 30, 2013, we have sold an aggregate amount of 7.8 million shares of common stock at an average price of $3.18 pursuant to the ATM for net proceeds of $24.2 million. There were no sales of common stock under our ATM arrangement in the third quarter of 2013.

We have attempted to contain costs and reduce cash flow requirements by closely managing our third party costs and headcount, 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 in general, and specifically related to our clinical trial activity. We also expect to incur substantial expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical products advance through later stages of development. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

At December 31, 2012, we had long-term operating lease obligations, which provide for aggregate minimum payments of approximately $1.0 million in 2013, $1.0 million in 2014 and $0.4 million in 2015. 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 BARDA/HHS, NIAID and from other U.S. Government entities;
- 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 equity financing.

As our clinical programs continue to progress and patient enrollment increases, our costs will increase. Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing development of our product candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and cash burn rate could vary significantly

depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount and timing of funding we receive from BARDA/HHS for peramivir and NIAID for BCX4430, the amount of funding or assistance, if any, we receive from other governmental agencies or other new partnerships with third parties for the development of our product candidates, the progress and results of our current and proposed clinical trials for our most advanced product candidates, the progress made in the manufacturing of our lead product candidates and the progression of our other programs.

With the funds available at September 30, 2013, future amounts that are expected to be received from BARDA/HHS and NIAID, and our other financing sources, we believe these resources will be sufficient to fund our operations through 2014. However, this is a forward looking statement, and there may be changes that would consume available resources significantly before such time.

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

- our ability to perform under the contracts with BARDA/HHS and NIAID and receive reimbursement;
- the progress, number of programs and magnitude of our research, drug discovery and development activities;
- changes in existing collaborative relationships or government contracts;
- our ability to establish new and 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 product candidates or a decision to build or expand internal development and commercial capabilities;
- our, or our partners', ability to obtain regulatory approval of our product candidates;
- 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 product candidates;
- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our product candidates to support our preclinical research and clinical trials;
- changes in personnel and related costs to support the development of our product 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 and we may seek to raise capital at any time we deem market conditions to be favorable. Additional funding, whether through additional sales of equity or debt securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from the BARDA/HHS and NIAID contracts 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. Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates as well as rate of reimbursement by BARDA/HHS of our peramivir expenses and NIAID of our BCX4403 expenses. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our product candidates; obtaining funding from collaborative partners; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our product candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; and the level of required administrative support for our daily operations.

Financial Outlook for 2013

Based upon our strategic and development operations, we expect 2013 operating cash usage to be in the range of $22 to $26 million, and expect our total 2013 operating expenses to be in the range of $45 to $55 million. Our operating cash forecast remains unchanged from the guidance originally provided in February 2013. Our operating expense range increased from our February guidance range of $25 to $35 million based upon the incremental operating expenses associated with the pending peramivir NDA filing and the write-off of deferred collaboration costs associated with our PNP agreement. Our operating cash forecast excludes any impact of our royalty monetization, hedge collateral posted or returned, sale of stock in the marketplace, and any other non-routine cash outflows or inflows, such as restructuring and transaction costs. Our ability to remain within our operating expense and operating cash target ranges is subject to multiple factors, including unanticipated or additional general development and administrative costs and other factors described under the “Risk Factors” section located elsewhere in this report.

Off-Balance Sheet Arrangements

As of September 30, 2013, we are not involved in any unconsolidated entities or off-balance sheet arrangements.

Critical Accounting Policies

We have established various accounting policies that govern the application of U.S. GAAP, which were utilized in the preparation of our consolidated 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 consolidated financial statements included in our 2012 Annual Report on Form 10-K, 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 consolidated financial statements.

Accrued Expenses

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost 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 based on the 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 CROs 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 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 expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Revenue Recognition

The Company recognizes revenues from collaborative and other research and development arrangements and product sales. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees is 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 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, we evaluate whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of our license agreements, we receive royalty payments based upon our licensees' net sales of covered products. Generally, under these agreements, we receive royalty reports from our licensees. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured. Royalty revenue paid by Shionogi on their product sales is subject to returns.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. Event payments are recognized as revenue upon the achievement of specified events if (1) the event is substantive in nature and the achievement of the event was not reasonably assured at the inception of the agreement and (2) the fees are non-refundable and non-creditable. Any event payments received prior to satisfying these criteria are recorded as deferred revenue. Under our contracts with BARDA/HHS and NIAID, revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates.

Research and Development Expenses

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

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

At September 30, 2013, we had deferred collaboration expenses of approximately $0.3 million. These deferred expenses were sub-license payments, paid to our academic partners upon receipt of consideration from various commercial partners. These deferred expenses would not have been incurred without receipt of such payments or modifications from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

We group our R&D expenses into two major categories: direct external expenses and indirect expenses. Direct expenses consist of compensation for R&D personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, patent-related costs, as well as other costs related to our clinical and preclinical studies. These costs are accumulated and tracked by program. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. These costs apply to work on our clinical and preclinical candidates as well as our discovery research efforts.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock awards, are recognized in our Consolidated Statements of Comprehensive Loss based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis 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. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock awards is based on the grant date closing price of the common stock. Compensation expense is recognized on a straight-line basis over the vesting periods. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. Significant management judgment is also required in determining estimates of future stock price volatility and forfeitures to be used in the valuation of the options. Actual results, and future changes in estimates, may differ substantially from our current estimates.

Foreign Currency Hedge

In connection with our issuance of the PhaRMA Notes, we entered into a foreign Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2014 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of $2.0 million will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement. In conjunction with establishing the Currency Hedge Agreement, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our financial results. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. In establishing the hedge, we provided initial funds of approximately $2.0 million to support our potential hedge obligations. Subject to certain obligations we have in connection with the PhaRMA Notes, we have the right to terminate the Currency Hedge Agreement with respect to the 2016 through 2020 period by giving notice to the counterparty prior to May 18, 2014 and payment of a $2.0 million termination fee. Prior to this termination date, the maximum amount of hedge collateral we may be required to post would be $5.9 million.

The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark-to-market adjustments will be recognized in our Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments for the nine months ended September 30, 2013 resulted in a $3.2 million gain. Mark-to-market adjustments are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by U.S. GAAP Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds and $1.9 million was posted under the agreement as of September 30, 2013.

Tax

We account for uncertain tax positions in accordance with U.S. GAAP. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income in each of the jurisdictions in which we operate and the period over which our deferred tax assets will be recoverable.

Information Regarding Forward-Looking Statements

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

- the initiation, timing, progress and results of our preclinical testing, clinical trials, and other research and development efforts;

- the potential funding from our contract with BARDA/HHS for the development and support of the NDA filing for peramivir and the potential funding from our contract with NIAID for the development of BCX4430;
- the NDA filing or FDA approval of peramivir;
- the potential for a stockpiling order or profit from any order for peramivir;
- the potential use of peramivir as a treatment for H1N1, H5N1 and H7N9 or other strains of influenza;
- the further preclinical or clinical development and commercialization of our product candidates, including our HAE program, peramivir, BCX4430, forodesine, ulodesine and other PNP inhibitor development programs;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our ability to establish and maintain collaborations or out-license rights to our drug candidates;
- plans, programs, progress and potential success of our collaborations, including Mundipharma for forodesine and Shionogi and Green Cross for peramivir in their territories;
- Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub;
- the foreign currency hedge agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, revenues, capital requirements and our needs for additional financing, including our financial outlook for the remainder of 2013;
- the timing or likelihood of regulatory filings and approvals;
- our ability to raise additional capital to fund our operations
- our financial performance; and
- competitive companies, technologies and our industry.

