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

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014

or

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 001-32587

PHARMATHENE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-2726770**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Park Place, Suite 450, Annapolis, Maryland	**21401**
(Address of principal executive offices)	(Zip Code)

(410) 269-2600
(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 x 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 (§232.405 of this chapter) 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, 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 Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: The number of shares of the registrant's Common Stock, par value $0.0001 per share, outstanding as of November 3, 2014 was 63,373,584.

PHARMATHENE, INC.

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Item 1. Financial Statements

PHARMATHENE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,620,392	$ 10,480,979
Billed accounts receivable	-	1,427,113
Unbilled accounts receivable	303,667	2,199,525
Prepaid expenses and other current assets	661,360	231,491
Total current assets	20,585,419	14,339,108
Property and equipment, net	362,458	386,068
Other long-term assets and deferred costs	53,384	65,660
Goodwill	2,348,453	2,348,453
Total assets	$ 23,349,714	$ 17,139,289
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 282,024	$ 1,128,172
Accrued expenses and other liabilities	2,552,674	3,182,687
Deferred revenue	56,786	341,723
Current portion of long-term debt	993,322	999,996
Current portion of derivative instruments	-	51,663
Short-term debt	-	1,091,740
Total current liabilities	3,884,806	6,795,981
Other long-term liabilities	507,072	588,745
Long-term debt, less current portion	-	730,279
Derivative instruments, less current portion	851,793	1,688,572
Total liabilities	5,243,671	9,803,577
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized; 62,215,986 and 52,304,246 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	6,222	5,230
Additional paid-in-capital	235,979,613	217,877,117
Accumulated other comprehensive loss	(225,872)	(218,710)
Accumulated deficit	(217,653,920)	(210,327,925)
Total stockholders' equity	18,106,043	7,335,712
Total liabilities and stockholders' equity	$ 23,349,714	$ 17,139,289

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

PHARMATHENE, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Contract revenue	$ 962,451	$ 3,488,142	$ 8,363,909	$ 14,258,680
Operating expenses:				
Research and development	1,728,929	2,556,383	7,528,616	11,192,403
General and administrative	3,192,427	4,086,348	8,289,788	8,698,873
Depreciation	37,125	44,593	113,272	139,049
Total operating expenses	4,958,481	6,687,324	15,931,676	20,030,325
Loss from operations	$ (3,996,030)	$ (3,199,182)	$ (7,567,767)	$ (5,771,645)
Other income (expense):				
Interest income	8	31	690	2,470
Interest expense	(46,938)	(89,817)	(174,046)	(289,635)
Change in fair value of derivative instruments	(560,487)	(628,622)	464,703	(1,181,575)
Other income (expense)	80	507	(1,470)	(3,506)
Total other income (expense)	(607,337)	(717,901)	289,877	(1,472,246)
Net loss before income taxes	(4,603,367)	(3,917,083)	(7,277,890)	(7,243,891)
Income tax provision	(25,068)	(28,804)	(48,105)	(49,753)
Net loss	$ (4,628,435)	$ (3,945,887)	$ (7,325,995)	$ (7,293,644)
Basic and diluted net loss per share	$ (0.08)	$ (0.08)	$ (0.13)	$ (0.15)
Weighted average shares used in calculation of basic and diluted net loss per share	58,952,731	52,166,733	55,577,550	50,105,641

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

PHARMATHENE, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Net loss	$ (4,628,435)	$ (3,945,887)	$ (7,325,995)	$ (7,293,644)
Other comprehensive loss:				
Foreign currency translation adjustments	(5,869)	164	(7,162)	(2,782)
Comprehensive loss	$ (4,634,304)	$ (3,945,723)	$ (7,333,157)	$ (7,296,426)

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

PHARMATHENE, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30,	
	2014	**2013**
Operating activities		
Net loss	$ (7,325,995)	$ (7,293,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,172,703	957,261
Change in fair value of derivative instruments	(464,703)	1,181,575
Depreciation expense	113,272	139,049
Deferred income taxes	48,105	49,753
Non-cash interest expense	68,130	104,726
Gain on the disposal of property and equipment	(5,393)	(3,500)
Changes in operating assets and liabilities:		
Accounts receivable	1,427,113	2,432,641
Unbilled accounts receivable	1,895,858	2,501,117
Prepaid expenses and other current assets	23,869	313,384
Accounts payable	(846,090)	(588,086)
Accrued expenses and other liabilities	(773,517)	203,951
Deferred revenue	(284,937)	(909,939)
Net cash used in operating activities	(4,951,585)	(911,712)
Investing activities		
Purchases of property and equipment	(92,269)	(84,579)
Proceeds from the sale of property and equipment	8,000	3,500
Net cash used in investing activities	(84,269)	(81,079)
Financing activities		
Repayment of debt	(749,997)	(499,998)
Net repayment of revolving credit agreement	(1,091,740)	(1,330,507)
Net proceeds from exercise of warrants	683,325	-
Proceeds from issuance of common stock, net of offering costs	15,341,264	6,068,891
Net cash provided by financing activities	14,182,852	4,238,386
Effects of exchange rates on cash	(7,585)	(3,713)
Increase in cash and cash equivalents	9,139,413	3,241,882
Cash and cash equivalents, at beginning of period	10,480,979	12,701,517
Cash and cash equivalents, at end of period	$ 19,620,392	$ 15,943,399
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 105,916	$ 184,909

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

PHARMATHENE, INC.

Notes to Unaudited Condensed Consolidated Financial Statements
September 30, 2014

Note 1 - Organization and Business

We are a biodefense company engaged in the development and commercialization of next generation medical countermeasures against biological and chemical threats. We are subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development and whose products require review and approval by the U.S. Food and Drug Administration ("FDA"). There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and are largely dependent on the services and expertise of our employees, consultants and other third parties.

Historically, we have performed under government contracts and grants and raised funds from investors (through equity and debt issuance) to sustain our operations. We have spent and will continue to spend substantial funds in the research, development, clinical and preclinical testing in excess of revenues, to support our product candidates with the goal of ultimately obtaining approval from the FDA, to market and sell our products. We have incurred losses in each year since inception, and had an accumulated deficit of $217.7 million as of September 30, 2014. Our cash and cash equivalents balance as of September 30, 2014 was $19.6 million, our accounts receivable (billed and unbilled) was $0.3 million, and our current liabilities were $3.9 million. We anticipate that our current cash and cash equivalents as well as cash to be collected from expected revenue under contracts currently in place, will be sufficient to fund our operations through 2015. If our current expectations and estimates about future operating costs prove to be incorrect, or if our expenses related to the SIGA litigation are greater than anticipated, we may need to raise additional capital in 2015. With the de-scoping by the Biomedical Advanced Research and Development Authority ("BARDA"), of the current SparVax® anthrax vaccine contract in April 2014, we expect revenue to decline significantly from historical levels. While we have undertaken efforts to reduce expenses, we expect increased losses in the future. The need to raise additional capital will depend on many factors, including, but not limited to, our future cash requirements, future contract funding, the ongoing proceedings in our litigation with SIGA Technologies, Inc., or SIGA, (See Note 4-*Commitments and Contingencies*), the timing, amount, and profitability of sales of Tecovirimat, also known as ST-246® (formerly referred to as "Arestvyr™" and referred to by SIGA in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 as "Tecovirimat"), if any, and the amount of the award to which we are entitled under the August 8, 2014 order of the Delaware Court of Chancery. In addition, there are other factors, including, but not limited to, our ability to collect amounts due from SIGA, the final judgment and order from the Delaware Court of Chancery in response to SIGA's appeal of the Chancery Court's original decision, SIGA's filing for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York, and future funding required to develop SparVax® in light of the notice we received from BARDA advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. There can be no assurance that we will be able to raise additional capital in the future. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®; however, we are pursuing other potential funding sources.

On September 9, 2014, we signed an agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of the National Institutes of Health, for the development of a next generation anthrax vaccine based on the Company's proprietary rPA anthrax vaccine technology platform. The agreement is incrementally funded. Over the base period of the agreement, we were awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events. The agreement has a total value of up to approximately $28.1 million, assuming all development milestones are met and all eight contract options are exercised by NIAID, at its sole discretion. If NIAID elects to exercise all options, the contract would continue approximately five years.

We are currently working on an approximately $1.0 million fixed price order under an indefinite delivery, indefinite quantity ("IDIQ") contract, awarded by BARDA in 2013 for Valortim®. Delivery under the contract is expected in the fourth quarter of 2014.

During the third quarter of 2014 we formed a strategic alliance with Nanotherapeutics, Inc., a company that has extensive manufacturing and formulation capabilities. Under the strategic alliance agreement, each company will contribute its specific expertise and resources with the objective of advancing biodefense products to be agreed to under individual project plans.

Note 2 - Summary of Significant Accounting Policies

Basis of Presentation

Our unaudited condensed consolidated financial statements include the accounts of PharmAthene, Inc. and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation. Our unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2013 has been derived from audited consolidated financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the Consolidated Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC. We currently operate in one business segment.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Our unaudited condensed consolidated financial statements include significant estimates for our share-based compensation and the value of our derivative instruments, among other things. Because of the use of estimates inherent in the financial reporting process, actual results could differ significantly from those estimates.

Foreign Currency Translation

The functional currency of our wholly owned foreign subsidiary is its local currency. Assets and liabilities of our foreign subsidiary are translated into United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments for subsidiaries that have not been sold, substantially liquidated or otherwise disposed of are accumulated in other comprehensive loss, a component of stockholders' equity. Foreign currency translation adjustments are the sole component of accumulated other comprehensive loss at September 30, 2014 and December 31, 2013. Transaction gains or losses are included in the determination of net loss.

Cash and Cash Equivalents

Cash and cash equivalents are stated at market value. We consider all highly liquid investments with original maturities of three months or less to be cash equivalents, which, among other things, consist of investments in money market funds with financial institutions. We maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses on such cash balances.

Revolving Line of Credit and Term Loan

As discussed further in Note 6-*Financing Transactions*, we entered into a loan agreement with General Electric Capital Corporation ("GE Capital") in March 2012. As part of that agreement, we issued stock purchase warrants to GE Capital that expire in March 2022. The fair value of the warrants was charged to additional paid-in-capital, resulting in a debt discount to the term loan at the date of issuance. The debt discount and the financing costs incurred in connection with the agreement are being amortized over the term of the loan using the effective interest method and are included in interest expense in the unaudited condensed consolidated statements of operations.

Significant Customers and Accounts Receivable

Our primary customers are BARDA, NIAID, and the Department of Defense Chemical Biological Medical Systems ("CBMS"). We had no billed receivable balance as of September 30, 2014, and our unbilled receivable balance consisted of amounts due from both BARDA and NIAID. Our December 31, 2013 receivable balances (both billed and unbilled) were comprised solely of receivables from BARDA.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with acquisitions. We review the recoverability of goodwill annually at the end of our fiscal year and whenever events or changes in circumstances indicate that it is more likely than not that impairment exists. We completed our annual impairment assessment of goodwill on December 31, 2013 and determined that there was no impairment as of that date. Changes in our business strategy or adverse changes in market conditions could impact the impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value over its estimated fair value.

Financial Instruments

Our financial instruments, and/or embedded features contained in those instruments, often are classified as derivative liabilities and are recorded at their fair values. The determination of fair value of these instruments and features requires estimates and judgments. Some of our stock purchase warrants are considered to be derivative liabilities due to the presence of net settlement features and/or non-standard anti-dilution provisions; the fair value of our warrants is determined based on the Black-Scholes option pricing model. Use of the Black-Scholes option pricing model requires the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. See Note 3—*Fair Value Measurements* for further details.

Revenue Recognition

We generate our revenue from different types of contractual arrangements: cost-plus-fee contracts and fixed price contracts.

Revenues on cost-plus-fee contracts are recognized in an amount equal to the costs incurred during the period plus an estimate of the applicable fee earned. The estimate of the applicable fee earned is determined by reference to the contract: if the contract defines the fee in terms of risk-based milestones and specifies the fees to be earned upon the completion of each milestone, then the fee is recognized when the related milestones are earned, as further described below; otherwise, we estimate the fee earned in a given period by using a proportional performance method based on costs incurred during the period as compared to total estimated project costs and application of the resulting fraction to the total project fee specified in the contract.

Under the milestone method of revenue recognition, milestone payments (including milestone payments for fees) contained in research and development arrangements are recognized as revenue when: (i) the milestones are achieved; (ii) no further performance obligations with respect to the milestone exist; (iii) collection is reasonably assured; and (iv) substantive effort was necessary to achieve the milestone.

Milestones are considered substantive if all of the following conditions are met:

- it is commensurate with either our performance to meet the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone;
- it relates solely to past performance; and
- the value of the milestone is reasonable relative to all the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

If a milestone is deemed not to be substantive, we recognize the portion of the milestone payment as revenue that correlates to work already performed using the proportional performance method; the remaining portion of the milestone payment is deferred and recognized as revenue as we complete our performance obligations.

Revenue on fixed price contracts (without substantive milestones as described above) is recognized on the percentage-of-completion method. The percentage-of-completion method recognizes income as the contract progresses (generally related to the costs incurred in providing the services required under the contract). The use of the percentage-of-completion method depends on the ability to make reasonable dependable estimates and the fact that circumstances may necessitate frequent revision of estimates does not indicate that the estimates are unreliable for the purpose for which they are used.

As a result of our revenue recognition policies and the billing provisions contained in our contracts, the timing of customer billings may differ from the timing of recognizing revenue. Amounts invoiced to customers in excess of revenue recognized are reflected on the balance sheet as deferred revenue. Amounts recognized as revenue in excess of amounts billed to customers are reflected on the balance sheet as unbilled accounts receivable.

Upon notice of termination of a contract from the government, all related termination costs are expensed. Revenue is recognized on the termination costs to the extent those costs are allowable and billable under the contract.

