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, 2008

OR

o **Transition Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Transition Period from _____ to _____

Commission File No. 0-23047

SIGA Technologies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**13-3864870**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification. No.)
420 Lexington Avenue, Suite 408 **New York, NY** (Address of principal executive offices)	**10170** (zip code)

Registrant's telephone number, including area code: (212) 672-9100

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 o.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one): Large Accelerated Filer o Accelerated Filer x Non-Accelerated Filer o Smaller Reporting Company o.

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

As of October 31, 2008 the registrant had 35,352,700 shares of common stock outstanding.

SIGA Technologies, Inc.

Form 10-Q

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1 – Financial Statements

SIGA TECHNOLOGIES, INC.

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,957,755	$ 6,832,290
Accounts receivable	2,313,677	986,489
Deferred transaction costs	581,358	—
Prepaid expenses	1,337,694	130,115
Total current assets	7,190,484	7,948,894
Property, plant and equipment, net	1,425,979	1,479,678
Goodwill	898,334	898,334
Other assets	282,712	261,766
Total assets	$ 9,797,509	$ 10,588,672
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,155,464	$ 1,321,146
Accrued expenses and other	889,765	796,524
Deferred revenue	1,302,600	—
Total current liabilities	3,347,829	2,117,670
Common stock warrants	4,166,014	3,242,797
Total liabilities	7,513,843	5,360,467
Commitments and contingencies	—	—
Stockholders' equity		
Common stock ($.0001 par value, 100,000,000 shares authorized, 35,206,892 and 33,937,549 issued and outstanding at September 30, 2008 and December 31, 2007, respectively)	3,566	3,394
Additional paid-in capital	71,314,197	67,230,987
Accumulated deficit	(69,034,097)	(62,006,176)
Total stockholders' equity	2,283,666	5,228,205
Total liabilities and stockholders' equity	$ 9,797,509	$ 10,588,672

The accompanying notes are an integral part of these unaudited financial statements.

SIGA TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
Revenues				
Research and development	$ 1,862,557	$ 1,609,123	$ 5,577,055	$ 4,936,258
Operating expenses				
Selling, general and administrative	945,347	793,045	3,115,222	2,811,701
Research and development	2,853,473	2,342,303	8,189,625	7,193,191
Patent preparation fees	198,115	58,637	461,687	323,433
Total operating expenses	3,996,935	3,193,985	11,766,534	10,328,325
Operating loss	(2,134,378)	(1,584,862)	(6,189,479)	(5,392,067)
Increase in fair market value of common stock rights and common stock warrants	(912,728)	(998,074)	(923,217)	(32,198)
Other income, net	18,225	89,640	84,775	316,040
Net loss	$ (3,028,881)	$ (2,493,296)	$ (7,027,921)	$ (5,108,225)
Weighted average shares outstanding: basic	35,109,434	33,519,119	34,525,260	33,140,524
Net loss per share: basic	$ (0.09)	$ (0.07)	$ (0.20)	$ (0.15)

The accompanying notes are an integral part of these unaudited financial statements.

SIGA TECHNOLOGIES, INC.

CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$ (7,027,921)	$ (5,108,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	343,038	785,316
Amortization of intangible assets	—	136,325
Increase in fair market value of rights and warrants	923,217	32,198
Stock based compensation	691,115	411,298
Changes in assets and liabilities:		
Accounts receivable	(24,588)	(399,841)
Prepaid expenses	(1,207,579)	26,325
Other assets	(20,946)	(15,272)
Accounts payable and accrued expenses	(72,441)	(271,297)
Net cash used in operating activities	(6,396,105)	(4,403,173)
Cash flows from investing activities:		
Capital expenditures	(289,339)	(748,830)
Net cash used in investing activities	(289,339)	(748,830)
Cash flows from financing activities:		
Net proceeds from exercise of warrants and options	2,969,936	2,708,535
Deferred transaction costs	(159,027)	—
Repayment of notes payable	—	(130,329)
Net cash provided by financing activities	2,810,909	2,578,206
Net decrease in cash and cash equivalents	(3,874,535)	(2,573,797)
Cash and cash equivalents at beginning of period	6,832,290	10,639,530
Cash and cash equivalents at end of period	$ 2,957,755	$ 8,065,733

The accompanying notes are an integral part of these unaudited financial statements.

1. Basis of Presentation

SIGA Technologies, Inc. ("SIGA" or the "Company") is a bio-defense company engaged in the discovery, development and commercialization of products for use in defense against biological warfare agents such as smallpox and Arenaviruses. The Company is also engaged in the discovery and development of other novel anti-infectives, and antibiotics for the prevention and treatment of serious infectious diseases. The Company's anti-viral programs are designed to prevent or limit the replication of viral pathogens. SIGA's anti-infectives programs target the increasingly serious problem of drug resistant bacteria and emerging pathogens.

The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the rules and regulations of the Securities and Exchange Commission (the "SEC") for quarterly reports on Forms 10-Q and should be read in conjunction with the Company's consolidated audited financial statements and notes thereto for the year ended December 31, 2007, included in the 2007 Form 10-K. All terms used but not defined elsewhere herein have the meaning ascribed to them in the Company's 2007 annual report on Form 10-K filed on March 13, 2008. In the opinion of management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results of the interim periods presented have been included. The 2007 year-end balance sheet data was derived from the audited financial statements but does not include all disclosures required by accounting principles generally accepted in the Unites States of America. The results of operations for the three and nine months ended September 30, 2008 are not necessarily indicative of the results expected for the full year.