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio and borrowings under our PhaRMA Notes.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities 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.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments. We generally have the ability to hold our fixed-income investments to maturity and therefore

do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

Foreign Currency Risk

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we are required to post collateral based on our potential obligations under the Currency Hedge Agreement as determined by periodic mark to market adjustments. Provided the Currency Hedge Agreement remains in effect, we may be required to pay a premium in the amount of $2.0 million in each year beginning in May 2014 and continuing through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the Currency Hedge Agreement) is such that the U.S. dollar is worth 100 yen or less.

Item 4. Controls and Procedures

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Exchange Act is recorded, processed, summarized and reported in a timely manner under the Exchange Act. We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2013, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. *RISK FACTORS*

An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the Securities and Exchange Commission, before deciding to buy our common stock.

Risks Relating to Our Business

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

Since our inception, we have not achieved profitability. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. We expect that such losses will fluctuate from quarter to quarter and losses and fluctuations may be substantial.

To become profitable, we, or our collaborative partners, must successfully manufacture and develop product candidates, receive regulatory approval, and successfully commercialize and/or enter into profitable agreements with other parties. It could be several years, if ever, before we receive significant royalties from any current or future license agreements or revenues directly from product sales.

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

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

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The clinical trial process is complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the clinical trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have a reasonable commercial potential. We may suffer significant setbacks in pivotal clinical trials, even after earlier clinical trials show promising results. Clinical trials may not be adequately designed or executed, which could affect the potential outcome and analysis of study results. Regulatory authorities may interrupt, delay or halt clinical trials for a product candidate for any number or reasons.

Any of our product candidates may produce undesirable side effects in humans. These side effects could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. These side effects could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability.

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

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

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Lack of adequate drug supply or delays in patient enrollment, including in our planned trials for HAE, 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, including with respect to our planned NDA filing for peramivir.

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

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the trial protocols. Failure to achieve either of these in any of our programs, including BCX4161, could result in delays in our trials or require the performance of additional unplanned trials. This could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.

If we are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, or development and commercial diligence obligations, are unable or fail to make milestone payments or material data use payments in accordance with applicable provisions, or fail to pay the minimum annual payments under our respective licenses, our licensors may terminate the applicable license or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

If we fail to obtain additional financing or acceptable partnership arrangements, we may be unable to complete the development and commercialization of our product candidates or continue operations.

As our programs advance, our costs are likely to increase. Our current and planned clinical trials plus the related development, manufacturing, regulatory approval process requirements, and additional personnel resources and testing required for supporting the development of our product candidates will consume significant capital resources. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to raise additional capital; the development progress of our collaborative agreements for our product candidates; the amount of funding we receive from BARDA/HHS for peramivir; the amount of funding or assistance we receive from the National Institute of Allergy and Infectious Diseases ("NIAID") or other government agencies for BCX4430 or from other new partnerships with third parties for the development of our product candidates including ulodesine or BCX4161; the amount or profitability of any orders for peramivir or BCX4430 by any government agency or other party; the progress and results of our current and proposed clinical trials for our most advanced drug product candidates, including BCX4161; the progress made in the manufacturing of our lead products and the progression of our other programs. We expect that we will be required to enter into one or more acceptable partnership arrangements in order to complete the development of ulodesine for the treatment of gout. The inability to enter into sufficient acceptable partnership arrangements may require us to terminate the development of ulodesine.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time. Additional funding, whether through additional sales of securities or collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and from any BARDA/HHS or NIAID 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 or lack of an acceptable partnership may require us to delay, scale-back or eliminate certain of our research and development programs.

In order to continue future operations and continue our drug development programs, we will be required to raise additional capital. In addition to seeking strategic partnerships, transactions and government funding, we may decide to access the equity or debt markets or seek other sources to meet liquidity needs. Our ability to raise additional capital may be limited and may greatly depend upon the success of ongoing development related to our current drug development programs, including the planned NDA filing for peramivir, the Phase 2a clinical trial of BCX4161, progress of our second generation HAE compounds, and funding for and continued successful development of BCX4430. In addition, constriction and volatility in the equity and debt markets may restrict our future flexibility to raise capital when such needs arise. Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, and the U.S. Government) which may be unstable or may become unstable in the current economic and political environment. Any such instability may impact these parties' ability to fulfill contractual obligations to us or they might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted. Any such unfavorable outcomes in our current programs or unfavorable economic conditions could place severe downward pressure on the stock and credit markets, which could reduce the return available on invested corporate cash, which if severe and sustained could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development of our product candidates.

If BARDA/HHS were to eliminate, reduce or delay funding from our contract, this would have a significant negative impact on our revenues, cash flows and the development of peramivir.

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

In contracting with BARDA/HHS, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination.
U.S. Government contracts typically contain extraordinary provisions that would not typically be found in commercial contracts. For instance, government contracts permit unilateral modification by the government, interpretation of relevant regulations (i.e., federal acquisition regulation clauses), and the ability to

terminate without cause. In addition, U.S. Government contracts are subject to an in-process review, where the U.S. Government will review the project and will consider its options under the contract. As such, we may be at a disadvantage as compared to other commercial contracts. U.S. Government contracts are subject to audit and modification by the government at its sole discretion. If the U.S. Government terminates its contract with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

Our government contracts with BARDA/HHS and NIAID have special contracting requirements, which create additional risks of reduction or loss of funding.

We have entered into a contract with BARDA/HHS for the advanced development of our neuraminidase inhibitor, peramivir. We have also entered into a contract with NIAID for the development of BCX4430 as a treatment for Marburg virus disease.

In contracting with these government agencies, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. U.S. Government contracts typically contain extraordinary provisions that would not typically be found in commercial contracts. For instance, government contracts permit unilateral modification by the government, interpretation of relevant regulations (i.e., federal acquisition regulation clauses), and the ability to terminate without cause. In addition, U.S. Government contracts are subject to an in-process review, where the U.S. Government will review the project and will consider its options under the contract. As such, we may be at a disadvantage as compared to other commercial contracts.

U.S. Government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, each of which subjects us to additional risks. These risks include the ability of the U.S. Government to unilaterally:

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

The U.S. Government may terminate its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination for default provisions do not permit these recoveries. In the event of termination, the U.S. Government may dispute wind down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. Government for denying certain payments under the contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, if the U.S. Government terminates its contract with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

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. Audits conducted by the U.S. Government for the BARDA/HHS contract have been performed and concluded through fiscal 2009; all subsequent fiscal years are still open and auditable. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event BARDA/HHS or NIAID determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA/HHS or NIAID would be entitled to recoup any overpayment from us as a result. 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 product candidates or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.

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

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;

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

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our product candidates would severely affect our business, because if our product candidates 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 milestone, product sales or royalty payments.

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

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

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

- we or our collaborators may fail to successfully complete clinical trials sufficient to obtain FDA marketing approval;
- many competitors are more experienced, have significantly more resources, and their products could reach the market before ours, be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy which could result in decreased commercial value of our Company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products is 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 from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and manufacture, market and commercialize any approved drugs.

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

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

- discovery of compounds that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;
- licensing or design of enzyme inhibitors for development as product candidates;
- execution of some preclinical studies and late-stage development for our compounds and product candidates;

- management of our clinical trials, including medical monitoring and data management;
- execution of additional toxicology studies that may be required to obtain approval for our product candidates; and
- manufacturing the starting materials and drug substance required to formulate our drug products and the product candidates to be used in both our clinical trials and toxicology studies.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our drug 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 or perform their services inconsistent with industry standards and not in accordance with the required regulations, this would delay or prevent the development of our product candidates.