Share-Based Compensation

We expense the estimated fair value of share-based awards granted to employees under our stock compensation plans. The fair value of stock options is determined at the grant date using the Black-Scholes option pricing model. The Black-Scholes model considers, among other factors, the expected life of the award and the expected volatility of our stock price. The value of the award that is ultimately expected to vest is recognized as expense on a straight line basis over the employee's requisite service period.

The fair value of share-based awards granted to nonemployees is determined at the grant date using the Black-Scholes option pricing model and remeasured at each quarterly reporting date over their requisite service period. The value of the award that is ultimately expected to vest is recognized as expense on a straight line basis over their requisite service period.

The fair value of restricted stock grants is determined based on the closing price of our common stock on the award date and is recognized as expense ratably over the requisite service period.

Share-based compensation expense recognized in the three and nine months ended September 30, 2014 and 2013 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures based on historical forfeitures.

Share-based compensation expense for the three months ended September 30, 2014 and 2013 was:

	Three months ended September 30,	
	2014	2013
Research and development	$ 52,434	$ 105,796
General and administrative	228,286	198,876
Total share-based compensation expense	$ 280,720	$ 304,672

During the three months ended September 30, 2014 and September 30, 2013, no options were granted to employees and nonemployee directors and we made no restricted stock grants.

Share-based compensation expense for the nine months ended September 30, 2014 and 2013 was:

	Nine months ended September 30,	
	2014	2013
Research and development	$ 329,655	$ 268,289
General and administrative	843,048	688,972
Total share-based compensation expense	$ 1,172,703	$ 957,261

During the nine months ended September 30, 2014, we granted 1,357,755 options to employees, nonemployee directors and consultants and made no restricted stock grants. During the nine months ended September 30, 2013, we granted 205,000 options to employees and nonemployee directors and made no restricted stock grants.

At September 30, 2014, we had total unrecognized share-based compensation expense related to unvested awards of approximately $1.7 million, net of estimated forfeitures, which we expect to recognize as expense over a weighted-average period of 2.6 years.

Income Taxes

We account for income taxes using the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. We also recognize a tax benefit from uncertain tax positions only if it is “more likely than not” that the position is sustainable based on its technical merits. Our policy is to recognize interest and penalties on uncertain tax positions as a component of income tax expense.

Income tax expense was $0.03 million during the three months ended September 30, 2014 and 2013, and $0.05 million during the nine months ended September 30, 2014 and 2013, relating exclusively to the generation of a deferred tax liability associated with the tax amortization of goodwill, which is included as a component of other long-term liabilities on our condensed consolidated balance sheets. The income tax expense results from the difference between the treatment of goodwill for income tax purposes and for U.S. GAAP.

Basic and Diluted Net Loss Per Share

Loss per share: Basic income (loss) per share is computed by dividing consolidated net income (loss) by the weighted average number of common shares outstanding during the period, excluding unvested restricted stock.

For periods of net income when the effects are not anti-dilutive, diluted earnings per share is computed by dividing our net income by the weighted average number of shares outstanding and the impact of all potential dilutive common shares, consisting primarily of stock options, unvested restricted stock and stock purchase warrants. The dilutive impact of our potential dilutive common shares resulting from stock options and stock purchase warrants is determined by applying the treasury stock method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive due to the net losses. A total of approximately 10.9 million and 11.6 million potential dilutive securities have been excluded in the calculation of diluted net loss per share in the three and nine months ended September 30, 2014 and 2013, respectively, because their inclusion would be anti-dilutive.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, Revenue From Contracts With Customers, or ASU 2014-09. Pursuant to this update an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. For a public entity, the amendments in this Update are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. We have not yet determined the impact of adoption on our financial statements.

In August 2014, FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements – Going Concern, or ASU 2014-15. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 further describes the disclosures that must be made in the financial statements if conditions or events raise substantial doubt about an entity's ability to continue as a going concern. The amendments in this Update are effective for the periods ending after December 15, 2016. Early application is permitted. We have not yet determined the impact of adoption on our financial statements.

Note 3 - Fair Value Measurements

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. We report assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

We have segregated our financial assets and liabilities that are measured at fair value into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. We have no non-financial assets and liabilities that are measured at fair value on a recurring basis.

The following table represents the fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis:

	As of September 30, 2014			
	Level 1	Level 2	Level 3	Balance
Assets				
Investment in money market funds[(1)]	$ 6,429,125	$ -	$ -	$ 6,429,125
Total investment in money market funds	$ 6,429,125	$ -	$ -	$ 6,429,125
Liabilities				
Current and non-current portion of derivative instruments related to stock purchase warrants	$ -	$ -	$ 851,793	$ 851,793
Total derivative instruments related to stock purchase warrants	$ -	$ -	$ 851,793	$ 851,793

	As of December 31, 2013			
	Level 1	Level 2	Level 3	Balance
Assets				
Investment in money market funds[(1)]	$ 7,928,807	$ -	$ -	$ 7,928,807
Total investment in money market funds	$ 7,928,807	$ -	$ -	$ 7,928,807
Liabilities				
Current and non-current portion of derivative instruments related to stock purchase warrants	$ -	$ -	$ 1,740,235	$ 1,740,235
Total derivative instruments related to stock purchase warrants	$ -	$ -	$ 1,740,235	$ 1,740,235

[(1)] Included in cash and cash equivalents on the condensed consolidated balance sheets.

During September 2014, derivative instruments related to stock purchase warrants with 419,218 underlying common shares were exercised. The fair value of the exercised stock purchase warrants was $423,739. In addition, derivative instruments related to stock purchase warrants with 705,354 underlying common shares expired during the three and nine months ended September 30, 2014. During the three and nine months ended September 30, 2014 and 2013, we did not have any transfers between Level 1 and Level 2 assets or liabilities.

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2014:

Description	Balance as of December 31, 2013	Unrealized (Gains) 2014	Exercised Stock Purchase Warrants 2014	Balance as of September 30, 2014
Derivative liabilities related to stock purchase warrants	$ 1,740,235	$ (464,703)	$ (423,739)	$ 851,793

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the nine months ended September 30, 2013:

Description	Balance as of December 31, 2012	Unrealized Losses 2013	Exercised Stock Purchase Warrants 2013	Balance as of September 30, 2013
Derivative liabilities related to stock purchase warrants	$ 1,295,613	$ 1,181,575	$ -	$ 2,477,188

At September 30, 2014 and December 31, 2013, derivative liabilities are comprised of warrants to purchase 1,775,419 and 2,899,991 shares of common stock, respectively. The warrants are considered to be derivative liabilities due to the presence of net settlement features and/or non-standard anti-dilution provisions, and as a result, are recorded at fair value at each balance sheet date, with changes in fair value recorded in the unaudited condensed consolidated statements of operations. The fair value of our warrants is determined based on the Black-Scholes option pricing model. Use of the Black-Scholes option pricing model requires the use of unobservable inputs such as the expected term, anticipated volatility and expected dividends. Changes in any of the assumptions related to the unobservable inputs identified above may change the stock purchase warrants' fair value; increases in expected term, anticipated volatility and expected dividends generally result in increases in fair value, while decreases in the unobservable inputs generally result in decreases in fair value. Unrealized gains and losses on the fair value adjustments for these derivative instruments are classified in other income (expense) as the change in fair value of derivative instruments in our unaudited condensed consolidated statements of operations.

Quantitative Information about Level 3 Fair Value Measurements

Fair Value at September 30, 2014	Valuation Technique	Unobservable Inputs
$ 851,793	Black-Scholes option pricing model	Expected term
		Expected dividends
		Anticipated volatility

Assets Measured at Fair Value on a Nonrecurring Basis

We measure our long-lived assets, including, property and equipment and goodwill, at fair value on a nonrecurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. (See Note 2—*Summary of Significant Accounting Policies*). As of September 30, 2014, we had no other assets or liabilities that were measured at fair value on a nonrecurring basis.

Note 4 - Commitments and Contingencies

SIGA Litigation

In December 2006, we filed a complaint against SIGA in the Delaware Court of Chancery. The complaint alleged, among other things, that we have the right to license exclusively the development and marketing rights for SIGA's drug candidate, Tecovirimat, pursuant to a merger agreement between the parties that was terminated in 2006. The complaint also alleged that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement with us.

In September 2011, the Delaware Court of Chancery issued an opinion in the case finding that SIGA had breached certain contractual obligations to us and upholding our claims of promissory estoppel. The Delaware Court of Chancery awarded us the right to receive 50% of all net profits (as defined in the court's final judgment) related to the sale of Tecovirimat and related products for 10 years following initial commercial sale of the drug once SIGA earns $40.0 million in net profits from the sale of Tecovirimat and related products. The Delaware Court of Chancery also awarded us a portion of our attorney's fees and expert witness and other costs. In May 2012, the Delaware Court of Chancery issued its judgment. SIGA appealed aspects of the decision to the Delaware Supreme Court. In response, we cross-appealed other aspects of the decision.

In May 2013, the Delaware Supreme Court issued its ruling on the appeal, affirming the Delaware Court of Chancery's finding that SIGA had breached certain contractual obligations to us, reversed its finding of promissory estoppel, and remanded the case back to the Delaware Court of Chancery to reconsider the remedy and award of attorney's fees and expert witness and other costs in light of the Delaware Supreme Court's opinion.

On August 8, 2014, the Delaware Court of Chancery issued a Memorandum Opinion and Order, or Chancery Court Order, finding that we are entitled to receive lump sum expectation damages for the value of the Company's lost profits for Tecovirimat. In addition, the Delaware Court of Chancery found that the Company is entitled to receive pre-judgment interest and varying percentages of the Company's reasonable attorneys' and expert witness fees. On October 17, 2014, the Company and SIGA each filed opinions of our respective financial experts and Draft Orders and Judgments in accordance with the instructions of the Chancery Court Order. We now await a decision of the Court of Chancery in regards to a calculation of the damages awarded.

On September 16, 2014, SIGA announced that it filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York. In connection therewith, SIGA filed with the Bankruptcy Court an affidavit of Eric A. Rose, Chief Executive Officer and Chairman of the Board of SIGA, in which he stated that, "[a]lthough the Court of Chancery has not yet issued a final judgment specifying the dollar amount of such damages, SIGA expects it to be substantial – as much as $232 million (or more with post-judgment interest and attorneys' and expert fees)" and "SIGA has assumed that any judgment to be entered in this matter will be no less than $180 million (inclusive of pre-judgment interest through the date of entry of judgment by the Court of Chancery as well as professional fees and expenses)."

SIGA has indicated in its September 16, 2014 bankruptcy affidavit that it expects to continue to perform under its contract with BARDA. SIGA's petition for bankruptcy initiated a process whereby its assets are protected from creditors, including us.

The Delaware Court of Chancery's most recent decision does not specify an amount of damages, and such amount is subject to dispute between the parties. The amount of the award remains subject to further calculation and approval by the Delaware Court of Chancery and there will be further proceedings before the final amount is approved by the Delaware Court of Chancery, which determination, along with the decision itself will remain subject to appeal by SIGA to the Delaware Supreme Court. As a result, the decision could be reversed, remanded or otherwise changed. There can be no assurances as to whether or when the Company will receive any payments from SIGA as a result of the decision. SIGA has stated publicly that it does not currently have cash sufficient to satisfy the potential award. Furthermore, because SIGA has filed for protection under the federal bankruptcy laws, the Company is automatically stayed from taking any enforcement action in the Delaware Court of Chancery. By agreement of the parties, and with the approval of the Bankruptcy Court, the automatic stay has been lifted for the sole purpose of allowing the Delaware Court of Chancery to enter a money judgment and to allow the parties to exercise their appellate rights. Our ability to collect a money judgment from SIGA remains subject to further proceedings in the Bankruptcy Court.

Government Contracting

Payments we receive on cost-plus-fee contracts are provisional. The accuracy and appropriateness of costs charged to U.S. Government contracts are subject to regulation, audit and possible disallowance by the Defense Contract Audit Agency ("DCAA") and other government agencies such as BARDA. Accordingly, costs billed or billable to U.S. Government customers are subject to potential adjustment upon audit by such agencies. In our opinion, adjustments that may result from audits are not expected to have a material effect on our financial position, results of operations, or cash flows. Changes in government policies, priorities or funding levels through agency or program budget reductions by the U.S. Congress or executive agencies could materially adversely affect the Company's financial condition or results of operations. Furthermore, contracts with the U.S. Government may be terminated or suspended by the U.S. Government at any time, with or without cause. Such contract suspensions or terminations could result in unreimbursable expenses or charges or otherwise adversely affect our financial condition and/or results of operations.

Registration Rights Agreements

We entered into a Registration Rights Agreement with the investors who participated in the July 2009 private placement of convertible notes and related warrants. We subsequently filed two registration statements on Form S-3 with the SEC to register the resale of the shares issuable upon conversion of the convertible notes and exercise of the related warrants, which registration statements have been declared effective. We are obligated to maintain the registration statements effective until the date when such shares (and any other securities issued or issuable with respect to or in exchange for such shares) have been sold. The convertible notes were converted or extinguished in 2010, although the related warrants remain outstanding. The warrants will expire on January 28, 2015.

Under the terms of the convertible notes, which were converted or extinguished in 2010, if after the 2nd consecutive business day (other than during an allowable blackout period) on which sales of all of the securities required to be included on the registration statement cannot be made pursuant to the registration statement (a "Maintenance Failure"), we will be required to pay to each selling stockholder a one-time payment of 1.0% of the aggregate principal amount of the convertible notes relating to the affected shares on the initial day of a Maintenance Failure. Our total maximum obligation under this provision at September 30, 2014, which is not probable of payment, would be approximately $0.2 million.