The accompanying consolidated financial statements have been prepared on a basis which assumes that the Company 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. The Company has incurred cumulative net losses and expects to incur additional losses to perform further research and development activities. The Company does not have commercial products and has limited capital resources. Management's plans with regard to these matters include continued development of its products as well as seeking additional research support funds and future financial arrangements. Although management will continue to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient future financing on commercially reasonable terms or that the Company will be able to secure funding from anticipated government contracts and grants. Management believes that existing cash balances combined with cash flows primarily from continuing government grants and contracts, anticipated new government grants and contracts and potential proceeds from its investment commitment will be sufficient to support its operations beyond the next twelve months, and will fund the Company's business objectives during that period. If the Company is unable to raise adequate capital or achieve profitability, future operations will need to be scaled back or discontinued. Continuance of the Company as a going concern is dependent upon, among other things, the success of the Company's research and development programs and the Company's ability to obtain adequate financing. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

2. Significant Accounting Policies

Use of Estimates

The consolidated financial statements and related disclosures are prepared in conformity with accounting principles generally accepted in the United States of America. Management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and revenue and expenses during the period reported. These estimates include the realization of deferred tax assets, useful lives and impairment of tangible assets and goodwill, and the value of options and warrants granted or issued by the Company. Estimates and assumptions are reviewed periodically and the effects of revisions are reflected in the financial statements in the period they are determined to be necessary. Actual results could differ from these estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of short–term, highly liquid investments, with original maturities of less than three months when purchased and are stated at cost. Interest is accrued as earned.

Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is provided on the straight-line method over the estimated useful lives of the various asset classes. Estimated lives are 5 years for laboratory equipment; 3 years for computer equipment; 7 years for furniture and fixtures; and the life of the lease for leasehold improvements. Maintenance, repairs and minor replacements are charged to expense as incurred. Upon retirement or disposal of assets, the cost and related accumulated depreciation are removed from the Consolidated Balance Sheet and any gain or loss is reflected in the Consolidated Statement of Operations.

Revenue Recognition

The Company recognizes revenue from contract research and development and research payments in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition, ("SAB 104"). In accordance with SAB 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed or determinable, collectibility is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. The Company recognizes revenue from non-refundable up-front payments, not tied to achieving a specific performance milestone, over the period which the Company is obligated to perform services or based on the percentage of costs incurred to date, estimated costs to complete and total expected contract revenue. Payments for development activities are recognized as revenue as earned, over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, providing there is no future service obligation associated with that milestone. In situations where the Company receives payment in advance of the performance of services, such amounts are deferred and recognized as revenue as the related services are performed.

For the nine months ended September 30, 2008 and 2007, revenues from National Institutes of Health ("NIH") contracts and grants were 99% and 65%, respectively, of total revenues recognized by the Company. Revenues from contracts with the United States Air Force for the nine months ended September 30, 2008 and 2007 were 1% and 35%, respectively.

Accounts Receivable

Accounts receivable are recorded net of provisions for doubtful accounts. An allowance for doubtful accounts is based on specific analysis of the receivables. At September 30, 2008 and December 31, 2007, the Company had no allowance for doubtful accounts.

Research and Development

Research and development expenses include costs directly attributable to the conduct of research and development programs, including employee related costs, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside contractors, and facility costs, such as rent, utilities, and general support services. All costs associated with research and development are expensed as incurred. Costs related to the acquisition of technology rights, for which development work is still in process, and that have no alternative future uses, are expensed as incurred.

Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired.

The Company evaluates goodwill for impairment annually, in the fourth quarter of each year. In addition, the Company would test goodwill for recoverability between annual evaluations whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Examples of such events could include a significant adverse change in legal matters, liquidity or in the business climate, an adverse action or assessment by a regulator or government organization, loss of key personnel, or new circumstances that would cause an expectation that it is more likely than not that we would sell or otherwise dispose of a reporting unit. Goodwill impairment is determined using a two-step approach in accordance with Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"). The impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. In 2007, the Company operated as one business segment and one reporting unit. Therefore, the goodwill impairment analysis was performed on the basis of the Company as a whole using the market capitalization of the Company as an estimate of its fair value.

Income Taxes

Income taxes are accounted for under the asset and liability method prescribed by SFAS No. 109, "Accounting for Income Taxes." Deferred income taxes are recorded for temporary differences between financial statement carrying

amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or the entire deferred tax asset will not be realized.

The Company applies the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes —an Interpretation of FASB Statement 109* ("FIN 48"). FIN 48 prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return.

The Company has no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months from December 31, 2007, or from September 30, 2008. As of September 30, 2008, the only tax jurisdiction to which the Company is subject is the United States. Open tax years relate to years in which unused net operating losses were generated. Thus, upon adoption of FIN 48, the Company's open tax years extend back to 1995. In the event that the Company concludes that it is subject to interest and/or penalties arising from uncertain tax positions, the Company will present interest and penalties as a component of income taxes. No amounts of interest or penalties were recognized in the Company's Consolidated Statements of Operations or Consolidated Balance Sheets on December 31, 2007, or as of and for the three and nine months ended September 30, 2008.

Net Income per Common Share

The Company computes, presents and discloses earnings per share in accordance with SFAS No. 128 "Earnings Per Share" ("EPS") which specifies the computation, presentation and disclosure requirements for earnings per share of entities with publicly held common stock or potential common stock. The statement defines two earnings per share calculations, basic and diluted. The objective of basic EPS is to measure the performance of an entity over the reporting period by dividing income (loss) by the weighted average shares outstanding. The objective of diluted EPS is consistent with that of basic EPS, which is to measure the performance of an entity over the reporting period, while giving effect to all dilutive potential common shares that were outstanding during the period. The calculation of diluted EPS is similar to basic EPS except the denominator is increased for the conversion of potential common shares, unless the impact of such common shares is anti-dilutive.

The Company incurred losses for the three and nine months ended September 30, 2008 and 2007. As a result, certain equity instruments are excluded from the calculation of diluted loss per share. At September 30, 2008 and 2007, outstanding options to purchase 7,260,084 and 8,205,003 shares, respectively, of the Company's common stock with exercise prices ranging from $0.94 to $3.94 have been excluded from the computation of diluted loss per share as the effect of such shares is anti-dilutive. At September 30, 2008 and 2007, outstanding warrants to purchase 7,588,052 and 8,415,865 shares, respectively, of the Company's common stock, with exercise prices ranging from $1.18 to $4.99 have been excluded from the computation of diluted loss per share as they are anti-dilutive.

Fair Value of Financial Instruments

The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock warrants which are classified as liabilities under the provisions of Emerging Issues Task Force ("EITF") 00-19, are recorded at their fair market value as of each reporting period.

Concentration of Credit Risk

The Company has cash in bank accounts that exceed the Federal Deposit Insurance Corporation insured limits. The Company has not experienced any losses on its cash accounts. No allowance has been provided for potential credit losses because management believes that any such losses would be minimal.