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

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

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

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

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

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

To the extent that peramivir is used as a treatment for influenza, there can be no assurance that it will prove to be generally safe, well-tolerated and effective. Emergency use of peramivir may create certain liabilities for us. There is no assurance that we or our manufacturers will be able to fully meet the demand for peramivir in the event of additional orders. Further, we may not achieve a favorable price for additional orders of peramivir in the U.S. or in any other country. Our competitors may develop products that could compete with or replace peramivir. We may face competition in markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

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

Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our 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 product candidates and most of the preclinical and clinical quantities of our product candidates. We depend on these third-party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party manufacturers may encounter difficulties with meeting our requirements, including but not limited to problems involving:

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

These contract manufacturers may not be able to manufacture the materials required for our 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 cGMP 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 maintain current manufacturing or other contract relationships, or enter into new agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance or failure to comply with any regulatory agency on the part of any of our third-party manufacturers, we may not be able to complete development of, seek timely approval 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 product candidate material for further preclinical testing and clinical trials.

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

In March 2011, our wholly-owned subsidiary Royalty Sub issued $30.0 million in aggregate principal amount of PhaRMA Notes. The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and, if approved for commercial sale, Taiwan, (ii) rights to certain payments under a Japanese yen/U.S. dollar foreign currency hedge arrangement put into place by us in connection with the issuance of the PhaRMA Notes and (iii) the pledge by us of our equity interest in Royalty Sub. Payments from Shionogi to us under the Shionogi Agreement will generally not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes. Accordingly, these funds will be required to be dedicated to Royalty Sub's debt service and not available to us for product development or other purposes.

If royalties from Shionogi are insufficient for Royalty Sub to make payments under the PhaRMA Notes or if an event of default occurs under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub, in which case we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes.

Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub, is subject to numerous risks. Peramivir was first approved for marketing and manufacturing in Japan in October 2009 and has been offered for sale in Japan only since January 2010. As a result, there is very little sales history for peramivir in Japan, and there can be no assurance that peramivir will gain market acceptance in the Japanese market. In addition, Shionogi's sales of peramivir are expected to be highly seasonal and vary significantly from year to year, and the market for products to treat or prevent influenza is highly competitive. Under our license agreement with Shionogi, Shionogi has control over the commercial process for peramivir in Japan and Taiwan. Royalty Sub's ability to service the PhaRMA Notes may be adversely affected by, among other things, changes in or any termination of our relationship with Shionogi, reimbursement, regulatory, manufacturing and/or intellectual property issues, product returns, product recalls, product liability claims and allegations of safety issues, as well as other factors. In the event that for any reason Royalty Sub is unable to service its obligations under the PhaRMA Notes or an event of default were to occur under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and exercise other remedies available to them under the indenture in respect of the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes and we might otherwise be adversely affected.

On September 3, 2013, we paid $1.8 million of interest on the PhaRMA Notes from royalty payments received from RAPIACTA® sales from the preceding four calendar quarters. This payment resulted in an obligation shortfall of $2.4 million associated with accrued interest due September 3, 2013. As stipulated under the PhaRMA Notes indenture, if the amount available for payment is insufficient to pay all of the interest due on a Payment Date, the shortfall in interest will accrue interest at the interest rate applicable to the PhaRMA Notes compounded annually. Accordingly, commencing on September 3, 2013, we began accruing interest at 14% per annum on the interest shortfall of $2.4 million. Under the terms of the indenture relating to the PhaRMA Notes, the inability to pay the full amount of interest payable on September 3, 2013 did not constitute an event of default under the PhaRMA Notes unless we fail to pay such unpaid interest, plus interest thereon, on or prior to the next succeeding Payment Date for the PhaRMA Notes, which is September 1, 2014. Based on sales forecasts of RAPIACTA® provided to us by Shionogi, we currently estimate sufficient royalties will be received to fund the September 3, 2013 interest shortfall prior to September 1, 2014, however, no assurances can be given that these royalties will be received and available for payment of the interest shortfall.

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

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

We may be required to pay significant premiums under the foreign Currency Hedge Agreement entered into by us in connection with the issuance of the PhaRMA Notes. In addition, because our potential obligations under the foreign currency hedge are marked to market, we may experience additional quarterly volatility in our operating results and cash flows attributable to the foreign Currency Hedge Agreement.

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

additional quarterly volatility in our operating results and cash flows as a result. Additionally, we may be required to pay significant premiums or a termination fee under the foreign currency hedge agreement entered into by us in connection with the issuance of the PhaRMA Notes. As of September 30, 2013, we have realized a foreign currency hedge gain of approximately $3.2 million and posted cash collateral of approximately $1.9 million.

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

We or our partners must obtain regulatory approval before marketing or selling our future drug products. If we or our partners are unable to receive regulatory approval and do not market or sell our future drug products, we will never receive any revenue from such product sales. In the United States, we or our partners must obtain FDA approval for each drug that we intend to commercialize. The process of preparing for and obtaining FDA approval may be lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation and export laws of the U.S. The FDA has not approved any of our product candidates. Because of the risks and uncertainties in biopharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our product candidates, our management's credibility, our company's value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a product candidate, the approval may limit the indicated uses for a product candidate and/or may require post-marketing studies.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage, or if our vendor data systems fail, suffer damage or are destroyed. If we receive 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.

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. There are many companies seeking to develop products for the same indications that we are working on. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced marketing and manufacturing organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the licensing of desirable disease targets, licensing of desirable 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 influenza, gout, HAE, and recurrent/refractory peripheral t-cell lymphoma, as well as broad spectrum antivirals which may be developed as medical countermeasures. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required funding or government support, obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai Co. Ltd.'s TARGRETIN ® for CTCL and the current neuraminidase inhibitors marketed by GSK and Roche for influenza and CINRYZE, for HAE, marketed by ViroPharma Incorporated. With respect to the neuraminidase inhibitors, these companies may develop i.v. formulations that could compete with peramivir. Further, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and in the fields of PNP, influenza, HAE, 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 impede our funding efforts, render technology and product candidates non-competitive or eliminate or reduce demand for our product candidates.

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, trademark 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 U.S. and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no guarantee that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

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 product candidates to produce revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including but not limited to any trade name, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions have issued to us a number of patents for our various inventions and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate.

We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- 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 cannot be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

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

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

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

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our clinical trials. 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.

Insurance coverage is increasingly more costly and difficult to obtain or maintain.

While we currently have insurance for our business, property, directors and officers, and our products, insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

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

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

In addition, we store most of our preclinical and clinical data at our facilities. Duplicate copies of most critical data are secured off-site. 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.

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

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

Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.

We have a number of shareholders who own greater than 5% of our outstanding common stock. These stockholders, if they act together, may be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions.

Our stock price has been, and is likely to continue to be, highly volatile, which could result in the value of an investment to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended September 30, 2013, the 52-week range of the market price of our stock was from $1.08 to $7.59 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales of our common stock or other derivative securities;

- status of new or existing licensing or collaborative agreements and government contracts;
- announcements relating to the status of our programs;
- developments and announcements regarding new and virulent strains of influenza;
- 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.

Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.

Future sales of our common stock by current stockholders into the public market could cause the market price of our stock to fall. As of October 31, 2013, there were 59,091,393 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition.

On June 28, 2011, we filed with the SEC a shelf registration statement on Form S-3. This shelf registration statement has been declared effective and allows us to sell up to $70.0 million of securities, including common stock, preferred stock, depository shares, stock purchase contracts and warrants, from time to time at prices and on terms to be determined at the time of sale. As of September 30, 2013, we have issued approximately $24.9 million of common stock under this shelf registration utilizing an ATM facility. In addition, we issued 4,600,000 shares of common stock for gross proceeds of $20.2 million, under this shelf registration on August 6, 2013 in a public offering.

As of October 31, 2013, there were 9,557,570 stock options and shares of restricted stock outstanding and 958,958 shares available for issuance under our Amended and Restated Stock Incentive Plan and 87,535 shares available for issuance under our Employee Stock Purchase Plan and we could also make equity compensation grants outside of our Stock Incentive Plan. The shares underlying existing stock options and restricted stock and possible future stock options, stock appreciation rights and stock awards have been registered pursuant to registration statements on Form S-8.