Following a Maintenance Failure, we will also be required to make to each selling stockholder monthly payments of 1.0% of the aggregate principal amount of the convertible notes relating to the affected shares on every 30th day after the initial day of a Maintenance Failure, in each case prorated for shorter periods and until the failure is cured. Our total maximum obligation under this provision, which is not probable of payment, would be approximately $0.2 million for each month until the failure, if it occurs, is cured.

We have separate registration rights agreements with investors, under which we have obligations to keep the corresponding registration statements effective until the registrable securities (as defined in each agreement) have been sold, and under which we may have separate obligations to file registration statements in the future on either a demand or "piggy-back" basis or both.

Note 5 - Stockholders' Equity

Long-Term Incentive Plan

In 2007, the Company's stockholders approved the 2007 Long-Term Incentive Compensation Plan (the "2007 Plan") which provides for the granting of incentive and non-qualified stock options, stock appreciation rights, performance units, restricted stock awards and performance bonuses (collectively "awards") to Company officers and employees. Additionally, the 2007 Plan authorizes the granting of non-qualified stock options and restricted stock awards to Company directors and to independent consultants.

In 2008, our shareholders approved amendments to the 2007 Plan, increasing from 3.5 million shares to 4.6 million shares the maximum number of shares authorized for issuance under the plan and adding an evergreen provision pursuant to which the number of shares authorized for issuance under the plan would increase automatically in each year, beginning in 2009, in accordance with certain limits set forth in the 2007 Plan. Under the terms of the evergreen provision, the annual increases would continue through 2015, subject to an aggregate limitation on the number of shares that could be authorized for issuance pursuant to such increases. This aggregate limitation was reached on January 1, 2014, so that the number of shares authorized for issuance under the plan will not automatically increase on January 1, 2015. At September 30, 2014, there are approximately 10.3 million shares approved for issuance under the 2007 Plan, of which approximately 2.9 million shares are available for grant. The Board of Directors in conjunction with management determines who receives awards, the vesting conditions and the exercise price. Options may have a maximum term of ten years.

Stock Purchase Warrants

At September 30, 2014 there were warrants outstanding to purchase 4,495,556 shares of our common stock. The warrants outstanding as of September 30, 2014 were as follows, and all are exercisable:

Number of Common Shares Underlying Warrants As of September 30, 2014	Issue Date	Exercise Price	Expiration Date
100,778(1)	March 2007	$ 3.97	March 2017
2,572,775(1)	July 2009	$ 2.50	January 2015
500,000(2)	April 2010	$ 1.89	October 2015
903,996(2)	July 2010	$ 1.63	January 2017
371,423(2)	June 2011	$ 3.50	June 2016
46,584(1)	March 2012	$ 1.61	March 2022
4,495,556			

(1) These warrants to purchase common stock are classified as equity.

(2) Because of the presence of net settlement provisions, these warrants to purchase common stock are classified as derivative liabilities. The fair value of these liabilities (See Note 3-*Fair Value Measurements*) is remeasured at the end of every reporting period and the change in fair value is reported in the unaudited condensed consolidated statements of operations as other income (expense).

During the three months ended September 30, 2014, stock purchase warrants issued July 2010 with 419,218 underlying common shares were exercised. In addition, stock purchase warrants issued March 2009 with 705,354 underlying common shares expired.

Note 6 – Financing Transactions

Controlled Equity Offering

On March 25, 2013, we entered into a controlled equity offering sales agreement with a sales agent, and filed with the SEC a prospectus supplement, dated March 25, 2013 to our prospectus dated July 27, 2011, or the 2011 Prospectus, pursuant to which we could offer and sell, from time to time, through the agent shares of our common stock having an aggregate offering price of up to $15.0 million.

On May 23, 2014, we entered into an amendment, or the 2014 Amendment, to the controlled equity offering sales agreement with the sales agent, pursuant to which we may offer and sell, from time to time, through the agent shares of our common stock having an aggregate offering price of up to an additional $15.0 million. On that day, we filed a prospectus supplement to the 2011 Prospectus for use in any sales of these additional shares of common stock through July 26, 2014, the date the underlying registration statement (File No. 333-175394) expired. As a result of this expiration, the 2011 Prospectus, as supplemented on March 25, 2013 and May 23, 2014, may no longer be used for the sale of shares of common stock under the controlled equity offering sales agreement, as amended.

On May 23, 2014, we also filed a new universal shelf registration statement (File No. 333-196265) containing, among other things, a prospectus, or the 2014 Prospectus, for use in sales of the common stock under the 2014 Amendment. This registration statement was declared effective on May 30, 2014. Since the expiration of the 2011 Prospectus, all sales under the controlled equity offering sales agreement, as amended, are being effected under the 2014 Prospectus.

Under the controlled equity offering sales agreement, as amended, the agent may sell shares by any method permitted by law and deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on NYSE MKT, or any other existing trading market for our common stock or to or through a market maker. Subject to the terms and conditions of that agreement, the agent will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NYSE MKT, to sell shares from time to time based upon our instructions. We are not obligated to sell any shares under the arrangement. We are obligated to pay the agent a commission of 3.0% of the aggregate gross proceeds from each sale of shares under the arrangement.

As of September 30, 2014, shares having an aggregate offering price of $5.3 million remained available under the controlled equity offering sales agreement, as amended. During the nine months ended September 30, 2014, we sold 9,194,591 shares of our common stock under this arrangement resulting in net proceeds (net of commission) to us of approximately $15.5 million. Included in the aforementioned nine month total is $0.5 million in proceeds received subsequent to September 30, 2014, which are included in prepaid expenses and other current assets on the condensed consolidated balance sheets.

Loan Agreement with GE Capital

On March 30, 2012, we entered into a Loan Agreement with GE Capital. The Loan Agreement provides for a senior secured debt facility including a $2.5 million term loan and a revolving line of credit of up to $5.0 million based on our outstanding qualified accounts receivable. On March 30, 2012, the term loan was funded for an aggregate amount of $2.5 million.

Under the terms of the revolving line of credit, we may draw down from the revolving line of credit up to 85% of qualified billed accounts receivable and 80% of qualified unbilled accounts receivable. As of September 30, 2014, the total amount available to draw was approximately $0.1 million, of which none was drawn and outstanding.

The fixed interest rate on the term loan is 10.14% per annum. The revolving line of credit has an adjustable interest rate based upon the 3-month London Interbank Offered Rate (“LIBOR”), with a floor of 1.5%, plus 5%. As of September 30, 2014, the interest rate was 6.5%. Both the term loan and the revolving line of credit mature in September 2015. Remaining principal payments on the term loan are scheduled as follows:

Year	Principal Payments
2014	$ 249,999
2015	750,007
	$ 1,000,006

The term loan, net of a debt discount of $6,684, is recorded on the condensed consolidated balance sheet as of September 30, 2014, as follows:

Current portion of long-term debt	$	993,322
Long-term debt, less current portion		-
	$	993,322

If we prepay the term loan and terminate the revolving line of credit prior to the scheduled maturity date, we are obligated to pay a prepayment premium equal to 2% of the then outstanding principal amount of the term loan. In addition, we are obligated to pay a final payment fee of 3% of the term loan balance. The final payment fee is being accrued and expensed over the term of the agreement, using the effective interest method and is included in accrued expenses and other liabilities on the condensed consolidated balance sheets.

Our obligations under the Loan Agreement are collateralized by a security interest in substantially all of our assets. While the security interest does not, except in limited circumstances, cover our intellectual property, it does cover any proceeds received by us from the use or sale of our intellectual property.

In connection with the Loan Agreement, we issued to GE Capital warrants to purchase 46,584 shares of our common stock at an exercise price of $1.61 per share. The warrants are exercisable immediately and subject to customary and standard anti-dilution adjustments. The warrants are classified in equity and, as a result, the fair value of the warrants was charged to additional paid-in-capital resulting in a debt discount at the date of issuance. The debt discount is being amortized over the term of the loan agreement using the effective interest method. Financing costs incurred in connection with this agreement are also being amortized over the term of the agreement using the effective interest method.

We currently owe GE Capital an aggregate of approximately $1.0 million under the GE Loan Agreement. As a result of the receipt of the notice that we received from BARDA on April 4, 2014 advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience, GE Capital could assert that there has occurred an event of default under the GE Loan Agreement, which would allow GE Capital to terminate the commitment and the loans under the GE Loan Agreement and declare any or all of the obligations thereunder to be immediately due and payable. We have not received notice from GE Capital that an event of default has occurred.

We determined that the fair value of the term loan approximated its carrying value as of September 30, 2014 based on market comparables.

Note 7 – Subsequent Events

Subsequent to September 30, 2014, we sold 1,325,863 shares of our common stock under the controlled equity offering sales agreement, as amended, which resulted in net proceeds of approximately $2.2 million (See Note 6–*Financing Transactions*). Aggregate gross proceeds of up to $3.0 million remain available under this arrangement.

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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. This information may involve known and unknown risks, uncertainties and other factors that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- *the reliability of the results of the studies relating to efficacy and safety, and possible adverse effects resulting from the administration, of the Company's product candidates;*
- *funding delays, reductions in or elimination of U.S. Government funding and/or non-renewal of expiring funding for one or more of our development programs;*
- *our common stock;*

- *the GE Loan Agreement;*
- *our net operating loss carryforwards, or NOLs;*
- *the award of government contracts to our competitors or delays caused by third parties challenging government contract awards to us;*
- *unforeseen safety and efficacy issues;*
- *challenges related to the development, technology transfer, scale-up, and/or process validation of manufacturing processes for our product candidates;*
- *unexpected determinations that these product candidates are not effective and/or capable of being marketed as products;*
- *risk associated with accomplishing any future strategic acquisitions or business combinations;*
- *continuing funding requirements and dilution relating thereto; and*
- *continuing litigation with SIGA and the risk that we will not be able to collect any amounts related thereto.*

In addition to the foregoing, please review the risks detailed under the caption "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, and in our other reports filed with the SEC from time to time thereafter, including in this Quarterly Report. In particular, the Delaware Court of Chancery's most recent decision related to the sale of Tecovirimat, also known as ST-246® (formerly referred to as "Arestvyr™" and referred to by SIGA in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 as "Tecovirimat") does not specify an amount of damages, and such amount is subject to dispute between the parties. The amount of the award remains subject to further calculation and approval by the Delaware Court of Chancery and there will be further proceedings before the final amount is approved by the Delaware Court of Chancery, which determination, along with the decision itself will remain subject to appeal by SIGA to the Delaware Supreme Court. As a result, the decision could be reversed, remanded or otherwise changed. There can be no assurances as to whether or when we will receive any payments from SIGA as a result of the decision. SIGA has stated publicly that it does not currently have cash sufficient to satisfy the potential award. Furthermore, because SIGA has filed for protection under the federal bankruptcy laws, we are automatically stayed from taking any enforcement action in the Delaware Court of Chancery. By agreement of the parties, and with the approval of the Bankruptcy Court, the automatic stay has been lifted for the sole purpose of allowing the Delaware Court of Chancery to enter a money judgment and to allow the parties to exercise their appellate rights. Our ability to collect a money judgment from SIGA remains subject to further proceedings in the Bankruptcy Court.

Moreover, at this point, future government funding to support the development of Valortim®, rBChE and SparVax® is unlikely. Even if we received such funding, significant additional non-clinical animal studies, human clinical trials, and manufacturing development work remain to be completed for all our products candidates, including Valortim®, rBChE and SparVax®. It is also uncertain whether any of our product candidates will be shown to be safe and effective and approved by regulatory authorities for use in humans. Forward-looking statements describe management's current expectations regarding our future plans, strategies and objectives and are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," "project," "potential" or "plan" or the negative of these words or other variations on these words or comparable terminology. Such statements include, but are not limited to:

- *statements about potential future government contract or grant awards;*
- *potential payments under government contracts or grants;*
- *potential regulatory approvals;*
- *anticipated results of pending litigation;*
- *future product advancements; and*
- *anticipated financial or operational results.*

Forward-looking statements are based on assumptions that may be incorrect, and we cannot assure you that the projections included in the forward-looking statements will come to pass.

We have based the forward-looking statements included in this Quarterly Report on Form 10-Q on information available to us on the date of this Quarterly Report, and we assume no obligation to update any such forward-looking statements, other than as required by law. Although we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise, you are advised to consult any additional disclosures that we may make directly to you or through reports that we, in the future, may file with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

The following discussion should be read in conjunction with our unaudited condensed consolidated financial statements which present our results of operations for the three and nine months ended September 30, 2014 and 2013, as well as our financial positions at September 30, 2014 and December 31, 2013, contained elsewhere in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with the Annual Report on Form 10-K for the year ended December 31, 2013, filed on March 11, 2014, and amended on Form 10-K/A filed on April 30, 2014, including the audited consolidated financial statements contained therein.

Overview

We are a biodefense company engaged in the development and commercialization of next generation medical countermeasures against biological and chemical threats. Our current biodefense portfolio includes the following product candidates:

- SparVax®, a next generation recombinant protective antigen, or rPA, anthrax vaccine (liquid and lyophilized formulations);
- rBChE (recombinant butyrylcholinesterase) bioscavenger, a medical countermeasure for nerve agent poisoning by organophosphorous compounds, including nerve gases and pesticides; and
- Valortim®, a fully human monoclonal antibody for the prevention and treatment of anthrax infection.

In May 2013, the Delaware Supreme Court affirmed a September 2011 ruling of the Delaware Court of Chancery that SIGA had breached certain contractual obligations to us. The matter is on remand to the Delaware Court of Chancery to determine a remedy in light of the Delaware Supreme Court's decision.