Share-based Compensation

The Company accounts for its stock-based compensation programs under the provisions of SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases") based on estimated fair values. The Company does not have a stock purchase plan at the current time.

Segment Information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial

information with respect to separate product areas or by location and only has one reportable segment as defined by SFAS No. 131, “Disclosures about Segments of an Enterprise and Related Information”.

Recent Accounting Pronouncements

In April 2008, the FASB issued EITF 07-05, “Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity’s Own Stock”, (“EITF 07-05”). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of FAS 133. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and early application is not permitted. Management is evaluating what effect EITF 07-05 will have on SIGA’s financial position and operating results.

In March 2008, the FASB issued SFAS No. 161, “Disclosures about Derivative Instruments and Hedging Activities,” (“SFAS No. 161”). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities.” SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No. 161 will not affect our consolidated financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

Effective January 1, 2008, the Company implemented SFAS 157, “Fair Value Measurement”, (SFAS 157), for financial assets and liabilities that are required to be measured at fair value. The adoption of FAS 157 did not have an impact on our financial position or results of operations.

In February 2008, the FASB issued FASB Staff Position 157-2 (FSP 157-2), which delayed the implementation of SFAS 157 until January 1, 2009, for non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. Pursuant to FSP 157-2, the Company did not adopt FAS 157 for non-financial assets and liabilities that include goodwill. We are currently assessing the impact of FAS 157-2 on our non-financial assets and liabilities.

SFAS 157 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.

- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.

- Level 3 – Instruments where significant value drivers are unobservable to third parties.

The Company uses model-derived valuations where inputs are observable in active markets to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 2. At September 30, 2008, the fair value of such warrants was $4,166,014.

3. Stockholders’ Equity

On September 30, 2008, the Company’s authorized share capital consisted of 110,000,000 shares, of which 100,000,000 are designated common shares and 10,000,000 are designated preferred shares. The Company’s Board of Directors is authorized to issue preferred shares in series with rights, privileges and qualifications of each series determined by the Board.

2008 Financing

On June 19, 2008, SIGA entered into a letter agreement (the “Letter Agreement”), with MacAndrews & Forbes, LLC (“M&F”), a related party, for M&F’s commitment to invest, at SIGA’s discretion, of up to $8 million over a one–year period (the “Investment Period”) in exchange for (i) SIGA common stock at per share price equal to the lesser of (A) $3.06 and (B) the average of the volume-weighted average price per share for the 5 trading days immediately preceding each funding date, and (ii) warrants to purchase 40% of the number of SIGA shares acquired by the Investor, exercisable at 115% of the common stock purchase price on such funding date (the “Consideration Warrants”). The Consideration Warrants will be exercisable for up to 4 years following the issuance of such warrants. M&F has the option, during the Investment Period, to invest in the Company under the same investment terms.

In addition and in consideration for the commitment of M&F, M&F received warrants to purchase 238,000 shares of SIGA common stock, exercisable at $3.06 (the "Commitment Warrants"). The Commitment Warrants are exercisable until June 19, 2012. The Company recorded all costs related to the Letter Agreement, including the fair value of the Commitment Warrants, as deferred transaction costs. The deferred costs will reduce the Company's additional paid-in capital upon issuance of common stock and warrants under the Letter Agreement.

2006 and 2005 Placements

On October 19, 2006, the Company sold 2,000,000 shares of the Company's common stock at $4.54 per share and warrants to purchase 1,000,000 shares of the Company's common stock. The warrants have an initial exercise price of $4.99 per share and may be exercised at any time and from time to time through and including the seventh anniversary of the closing date. As of September 30, 2008, warrants to acquire 1,000,000 shares of common stock were outstanding.

In November 2005, the Company sold 2,000,000 shares of the Company's common stock at $1.00 per share and warrants to purchase 1,000,000 shares of the Company's common stock at an initial exercise price of $1.18 per share, at any time and from time to time through and including the seventh anniversary of the closing date. As of September 30, 2008, warrants to acquire 725,000 shares of common stock were outstanding.

The Company accounted for the transactions under the provisions of EITF 00-19 which requires that free standing derivative financial instruments that require net cash settlement be classified as assets or liabilities at the time of the transaction, and recorded at their fair value. EITF 00-19 also requires that any changes in the fair value of the derivative instruments be reported in earnings or loss as long as the derivative contracts are classified as assets or liabilities. At September 30, 2008, the fair market value of the warrants sold in 2006 and 2005 was $2.0 million and $2.1 million, respectively. The Company applied the Black-Scholes model to calculate the fair values of the respective derivative instruments using the contracted term of the warrants. Management estimates the expected volatility using a combination of the Company's historical volatility and the volatility of a group of comparable companies. SIGA recorded a loss of $920,000 representing the increase in the instruments' fair value from December 31, 2007 to September 30, 2008.

4. Research Agreements

Effective September 1, 2008, the Company was awarded a five-year, $55.0 million contract from the National Institute of Allergy and Infectious Diseases ("NIAID") of the NIH, to support the development of additional formulations and smallpox-related indications for ST-246, the Company's lead smallpox drug candidate.

In September 2008, SIGA was awarded $20.0 million from the NIAID in supplemental funding to the Company's existing $16.5 million contract, to accelerate process development related to large-scale manufacturing and packaging of ST-246 and commercial-scale validation. The term of the contract was extended through September 28, 2011.

In September 2008, SIGA received a two-year, $1.0 million Phase I grant from the NIH to fund lead optimization and animal efficacy trials for the Company's Dengue antiviral program.

5. Related Parties

During the nine months ended September 30, 2008, the Company incurred costs of $5,700 related to work performed by TransTech Pharma, Inc., a related party, and its affiliates. There are no outstanding accounts payable to related parties as of September 30, 2008.

6. Stock Compensation Plans

In January 1996, the Company implemented its 1996 Incentive and Non-Qualified Stock Option Plan (the "Plan"). The Plan as amended provides for the granting of up to 11,000,000 shares of the Company's common stock to employees, consultants and outside directors of the Company. The exercise period for options granted under the Plan, except those granted to outside directors, is determined by a committee of the Board of Directors. Stock options granted to outside directors pursuant to the Plan must have an exercise price equal to or in excess of the fair market value of the Company's common stock at the date of grant.