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

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 or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Table of Contents

Item 6. Exhibits

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

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 8th day of November, 2013.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse

Jon P. Stonehouse
President and Chief Executive Officer (Principal Executive Officer)

/s/ Thomas R. Staab, II

Thomas R. Staab, II
Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Principal Accounting Officer)

INDEX TO EXHIBITS

Number	Description
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 4, 2008.
3.4	Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed November 4, 2008.
(10.1)*	Amendment #15 to the Agreement between BioCryst Pharmaceuticals, Inc. and the U.S. Department of Health and Human Services dated September 5, 2013.
(10.2)*	Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases dated September 12, 2013.
(31.1)	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(31.2)	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32.1)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(32.2)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three and nine months ended September 30, 2013, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.*

( ) Filed herewith.
* Confidential treatment requested.

Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked " * * * " and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
Fifteen (15)	See Block 16C	N/A	N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
HHS/OS/ASPR/AMCG 330 Independence Avenue, SW, Room G640 Washington, DC 20201		HHS/OS/ASPR/AMCG	

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

BioCryst Pharmaceuticals, Inc.
4505 Emperor Boulevard, Suite 200
Durham, NC 27703

CODE _____ FACILITY CODE _____

(X) ☐ 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

☒ 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSO100200700032C

10B. DATED (SEE ITEM 13)
January 3, 2007

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 ACKNOWLEDGMENT 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 your 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)

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

CHECK ONE	
☐	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: FAR 52.242-15, Stop-Work Order
☐	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ 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: To extend the period of the Stop-Work Order for an additional 116 days until December 31, 2013. The Stop-Work Order is revised to include three (3) additional activities: 1) $*** cap for NDA package preparation including all related activities, virology testing/ analysis; 2) Shionogi Transfer Fee not to exceed $*** and access to all the Shionogi data sets for BARDA review; and 3) Work associated with formalizing pediatric plan.

Total contract amount remains unchanged ($234,852,147).
Contract completion date remains unchanged (December 31, 2013).

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
		Kim Morris	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA (Signature of Contracting Officer)	16C. DATE SIGNED

NSN 7540-01-152-8070
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA FAR (48 CFR) 53.243

Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked " * * * * " and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.

OMB Approval 2700-0042

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE 1 OF PAGES 58
	▶	N/A	

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
HHSN272201300017C	09/16/2013	313360, 3133364 & 3133371

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3156, MSC 7612 Bethesda, Maryland 20892-7612		MID RCB-A BAA-NIAID-DMID-NIHAI2012149	N/A

7. NAME AND ADDRESS OF CONTRACTOR (No. street, county, state and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT	10. SUBMIT INVOICES	ITEM
BioCryst Pharmaceuticals, Inc. 4505 Emperor Blvd., Suite 200 Durham, NC 27703	☐ FOB ORIGIN ☒ OTHER (See below) FOB Destination	N/A	ADDRESS SHOWN IN:	Art. G.3

CODE	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
Article F.2	N/A	See Article G.3	N/A

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c)( ) ☒ 41 U.S.C. 253(c)(1)

ACCOUNTING AND APPROPRIATION DATA:
VIN:1231665 SOCC 25.55
CAN: 13-8470098 Obligation Amount: $ 4,996,104

16A. ITEM NO.	16B. SUPPLIES/SERVICES	16C. QUANTITY	16D. UNIT	16E. UNIT PRICE	16F. AMOUNT
	Title: Development of Therapeutic Medical Countermeasures for Biodefense and Emerging Infectious Diseases Period: September 16, 2013 through September 15, 2017 Contract Type: Cost Reimbursement CPFF- Completion	Base Year Option 1 Option 2			$ *** $ *** ***

15G. TOTAL AMOUNT OF CONTRACT ▶ $ 4,996,104

16. TABLE OF CONTENTS

(✓)	SEC.	DESCRIPTION	PAGE(S)	(✓)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
☒	A	SOLICITATION/CONTRACT FORM	1	☒	I	CONTRACT CLAUSES	48
☒	B	SUPPLIES OR SERVICES AND PRICE/COST	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
☒	C	DESCRIPTION/SPECS./WORK STATEMENT	10	☒	J	LIST OF ATTACHMENTS	56
☒	D	PACKAGING AND MARKING	17			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
☒	E	INSPECTION AND ACCEPTANCE	17	☒	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	58
☒	F	DELIVERIES OR PERFORMANCE	18				
☒	G	CONTRACT ADMINISTRATION DATA	24	☐	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
☒	H	SPECIAL CONTRACT REQUIREMENTS	28	☐	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ 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. ☐ 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 continuation 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)	20A. NAME OF CONTRACTING OFFICER
Jon P. Stonehouse CEO	Charles H. Jackson, Jr., Contracting Officer, MID RCB-A,OA,DEA,NIAID

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
(Signature of person authorized to sign)	9-12-13	BY (Signature of Contracting Officer)	9/12/13

NSN 7540-01-152-8069
PREVIOUS EDITION UNUSABLE

26-107
Computer Generated

STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

CONTRACT TABLE OF CONTENTS

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

PART I - THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The focus of this project is to file an IND application for BCX4430 for the treatment of MARV disease delivered IV, IM and to conduct an initial phase 1 human clinical study. BCX4430 shall be developed through the appropriate IND-enabling studies to assess genetic toxicity, drug disposition, toxicology, and safety pharmacology. These studies shall be conducted under GLP conditions, consistent with FDA guidance.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $***.

b. The fixed fee for the Base Period of this contract is $***. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $***.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

Base and Options

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base	***	***	***
Option 1:	***	***	***
Option 2:	***	***	***
Option 3:	***	***	***
Option 4:	***	***	***
Option 5:	***	***	***
Option 6:	***	***	***
Option 7:	***	***	***
Option 8:	***	***	***
Option 9:	***	***	***
Option 10:	***	***	***
Total Base and all Options	***	***	21,956,107

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE B.3. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Establishment of Indirect Cost Rate**

Indirect costs are funded at a rate of ***% of Direct Labor costs; however, the Contractor shall not bill or be reimbursed for indirect costs until such time as an indirect cost proposal has been submitted to the cognizant office responsible for negotiating the indirect cost rates, unless a temporary billing rates has been included herein. Unless otherwise specified below, the indirect cost rate proposal shall be submitted no later than three (3) months after the date of contract award.

The Contractor may bill indirect costs at a temporary billing rate of ***% of Direct Labor costs; until such time as indirect costs have been established, provided, that the Contractor's indirect cost proposal is submitted to the cognizant office responsible for negotiating indirect costs no later than 24 month. If, the indirect cost proposal is not submitted in a timely manner, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

b. ***

To negotiate a Fixed Price type subcontract with*** for GLP in vitro genetic toxicity and reports for an amount not to exceed $*** for the period of ***. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

c. ***

To negotiate a cost reimbursement type subcontract with *** for IND Manufacture of GMP drug substance and reports for an amount not to exceed $*** for the funded Option 1 of ***. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

d. ***

To negotiate a cost reimbursement type subcontract with *** for Drug substance and Drug Product stability and reports for an amount not to exceed $*** for the funded Base Period and Option 2 of ***. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

e. ***

To negotiate a Fixed Price type subcontract with *** for GLP in vitro and in vivo drug disposition/ADME studies and reports for an amount not to exceed $*** for the Base Period of ***. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

f. ***

To negotiate a Fixed Price type subcontract with *** for dose solutions and reports for an amount not to exceed $*** for the Base Period of ***. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

g. **Consultants** Consultant fees to be paid to the following individuals:

Base Period

Name	Rate Per Hour	Number of Hours	Travel (Requires CO approval)	Total Cost Including Travel Not to Exceed
***	$***	***	$***	$***
***	$***	***	$***	$***
***	$***	***	$***	$***
***	$***	***	$***	$***
***	$***	***	$***	$***
Total				$***

Option 1

Name	Rate Per Hour	Number of Hours	Travel (Requires CO approval)	Total Cost Including Travel Not to Exceed
***	$***	***	$***	$***
***	$***	***		$***
***	$***	***		$***
***	$***	***		$***
				$***

Option 2

Name	Rate Per Hour	Number of Hours	Total Cost Including Travel Not to Exceed
***	$***	***	$***
***	$***	***	$***
***	$***	***	$***
			$***

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

h. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

i. **Special Copyright Provisions**

1. In accordance with FAR Clause 52.227-14, Rights in Data General, the Contractor shall seek written permission from the Contracting Officer before establishing a copyright for any software and associated data generated under this contract. Additionally, the Government shall be provided a paid-up, world-wide, irrevocable, nonexclusive license to all rights under any copyright obtained.

j. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. HHSN272201300017C.