On August 8, 2014, the Delaware Court of Chancery issued a Memorandum Opinion and Order, or Chancery Court Order, finding that we are entitled to receive lump sum expectation damages for the value of the Company's lost profits for Tecovirimat. In addition, the Delaware Court of Chancery found that the Company is entitled to receive pre-judgment interest and varying percentages of the Company's reasonable attorneys' and expert witness fees. On October 17, 2014, the Company and SIGA each filed opinions of our respective financial experts and Draft Orders and Judgments in accordance with the instructions of the Chancery Court Order. We now await a decision of the Court of Chancery in regards to a calculation of the damages awarded.

On September 16, 2014, SIGA announced that it filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York. In connection therewith, SIGA filed with the Bankruptcy Court an affidavit of Eric A. Rose, Chief Executive Officer and Chairman of the Board of SIGA, in which he stated that, "[a]lthough the Court of Chancery has not yet issued a final judgment specifying the dollar amount of such damages, SIGA expects it to be substantial – as much as $232 million (or more with post-judgment interest and attorneys' and expert fees)" and "SIGA has assumed that any judgment to be entered in this matter will be no less than $180 million (inclusive of pre-judgment interest through the date of entry of judgment by the Court of Chancery as well as professional fees and expenses)."

SIGA has indicated in its September 16, 2014 bankruptcy affidavit that it expects to continue to perform under its contract with BARDA. SIGA's petition for bankruptcy initiated a process whereby its assets are protected from creditors, including us.

The Delaware Court of Chancery's most recent decision does not specify an amount of damages, and such amount is subject to dispute between the parties. The amount of the award remains subject to further calculation and approval by the Delaware Court of Chancery and there will be further proceedings before the final amount is approved by the Delaware Court of Chancery, which determination, along with the decision itself will remain subject to appeal by SIGA to the Delaware Supreme Court. As a result, the decision could be reversed, remanded or otherwise changed. There can be no assurances as to whether or when the Company will receive any payments from SIGA as a result of the decision. SIGA has stated publicly that it does not currently have cash sufficient to satisfy the potential award. Furthermore, because SIGA has filed for protection under the federal bankruptcy laws, the Company is automatically stayed from taking any enforcement action in the Delaware Court of Chancery. By agreement of the parties, and with the approval of the Bankruptcy Court, the automatic stay has been lifted for the sole purpose of allowing the Delaware Court of Chancery to enter a money judgment and to allow the parties to exercise their appellate rights. Our ability to collect a money judgment from SIGA remains subject to further proceedings in the Bankruptcy Court.

On April 4, 2014, we received notification from BARDA, advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. BARDA has subsequently provided guidance authorizing the completion of six activities under the contract. All other activities were de-scoped, including the proposed Phase 2 clinical trial. We proposed an estimated timeline for the completion of these contract activities and the submission of a final settlement proposal. BARDA has accepted our proposed estimated timeline. We expect these events to occur in the fourth quarter of 2014. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®. Therefore, unless we are able to secure additional funding for our SparVax® development program from other sources, we anticipate that revenues for this program will be significantly less in future periods than in prior periods. We are continuing to explore different options for the future of the SparVax® program.

On September 9, 2014, we signed an agreement with NIAID for the development of a next generation anthrax vaccine based on the Company's proprietary rPA anthrax vaccine technology platform. The agreement is incrementally funded. Over the base period of the agreement, we were awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events. The agreement has a total value of up to approximately $28.1 million, assuming all development milestones are met and all eight contract options are exercised by NIAID, at its sole discretion. If NIAID elects to exercise all options, the contract would continue approximately five years.

We are currently working on an approximately $1.0 million fixed price order under an indefinite delivery, indefinite quantity (“IDIQ”) contract, awarded by BARDA in 2013 for Valortim®. Delivery under the contract is expected in the fourth quarter of 2014.

During the third quarter of 2014 we formed a strategic alliance with Nanotherapeutics, Inc., a company that has extensive manufacturing and formulation capabilities. Under the strategic alliance agreement, each company will contribute its specific expertise and resources with the objective of advancing biodefense products to be agreed to under individual project plans.

Critical Accounting Policies

A “critical accounting policy” is one that is both important to the portrayal of our financial condition and results of operations and that requires management’s most difficult, subjective or complex judgments. Such judgments are often the result of a need to make estimates about the effect of matters that are inherently uncertain. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the audited consolidated financial statements and notes included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the U.S. Securities and Exchange Commission.

During the nine months ended September 30, 2014, there were no significant changes in critical accounting policies from those at December 31, 2013.

Results of Operations

Revenue

We recognized revenue of $1.0 million and $3.5 million during the three months ended September 30, 2014 and 2013, respectively. We recognized revenue of $8.4 million and $14.3 million during the nine months ended September 30, 2014 and 2013, respectively.

	Three months ended September 30,		
Revenue ($ in millions)	2014	2013	% Change
SparVax®and Valortim®	$ 1.0	$ 3.4	(70.6)%
rBChE bioscavenger	-	0.1	(100.0)%
Total revenue	$ 1.0	$ 3.5	(71.4)%

Revenue ($ in millions)	Nine months ended September 30, 2014	2013	% Change
SparVax® and Valortim®	$ 7.9	$ 12.0	(34.2)%
rBChE bioscavenger	0.5	2.3	(78.3)%
Total revenue	$ 8.4	$ 14.3	(41.3)%

Our revenue was derived primarily from contracts with the U.S. Government for the development of SparVax® and our rBChE bioscavenger. Our revenue in the three and nine months ended September 30, 2014 changed from the comparable periods of 2013 primarily due to the following:

- Under our contract for the development of SparVax®, we recognized approximately $1.0 million and $3.4 million of revenue for the three months ended September 30, 2014 and 2013, respectively, and approximately $7.9 million and $12.0 million of revenue for the nine months ended September 30, 2014 and 2013, respectively. During the three and nine months ended September 30, 2014, revenue was primarily attributable to completion of Final Drug Product stability testing and a non-clinical animal study and ongoing activities necessary to close out the BARDA contract. Milestone revenue for the nine months ended September 30, 2014 was $0.3 million. During the same nine months, we received the payment of the BARDA contract Fixed Fee of $2.1 million, provided for under the SparVax® development contract, which was paid to PharmAthene as a result of the contract's partial termination. During the three and nine months ended September 30, 2013 revenue was primarily attributable to chemistry, manufacturing, and controls ("CMC") work and non-clinical animal studies. Milestone revenue for the three months and nine months ended September 30, 2013 was $0.3 million and $0.4 million, respectively.

  We received notification from BARDA advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. BARDA has subsequently provided guidance authorizing the completion of six activities under the contract. All other activities were de-scoped, including the proposed Phase 2 clinical trial. We have proposed an estimated timeline for completing these contract activities up to and including the submission of a final settlement proposal. We expect these events to occur in the fourth quarter of 2014. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®. Therefore, unless we are able to secure additional funding for our SparVax® development program from other sources, we anticipate that revenues for this program will be significantly less in future periods than in prior periods.

  On September 9, 2014, we signed an agreement with NIAID for the development of a next generation anthrax vaccine based on the Company's proprietary rPA anthrax vaccine technology platform. The agreement is incrementally funded. Over the base period of the agreement, we were awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events. The agreement has a total value of up to approximately $28.1 million, assuming all development milestones are met and all eight contract options are exercised by NIAID, at its sole discretion. If NIAID elects to exercise all options, the contract would continue approximately five years.

- Under our contract with CBMS for our second generation rBChE bioscavenger, we recognized no revenue for the three months ended September 30, 2014 and approximately $0.1 million of revenue for the three months ended September 30, 2013. We recognized approximately $0.5 million and $2.3 million of revenue for the nine months ended September 30, 2014 and 2013, respectively. In the first nine months of 2014, our activities were focused on the execution and completion of planned pharmacokinetic ("PK") non-clinical studies (with a substantial portion of those activities occurring prior to June 30, 2014), while in the comparable 2013 period we completed process development work and material generation activities and continued to execute activities to support non-clinical studies. The decrease in revenue is attributable to the decision by CBMS to remove the efficacy studies originally planned under this contract. Unless we are able to secure additional funding for our rBChE bioscavenger development program, we anticipate that revenues for this program in future periods will be less than in prior periods.

Research and Development Expenses

Our research and development expenses were $1.7 million and $2.6 million for the three months ended September 30, 2014 and 2013, respectively. Our research and development expenses were $7.5 million and $11.2 million for the nine months ended September 30, 2014 and 2013, respectively. These expenses resulted from research and development activities in all periods related primarily to our SparVax® and rBChE bioscavenger programs. Direct expenses included salaries and other costs of personnel, raw materials and supplies, and an allocation of indirect expenses. We also incurred third-party costs, such as contract research, consulting and clinical development costs for individual projects.

Research and development expenses for the three and nine months ended September 30, 2014 and 2013 were attributable to research programs as follows:

	Three months ended September 30,		
Expenses ($ in millions)	2014	2013	% Change
SparVax®and Valortim®	$ 1.3	$ 2.5	(48.0)%
rBChE bioscavenger	-	0.1	(100.0)%
Internal research and development	0.4	-	100.0%
Total research and development expenses	$ 1.7	$ 2.6	(34.6)%

	Nine months ended September 30,		
Expenses ($ in millions)	2014	2013	% Change
SparVax®and Valortim®	$ 6.3	$ 10.2	(38.2)%
rBChE bioscavenger	0.4	1.5	(73.3)%
Internal research and development	0.8	(0.5)	(260.0)%
Total research and development expenses	$ 7.5	$ 11.2	(33.0)%

For the three and nine months ended September 30, 2014, research and development expenses decreased $0.9 million and $3.7 million, respectively, from the same periods in the prior year, due to decreased costs related to our SparVax® program, as a result of BARDA's de-scoping of the contract and the change in scope from manufacturing to non-clinical studies for the rBChE bioscavenger program, and corresponds with our transition to our next generation, lyophilized rPA anthrax vaccine program. For the three months ended September 30, 2014, the decreased costs related to our SparVax® program was offset by increased severance costs due to a reduction in force.

General and Administrative Expenses

General and administrative functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. For each function, we may incur expenses such as salaries, supplies and third-party consulting and other external costs and non-cash expenditures such as expense related to stock option and restricted share awards. An allocation of indirect costs such as facilities, utilities and other administrative overhead is also included in general and administrative expenses.

Expenses associated with general and administrative functions were $3.2 million for the three months ended September 30, 2014 and $4.1 million for the three months ended September 30, 2013. Expenses associated with general and administrative functions were $8.3 million for the nine months ended September 30, 2014 and $8.7 million for the nine months ended September 30, 2013. The reduction in expenses for three-month and nine-month periods is primarily due to a reduction in merger and acquisition expenses, partially offset by increased share-based compensation expenses and, for the nine months ended September 30, 2014, severance costs. On July 1, 2013, we entered into an agreement and a plan of merger with Theraclone Sciences, Inc. On December 1, 2013, we entered into a Termination Agreement to terminate the merger with Theraclone Sciences, Inc.

Other Income (Expense)

Other income (expense) primarily consists of changes in the fair value of our derivative financial instruments and interest expense on our debt and other financial obligations. For the three months ended September 30, 2014, other expense was $0.6 million compared to $0.7 million in the comparable period in 2013. The change was primarily the result of a decrease in the fair value of our derivative instruments during the three months ended September 30, 2014 that was less pronounced than during the comparable three months in 2013.

For the nine months ended September 30, 2014, other income was $0.3 million compared to other expense of $1.5 million for the nine-months ended September 30, 2013. This was primarily the result of the change in the fair value of our derivative instruments, from an unrealized loss of $1.2 million to an unrealized gain of $0.5 million, for the nine months ended September 30, 2013 and 2014, respectively.

Income Taxes

The income tax provision was $0.03 million during the three months ended September 30, 2014 and 2013. The income tax provision was $0.05 million during the nine months ended September 30, 2014 and 2013. Our provision for income taxes results from the difference between the treatment of goodwill for income tax purposes and for U.S. GAAP.

Liquidity and Capital Resources

Overview

Our primary source of cash during the third quarter and first nine months of 2014 were proceeds from sales of shares of our common stock under the controlled equity offering arrangement, which we commenced in March 2013 and amended in May 2014. Our primary source of cash during the third quarter and first nine months of 2013 was provided by sales of shares of our common stock under the controlled equity offering arrangement, in addition to amounts received under our development contract for SparVax®.

With the de-scoping of the current SparVax® anthrax vaccine contract, we expect revenue to decline significantly. While we have undertaken efforts to reduce expenses, including a reduction in force of 11 employees, or approximately one third of our technical staff, we expect increased losses in the future. The need to raise additional capital will depend on many factors, including, but not limited to, our future cash requirements, future contract funding, the ongoing proceedings in our litigation with SIGA Technologies, Inc., or SIGA, (See Note 4-*Commitments and Contingencies*), the timing, amount, and profitability of sales of Tecovirimat, also known as ST-246® (formerly referred to as "Arestvyr™" and referred to by SIGA in its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014 as "Tecovirimat"), if any, and the amount of the award to which we are entitled under the August 8, 2014 order of the Delaware Court of Chancery. In addition, there are other factors, including, but not limited to, our ability to collect amounts due from SIGA, the final judgment and order from the Delaware Court of Chancery in response to SIGA's appeal of the Chancery Court's original decision, SIGA's filing for relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York, and future funding required to develop SparVax® in light of the notice we received from BARDA, advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. There can be no assurance that we will be able to raise additional capital in the future. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®; however, we are pursuing other potential funding sources.

Historically, we have not generated positive cash flows from operations. To bridge the gap between payments made to us under our U.S. government contracts and grants and our operating and capital needs, we have had to rely on a variety of financing sources, including the issuance of equity and equity-linked securities and proceeds from loans and other borrowings. On March 25, 2013, we entered into a controlled equity offering arrangement pursuant to which we could offer and sell, from time to time, through a sales agent, shares of our common stock having an aggregate offering price of up to $15.0 million, which we later amended on May 23, 2014 to increase the offering amount by $15.0 million. Due to the current economic environment, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts with us and/or the likelihood that the government would procure products from us.