For the nine months ended September 30, 2008 and 2007, the Company recorded compensation expense of approximately $691,000 and $411,000, respectively, related to employees and directors stock options. The total fair value of options vested during the nine months ended September 30, 2008 and 2007, was $586,000 and $201,000, respectively. The total compensation cost not yet recognized related to non-vested awards at September 30, 2008, is $1.6 million. The weighted average period over which total compensation cost is expected to be recognized is 1.6 years.

7. Commitments and Contingencies

As of September 30, 2008, our purchase obligations are not material. We lease certain facilities and office space under operating leases. On December 31, 2007, minimum future rental commitments under operating leases having non-cancelable lease terms in excess of one year are as follows:

Year ended December 31,	Lease obligations
2008	$ 576,948
2009	579,648
2010	466,448
2011	443,748
Total	$ 2,066,792

Other

On December 20, 2006, PharmAthene, Inc. (“PharmAthene”) filed an action against SIGA in the Court of Chancery in the State of Delaware, captioned *PharmAthene, Inc. v. SIGA Technologies, Inc.*, C.A. No. 2627-N. In its Complaint, PharmAthene asks the Court to order the Company to enter into a license agreement with PharmAthene with respect to SIGA-246, as well as issue a declaration that SIGA is obliged to execute such a license agreement, and award damages resulting from SIGA’s supposed breach of that obligation. PharmAthene also alleges that SIGA breached an obligation to negotiate such a license agreement in good faith, as well as seeks damages for promissory estoppel and unjust enrichment based on supposed information, capital and assistance that PharmAthene allegedly provided to SIGA during the negotiation process. On January 9, 2007, SIGA filed a motion to dismiss the Complaint in its entirety for failure to state a claim upon which relief can be granted. The Company moved to stay discovery on January 26, 2007 and this motion was granted on March 8, 2007. On January 16, 2008, the Court of Chancery denied SIGA’s motion to dismiss and lifted the stay of discovery. Discovery is proceeding. The Company filed its answer to the Complaint on January 31, 2008. SIGA plans to continue to defend itself vigorously.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and notes to those statements and other financial information appearing elsewhere in this Quarterly Report. In addition to historical information, the following discussion and other parts of this Quarterly Report contain forward-looking information that involves risks and uncertainties.

Overview

Since our inception in December 1995, SIGA has pursued the research and development of novel products for the prevention and treatment of serious infectious diseases, including products for use in the defense against biological warfare agents such as smallpox and hemorrhagic fever viruses.

Effective September 1, 2008, we were awarded a five-year, $55.0 million contract from the National institute of Allergy and Infectious Diseases ("NIAID") of the NIH, to support the development of additional formulations and smallpox-related indications for ST-246, our lead smallpox drug candidate. In September 2008, we were awarded $20.0 million from the NIAID in supplemental funding to our existing $16.5 million contract, to accelerate process development related to large-scale manufacturing and packaging of ST-246 and commercial-scale validation. The term of the contract was extended through September 28, 2011. During the third quarter of 2006, we were awarded a three-year, $4.8 million Phase II continuation grant from the NIH to support the continuing development of our smallpox drug candidate, ST-246. Our efforts to develop ST-246 were also supported by previous grants from the NIH totaling $5.8 million, a $1.0 million agreement with Saint Louis University, and a $1.6 million contract with the U.S. Army. In September 2007, the Company received a two-year grant for a total of approximately $600,000, supporting the Company's development of ST-246 treatment of smallpox vaccine-related adverse events.

Our initiative to advance SIGA's hemorrhagic fevers programs is supported by a three year, $6.0 million grant from the NIH for the development of an antiviral drug for Lassa fever virus, received in September 2006, and previous grants from the NIH totaling $6.3 million for the development of antiviral drugs for Category A arenavirus.

In September 2008, we received a two-year, $1.0 million Phase I grant from the NIH to fund lead optimization and animal efficacy trials for our Dengue antiviral program.

Our anti-viral programs are designed to prevent or limit the replication of the viral pathogen. Our anti-infectives programs are aimed at the increasingly serious problem of drug resistance. These programs are designed to block the ability of bacteria to attach to human tissue, the first step in the infection process. In July 2007, we were awarded a two-year grant for a total of $530,000 to support our Strep program.

We do not have commercial products, and we cannot predict with certainty when our products will be able to be sold in substantial quantities. We will need additional funds to complete the development of our products. Our plans with regard to these matters include continued development of our products as well as seeking additional research support funds and financial arrangements. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on terms acceptable to us. Management believes that its existing cash balances combined with cash flows primarily from continuing government grants and contracts, anticipated new government grants and contracts and potential proceeds from its investment commitment will be sufficient to support SIGA's operations beyond the next twelve months, and that sufficient cash flows will be available to meet the Company's business objectives during that period.

Our technical operations are based in our research facility in Corvallis, Oregon. We continue to seek to fund a major portion of our ongoing antiviral, antibiotic and vaccine programs through a combination of government grants, contracts and strategic alliances. While we have had success in obtaining strategic alliances, contracts and grants, there is no assurance that we will continue to be successful in obtaining funds from these sources. Until additional relationships are established, we expect to continue to incur significant research and development costs and costs associated with the manufacturing of product for use in clinical trials and pre-clinical testing. It is expected that general and administrative costs, including patent and regulatory costs, necessary to support clinical trials and research and development will continue to be significant in the future. We expect to incur operating losses for the foreseeable future and there can be no assurance that we will ever achieve profitable operations.

Critical Accounting Estimates

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on the results we report in our consolidated financial statements, which we discuss under the heading "Results of Operations" following this section of our Management's Discussion and Analysis. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Our most critical accounting estimates include the assessment of recoverability of goodwill, which could impact goodwill impairments, and the assessment of recoverability of long-lived assets, which primarily impacts operating income if impairment exists. Below, we discuss these policies further, as well as the estimates and judgments involved. Other key accounting policies, including revenue recognition, are less subjective and involve a far lower degree of estimation and judgment.