NIAID Control No. N01-AI-2013-00017.

k. **Advance Copies of Press Releases**

The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Conferences and Meetings

2. Food for Meals, Light Refreshments, and Beverages

3. Promotional Items *includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.*

4. Acquisition, by purchase or lease, of any interest in real property;

5. Special rearrangement or alteration of facilities;

6. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

7. Travel to attend general scientific meetings;

8. Foreign travel;

9. Consultant costs;

10. Subcontracts;

11. Patient care costs;

12. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of $1,000 or more and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to person use), regardless of acquisition value.

13. Printing Costs (as defined in the Government Printing and Binding Regulations).

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

b. **Travel Costs**

1. Domestic Travel

   Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $0 without the prior written approval of the Contracting Officer.

2. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 S- Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. DESCRIPTION-STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated September 10, 2013, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format via the NIAID electronic Report Deliverable System, available at https://erds.niaid.nih.gov/.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under “Making Files Accessible.”

a. **Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. **Monthly Progress Report**

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The first report shall be due November 14, 2013. Thereafter, reports shall be due on or before the 14th Calendar day following each reporting period.

2. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. An annual report will not be required for the period when the Final Report is due. A Monthly Report shall not be submitted when an Annual Report is due.

The first report shall cover the period September 16, 2013 through September 30, 2014 of this contract and shall be due October 30, 2014within 30 days after the Anniversary Date of the Contract. Thereafter, reports shall be due on or before the 30th Calendar day following the reporting period.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, “Inclusion Enrollment Report,” which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

4. **Final Report**
This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. An Annual report will not be required for the period when the Final Report is due.

5. **Product Development Plan and Work Plan**

The Contractor shall update the Product Development Plan and the Work Plan to incorporate the progress from the effective date of the contract. The Contractor shall submit an updated Product Development Plan and Work Plan for review in accordance with Article F.2. Deliveries, unless otherwise negotiated with the COR and the Contracting Officer. This updated Product Development Plan shall include:

i. Clearly defined goals, product development stages and product development activities.

ii. Go/No Go decision gates.

iii. Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.

iv. A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget linked to each stage. The Work Plan shall include a description of the studies to be performed within each stage of the project. The Contractor shall also be required to submit a revised Product Development Plan and associated Work Plan when a change to the approved plans is requested.
NOTE: for purposes of this BAA:

- The Product Development Plan describes the critical path and for the proposed candidate/ product toward eventual licensure and identifies the decision points/gates for progress of the candidate/product.

- The Work Plan describes the studies to be performed at each stage of the project within the 5 year term of award in order to implement the Product Development Plan and advance the product through phase I testing.

v. Milestone Completion/Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the Work Plan for the Implementation of the Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/ or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project. Offerors should propose the timing of these reports to coincide with the decision points specified in their SOW and workplan. Note: Contract activities will be divided into manageable time frames with initial funding of only a Base Period. Funding of subsequent timeframes will be funded by Options. Each Option will be fully funded when exercised and will be dependent on successful completion of critical Milestones, including USG acceptance of associated deliverables when applicable. The critical predecessor activities should constitute Go/No Go criteria for successor activities. The contract budget will be aligned with the Base Period, Options and associated tasks identified in the Product Development Plan and associated Gantt Chart.

vi. Audit Reports

The Contractor shall provide copies of the audit report and a plan in accordance with Article F.2. Deliveries for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

vii. Draft and Final Clinical Trial Protocols

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in the NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit draft protocols for review and all final protocols and protocol amendments for approval by the COR. The consultative review period for submission of draft protocols will be negotiated with the COR. The review period of final protocols will be negotiated with the COR and must occur prior to FDA submission and enrollment. An additional review and approval period may be required for changes in the final protocol. Three (3) weeks should be planned for each review period. It is recommended that protocols be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subject research are available at http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/.

viii. Clinical Study Report

For each clinical study performed with contract support, The contractor shall provide a Draft Clinical Study Report in accordance with Article F.2. Deliveries which includes an analysis of all data generated in the clinical trial. Final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationsheetsandNotices/default.htm#ich).

ix. Animal Study Protocols

The contractor shall provide electronic copies of protocols for all animal studies for review and approval to the COR, in accordance with Article F.2. Deliveries, before review and finalization of the protocol unless otherwise agreed upon by the COR. The animal study protocols are expected to undergo at least one round of revision and resubmission for final approval.

x. Animal Efficacy Reports

For each animal efficacy study performed with contract support, the contractor shall provide a Draft Animal Efficacy Study Report in accordance with Article F.2. Deliveries, unless otherwise approved by the COR, of the completion of the analysis of all data and submitted to COR for review. A Final Animal Efficacy Study Report shall be submitted in accordance with Article F.2. Deliveries after the draft reports have been reviewed. At least one round of revision and resubmission for final approval is to be expected. The Animal Efficacy Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought. For GLP studies the Draft and Final Animal Efficacy Study Report shall have been audited for quality assurance by the Contractor or subcontractor.

xi. FDA Correspondence and Review Summaries

The contractor shall submit electronic copies of the correspondence for review, in accordance with Article F.2. Deliveries, after receiving correspondence from or holding a meeting with the FDA.

xii. Human Subject IRB Annual Report (Form OMB No. 0990-0263)

The contractor shall submit Human Subject Annual Report in accordance with Article F.2. Deliveries.

xiii. Samples of Products

The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. At the time of manufacturing, the contractor shall advise the Contracting Officer Representative concerning the type of material. One hundred therapeutic regimens will be supplied under this contract.

xiv. Technology Transfer

In accordance with Article F.2. Deliveries, the contractor shall submit Technology Transfer packages that include complete protocols, critical reagents for animal models developed and critical, assays or procedures developed and/or improved with contract funding.

xv. Institutional Biosafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments in accordance with Article F.2. Deliveries.

6. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

7. **Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents**

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, the following information shall also be included in each Annual Progress Report:

i. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

ii. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:

a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;

b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Restricted%20Experiments.html);

c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.

d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Annual Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Annual Progress Report.

b. **Other Reports/Deliverables**

1. **Reporting of Financial Conflict of Interest (FCOI)**

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer via the NIAID electronic Report Deliverable System, available at https://erds.niaid.nih.gov/. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

45 CFR Part 94 is available at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45 . See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

(Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

2. **Information Security and Physical Access Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

a. **Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer’s Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. **IT Security Plan (IT-SP)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-SP within thirty (30) days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor’s bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

The Contractor shall review and update the IT-SP in accordance with NIST SP
800-53A, Guide for Assessing the Security Controls in Federal Information Systems and Organizations, on an annual basis.

(Reference subparagraph D.c.1. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

c. **IT Risk Assessment (IT-RA)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

The Contractor shall update the IT-RA on an annual basis.

(Reference subparagraph D.c.2. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

d. **FIPS 199 Assessment**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

(Reference subparagraph D.c.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.

e. **IT Security Certification and Accreditation (IT-SC&A)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

The Contractor shall perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid.