On April 4, 2014, we received notification from BARDA advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. BARDA has subsequently provided guidance, authorizing the completion of six activities under the contract. All other activities were de-scoped, including the proposed Phase 2 clinical trial. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®. Unless we are able to secure additional funding for our SparVax® development program from other sources, we anticipate that revenues for this program will be significantly less in future periods than in prior periods.

On September 9, 2014, we signed an agreement with NIAID for the development of a next generation anthrax vaccine based on the Company's proprietary rPA anthrax vaccine technology platform. The agreement is incrementally funded. Over the base period of the agreement, we were awarded initial funding of approximately $5.2 million, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events. The agreement has a total value of up to approximately $28.1 million, assuming all development milestones are met and all eight contract options are exercised by NIAID, at its sole discretion. If NIAID elects to exercise all options, the contract would continue approximately five years.

We currently owe GE Capital an aggregate of approximately $1.0 million under the Loan Agreement. As a result of the notification from BARDA on April 4, 2014 advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience, GE Capital could assert that there has occurred an event of default under the Loan Agreement, which would allow GE Capital to terminate the commitment and the loans under the Loan Agreement and declare any or all of the obligations thereunder to be immediately due and payable. We have not received notice from GE Capital that an event of default has occurred.

Our unaudited condensed consolidated financial statements have been prepared on a basis which assumes that we will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business and do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized. As described in Note 2 – *Summary of Significant Accounting Policies*, in August 2014, FASB issued Accounting Standards Update No 2014-15, Presentation of Financial Statements – Going Concern, or ASU 2014-15, which requires management, in connection with preparing financial statements for each annual and interim reporting period, to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The amendments in this Update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We have not yet determined the impact of adoption on our financial statements.

Cash and cash equivalents were $19.6 million and $10.5 million at September 30, 2014 and December 31, 2013, respectively.

During the nine months ended September 30, 2014 we generated net proceeds of approximately $15.5 million under the controlled equity offering sales agreement, as amended. Included in the aforementioned nine month total is $0.5 million in proceeds received subsequent to September 30, 2014, which are included in prepaid expenses and other current assets on the condensed consolidated balance sheets. Since September 30, 2014, we generated an additional $2.2 million in net proceeds under the controlled equity offering sales agreement, as amended. Aggregate gross proceeds of up to $3.0 million remain available under this arrangement.

We anticipate that our current cash and cash equivalents on hand, as well as cash to be collected from expected revenue under contracts currently in place, will be sufficient to fund PharmAthene's current operations through 2015. However, we may elect to raise additional capital prior to such date to strengthen our financial position. Furthermore, if our current expectations and estimates about future operating costs prove to be incorrect, or if our expenses related to the SIGA litigation are greater than anticipated, we may need to raise additional capital in 2015. Additional sales of common stock may be made at prices that are dilutive to existing stockholders. There can be no assurance that we will be able to raise additional capital on terms favorable or acceptable to us, or at all.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2014 and 2013.

	Nine months ended September 30,	
	2014	2013
Net cash provided by (used in):		
Operating activities	$ (4,951,585)	$ (911,712)
Investing activities	(84,269)	(81,079)
Financing activities	14,182,852	4,238,386
Effects of exchange rates on cash	(7,585)	(3,713)
Total increase in cash and cash equivalents	$ 9,139,413	$ 3,241,882

Operating Activities

Net cash used in operating activities was $5.0 million and $0.9 million for the nine months ended September 30, 2014 and 2013, respectively.

Net cash used in operating activities during the nine months ended September 30, 2014 reflects our net loss of $7.3 million, adjusted for $1.2 million of non-cash share-based compensation expense, and a $0.5 million decrease in the fair value of derivative instruments. A decrease in receivables (billed and unbilled) of approximately $3.3 million was partially offset by a decrease in liabilities of $1.6 million and deferred revenue of $0.3 million. The decrease in the fair value of the derivative instruments primarily relates to the warrant exercise and expiration that occurred in September 2014 and the change in our stock price from $1.86 per share at December 31, 2013 to $1.78 per share at September 30, 2014.

Net cash used by operating activities during the nine months ended September 30, 2013 reflects our net loss of $7.3 million, adjusted for $1.0 million of noncash share-based compensation expense, and a $1.2 million increase in the fair value of derivative instruments, and a decrease in receivables (billed and unbilled) of $4.9 million. The increase in the fair value of the derivative instruments primarily relates to the change in our stock price from $1.12 per share at December 31, 2012 to $2.10 per share at September 30, 2013.

Unless we are able to secure new contracts and orders from the U.S. government to fund additional development activities for our programs and for eventual procurement of our products, we anticipate net cash generated by operations will be lower in future periods than in past periods.

Investing Activities

There were no significant investing activities during the nine months ended September 30, 2014 and September 30, 2013.

Financing Activities

Net cash provided by financing activities was $14.2 million for the nine months ended September 30, 2014, as compared to, $4.2 million provided by financing activities for the nine months ended September 30, 2013, and was principally the result of net proceeds received from sales of our stock under the controlled equity offering arrangement.

On March 25, 2013, we entered into a controlled equity offering sales agreement with a sales agent, and filed with the SEC a prospectus supplement, dated March 25, 2013, to our prospectus, dated July 27, 2011, or the 2011 Prospectus, pursuant to which we could offer and sell, from time to time, through the agent shares of our common stock having an aggregate offering price of up to $15.0 million.

On May 23, 2014, we entered into an amendment, or the 2014 Amendment, to the controlled equity offering sales agreement with the sales agent, pursuant to which we may offer and sell, from time to time, through the agent shares of our common stock having an aggregate offering price of up to an additional $15.0 million. On that day, we filed a prospectus supplement to the 2011 Prospectus for use in any sales of these additional shares of common stock through July 26, 2014, the date the underlying registration statement (File No. 333-175394) expired. As a result of this expiration, the 2011 Prospectus, as supplemented on March 25, 2013 and May 23, 2014, may no longer be used for the sale of shares of common stock under the controlled equity offering sales agreement, as amended.

On May 23, 2014, we also filed a new universal shelf registration statement (File No. 333-196265) containing, among other things, a prospectus, or the 2014 Prospectus, for use in sales of the common stock under the 2014 Amendment. This registration statement was declared effective on May 30, 2014. Since the expiration of the 2011 Prospectus, all sales under the controlled equity offering sales agreement, as amended, are being effected under the 2014 Prospectus.

Under the controlled equity offering sales agreement, as amended, the agent may sell shares by any method permitted by law and deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on NYSE MKT, or any other existing trading market for our common stock or to or through a market maker. Subject to the terms and conditions of that agreement, the agent will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NYSE MKT, to sell shares from time to time based upon our instructions. We are not obligated to sell any shares under the arrangement. We are obligated to pay the agent a commission of 3.0% of the aggregate gross proceeds from each sale of shares under the arrangement.

As of September 30, 2014, shares having an aggregate offering price of $5.3 million remained available under the controlled equity offering sales agreement, as amended. During the nine months ended September 30, 2014, we sold 9,194,591 shares of our common stock under this arrangement resulting in net proceeds (net of commission) to us of approximately $15.5 million. Included in the aforementioned nine month total is $0.5 million in proceeds received subsequent to September 30, 2014, which are included in prepaid expenses and other current assets on the condensed consolidated balance sheets.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

The following are contractual commitments at September 30, 2014:

Contractual Obligations[1]	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating facility leases	$ 2,226,542	$ 815,526	$ 1,411,016	$ -	$ -
Research and development agreements	821,161	821,161	-	-	-
Term loan, principal and interest payments	1,056,223	1,056,223	-	-	-
Total contractual obligations	$ 4,103,926	$ 2,692,910	$ 1,411,016	$ -	$ -

[1] This table does not include any royalty payments relating to future sales of products subject to license agreements we have entered into in relation to our in-licensed technology, as the timing and likelihood of such payments are not known. The table also excludes any obligations related to registration rights agreements, as a result of a Maintenance Failure (as defined in Note 4 – *Commitments and Contingencies* in the unaudited condensed consolidated financial statements which are included in Part I of the Form 10-Q), as the likelihood of such payment is not probable. In addition, the table does not include the final payment fee of $0.07 million on the term loan, which is being accrued and expensed over the term of the agreement, using the effective interest method, or the debt discount, which is being amortized over the term of the agreement. See additional discussion in Note 6-*Financing Transactions* in the unaudited condensed consolidated financial statements which are included in Part I of this Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is currently confined to our cash and cash equivalents, our revolving line of credit, and our derivative instruments. We currently do not hedge interest rate exposure or foreign currency exchange exposure. We have not used derivative financial instruments for speculation or trading purposes.

The Company's current operations in foreign countries are minimal. We have closed our active operations in Canada and maintain only nominal operations in the United Kingdom. A 10% change in exchange rates (against the U.S. dollar) would not have a material impact on earnings, fair values or cash flow.

Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market interest rates would have a significant impact on their realized value. Our term loan with GE Capital is at a fixed 10.14% rate. Because of the fixed rate, a change in market interest rates would not have a material impact on interest expense associated with the loan. The interest rate on the revolving line of credit is variable; therefore, a 1% increase in market interest rates above the interest rate floor of 1.5% would increase interest expense associated with the line by $50,000 if the maximum amount of the line ($5.0 million) was drawn for a full year.

The change in fair value of our derivative instruments is calculated utilizing the Black-Scholes model; therefore, a 10% increase/decrease over the closing price of our common stock at September 30, 2014 would result in a change in fair value of derivative instruments and our earnings of approximately $0.2 million.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Our management, including our principal executive and principal financial officers, has evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended September 30, 2014, and has concluded that there was no change that occurred during the quarterly period ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Except as noted below, we are not a party to any legal proceedings.

In December 2006, we filed a complaint against SIGA in the Delaware Court of Chancery. The complaint alleged, among other things, that we have the right to license exclusively the development and marketing rights for SIGA's drug candidate, Tecovirimat, pursuant to a merger agreement between the parties that was terminated in 2006. The complaint also alleged that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement with us.

In September 2011, the Delaware Court of Chancery issued an opinion in the case finding that SIGA had breached certain contractual obligations to us and upholding our claims of promissory estoppel. The Delaware Court of Chancery awarded us the right to receive 50% of all net profits (as defined in the court's final judgment) related to the sale of Tecovirimat and related products for 10 years following initial commercial sale of the drug once SIGA earns $40.0 million in net profits from the sale of Tecovirimat and related products. The Delaware Court of Chancery also awarded us a portion of our attorney's fees and expert witness and other costs. In May 2012, the Delaware Court of Chancery issued its judgment. SIGA appealed aspects of the decision to the Delaware Supreme Court. In response, we cross-appealed other aspects of the decision.

In May 2013, the Delaware Supreme Court issued its ruling on the appeal, affirming the Delaware Court of Chancery's finding that SIGA had breached certain contractual obligations to us, reversed its finding of promissory estoppel, and remanded the case back to the Delaware Court of Chancery to reconsider the remedy and award of attorney's fees and expert witness and other costs in light of the Delaware Supreme Court's opinion.

On August 8, 2014, the Delaware Court of Chancery issued a Memorandum Opinion and Order, or Chancery Court Order, finding that we are entitled to receive lump sum expectation damages for the value of our lost profits for Tecovirimat. In addition, the Delaware Court of Chancery found that the Company is entitled to receive pre-judgment interest and varying percentages of the our reasonable attorneys’ and expert witness fees. On October 17, 2014, the Company and SIGA each filed opinions of our respective financial experts and Draft Orders and Judgments in accordance with the instructions of the Chancery Court Order. We now await a decision of the Court of Chancery in regards to a calculation of the damages award.

On September 16, 2014, SIGA announced that it filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York. In connection therewith, SIGA filed with the Bankruptcy Court an affidavit of Eric A. Rose, Chief Executive Officer and Chairman of the Board of SIGA, in which he stated that, "[a]lthough the Court of Chancery has not yet issued a final judgment specifying the dollar amount of such damages, SIGA expects it to be substantial – as much as $232 million (or more with post-judgment interest and attorneys’ and expert fees)” and "SIGA has assumed that any judgment to be entered in this matter will be no less than $180 million (inclusive of pre-judgment interest through the date of entry of judgment by the Court of Chancery as well as professional fees and expenses)."

SIGA has indicated in its September 16, 2014 affidavit that it expects to continue to perform under its contract with BARDA. SIGA’s petition for bankruptcy initiated a process whereby its assets are protected from creditors, including us.

The Delaware Court of Chancery's most recent decision does not specify an amount of damages, and such amount is subject to dispute between the parties. The amount of the award remains subject to further calculation and approval by the Delaware Court of Chancery and there will be further proceedings before the final amount is approved by the Delaware Court of Chancery, which determination, along with the decision itself will remain subject to appeal by SIGA to the Delaware Supreme Court. As a result, the decision could be reversed, remanded or otherwise changed. There can be no assurances as to whether or when the Company will receive any payments from SIGA as a result of the decision. SIGA has stated publicly that it does not currently have cash sufficient to satisfy the potential award. Furthermore, because SIGA has filed for protection under the federal bankruptcy laws, the Company is automatically stayed from taking any enforcement action in the Delaware Court of Chancery. By agreement of the parties, and with the approval of the Bankruptcy Court, the automatic stay has been lifted for the sole purpose of allowing the Delaware Court of Chancery to enter a money judgment and to allow the parties to exercise their appellate rights. Our ability to collect a money judgment from SIGA remains subject to further proceedings in the Bankruptcy Court.