Significant Accounting Policies

The following is a brief discussion of the more significant accounting policies and methods used by us in the preparation of our unaudited consolidated financial statements. Note 2 of the Notes to the Unaudited Consolidated Financial Statements includes a summary of all of the significant accounting policies.

Share-based Compensation

The Company accounts for its stock-based compensation programs under the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123(R)"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases") based on estimated fair values. SFAS 123(R) requires companies to estimate the fair value of share-based awards on the grant date using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite periods in the Company's consolidated statement of operations.

Fair value of Financial Instruments

The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to the relatively short maturity of these instruments. Common stock rights and warrants which are classified as assets or liabilities under the provisions of EITF 00-19 are recorded at their fair market value as of each reporting period. The Company applies the Black-Scholes pricing model to calculate the fair values of common stock rights and warrants using the contracted term of the instruments and expected volatility that is calculated as a combination of the Company's historical volatility and the volatility of a group of comparable companies.

Revenue Recognition

The Company recognizes revenue from contract research and development and research progress payments in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, ("SAB 104"). In accordance with SAB 104, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, collectibility is reasonably assured, contractual obligations have been satisfied and title and risk of loss have been transferred to the customer. The Company recognizes revenue from non-refundable up-front payments, not tied to achieving a specific performance milestone, over the period during which the Company is obligated to perform services or based on the percentage of costs incurred to date, estimated costs to complete and total expected contract revenue. Payments for development activities are recognized as revenue is earned, over the period of effort. Substantive at-risk milestone payments, which are based on achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, providing there is no future service obligation associated with that milestone. In situations in which the Company receives payment in advance of the performance of services, such amounts are deferred and recognized as revenue as the related services are performed.

Goodwill

Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired.

The Company evaluates goodwill for impairment annually, in the fourth quarter of each year. In addition, the Company would test goodwill for recoverability between annual evaluations whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Examples of such events could include a significant adverse change in legal matters, liquidity or in the business climate, an adverse action or assessment by a regulator or government organization, loss of key personnel, or new circumstances that would cause an expectation that

it is more likely than not that we would sell or otherwise dispose of a reporting unit. Goodwill impairment is determined using a two-step approach in accordance with SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The impairment review process compares the fair value of the reporting unit in which goodwill resides to its carrying value. In 2007, the Company operated as one business and one reporting unit. Therefore, the goodwill impairment analysis was performed on the basis of the Company as a whole using the market capitalization of the Company as an estimate of its fair value. In the past, our market capitalization has been significantly in excess of the Company's carrying value. It is reasonably likely that the future market capitalization of SIGA may exceed or fall short of our current market capitalization. If future market capitalization falls short of the Company's carrying value, a potential impairment might result. The use of the discounted expected future cash flows to evaluate the fair value of the Company as a whole is reasonably likely to produce different results than the Company's market capitalization.

Recent Accounting Pronouncements

In April 2008, the FASB issued EITF 07-05, "Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock", ("EITF 07-05"). EITF 07-05 provides guidance on determining what types of instruments or embedded features in an instrument held by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in paragraph 11(a) of FAS 133. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and early application is not permitted. Management is evaluating what effect EITF 07-05 will have on SIGA's financial position and operating results.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities," ("SFAS No. 161"). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 161 requires qualitative disclosures about objectives and strategies for using derivatives, quantitative disclosures about fair value amounts of gains and losses on derivative instruments and disclosures about credit-risk-related contingent features in derivative agreements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008. The adoption of SFAS No. 161 will not affect our consolidated financial condition and results of operations, but may require additional disclosures if we enter into derivative and hedging activities.

Effective January 1, 2008, the Company implemented SFAS No. 157, "Fair Value Measurement", (SFAS 157), for financial assets and liabilities that are required to be measured at fair value. The adoption of FAS 157 did not have an impact on our financial position or results of operations.

In February 2008, the FASB issued FASB Staff Position 157-2 (FSP 157-2), which delayed the implementation of FAS 157 until January 1, 2009, for non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. Pursuant to FSP 157-2, the Company did not adopt FAS 157 for non-financial assets and liabilities that include goodwill. We are currently assessing the impact of FAS 157-2 on our non-financial assets and liabilities.

SFAS 157 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 – Quoted prices for identical instruments in active markets.

- Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.

- Level 3 – Instruments where significant value drivers are unobservable to third parties.

We use model-derived valuations where inputs are observable in active markets to determine the fair value of certain common stock warrants on a recurring basis and classify such warrants in Level 2. At September 30, 2008, the fair value of such warrants was $4,166,014.

Results of Operations

Three months ended September 30, 2008 and 2007

Revenues from research and development contracts and grants for the three months ended September 30, 2008 and 2007 were $1.86 million and $1.61 million, respectively. The increase of $250,000 or 16% relates to $680,000 additional revenue recognized from our contracts with the NIH supporting the development of our lead smallpox drug candidate, ST-246. In January 2008, we completed a one-year agreement with the USAF for approximately $1.4 million, for the development of counter-measures against Dengue viruses and other water-related viral agents. In April 2008, we completed a one-year agreement with the USAF for approximately $873,000 for the USAF's Rapid Identification and Treatment program. Revenues recorded from these programs for the three months ended September 30, 2007 were $480,000.

Selling, general and administrative expenses ("SG&A") for the three months ended September 30, 2008 and 2007 were $945,000 and $793,000, respectively. The increase of $152,000 or 19% is due to higher legal and accounting fees related to transaction and litigation support, incurred during the three months ended September 30, 2008.

Research and development ("R&D") expenses for the three months ended September 30, 2008 and 2007 were $2.8 million and $2.3 million, respectively. R&D expenses increased $500,000 or 21% mainly due to a $367,000 increase in charges related to clinical and pre-clinical testing and manufacturing of our lead drug candidates and an increase of $300,000 in employee–related expenses due to the hiring of additional research and development employees. These increases were partially off-set by a decline of $154,000 in depreciation expenses for the three months ended September 30, 2008.