(Reference subparagraph D.c.4. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

f. **Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

g. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/ Nondisclosure.pdf.

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

h. **Vulnerability Scanning Reports**

The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under separate cover on a monthly basis.

(Reference subparagraph E.5. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

3. **Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under “Vendor Information and Documents.”

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, Contracting Officer Representative is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Microbiology and Infectious Diseases
Office of Biodefense Research Affairs
Drug Development Section
6610 Rockledge Drive, Room 3610
Bethesda, Maryland 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from September 16, 2013 through September 14, 2017.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased from the initiation date by the number of months listed below:

Option	Option Period
Base Period	***
Option 1	***
Option 2	***
Option 3	***
Option 4	***
Option 5	***
Option 6	***
Option 7	***
Option 8	***
Option 9	***
Option 10	***

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Progress Report (See Article C.2.a.1)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	First Report is due on or before November 15, 2013. Thereafter this report is due on or before the 15th of each month following each reporting period.
(2)	Annual Progress Report (See Article C.2.a.2)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due on or before the 30th of the month following the end of each 12-month period beginning with the base and exercised options.
(3)	Annual Technical Progress Report for Clinical Research Study Populations (See Article C.2.a.3)	One (1) electronic copy to Contracting Officer (CO), Contracting Officer Representative (COR) and to eRDS.	Report is due on or before the completion of each study.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

Item	Description	Quantity	Delivery Schedule
(4)	Draft and Final Report (See Article C.2.a.4)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Draft report is due on or before 30 calendar days prior to the completion of the contract. Final Report is due on or before the completion date of the contract.
(5)	Product Development Plan and Work Plan (See Article C.2.a.5)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Plan are due within 30 calendar day after the effective date of the contract and prior to the initiation of product development activities.
(6)	Milestone Completion/ Decision Gate Report (See Article C.2.a.5.i, ii, iii, iv & v)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due 14 days after reaching Go/No Go decision point.
(7)	Audit Reports (Refer to Article C.2.a.5.vi)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due within 30 calendar days after the completion of the audit.
(8)	Clinical Trials Protocols (Draft and Final) (Refer to Article C.2.a.5.vii)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Draft Protocol are require a 3 week review period for each submission. Final Protocols must be approved before initition of each clinical trial.
(9)	Clinical Study Report (Draft and Final) (Refer to Article C.2.a.5.viii)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due 30 calendar days prior to the completion of the analysis of the data generated in the clinical trial.
(10)	Animal Safety Protocols (Refer to Article C.2.a.5.ix)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Protocol is due on or before 10 calendar days prior to the initiation of each animal study. Final Study reports are due on or before 60 calendar days after the completion of each animal safety study.
(11)	Animal Efficacy and Toxicology Study protocols (Refer to Article C.2.a.5.ix)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Protocol is due on or before 10 calendar days prior to the initiation of each animal study. Final Study reports are due on or before 60 calendar days after the completion of each animal efficacy study.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

Item	Description	Quantity	Delivery Schedule
(12)	Roster of External Advisory Group (Refer to SOW Section 6)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Roster is due within 6 months after the effective date of the contract.
(13)	External Advisory Group Report (Refer to SOW Section 6)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due within 21 calendar days after any review with the EAG members.
(14)	Post Award Contract Initiation Review Report (Refer to SOW Section 6)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due within 21 calendar days after any review with the EAG members.
(15)	Annual Review Meeting Report (Refer to SOW Section 6)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Due within 21 calendar days following the date of the Annual Review Meeting.
(16)	FDA Correspondence and Meeting Summaries (Refer to Article C.2.a.5.xi)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Correspondence and summaries are due within 5 calendar days after recieving correspondence or meeting with the FDA.
(17)	Human Subjects IRB Annual (Refer to Article C.2.a.5.xii)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Report is due within 30 calendar days after the each anniversary date of the contract award.
(18)	Samples of Products (Refer to Article C.2.a.5.xiii)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Samples products are due within 1 week after the non-GMP candidate therapeutics and GMP materials are manufactured.
(19)	Tech Transfer Reports (Refer to Article C.2.a.5.xiv)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Reports ares due 1 calendar day after each report becomes available.
(20)	Institutional Biosafety Approval (Refer to Article C.2.a.5.xv)	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Document(s) are due 1 calendar day after approval becomes available.

b. The items below are deliverables specific to the base award and each option:

Base and Options Deliverables

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

Item	Stage	Reporting Deliverables	Quantities	Days
Base Award	Non-GMP manufacture of drug substance, drug disposition, genetic toxicity and in vitro and small animal efficacy studies (Refer to SOW Section 2.1)	Study Reports and Decision Gate Report for exercising options 3 and 5.	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart.
Option 1	Manufacture of drug substance and drug product in compliance with cGMP guidance -GMP DP Development (Refer to SOW Section 2.2)	Development report, GMP product to support Phase 1 studies, and required documentation	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Deliverables cited for this option are due on the final day or before completion of this option.
Option 2	DS and DP Stability testing (Refer to SOW Section 2.3)	Final Stability study reports	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Reports for this option are due on the final day or before the completion of the option.
Option 3	IM IND-Enablement and Submission (Refer to SOW Section 2.4)	Study Reports, IND submission to FDA and Decision Gate Report for exercising option 4	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart.
Option 4	IM Phase 1 Clinical Trials (Refer to SOW Section 2.5)	Clinical trial protocols, study reports and Decision Gate Report for exercising Options 10	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart
Option 5	Characterization of Efficacy in a Therapeutic NHP infection model (Refer to SOW Section 2.6)	Study Protocol, Study Reports, Regulatory correspondence and audit reports	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Deliverables cited for this option are due identified in the previous chart

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

Item	Stage	Reporting Deliverables	Quantities	Days
Option 6	IV DP development and Non-GMP DS activities (Refer to SOW Section 2.7)	Development report, stability report, and Decision Gate Report for exercising Options Officer (CO), 7, 8 and 9	One (1) electronic copy each to Contracting option. Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart
Option 7	GMP DS and IV DP Manufacture (Refer to SOW Section 2.8)	Manufactoring summaries, Audit Reports and a Decision Gate Report for exercising Option 10	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart.
Option 8	IV DP Stability (Refer to SOW Section 2.9)	Stability Reports	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Reports for this option are on or before the completion date of this option.
Option 9	IV IND-Enablement and Submission (Refer to SOW Section 2.10)	IND Submission documents, Regulatory correspondence, Audit Reports, and Decision Gate Reports for exercing option 10	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Decision Gate Report is due at the completion of this option. All other deliverables for this option are due identified in the previous chart.
Option 10	Phase 1 IV Clinical Trials (Refer to SOW Section 2.11)	Clincial Trial Protocals and Study Reports	One (1) electronic copy each to Contracting Officer (CO), Contracting Officer Representative (COR) and eRDS.	Deliverables for this option are due identified in the previous chart but no later than the completion date of this option.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

c.

d. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity
Helen F. Schlitz Contracting Officer Representative (COR) e-mail: ***	See above	See above
Charles H. Jackson, Jr. Contracting Officer (CO) e-mail: ***	See above	See above
eRDS (https://erds.niaid.nih.gov/)	All deliverables	N/A

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its 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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER’S REPRESENTATIVE (COR)

The following Contracting Officer’s Representative (COR) will represent the Government for the purpose of this contract:

Helen F. Schiltz, MS, Ph.D

The COR 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.

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 for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
Ray Taylor	Project Leader
Dr. Y. S. Babu	Principal Investigator and Drug Discovery
Dr. William Sheridan	Medical

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a “proper invoice” pursuant to FAR Subpart 32.9, Prompt Payment.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following **designated billing office**:

   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

   b. One copy of the invoice shall be submitted to the following **approving official**:

   Charles H. Jackson, Jr.
   Contracting Officer
   Office of Acquisitions, NIAID, NIH
   6700-B Rockledge Drive Room 3212
   Bethesda, Maryland 20892-7612 MSC 7612
   _____- __

   E-Mail:NIAIDOAInvoices@niaid.nih.gov

   The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
   [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is NIAID.