Item 1A. Risk Factors

Investing in our securities involves risks. In addition to the other information in this quarterly report on Form 10-Q, stockholders and potential investors should carefully consider the risks and uncertainties discussed in the section titled "Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013. Except as set forth below, there have been no material changes to the risk factors included in the section titled "Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013. The following risk factors are updated from the comparably titled risk factors included in the Form 10-K for the year ended December 31, 2013. All capitalized terms used in this section titled "Item 1A. Risk Factors" and not otherwise defined herein shall have the respective meanings assigned to such terms in the section titled "Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013.

We have not commercialized any products or recognized any revenues from sales. All of our product candidates are still under development, and there can be no assurance of successful commercialization of any of our products.

We have not commercialized any product candidates or recognized any revenues from product sales. In general, our research and development programs are in development stages. There can be no assurances that any of our future product candidates will meet safety and efficacy standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize biodefense treatment and prophylactic product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate this data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. We cannot be sure that our approach to drug discovery will be effective or will result in the development of any drug. Our development efforts have been primarily focused on one product candidate, SparVax®. Even if our product candidates are successful when tested in animals, such success would not be a guarantee of the safety or effectiveness of such product candidates in humans.

All of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient revenues from these agreements to attain profitability.

For the foreseeable future, we believe our main customer will be the U.S. government. Substantially all of our revenues to date have been derived from grants and U.S. government contracts. There can be no assurances that we can enter into new contracts or receive new grants to supply the United States or other governments with our products. The process of obtaining government contracts is lengthy and uncertain.

On April 4, 2014, we received notification from BARDA, advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience. We do not expect that we will receive additional significant funding from BARDA for the further development of SparVax®. If the U.S. government makes significant contract awards for the supply to the SNS to our competitors, rather than to us, our business may be harmed and we may ultimately be unable to supply that particular treatment or product to foreign governments or other third parties. Further, changes in U.S. government budgets and agendas, funding strategies, cost overruns in our programs, or advances by our competitors, may result in changes in the timing of funding for, a decreased and de-prioritized emphasis on, or termination of, U.S. government contracts that support the development and/or procurement of the biodefense products we are developing.

Funding is subject to U.S. Congressional appropriations, which are generally made on an annual basis even for multi-year contracts. More generally, due to the ongoing economic uncertainty, the U.S. government may reduce or delay spending in the biodefense field or eliminate funding of certain programs altogether, which could decrease the likelihood of future government contract awards or that the government would procure products from us. Future funding levels for two of our key government customers, BARDA and the U.S. Department of Defense, for the advanced development and procurement of MCMs are uncertain, and may be subject to budget cuts as the U.S. Congress and the President look to balance a multitude competing priorities. The Pandemic and All-Hazards Preparedness Reauthorization Act, or PAHPRA, signed into law in March 2013, authorized $2.8 billion in funding for the SRF for fiscal years 2014-2018. These funds are for the procurement of MCMs. PAHPRA also authorized $415 million in funding to BARDA for advanced development activities. However, actual funding for BARDA is dependent on annual Congressional appropriations and Congress is not obligated to appropriate the authorized amount. The fiscal year 2014 appropriation for BARDA advanced development is consistent with PAHPRA at $415 million. The fiscal year 2014 appropriation for the SRF is $255 million.

Our product development contract for Valortim® with NIAID expired January 31, 2012. In 2013 we entered into a contract for approximately $1 million to supply 35 vials of master cell bank for Valortim® to BARDA. There can be no assurance we will be successful in obtaining additional financial support to develop or procure Valortim®.

Our fully-secured loan agreement with GE Capital is subject to acceleration in specified circumstances, which may result in GE Capital terminating the commitment, accelerating repayment of obligations or taking possession and disposing of any collateral.

In the first quarter 2012, we closed on a senior fully-secured debt facility with GE Capital providing for a $2.5 million term loan and a revolving line of credit of up to $5.0 million based on a percentage of our outstanding qualified accounts receivable. Our obligations under the GE Loan Agreement are secured by a security interest in substantially all of our assets. While the security interest does not, except in limited circumstances, cover our intellectual property, it does cover any proceeds to us from the use of intellectual property. The GE Loan Agreement contains customary representations, warranties and covenants, including limitations on acquisitions, dispositions, incurrence of indebtedness and the granting of security interests. Upon the occurrence and during the continuance of any event of default, GE Capital may, and at the written request of the requisite lenders shall, terminate the commitments under the facilities and declare any or all of the obligations to be immediately due and payable, without demand or notice to us. Any event of default relating to timely payment of debts, insolvency, liquidation, bankruptcy or similar events will result in automatic acceleration. Among the remedies available to GE Capital in case of an event of default are terminating the commitment, accelerating repayment of obligations or taking possession and disposition of any collateral under the GE Loan Agreement.

We currently owe GE Capital an aggregate of approximately $1.0 million under the GE Loan Agreement. As a result of the receipt of the notice that we received from BARDA on April 4, 2014 advising us of its decision to de-scope the current SparVax® anthrax vaccine contract through a partial termination for convenience, GE Capital could assert that there has occurred an event of default under the GE Loan Agreement, which would allow GE Capital to terminate the commitment and the loans under the GE Loan Agreement and declare any or all of the obligations thereunder to be immediately due and payable.

Even though the Delaware Court of Chancery has found that we are entitled to receive lump sum expectation damages for the value of our lost profits for Tecovirimat, the potential value of any damages that may be awarded to us is subject to several variables and uncertainties, which preclude the current calculation of a predictable value of the SIGA litigation. Uncertainties include SIGA's recent filing for relief under Chapter 11 of the United States Bankruptcy Code, initiating a process that protects its assets from creditors, including us.

In December 2006, we filed a complaint against SIGA in the Delaware Court of Chancery. The complaint alleged, among other things, that we have the right to license exclusively the development and marketing rights for SIGA's drug candidate, Tecovirimat, pursuant to a merger agreement between the parties that was terminated in 2006. The complaint also alleged that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement with us.

In September 2011, the Delaware Court of Chancery issued an opinion in the case finding that SIGA had breached certain contractual obligations to us, upholding our claims of promissory estoppel, and awarding us damages. SIGA appealed aspects of the decision to the Delaware Supreme Court. In response, we cross-appealed other aspects of the decision. In May 2013, the Delaware Supreme Court issued its ruling on the appeal, affirming the Delaware Court of Chancery's finding that SIGA had breached certain contractual obligations to us, reversed its finding of promissory estoppel, and remanded the case back to the Delaware Court of Chancery to reconsider the remedy and award in light of the Delaware Supreme Court's opinion.

On August 8, 2014, the Delaware Court of Chancery issued a Memorandum Opinion and Order, or Chancery Court Order, finding, among other things, that we are entitled to receive lump sum expectation damages for the value of the Company's lost profits for Tecovirimat. On October 17, 2014, the Company and SIGA each filed opinions of our respective financial experts and Draft Orders and Judgments in accordance with the instructions of the Chancery Court Order. We now await a decision of the Court of Chancery in regards to a calculation of the damages awarded.

On September 16, 2014, SIGA announced that it filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York. SIGA's petition for bankruptcy initiated a process whereby its assets are protected from creditors, including us.

The Delaware Court of Chancery's most recent decision does not specify an amount of damages, and such amount is subject to dispute between the parties. The amount of the award remains subject to further calculation and approval by the Delaware Court of Chancery and there will be further proceedings before the final amount is approved by the Delaware Court of Chancery, which determination, along with the decision itself, will remain subject to appeal by SIGA to the Delaware Supreme Court. As a result, the decision could be reversed, remanded or otherwise changed. There can be no assurances as to whether or when the Company will receive any payments from SIGA as a result of the decision. SIGA has stated publicly that it does not currently have cash sufficient to satisfy the potential award. Furthermore, because SIGA has filed for protection under the federal bankruptcy laws, the Company is automatically stayed from taking any enforcement action in the Delaware Court of Chancery. By agreement of the parties, and with the approval of the Bankruptcy Court, the automatic stay has been lifted for the sole purpose of allowing the Delaware Court of Chancery to enter a money judgment and to allow the parties to exercise their appellate rights. Our ability to collect a money judgment from SIGA remains subject to further proceedings in the Bankruptcy Court.

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

None.

Item 3. Default upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

No.	Description
10.61	Contract with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health for the Development of Vaccine Formulations Effective Against NIAID Priority Pathogens, dated September 9, 2014 (Contract No. HHSN272201400040C). +
31.1	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
31.2	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350
(101)	The following condensed consolidated financial statements from the PharmAthene, Inc. Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, formatted in Extensive Business Reporting Language ("XBRL"): (i) Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013, (ii) Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and 2013, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013, (iv) Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013, and (v) Notes to consolidated financial statements.
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Certain confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused the report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMATHENE, INC.

Dated: November 6, 2014

By: /s/ Eric I. Richman
Eric I. Richman
President and Chief Executive Officer

Dated: November 6, 2014

By: /s/ Linda L. Chang
Linda L. Chang
Senior Vice President, Chief Financial Officer and Corporate Secretary

Exhibit 10.61

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 of the Exchange Act of 1934, as amended. Confidential Portions are marked: [***].

OMB Approval 2700-0042

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ►	RATING N/A	PAGE OF PAGES 1 54
2. CONTRACT (Proc. Inst Ident.) NO. HHSN272201400040C	3. EFFECTIVE DATE September 10, 2014	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 3504714	

5. ISSUED BY	CODE	IO-NIAID	6. ADMINISTERED BY (*If other than Item 6*)	CODE	N/A
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3108, MSC 7612 Bethesda, Maryland 20892-7612			MID RCB-B RFP-NIH-NIAID-DMID-AI2013174		

7 NAME AND ADDRESS OF CONTRACTOR (No. street, county, state and ZIP Code)	8. Delivery [_] FOB ORIGIN [X] OTHER (*See below*) FOB Destination
PharmAthene, Inc. One Park Place, Suite 450 Annapolis, MD 21401	9. DISCOUNT FOR PROMPT PAYMENT N/A
CODE FACILITY CODE	10. SUBMIT INVOICES ADDRESS SHOWN IN: ITEM Art. G.3.

11. SHIP TO/MARK FOR CODE N/A	12. PAYMENT WILL BE MADE BY CODE N/A
Article F.2.	See Article G.3.
13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION: [_] 10 U.S.C.2304(c) ( ) [_] 41 U.S.C. 253(c)( )	14. ACCOUNTING AND APPROPRIATION DATA: SOCC 25.55

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Title: "Development of Vaccine Formulations Effective Against NIAID Priority Pathogens" Period: September 10, 2014 through January 5, 2016 Contract Type: Cost Plus Fixed Fee, Term with Options		FY 14	$5,206,725		
			15G. TOTAL AMOUNT OF CONTRACT ►		**$5,206,725**

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(ü)	SEC.	DESCRIPTION	PAGE(S)	(ü)	SEC.	DESCRIPTION	PAGE(S)
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [X] 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*) Eric I. Richman, President & CEO	20A. NAME OF CONTRACTING OFFICER Michael C. Finn Contracting Officer, OA, DEA, NIAID, NIH, DHHS

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA BY	20C. DATE SIGNED
/s/ Eric I. Richman (*Signature of person authorized to sign*)	09/09/2014	BY /s/ Michael C. Finn (*Signature of Contracting Officer*)	09/09/2014

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CONTRACT TABLE OF CONTENTS

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PART I - THE SCHEDULE

SECTION A - SOLICITATION/CONTRACT FORM

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to support the advanced development of candidate products, which consist of a vaccine component in combination with a dry formulation technology (also referred to as solid vaccine formulations), that increase duration of stability and minimize cold chain or preservative requirements. These products will likely be used to minimize the need for preservatives for in post-event settings following the intentional release of NIAID Category A, B and C Priority Pathogens or in response to naturally occurring outbreaks of infectious diseases caused by NIAID Category A, B and C Priority Pathogens.

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 fee payment schedule paragraph f. of this Article. 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 $5,206,725.

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 Periods	**Estimated Cost ($)**	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period (exercised)	$ ***	$ ***	$ 5,206,725
Option Period 1	$ ***	$ ***	$ ***
Option Period 2	$ ***	$ ***	$ ***
Option Period 3	$ ***	$ ***	$ ***
Option Period 4	$ ***	$ ***	$ ***
Option Period 5	$ ***	$ ***	$ ***
Option Period 6	$ ***	$ ***	$ ***
Option Period 7	$ ***	$ ***	$ ***
Option Period 8	$ ***	$ ***	$ ***
Total (Base Period and Options)	**$ *****	**$ *****	**$ 28,119,635**

e. Payments will be made from the following PRISM/NBS Line Items as follows:

PRISM/NBS Line Item No.	Option/Increment Description	PRISM/NBS Line Item Period of Performance	Funded Amount
Line 1	Base Period	09/10/2014 - 01/05/2016	$5,206,725

f. Fee Payment Schedule Based on Contract Milestones:

The Contractor shall complete all work in accordance with the Statement of Work and the contract milestones set forth herein. The distribution of the fixed fee shall be paid in installments based on the COR's written certification regarding the completion of these milestones (Tasks) as follows:

Period of Performance	Task	Tasks Description	Deliverable	Fixed Fee
Base	***	***	***	***
Base	***	***	***	***
Base	***	***	***	***
Base	***	***	***	***
Option 1	***	***	***	***
Option 2	***	***	***	***
Option 2	***	***	***	***
Option 2	***	***	***	***
Option 2	***	***	***	***
Option 3	***	***	***	***
Option 3	***	***	***	***
Option 4	***	***	***	***
Option 4	***	***	***	***
Option 5	***	***	***	***
Option 5	***	***	***	***
Option 6	***	***	***	***

Period of Performance	Task	Tasks Description	Deliverable	Fixed Fee
Option 6	***	***	***	***
Option 7	***	***	***	***
Option 7	***	***	***	***
Option 8	***	***	***	***
Option 8	***	***	***	***
Option 8	***	***	***	***
Option 8	***	***	***	***

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. **Subcontract**

1. To negotiate a subcontract agreement with Battelle for an amount not to exceed as follows:

• Option 2: $***

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.