During the three months ended September 30, 2008 and 2007, we spent $1.2 million and $600,000, respectively, on the development of our lead drug candidate, ST-246. For the three months ended September 30, 2008, we spent $330,000 on internal human resources and $870,000 mainly on clinical testing. For the three months ended September 30, 2007, we spent $220,000 on internal human resources and $380,000 on clinical testing of ST-246. From inception of the ST-246 development program to-date, we expended a total of $13.3 million related to the program, of which $3.3 million and $10.0 million were spent on internal human resources, and manufacturing, clinical and pre-clinical work, respectively. These resources reflect SIGA's research and development expenses directly related to the program. They exclude additional expenditures such as the cost to acquire the program, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the Department of Defense ("DoD").

During the three months ended September 30, 2008 and 2007, we spent $244,000 and $325,000, respectively, to support the development of ST-193, a drug candidate for Lassa fever virus, ST-294, a drug candidate for certain arenavirus pathogens, and other drug candidates for hemorrhagic fevers. For the three months ended September 30, 2008, we spent $62,000 on internal human resources and $181,000 mainly on pre-clinical testing of our drug candidates. For the three months ended September 30, 2007, we spent $54,000 on internal human resources and $270,000 on pre-clinical testing. From inception of our program to develop ST-193, ST-294 and other drug candidates for hemorrhagic fevers, to-date, we spent a total of $5.3 million related to the program, of which $2.0 million and $3.3 million were expended on internal human resources and pre-clinical work, respectively. These resources reflect SIGA's research and development expenses directly related to the program. They exclude additional expenditures such as the cost to acquire the program, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the DoD.

For the three months ended September 30, 2007, we spent $320,000 in expenses related to our USAF agreements, of which $301,000 were invested in internal human resources and $19,000 were spent on external R&D services. No expenses were incurred for these programs during the three months ended September 30, 2008. Costs related to our work on the USAF Agreements from September 2005 to date were $3.4 million, of which we spent $1.8 million and $1.6 million on internal human resources and external R&D services, respectively. These resources reflect SIGA's research and development expenses directly related to this agreement. They exclude additional expenditures such as patent costs and allocation of indirect expenses.

Patent preparation expenses increased to $198,000 for the three months ended September 30, 2008, from $59,000 for the same period in the prior year. The increase of $139,000 reflects our efforts to protect our lead drug candidates in expanded geographic territories.

Changes in the fair value of common stock rights and common stock warrants sold together with common stock in October 2006 and November 2005 are recorded as gains or losses. For the three months ended September 30, 2008, and 2007 we recorded losses of $913,000 and $998,000, respectively, reflecting increases in the fair market value of warrants to purchase common stock during the respective three month periods. The warrants and rights to purchase common stock of SIGA were recorded at fair market value and classified as liabilities at the time of the transaction.

For the three months ended September 30, 2008 and 2007, we recorded other income of $18,000 and $90,000, respectively, mainly related to interest income on our cash and cash equivalent balance. The decline in other income is due to lower average cash and cash equivalent balance during the three months ended September 30, 2008 as compared to the same period in the prior year.

Nine months ended September 30, 2008 and 2007

Revenues from research and development contracts and grants for the nine months ended September 30, 2008 and 2007 were $5.58 million and $4.94 million, respectively. The increase of $640,000 or 13% in revenues recorded for the nine months ended September 30, 2008 relates to an increase of $2.3 million in revenues recognized from NIH grants and contracts with the NIH supporting our lead programs. Revenue recognized from our programs with the USAF was $38,000 and $1.7 million for the nine months ended September 30, 2008 and 2007, respectively. In 2008, we completed our two, one-year programs with the USAF.

SG&A expenses for the nine months ended September 30, 2008 and 2007 were $3.1 million and $2.8 million, respectively. SG&A expenses increased $300,000 or 11% due to an increase of $120,000 in business development expenses, an increase of $69,000 in insurance costs and an increase of $171,000 in employee-related costs, including non-cash stock compensation.

Research and development expenses for the nine months ended September 30, 2008 and 2007 were $8.2 million and $7.2 million, respectively. The increase of $1.0 million or 14% reflects higher expenditures related to clinical and pre-clinical testing of our lead drug candidates, which increased $1.8 million from the same period in the prior year. The increase was partially offset by a decline of $580,000 in depreciation and amortization, and a decline of $316,000 in expenditures related to our agreements with the USAF, which were completed during 2008.

During the nine months ended September 30, 2008 and 2007, we spent $3.7 million and $2.3 million, respectively, on the development of ST-246. For the nine months ended September 30, 2008, we spent $850,000 on internal human resources and $2.9 million mainly on manufacturing and clinical testing. For the nine months ended September 30, 2007, we spent $711,000 on internal human resources and $1.6 million mainly on clinical testing. From inception of the ST-246 development program to-date, we expended a total of $13.3 million related to the program, of which $3.3 million and $10.0 million were spent on internal human resources, and clinical and pre-clinical work, respectively. These resources reflect SIGA's research and development expenses directly related to the program. They exclude additional expenditures such as the cost to acquire the program, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the DoD.

R&D expenses of $760,000 and $916,000 during the nine months ended September 30, 2008 and 2007, respectively, were used to support the development of ST-193, a drug candidate for Lassa fever virus, ST-294, a drug candidate for certain arenavirus pathogens, and other drug candidates for hemorrhagic fevers. For the nine months ended September 30, 2008, we spent $190,000 on internal human resources and $570,000 mainly on pre-clinical testing. For the nine months ended September 30, 2007, we spent $175,000 on internal human resources and $741,000 mainly on pre-clinical testing. From inception of our program to develop ST-294 and other drug candidates for hemorrhagic fevers, to-date, we spent a total of $5.3 million related to the program, of which $2.0 million and $3.3 million were expended on internal human resources and pre-clinical work, respectively. These resources reflect SIGA's research and development expenses directly related to the program. They exclude additional expenditures such as the cost to acquire the program, patent costs, allocation of indirect expenses, and the value of other services received from the NIH and the DoD.

For the nine months ended September 30, 2008 and 2007, we spent $102,000 and $1.16 million, respectively, in expenses related to our USAF agreements. For the nine months ended September 30, 2008 we spent $77,000 on internal human resources and $26,000 for external R&D services. During the same period in 2007, we spent $818,000 and $346,000 on internal human resources and external R&D services, respectively. Costs related to our work on the USAF Agreements from September 2005 to date were $3.4 million, of which we spent $1.8 million and $1.6 million on internal human resources and external R&D services, respectively. These resources reflect SIGA's research and development

expenses directly related to this agreement. They exclude additional expenditures such as patent costs and allocation of indirect expenses.