   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAID_MIDARCB_Invoices.

   c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

e. Invoice Matching Option. This contract requires a two-way match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. The Contract Title is:

Development of Therapeutic Medical Countermeasures for Biodefense and Emerging Infectious Diseases

h. Contract Line Items as follows:

Line Item #	Line Item Description
1	Base - ***
2	Option 1 - GMP DS and IM DP Manufacture
3	Option 2 - DS and IM DP Stability

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

a. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS

a. The Government encourages the contractor to pay small business subcontractors along an accelerated timetable to the maximum extent practicable. The Government recommends payment to small business subcontractors within 15 days of receipt of proper documentation.

b. Include the substance of this article, including this paragraph (b), in all subcontracts with small business concerns.

c. This policy does not modify the application or operation of the Prompt Payment Act.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on the anniversary date of the contract.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

http://www.cpars.gov

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor’s current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer’s written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor’s name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

ARTICLE H.2. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed “Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption”, Form OMB No. 0990-0263 (formerly Optional Form 310) certifying 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 “Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption”, Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed “Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption”, Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

ARTICLE H.3. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (January 2006)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer’s receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) designated under the Contractor’s Federal-wide assurance of compliance. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

Prisoners shall not be enrolled in any HHS research activities until all requirements of HHS Regulations at 45 CFR PART 46, Subpart C have been met. If a Research Subject becomes a prisoner during the period of this contract, 45 CFR PART 46, Subpart C will apply to research involving that individual.

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.5. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Board shall be established and approved prior to beginning the conduct of the clinical trial.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE H.6. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/ getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/ definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Contractor is the Sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

Additional information is available at: http://prsinfo.clinicaltrials.gov.

ARTICLE H.7. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

ARTICLE H.8. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.9. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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: (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.

ARTICLE H.10. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.11. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.12. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.13. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of Clause)

ARTICLE H.14. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http:// grants1.nih.gov/grants/olaw/references/phspol.htm

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated 08/23/2013, which is incorporated by reference.

ARTICLE H.15. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

http://oma.od.nih.gov/manualchapters/intramural/3044-2/

ARTICLE H.16. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

UNDER GOVERNING POLICY, FEDERAL FUNDS ADMINISTERED BY THE PUBLIC HEALTH SERVICE (PHS) SHALL NOT BE EXPENDED FOR RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS WITHOUT PRIOR APPROVAL BY THE OFFICE OF LABORATORY ANIMAL WELFARE (OLAW), OF [**AN ASSURANCE TO COMPLY WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS AND/OR A VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL**]. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES (e.g. COLLABORATING INSTITUTIONS, SUBCONTRACTORS, SUBGRANTEES) WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

ARTICLE H.17. OMB CLEARANCE

In accordance with HHSAR 352.201-70, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed. The clinical exemption will be obtained before data is collected under this contract or subcontract. NIS Manual Chapter 1825 provides additional guidance.

ARTICLE H.18. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.19. INFORMATION AND PHYSICAL ACCESS SECURITY

A. **HHS-Controlled Facilities and Information Systems Security**

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and

Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:

1. HHS-OCIO Information Systems Security and Privacy Policy (http://www.hhs.gov/ocio/policy/ #Security)

2. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)

3. Information regarding background checks/badges (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer’s discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

g. The Contractor shall include language similar to this “HHS Controlled Facilities and Information Systems Security” language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

i. Within 7 calendar days after the Government’s final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply: The contractor must submit monthly vulnerability scans of the IT Systems used to manage data for this contract.

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://nvd.nist.gov/validation.cfm. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered “sensitive” in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer’s Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor’s property management/ control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. **Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72,** (January 2010)

a. **Applicability**. This clause applies whether the entire contract or order (hereafter “contract”), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS’ mission. The term “information technology (IT)”, as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

b. **Contractor responsibilities**. The Contractor is responsible for the following:

1. Protecting Federal information and Federal information systems in order to ensure their -

   a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

   b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

   c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

c. **Contractor security deliverables**. In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

   a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:

      i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.

      ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/ PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

      iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government

on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor’s final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor’s final version into the contract.

4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer’s Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.

    a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor’s final version into the contract as a compliance requirement.

    b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:

        i. Annual testing of the system contingency plan; and

        ii. The performance of security control testing and evaluation.

d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer’s Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in “HHS-Controlled Facilities and Information Systems Security” requirements specified in the SOW/PWS of this contract.

e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor’s and subcontractors’ facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

    a. Have physical or electronic access to HHS’ computer systems, networks, or IT infrastructure; or

    b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor’s information system.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See http://csrc.nist.gov/ publications/PubsSPs.html to access NIST Special Publications (800 Series).

E. **Additional NIH Requirements**

1. **SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)**

a. Information Type:

[ ] Administrative, Management and Support Information:

[X] Mission Based Information:

Biodefense - Category A Pathogens

b. Security Categories and Levels:

Confidentiality Level:	[ ] Low	[X] Moderate	[ ] High
Integrity Level:	[ ] Low	[X] Moderate	[ ] High
Availability Level:	[ ] Low	[X] Moderate	[ ] High
Overall Level:	[ ] **Low**	[X] **Moderate**	[ ] **High**

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

2. **INFORMATION SECURITY TRAINING**

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a) (4), shall complete the NIH Computer Security Awareness Training course at http:// irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about “NIH Information Security Awareness and Training Policy,” at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (https://ocio.nih.gov/InfoSecurity/ training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov.

3. **PERSONNEL SECURITY RESPONSIBILITIES**

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/ Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

4. **LOSS AND/OR DISCLOSURE OF PERSONALLY IDENTIFIABLE INFORMATION (PII) - NOTIFICATION OF DATA BREACH**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email (IRT@mail.nih.gov) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII_Spillage_Proced.doc
NIH Lost or Stolen Assets Report at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO_Stolen_Device-Media_Handling_Procedures.doc

5. **VULNERABILITY SCANNING REQUIREMENTS**

This acquisition requires the Contractor to host an NIH webpage or database. The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (http://www.sans.org/top20/?ref=3706#w1). The Contractor shall report the results of these scans to the Project Officer/COR on a monthly basis, with reports due 10 calendar days following the end of each reporting period. The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE H.20. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/ order exceeding $100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (http://www.hhs.gov/web/508/contracting/technology/vendors.html).

[(End of HHSAR 352.239-73(b)]

d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

[End of HHSAR 352.239-73(c)]

ARTICLE H.21. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

   1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

   2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

   3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

   Significant financial interests do not include the following:

   1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

   2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution’s review of, and response to, such disclosures, and all actions under the Institution’s policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled “Certification of Institutional Policy on Financial Conflicts of Interest”.

If the failure of an Institution to comply with an Institution’s financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution’s review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution’s determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.22. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health 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 National Institute for Allergies and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201300017C.”

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE H.23. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH 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** and the mailing address is:

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

ARTICLE H.24. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

ARTICLE H.25. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://ott.od.nih.gov/pdfs/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

a. Sharing of Model Organisms for Biomedical Research

The plan for sharing model organisms submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

b. Transfer of Human Materials

All human materials transferred to the contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories," located at: http://www.ott.nih.gov/PDFs/Policy-for-the-Transfer-of-Materials.pdf.