2. To negotiate a subcontract agreement with BPS-Baxter for an amount not to exceed as follows:

• Base: $***
• Option 1: $***
• Option 3: $***
• Option 4: $***
• Option 5: $***
• Option 7: $***
• Option 8: $***

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.

3. To negotiate a subcontract agreement with BREL-BioReliance for an amount not to exceed as follows:

- Base: $***
- Option 1: $***
- Option 3: $***
- Option 4: $***
- Option 5: $***
- Option 7: $***
- Option 8: $***

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.

4. To negotiate a subcontract agreement with Charles River Laboratories-PA for an amount not to exceed as follows:

- Option 6: $***

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.

5. To negotiate a subcontract agreement with EPL Archives for an amount not to exceed as follows:

- Option 4: $***
- Option 7: $***
- Option 8: $***

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.

6. To negotiate a subcontract agreement with FUJIFILM Diosynth Biotechnologies-US for an amount not to exceed as follows:

- Base: $***
- Option 1: $***
- Option 4: $***
- Option 7: $***
- Option 8: $***

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.

7. To negotiate a subcontract agreement with INTERTEK for an amount not to exceed as follows:

- Base: $***
- Option 1: $***
- Option 3: $***
- Option 4: $***
- Option 5: $***
- Option 7: $***
- Option 8: $***

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.

8. To negotiate a subcontract agreement with *** for an amount not to exceed as follows:

- Base: $***
- Option 2: $***
- Option 3: $***
- Option 5: $***

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.

9. To negotiate a subcontract agreement with Public Health England for an amount not to exceed as follows:

- Base: $***
- Option1: $***
- Option 3: $***
- Option 4: $***
- Option 5: $***
- Option 7: $***
- Option 8: $***

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.

10. To negotiate a subcontract agreement with PPD Development for an amount not to exceed as follows:

- Base: $***
- Option 3: $***
- Option 5: $***

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.

11. To negotiate a subcontract agreement with Quantics for an amount not to exceed as follows:

    • Base: $***
    • Option 1: $***
    • Option 3: $***
    • Option 4: $***
    • Option 5: $***
    • Option 7: $***
    • Option 8: $***

    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.

12. To negotiate a subcontract agreement with Quintiles for an amount not to exceed as follows:

    • Option 8: $***

    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.

13. To negotiate a subcontract agreement with Sharp for an amount not to exceed as follows:

    • Base: $***
    • Option 1: $***
    • Option 4: $***
    • Option 7: $***
    • Option 8: $***

    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.

14. To negotiate a subcontract agreement with *** for an amount not to exceed as follows:

    • Base: $***
    • Option 1: $***

    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.

b. **Consultants** Consultant fee(s) to be paid to the following individual(s):

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

*PharmAthene has stated that the above individual is at or below the Salary Rate Limitation.

c. **Contract Number Designation**

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

Contract No. HHSN272201400040C.

d. **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.

e. **Indirect Costs**

1. The Contractor may bill indirect costs at temporary billing rates as follows:

Fringe Benefits = ***% of Direct Labor
Overhead = ***% of Direct Labor and Fringe
G&A = ***% of Total Costs including Direct Labor, Fringe, Overhead and allowable Other Direct Costs

These temporary rates may be utilized until such time as indirect cost rates 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 three (3) months after the effective date of this contract. If the indirect cost proposal is not submitted by that time, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

2. The final amount reimbursable for indirect costs shall not exceed the following rates. Once indirect costs rates have been established, these ceilings may be renegotiated between the Contractor and the Contracting Officer and the ceilings lifted:

Fringe Benefits = ***% of Direct Labor
Overhead = ***% of Direct Labor and Fringe
G&A = ***% of Total Costs including Direct Labor, Fringe, Overhead and allowable Other Direct Costs

The Government is not obligated to pay any additional amount should the negotiated indirect cost rates exceed these ceiling rates. In the event that the negotiated indirect cost rates are less than these ceilings rates, the Government's obligation should be reduced to conform to the lower rates.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clause[s], 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.

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 $*** 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 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

SECTION C - STATEMENT OF WORK

ARTICLE C.1. 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 5, 2014, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

b. Privacy Act System of Records Number 09-25-0200 is applicable to this contract and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Representative (COR).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

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."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

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 as set out in ARTICLE F.2.a. Thereafter, reports shall be due on or before the 15th 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 10, 2014 through September 9, 2015 of this contract and shall be due on/before 30 days after the Anniversary Date of the Contract.

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, "Cumulative 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 shall consist of the work performed and results obtained for the entire contract period of performance as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. An Annual report shall not be required for the period when the Final Report is due.

The Contractor shall provide the Contracting Officer with one electronic copy of the Final Report in draft form (in accordance with the DELIVERIES Article in SECTION F of this contract Calendar days prior to the expiration date of this contract.) The Contracting Officer's Representative (COR) will review the draft report and provide the Contracting Officer with comments within Calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

5. **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.

6. **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:

1. 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.

2. 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. **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.)

2. **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."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisition
6700B Rockledge Drive, Room 3110
Bethesda, Maryland 20892- 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

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, The Contracting Officer's 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
5601 Fishers Lane, MSC 9825
Rockville, MD 20892-9825

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 **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

Alternate I (April 1984) is not applicable to this contract.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from September 10, 2014 through January 5, 2016.

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 as listed below:

Option	Period of Performance
Base	September 10, 2014 to January 5, 2016
Option 1	*See note below.
Option 2	*See note below.
Option 3	*See note below.
Option 4	*See note below.
Option 5	*See note below.
Option 6	*See note below.
Option 7	*See note below.
Option 8	*See note below.

*Option is non-severable; therefore, the period of performance of the contract will extend by the period of time listed in the current GANTT Chart.

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. **Technical Progress Reports**

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Progress Report (or Annual Progress Report)	1 electronic copy to COR and CO	The first report is due on/before November 15, 2014. Thereafter, each report is due on/before the 15th of the month following each reporting period. Monthly Progress Reports are not required when an Annual Progress Report, Draft Final Report or Final Report is due.
2.	Annual Technical Progress Report for Clinical Research Study Populations	1 electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	The first report is due on/before November 15, 2015. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract.
3.	DRAFT Final Report	1 electronic copy to COR and CO	A Draft Final Report shall be provided approximately 30 calendar days before the conclusion of each option period and shall cover all Milestones within that option. The option Periods are defined in the Additional options and related tasks table. COR's comments are due to the Contractor within 15 calendars days after receipt.
4.	Final Report and Summary of Salient Results	1 electronic copy to COR and CO	A Final Report shall be provided on/before the completion date of the conclusion of each option period and shall cover all tasks within that option. The option periods are defined in the Additional options and related tasks table.

b. **Other Reports and Deliverables (Delivery Schedule)**

Item	Deliverables	Recipient	Delivery Schedule
1.	Product Development Plan including Process/ Formulation, Assay, Non-Clinical/ Regulatory, Assay, and Device Development Plans (as applicable)	1 electronic copy to COR and CO	The initial plan is due 30 calendar days following the effective date of the contract. Updated plans annually on/before the 30th of the month following each anniversary date of the contract or as required by the COR prior to the initiation of major product development activities or as necessary in support of contract modifications.
2.	Quality Systems Agreements	1 electronic copy to COR	Within 30 calendar days of the effective date of contract/ subcontract award and prior to initiation of any major product development activities.
3.	All Development, Qualification and Validation Plans, Protocols, SOPs, and Reports	1 electronic copy to COR	Draft plans or protocols, as appropriate, 21 days prior to implementation. Draft reports within 60 days after completion of laboratory phase. Final reports within 7 days after incorporation of NIAID comments and release by QA.
4.	Draft and Final Batch Records for each production process	1 electronic copy to COR	Draft records 21 days prior to implementation. Final records within 7 days of lot disposition or release by QA.
5.	Certificates of Analysis for non cGMP and cGMP products	1 electronic copy to COR	Within 7 days of lot disposition or release by QA.
6.	Draft and Final Manufacturing Campaign Summary Report	1 electronic copy to COR	Within 7 days of release by QA.
7.	Stability Reports for non cGMP and cGMP product	1 electronic copy to COR	In accordance with FDA and ICH guidelines.

Item	Deliverables	Recipient	Delivery Schedule
8.	Animal, and other non-clinical study designs, protocols and reports:	1 electronic copy to COR and NIAID Regulatory Affairs Designee	Draft study designs and protocols for approval prior to ordering animals. Draft Protocols at least 21 days prior to protocol initiation. COR's comments are due to the Contractor within 14 calendars days after receipt. Final protocols 7 days prior to protocol initiation. Draft Unaudited Reports within 6 weeks of termination of the last animal on protocol, 12 weeks if full histopathology is required. Final reports within 7 days of incorporation of NIAID comments and release by QA.
9.	Chemistry, Manufacturing and Controls (CMC) information	1 electronic copy to COR and NIAID Regulatory Affairs Designee	At least 21 days prior to submission to FDA.
10.	Raw data and/or specific analyses of data generated by this contract	1 electronic copy to COR and NIAID Regulatory Affairs Designee	Within 30 calendar days of the request.
11.	Internal Audit Reports: As needed to evaluate compliance with FDA required cGMP, GLP and GCP standards	1 electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	Within 30 calendar days of each audit.
12.	Audits by FDA involving contractor or subcontractor materials, facilities or operations related to this contract	1 Electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	Notification within 7 calendar days of each audit. Reports within 7 calendar days of receipt of each audit from the FDA.
13.	FDA Pre IND Meeting Materials and Minutes	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	-Pre IND Meeting materials. Within 21 calendar days prior to submission to FDA. COR's comments are due to the Contractor within 14 calendars days after receipt. -Pre IND Meeting Minutes. Within 7 calendar days after each meeting.
14.	Clinical Trial Protocols, Amendments, and Supporting Documents (draft, revisions and final)	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	In accordance with to timelines or specified by DMID clinical operation guidelines.

Item	Deliverables	Recipient	Delivery Schedule
15.	FDA IND Submissions and Meeting Minutes	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	-IND materials: At least 21 calendar days prior to submission to FDA. COR's comments are due to the Contractor within 14 calendars days after receipt. -IND Meeting minutes: Within 7 calendar days after each meeting.
16.	SAE Reports	1 Electronic copy to COR and NIAID Regulatory Affairs designee	In accordance with to timelines or specified by DMID clinical operation guidelines.
17.	FDA Correspondence and Meeting Summaries	1 Electronic copy to COR and NIAID Regulatory Affairs designee	-Within 5 business days after receipt from the FDA. -For correspondence to the FDA, within 5 business days prior to submission. -Meeting Minutes: Within 5 business days after each meeting.
18.	Draft and Final Clinical Study Reports	1 Electronic copy to COR and NIAID Regulatory Affairs designee	Draft Clinical Study Report shall be provided within ninety (90) calendar days of the completion of the 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
19.	Other clinical reports (for example, IND annual reports, NIH Clinical Population Reports, SMC Reports, Clinical Trial Monitoring Plan, Data Management Plan, Safety Oversight Plan, Quality Management Plan, and Clinical Monitoring Reports)	1 Electronic copy to COR	Submit according to timelines or specified by NIAID-DMID clinical operation guidelines.
20.	Contract Initiation Meeting, Annual Contract Review Meetings, and Additional Contract Meetings, Reports and Minutes.	1 electronic copy to COR and CO	Within 21 calendar days of each meeting.
21.	Publications and Presentations	1 electronic to COR	-For manuscripts, within 30 calendar days in advance of submission. COR's comments are due to the Contractor within 14 calendars days after receipt. -For abstracts and oral presentations, within 10 calendar days in advance of submission. COR's comments are due to the Contractor within 7 calendars days after receipt.

Item	Deliverables	Recipient	Delivery Schedule
22.	Annual Utilization Report	1 electronic to CO	Due on/before the 30th of the month following the anniversary date of the contract.
23.	Final Invention Statement	1 electronic to CO	Due on/before completion date of the contract.
24.	All reports and Documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 electronic to OPERA	As required by FAR Clause 52.227-11.
25.	Technology Transfer	Technology Transfer packages that include complete protocols, assays or procedures developed and/or improved with contract funding.	To be decided as part of finalization of the SOW and other terms and conditions of any contract during negotiations.
26.	Institutional Biosafety Approval	Documentation (as applicable to subcontractors)	To be decided as part of finalization of the SOW and other terms and conditions of any contract during negotiations.
27.	Final Container Candidate Product	Delivery of 500 units of final container product to NIAID, and the necessary supporting documentation and letters of cross-reference.	As requested by the COR.

ARTICLE F.3. ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY1998)

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/far.

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.

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:

***
Contracting Officer's Representative (COR)
***
***
Ph: ***
Work cell: ***
***

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.

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

Name	Project Role
***	***
***	***
***	***
***	***
***	***
***	***
***	***

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

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

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 **approving official via e-mail at**:

      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. 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.

   c. 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.*

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

e. 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.

f. The Contract Title is:

Development of Vaccine Formulations Effective Against NIAID Priority Pathogens

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance.

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."

ARTICLE G.4. 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.5. GOVERNMENT PROPERTY

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf.
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the following office:

Division of Logistics Services, NIH
Property Management Branch
6011 Building, Suite 639
6011 EXECUTIVE BLVD MSC 7670
BETHESDA MD 20892-7670
nihcontractproperty@nih.gov

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.

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

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)

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.

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 IND Sponser will be determined after contract award. The IND Sponser will be considered 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. HUMAN MATERIALS

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

ARTICLE H.8. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform

Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of 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 from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a 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).

ARTICLE H.9. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) available at: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines*.