Patent preparation expenses increased to $462,000 for the nine months ended September 30, 2008, from $323,000 for the same period in the prior year. The increase of $139,000 reflects our efforts to protect our lead drug candidates in expanded geographic territories.

Changes in the fair value of common stock rights and common stock warrants sold together with common stock in October 2006 and November 2005 are recorded as gains or losses. For the nine months ended September 30, 2008 and 2007, we recorded losses of $923,000 and $32,000, respectively, reflecting increases in the fair market value of warrants to purchase common stock during the respective periods. The warrants and rights to purchase common stock of SIGA were recorded at fair market value and classified as liabilities at the time of the transaction.

For the nine months ended September 30, 2008 and 2007, we recorded other income of $85,000 and $316,000, respectively, mainly related to interest income on our cash and cash equivalent balance. The decline in other income is due to lower cash and cash equivalent balance during the nine months ended September 30, 2008 as compared to the same period in the prior year.

Our product programs are in the early stage of development. At this stage of development, we cannot make reasonable estimates of the potential cost for most of our programs to be completed or the time it will take to complete the project. Our lead product, ST-246, is an orally administered anti-viral drug that targets the smallpox virus. In December 2005 the FDA accepted our IND application for ST-246 and granted it Fast-Track status. In December 2006, the FDA granted Orphan Drug designation to ST-246, for the prevention as well as the treatment of smallpox. We expect that costs to complete the program will approximate $20 million to $30 million, and that the project could be completed in 24 months to 36 months. There is a high risk of non-completion of any program, including ST-246, because of the lead time to program completion and uncertainty of the costs. Net cash inflows from any products developed from our programs is at least one to three years away. However, we could receive additional grants, contracts or technology licenses in the short-term. The potential cash and timing is not known and we cannot be certain if they will ever occur.

The risk of failure to complete any program is high, as each, other than our smallpox program which successfully completed 21-day dose-escalating studies in 2007, is in the relatively early stage of development. Products for the biological warfare defense market, such as the ST-246 smallpox anti-viral, could generate revenues in one to three years. We believe the products directed toward this market are on schedule. We expect the future research and development cost of our biological warfare defense programs to increase as the potential products enter animal studies and safety testing, including human safety trials. Funds for future development will be partially paid for by NIH contracts and grants, additional government funding and from future financing. If we are unable to obtain additional federal grants and contracts or funding in the required amounts, the development timeline for these products would slow or possibly be suspended. Delay or suspension of any of our programs could have an adverse impact on our ability to raise funds in the future, enter into collaborations with corporate partners or obtain additional federal funding from contracts or grants.

Liquidity and Capital Resources

On September 30, 2008, we had approximately $3.0 million in cash and cash equivalents.

Operating activities

Net cash used in operations during the nine months ended September 30, 2008 and 2007 was $6.4 million and $4.4 million, respectively. The increase in net cash used in operations relates to higher operating expenses incurred during the nine months ended September 30, 2008, and to an increase of approximately $1.2 million in our prepaid expenses as compared to the prior year.

Investing activities

Capital expenditures during the nine months ended September 30, 2008 and 2007, were $289,000 and $749,000, respectively, and mainly supported acquisitions of laboratory equipment in 2008, and the renovation of our office space in Oregon during the same period in 2007.

Financing activities

Cash provided by financing activities during the nine months ended September 30, 2008 and 2007 was $2.81 million and $2.58 million, respectively, generated from exercises of options and warrants to purchase common stock.

Other

On June 19, 2008, we entered into a letter agreement (the "Letter Agreement"), with MacAndrews & Forbes, LLC ("M&F"), a related party, for M&F's commitment to invest, at SIGA's discretion, up to $8 million over a one–year period (the "Investment Period") in exchange for (i) SIGA common stock at per share price equal to the lesser of (A) $3.06 and (B) the average of the volume-weighted average price per share for the 5 trading days immediately preceding each funding date, and (ii) warrants to purchase 40% of the number of SIGA shares acquired by the Investor, exercisable at 115% of the common stock purchase price on such funding date (the "Consideration Warrants"). The Consideration Warrants will be exercisable for up to four years following the issuance of such warrants. M&F has the option, during the Investment Period, to invest in the Company under the same investment terms.

In addition and in consideration for the commitment of M&F, M&F received warrants to purchase 238,000 shares of SIGA common stock, exercisable at $3.06 (the "Commitment Warrants"). The Commitment Warrants are exercisable until June 19, 2012. SIGA recorded all costs related to the Letter Agreement, including the fair value of the Commitment Warrants, as deferred transaction costs. The deferred costs will reduce our additional paid-in capital upon issuance of common stock and warrants under the Letter Agreement.

We have incurred cumulative net losses and expect to incur additional losses to perform further research and development activities. We do not have commercial products and have limited capital resources. Our plans with regard to these matters include continued development of our products as well as seeking additional working capital through a combination of collaborative agreements, strategic alliances, research grants, equity and debt financing. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining future financing on commercially reasonable terms or that we will be able to secure funding from anticipated government contracts and grants.

We believe that our existing cash balances combined with cash flows primarily from continuing government grants and contracts, anticipated new government grants and contracts and potential proceeds from our investment commitment will be sufficient to support our operations beyond the next twelve months, and that sufficient cash flows will be available to meet our business objectives during that period. We believe that we have sufficient liquidity to support our operations beyond the next twelve months despite the disruption of the capital markets. We are not dependent on the availability of short–term debt facilities and the limited availability of credit in the market has not affected our liquidity or materially impacted our funding.

Our working capital and capital requirements will depend upon numerous factors, including pharmaceutical research and development programs; pre-clinical and clinical testing; timing and cost of obtaining regulatory approvals; levels of resources that we devote to the development of manufacturing and marketing capabilities; technological advances; status of competitors; and our ability to establish collaborative arrangements with other organizations.

Off-Balance Sheet Arrangements

SIGA does not have any off-balance sheet arrangements.