The contractor shall coordinate with the **NCI Technology Transfer Center** (see http://ttc,nci.nih.gov) [or the contracting officer will insert name and contact information of the appropriate TDC] to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE H.26. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The contractor shall not conduct work involving a Select Agent or Toxin 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 a Select Agent or Toxin 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.selectagents.gov/Regulations.html) as required, before using NIH funds for work involving a *Select Agent or Toxin*. **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin*, before using NIH funds for any work directly involving a *Select Agent or Toxin*, the foreign institution must provide information satisfactory to the NIAID 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 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, 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 Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins 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. Site visits to foreign laboratories are conducted every three years after the initial review. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the Contracting Officer's Representative (COR) and request and obtain written approval from the Contracting Officer. **Domestic institutions** must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment. **Foreign institutions** require review by a NIAID representative. The prime contractor must contact the COR and the NIAID Office of International Extramural Activities (OIEA) at mailto:niaidforeignawards@niaid.nih.gov for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID website provides an overview of the review process at http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/saconproc.aspx. The Contracting Officer will notify the prime contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the Contracting Officer.**
Listings of HHS and USDA 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.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html.

For foreign institutions, see the NIAID Select Agent Award information:
(http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/default.aspx).

ARTICLE H.27. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm);

2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or

3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

ARTICLE H.28. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://www.usfa.fema.gov/hotel/index.htm.

ARTICLE H.29. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision 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.

ARTICLE H.30. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

ARTICLE H.31. REGISTRATION FEES FOR CONFERENCES, WORKSHOPS AND MEETINGS

A Non-Federal entity co-sponsoring a conference with an Institute/Center (IC) under a contract may charge and collect a registration fee from all participants for the purpose of defraying its portion of the expenses of the conference. Under these circumstances, the Contractor shall document that the registration fees associated with the event are being charged, collected and used solely by the co-sponsor.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government’s estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted by the Contractor from the total cost of the conference.

In addition, prior to each conference, the Contractor shall provide the following information and documentation to the Contracting Officer’s Representative (COR) and Contracting Officer:

1. Co-sponsor’s name
2. Conference name, location, dates, times
3. copy of the agenda
4. A completed ‘Contractor Pre-Conference Expense Offset Worksheet” (Attachment provided in SECTION J).
5. After the conference is held, the Contractor shall submit a completed “Post-Conference Expense Offset Worksheet” (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury. If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the “Post-Conference Expense Offset Worksheet” has been approved by the COR.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

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 as follows: FAR Clauses at: https://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Jan 2012*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*Apr 1984*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*Sep 2006*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*Oct 2010*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*Jan 1997*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*Jan 1997*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*Oct 2010*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-10	*Jul 2013*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.204-13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Aug 2013*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
52.215-2	*Oct 2010*	*Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $700,000)*
52.215-12	*Oct 2010*	*Subcontractor Cost or Pricing Data (Over $700,000)*
52.215-14	*Oct 2010*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $700,000)*

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

FAR CLAUSE NO.	***DATE***	***TITLE***
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*Oct 2010*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.215-23	*Oct 2009*	*Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)*
52.216-7	*Jun 2013*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-8	*Jul 2013*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*Jul 2013*	*Small Business Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Sep 2010*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Oct 2010*	*Affirmative Action for Workers with Disabilities*
52.222-37	*Sep 2010*	*Employment Reports on Veterans ($100,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Feb 2009*	*Combating Trafficking in Persons*
52.222-54	*Aug 2013*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*Aug 2011*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Feb 2009*	*Buy American Act - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*Dec 2007*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-14	*Dec 2007*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*Oct 2010*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*Jan 1986*	*Assignment of Claims*

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

FAR CLAUSE NO.	***DATE***	***TITLE***
52.232-25	*Jul 2013*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer--System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*Jul 2002*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2001*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Jul 2013*	*Subcontracts for Commercial Items*
52.245-1	*Apr 2012*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.253-1	*Jan 1991*	*Computer Generated Forms*

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	***DATE***	***TITLE***
352.202-1	*Jan 2006*	*Definitions - with Alternate paragraph (h) (Jan 2006)*
352.203-70	*Mar 2012*	*Anti-Lobbying*
352.216-70	*Jan 2006*	*Additional Cost Principles*
352.222-70	*Jan 2010*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Jan 2006*	*Publications and Publicity*
352.228-7	*Dec 1991*	*Insurance - Liability to Third Persons*
352.233-71	*Jan 2006*	*Litigation and Claims*
352.242-70	*Jan 2006*	*Key Personnel*
352.242-73	*Jan 2006*	*Withholding of Contract Payments*
352.242-74	*Apr 1984*	*Final Decisions on Audit Findings*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 08/2013].

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

a. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

ARTICLE 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.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

   ".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

4. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

   ".....The Contracting Officer may exercise the option by written notice to the Contractor within 30 days from the government's go decision.

5. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (January 2011).

   "(c) Waiver of evaluation preference.....
   [ ] Offeror elects to waive the evaluation preference."

6. FAR Clause **52.222-29, Notification of Visa Denial** (June 2003).

7. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

8. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

9. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

2. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

3. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

   Note: *P.L. 112-74 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective December 23, 2011.*

   See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/ .

   (For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

4. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (February 2012)

a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at https://www.acquisition.gov.

b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments--

1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

i. Government personnel and authorized users performing business on behalf of the Government; or

ii. The Contractor, when viewing data on itself; and

2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--

i. Past performance reviews required by subpart 42.15;

ii. Information that was entered prior to April 15, 2011; or

iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

c. The Contractor will receive notification when the Government posts new information to the Contractor’s record.

1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

3. As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

d. Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

"Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked "*" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission."**

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated September 10, 2013, 11 pages.

2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4

Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (8/12), 6 pages.

3. Inclusion Enrollment Report

Inclusion Enrollment Report, PHS 398/2590, (Rev. 6/09), 1 page. Located at: http://grants.nih.gov/grants/funding/phs398/enrollmentreport.pdf

4. Inclusion Table

Inclusion Table (Formerly Annual Technical Progress Report Format for Each Study), April, 1998, 1 page. Located at: http://grants.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf

5. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (1/06), 1 page.

6. Research Patient Care Costs

Research Patient Care Costs, NIH(RC)-11, 4/1/84, 1 page.

7. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

8. Commitment To Protect Non-Public Information

Commitment To Protect Non-Public Information, 1 page. Located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf

9. Roster of Employees Requiring Suitability Investigations

Roster of Employees Requiring Suitability Investigations, 1 page. Excel file located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx

10. Employee Separation Checklist

Employee Separation Checklist, 1 page. Fillable PDF format located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

11. Conference Expense Offset Worksheets

Contractor Pre-Conference Expense Offset Worksheet, dated 3/2008, 1 page. Located at: http://oamp.od.nih.gov/ DGS/FORMS/Pre-Conf-worksheet.pdf

Post Conference Expense Offset Worksheet, dated 3/2008, 2 pages. Located at: http://oamp.od.nih.gov/DGS/ FORMS/Post-Conf-worksheet.pdf

“Pursuant to 17 CFR 240.24b-2, confidential information has been omitted in places marked “*” and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application filed with the Commission.”**

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located in the Online Representations and Certifications Application (ORCA) at The System for Acquisition Mangement (SAM) website (http:// www.sam.gov). This includes the changes identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the Contractor’s proposal.

2. NIH Representations & Certifications, dated 08/16/2013

4. Human Subjects Assurance Identification Number FWA00011741.

5. Animal Welfare Assurance Number Pending.

END of the SCHEDULE

Exhibit 31.1

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: November 8, 2013

/s/ JON P. STONEHOUSE

Jon P. Stonehouse
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Thomas R. Staab, II, 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: November 8, 2013

/s/ THOMAS R. STAAB, II

Thomas R. Staab, II
Senior Vice President, Chief Financial Officer and Treasurer

Exhibit 32.1

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 September 30, 2013 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

Jon P. Stonehouse
President and Chief Executive Officer
Date: November 8, 2013

Exhibit 32.2

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 September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas R. Staab, II, 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/ Thomas R. Staab, II

Thomas R. Staab, II
Senior Vice President, Chief Financial Officer and Treasurer
Date: November 8, 2013