The NIH Guidelines stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the NIH Guidelines as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The NIH Guidelines apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with NIH OBA that complies with the requirements of the NIH Guidelines. Further information about compliance with the NIH Guidelines can be found on the NIH Office of Biotechnology Activities (OBA) website available at: http://oba.od.nih.gov/rdna_ibc/ibc.html.

ARTICLE H.10. 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.11. 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.12. 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.13. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.14. 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.

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

ARTICLE H.15. 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.16. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx 06/45cfr5b 06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http:// oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm.

ARTICLE H.17. 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.18. 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

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 July 23, 2014, which is incorporated by reference.

ARTICLE H.19. 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.od1.nih.gov/manualchapters/intramural/3044-2/

ARTICLE H.20. 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.

ARTICLE H.21. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS OMB CLEARANCE

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.22. GUN CONTROL OMB CLEARANCE

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.23. CERTIFICATION OF FILING AND PAYMENT OF TAXES OMB CLEARANCE

The contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.24. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., 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 52.217-6, Option for Increased Quantity and FAR Clause 52.217-7, Option for Increased Quantity—Separately Priced Line Item, set forth in SECTION I. 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.25. INFORMATION AND PHYSICAL ACCESS SECURITY

A. **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.

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.

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).

B. **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:

b. Security Categories and Levels:

Confidentiality Level:	[X] Low	[ ] Moderate	[ ] High
Integrity Level:	[ ] Low	[X] Moderate	[ ] High
Availability Level:	[X] Low	[ ] 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.

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.

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

ARTICLE H.26. 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/guidelines-and-standards.

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.27. 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. 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.

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.28. 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 of Alergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201400040C"

ARTICLE H.29. 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 website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.30. 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):

1. **Service Involving the Use of Information Technology**
YEAR 2000 COMPLIANCE—SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.31. 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://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.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.

ARTICLE H.32. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated July 16, 2014 is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.33. 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.34. 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/biosafety/publications/index.htm under "Publications");

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.

ARTICLE H.35. 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://apps.usfa.fema.gov/hotel/.

ARTICLE H.36. 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.37. 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.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		

ARTICLE H.38. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are 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. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

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: http://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	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*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	*May 2014*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*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)*
52.203-17	*Apr 2014*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
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)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*

FAR CLAUSE NO.	***DATE***	***TITLE***
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	*May 2014*	*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	*Jul 2014*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Jul 2014*	*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	*May 2014*	*Buy American - 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	*May 2014*	*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	*May 2014*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*May 2014*	*Assignment of Claims*
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	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*

FAR CLAUSE NO.	***DATE***	***TITLE***
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 2014*	*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 2014*	*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. 08/2014].

ARTICLE 1.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

a. **Alternate I**, (December 1991), of FAR Clause **52.233-1, Disputes** (December 1998) is added.

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.

b. 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 60 days before the contract expires or prior to the exercise of the options...."

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 **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

7. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

8. FAR Clause **52.224-2, Privacy Act** (April 1984).

9. **Alternate II** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Additional purposes for which the limited rights data may be used are:

(i) Use (except for manufacture) by support service contract.
(ii) Evaluation by nongovernmental evaluators.
(iii) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part

10. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Specific data items that are not subject to paragraph (j) include: None

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

12. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

13. FAR Clause **52.230-2, Cost Accounting Standards** (May 2012).

14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

15. FAR Clause **52.232-18, Availability of Funds** (April 1984).

16. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

17. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

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

c. 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).

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

Note: *P.L. 113-76 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective January 17, 2014.*

See the following website 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).

d. 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).

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

This contract incorporates the following clauses in full text.

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

1. *FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)*

   As prescribed in 32.706-1(b), insert the following clause:

   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 System for Award Management (SAM) database at http://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.*

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)

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

NONE

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 5, 2014, 9 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. Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment Report, PHS 398/2590, (Rev. 08/12), 1 page. Located at:

http://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf

4. Privacy Act System of Records, Number

Privacy Act System of Records, Number 09-25-0200

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. 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

9. 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

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 are completed and located in The System for Award Management (SAM) website (http://www.sam.gov).

2. NIH Representations & Certifications, dated July 9, 2014

3. Human Subjects Assurance Identification Number ***.

    - ***
    - ***

4. Animal Welfare Assurance Number _____.

    - ***
    - ***
    - ***

END of the SCHEDULE

(CONTRACT)

STATEMENT OF WORK

1.1 Research and Technical Objectives

The research and technical objectives of this proposal are:

1. ***
    a. ***
    b. ***
2. ***
3. ***
4. ***
5. ***
6. ***

1.2 Technical Approach and Method

We believe that the technical and delivery platform to be utilized in this proposal will result in a heat stable, *** anthrax vaccine that *** and simplifies the logistics of transporting and stockpiling the product.

This section describes the proposed technical plan and approach that has been devised to deliver the overall project goals to develop the vaccine ***

Table 1 provides a summary of the proposed development activities by funding period (base/options).

Table 1: Summary of Proposed Development Activities

WBS	Activity
***	***

1.3 Candidate Product Overview Table

Table 2 contains an overview of the program activities by the proposed Base and Option.

Table 2: Candidate Product Overview Table

***

1.4 Project Management

PharmAthene will provide *** to ensure the efficient planning, initiation, implementation, direction, management and completion of all contract activities.

1.5 Communications

PharmAthene will establish effective communications with NIAID and its proposed subcontractors to discuss all aspects of program activities, anticipated problems or obstacles, proposed approaches to resolve problems and overcome obstacles, and future plans through regular biweekly (or as applicable), team meetings.

1.6 Regulatory Compliance

PharmAthene will be responsible for ***, provide for ***; and ensure strict adherence to regulations and guidance for the activities to be undertaken.

1.7 Facilities

PharmAthene, in partnership with its selected subcontractors, operates facilities that are highly suitable for the development effort. All facilities meet local, state, and Federal requirements and are designed to promote safe and secure conduct of all contract operations. The proposed facilities have adequate floor space and equipment available to accommodate the projected needs throughout the performance period.

ATTACHMENT 2

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

Format: Submit payment requests on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall cite the amount(s) and month(s) in which the costs were incurred.

Contractor's Fiscal Year: Prepare payment requests in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract shall not exceed the United States dollars authorized.

Costs Requiring Advance Approval: Costs requiring advance approval by the Contracting Officer, which are not set forth in the Contract Schedule shall be identified by the Contracting Officer's Authorization (COA) Number as a separate expenditure category on the payment request. In addition, the Contractor shall show any cost limitation or ceiling set forth in the Contract Schedule, i.e. an Advance Understanding, as a separate expenditure category on the payment request.

Invoice/Financing Request Identification: Identify each payment as either:

(a) **Interim Invoice/Contract Financing Request**: These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice**: Submit the completion invoice promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice**: A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request:

The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request. ***All information must be legible or the invoice will be considered improper and returned to the Contractor***.

(a) **Designated Billing Office Name and Address**: Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number**: Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (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 System for Award Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Financing Request Number**: Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(d) **Date Invoice/Financing Request Prepared**: Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable)**: Insert the contract number and order number (as applicable).

(f) **Contract Title**: Insert the contract title exactly as it appears on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance**: Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Estimated Cost of Contract/Order**: Insert the total estimated cost of the contract, exclusive of fee. If billing under an order, insert the total estimated cost of the order, exclusive of fee. For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment.

(i) **Total Fixed-Fee**: Insert the total fixed-fee (where applicable). For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment (where applicable). **Note**: *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, insert the amount available to be earned as identified in the contract and indicate the type of fee to be billed on the payment request.*

(j) **Two-Way/Three-Way Match**: Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Office of Acquisitions**: Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Central Point of Distribution**: Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(m) **Billing Period**: Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(n) **Amount Billed - Current Period**: Insert the amount claimed for the current billing period by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Amount Billed - Cumulative**: Insert the cumulative amounts claimed by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(p) **Direct Costs**: Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

1) **Direct Labor**: Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the Contract Schedule) for the current billing period, and

- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

2) **Fringe Benefits**: List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

3) **Accountable Personal Property**: Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Contract of Government Property*). Show permanent research equipment separate from general purpose equipment.

   On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Precede the item with an asterisk (*) if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

   - item number for the specific piece of equipment listed in the Property Schedule, and,

   - Contracting Officer Authorization (COA) number, if the equipment is not covered by the Property Schedule.

   The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

4) **Materials and Supplies**: Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

5) **Premium Pay**: List remuneration in excess of the basic hourly rate.

6) **Consultant Fee**: List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

7) **Travel**: Include domestic and foreign travel. Foreign travel is travel outside of the United States and its territories and possessions. However, for an organization located outside the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

8) **Subcontract Costs**: List subcontractor(s) by name and amount billed.

9) **Other**: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(q) **Cost of Money (COM)**: Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(r) **Indirect Costs**: Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(s) **Fixed-Fee**: Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract. **Note**: *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, provide the same documentation for the amount claimed.*

(t) **Total Amounts Claimed**: Insert the total amounts claimed for the current and cumulative periods.

(u) **Adjustments**: Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(v) **Grand Totals**

(w) **Certification**: The Contractor shall include the following certification at the bottom of each payment request:

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

Note: *The contract may require additional certifications (See Invoice Submission Instructions in Section G of the Contract Schedule)*

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions correspond to the Columns on the Sample Invoice/Financing Request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission **shall not** be deemed as notice under the Limitation of Cost Clause in the contract.

Modifications: List all new modification(s) (not previously reported) in the amount negotiated for an item in the appropriate cost category.

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 of the Exchange Act of 1934, as amended. Confidential Portions are marked: [***].

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address: National Institutes of Health Office of Financial Management Commercial Accounts 2115 East Jefferson Street, Room 4B432, MSC 8500 Bethesda, MD 20892-8500 (b) Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number: **ABC CORPORATION** 100 Main Street Anywhere, U.S.A. Zip+4 Name, Title, Phone Number, and E-mail Address of Contractor's Point of Contact. DUNS or DUNS+4: _____ TIN: _____	(c) Invoice/Finance Request No.: _____ (d) Date Invoice/Financing Request Prepared: _____ (e) Contract No. and Order No. (if applicable): _____ (f) Contract Title: _____ (g) Current Contract Period of Performance: _____ (h) Total Estimated Cost of Contract/Order: _____ (i) Total Fixed Fee (if applicable): _____ (j) Two-Way Match: ____ Three-Way Match: ____ (k) Office of Acquisitions: _____ (l) Central Point of Distribution: _____

(m) This invoice/financing request represents reimbursable costs for the period from _____ to _____.

	Cumulative % of Effort/Hrs		Amount Billed				
Expenditure Category* A	Neg. B	Actual C	(n) Current D	(o) Cum E	Cost at Comp F	Contract Value G	Variance H
(p) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits __%							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(q) Cost of Money ___%							
(r) Indirect Costs ___%							
(s) Fixed Fee ___%							
(t) Total Amount Claimed							
(u) Adjustments							
(v) Grand Totals							

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

_____ _____

(Name of Official) (Title)

*Attach details as specified in the contract or requested by the Contracting Officer

INCLUSION TABLE
This report format should NOT be used for data collection from study participants.

Principal Investigator/Project Director _____
(Last, First, Middle)

Grant Number (if known): _____

STUDY TITLE: _____

Total Enrollment: _____Protocol Number:_____

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

Safety and Health, HHSAR 352.223-70 (January 2006)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR Part 1910. These regulations are available at: http://www.osha.gov.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at http://www.nap.edu/catalog/4911.html.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Technical Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

RESEARCH PATIENT CARE COSTS -- NIH(RC)-11

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 of the Exchange Act of 1934, as amended. Confidential Portions are marked: [***].

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	**2. Status of Federal Action:**	**3. Report Type:**
[_] a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	[_] a. bid/offer/application b. initial award c. post-award	[_] a. initial filing b. material change **For Material Change Only:** year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity:	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:**
[_] Prime [_] Subawardee Tier _____, *if known*: **Congressional District**, *if known*: 4c	**Congressional District**, *if known*:
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____
8. Federal Action Number, *if known*:	**9. Award Amount**, *if known*: $
10. a. Name and Address of Lobbying Registrant (*if individual, last name, first name, MI*):	**b. Individuals Performing Services** (*including address if different from No. 10a*) (*last name, first name, MI*):
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title:_____ Telephone No.: _____ Date: _____

Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 of the Exchange Act of 1934, as amended. Confidential Portions are marked: [***].

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, Eric I. Richman, certify that:

1. I have reviewed this Form 10-Q of PharmAthene, Inc. for the period ended September 30, 2014;

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.

Dated: November 6, 2014

/s/ Eric I. Richman
Name: Eric I. Richman
Title: President and Chief Executive Officer

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, Linda L. Chang, certify that:

1. I have reviewed this Form 10-Q of PharmAthene, Inc. for the period ended September 30, 2014;

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.

Dated: November 6, 2014

/s/ Linda L. Chang

Name: Linda L. Chang
Title: Senior Vice President, Chief Financial Officer and Corporate Secretary

Exhibit 32.1

Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

In connection with the Quarterly Report on Form 10-Q of PharmAthene, Inc. (the "Company") for the period ended September 30, 2014, as filed with the U.S. Securities and Exchange Commission (the "Report"), I, Eric I. Richman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Eric I. Richman

Name: Eric I. Richman
Title: President and Chief Executive Officer
November 6, 2014

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the U.S. Securities and Exchange Commission or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Exhibit 32.2

Certification Pursuant to Section 1350 of Chapter 63
of Title 18 of the United States Code

In connection with the Quarterly Report on Form 10-Q of PharmAthene, Inc. (the "Company") for the period ended September 30, 2014, as filed with the U.S. Securities and Exchange Commission (the "Report"), I, Linda L. Chang, Senior Vice President, Chief Financial Officer and Corporate Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Linda L. Chang
Name: Linda L. Chang
Title: Senior Vice President, Chief Financial Officer and Corporate Secretary
November 6, 2014

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the U.S. Securities and Exchange Commission or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.