Safe Harbor Statement

This report contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the efficacy of potential products, the timelines for bringing such products to market and the availability of funding sources for continued development of such products. Forward-looking statements are based on management's estimates, assumptions and projections, and are subject to uncertainties, many of which are beyond the control of SIGA. Actual results may differ materially from those anticipated in any forward-looking statement. Factors that may cause such differences include the risks that (a) potential products that appear promising to SIGA or its collaborators cannot be shown to be efficacious or safe in subsequent pre-clinical or clinical trials, (b) SIGA or its collaborators will not obtain appropriate or necessary governmental approvals to market these or other potential products, (c) SIGA may not be able to obtain anticipated funding for its development projects or other needed funding, (d) SIGA may not be able to secure funding from anticipated government contracts and grants, (e) SIGA may not be able to secure or enforce adequate legal protection, including patent protection, for its products, (f) regulatory approval for SIGA'S products may require further or additional testing that will delay or prevent approval, and (g) unanticipated internal control deficiencies or weaknesses or ineffective disclosure controls and procedures. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this presentation, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and in other documents that SIGA has filed with the Commission. SIGA urges investors and security holders to read those documents free of charge at the Commission's Web site at http://www.sec.gov. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements speak only as of the date they are made, and except for our ongoing obligations under the U.S. federal securities laws, we undertake no obligation to publicly update any forward-looking statements whether as a result of new information, future events or otherwise.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

None

Item 4. Controls and Procedures

(a) Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the fiscal period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures are effective.

(b) Internal Control Over Financial Reporting. There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II
Other information

Item 1. Legal Proceedings - On December 20, 2006, PharmAthene, Inc. ("PharmAthene") filed an action against us in the Court of Chancery in the State of Delaware, captioned *PharmAthene, Inc. v. SIGA Technologies, Inc.*, C.A. No. 2627-N. In its Complaint, PharmAthene asks the Court to order the Company to enter into a license agreement with PharmAthene with respect to SIGA-246, as well as issue a declaration that we are obliged to execute such a license agreement, and award damages resulting from our supposed breach of that obligation. PharmAthene also alleges that we breached an obligation to negotiate such a license agreement in good faith, as well as seeks damages for promissory estoppel and unjust enrichment based on supposed information, capital and assistance that PharmAthene allegedly provided to us during the negotiation process. On January 9, 2007, we filed a motion to dismiss the Complaint in its entirety for failure to state a claim upon which relief can be granted. The Company moved to stay discovery on January 26, 2007 and this motion was granted on March 8, 2007. On January 16, 2008, the Court of Chancery denied our motion to dismiss and lifted the stay of discovery. Discovery is proceeding. The Company filed its answer to the Complaint on January 31, 2008. SIGA plans to continue to defend itself vigorously.

Item 1A. Risk Factors – There are no material changes to the Risk Factors disclosed in our Annual report on Form 10-K for the fiscal year ended December 31, 2007.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds – None.

Item 3. Defaults upon Senior Securities – None.

Item 4. Submission of Matters to a Vote of Security Holders - None.

Item 5. Other Information – None.

Item 6. Exhibits

*	10.1	Contract dated September 1, 2008, between SIGA Technologies, Inc. and the National Institutes of Health, DHHS.
*	10.2	Modification of Contract dated September 17, 2008, between SIGA Technologies, Inc. and the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.
*	31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*	31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*	32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*	32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herein

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SIGA Technologies, Inc.
(Registrant)

Date: November 6, 2008

By: /s/ *Thomas N. Konatich*

Thomas N. Konatich
Chief Financial Officer

Exhibit 10.1

OMB Approval 2700-0042

AWARD/CONTRACT	1.THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ▶	RATING N/A	PAGE 1	OF PAGES 47
2. CONTRACT *(Proc. Inst. Ident.)* NO. HHSN272200800041C	3.EFFECTIVE DATE September 1, 2008	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 3962495		

5. ISSUED BY CODE
National Institutes of Health, DHHS
NIAID, DEA, OA
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, Maryland 20892-7612

6. ADMINISTERED BY *(If other than Item 6)* CODE
MID RCB-A

7. NAME AND ADDRESS OF CONTRACTOR *(No. street, county, state and ZIP Code)*
SIGA Technologies, Inc.
4575 SW Research Way
Corvallis, OR 97333

8. DELIVERY
o FOB ORIGIN x OTHER *(See below)*
FOB Destination

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
Article F.1.

12. PAYMENT WILL BE MADE BY CODE N/A
See Article G.3.

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION:**N/A**
o 10 U.S.C. 2304(c)( ) **o** 41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA
EIN# 1133864870A1 SOC 25.55 BARDA CAN 8475593 $9,570,599

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. UNIT PRICE	15D. AMOUNT	15E. UNIT PRICE	15F. AMOUNT
	Title: ST-246 Smallpox Antiviral: Expanded Utility and Additional Indications Period: September 1, 2008 through August 31, 2013 Contract Type: Cost Plus Fixed Fee	FY 08 FY 09 FY 10 FY 11 FY 12	$9,570,599 $7,153,880 $5,362,417 $15,780,413 $17,177,997		

15G. TOTAL AMOUNT OF CONTRACT ▶ $55,045,306

16. TABLE OF CONTENTS

(ü)	SEC.	DESCRIPTION	PAGE(S)	(ü)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
x	A	SOLICITATION/CONTRACT FORM	4	x	I	CONTRACT CLAUSES	37
x	B	SUPPLIES OR SERVICES AND PRICE/COST	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
x	C	DESCRIPTION/SPECS./WORK STATEMENT	11	x	J	LIST OF ATTACHMENTS	46
x	D	PACKAGING AND MARKING	18			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
x	E	INSPECTION AND ACCEPTANCE	19	x	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	47
x	F	DELIVERIES OR PERFORMANCE	20				
x	G	CONTRACT ADMINISTRATION DATA	23	o	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
x	H	SPECIAL CONTRACT REQUIREMENTS	26	o	M	EVALUATION FACTORS FOR AWARD	

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. o AWARD *(Contractor is not required to sign this document.)* Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Type or print)*

20A. NAME OF CONTRACTING OFFICER
Robert J. Singman
Contracting Officer

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
_____ *(Signature of person authorized to sign)*		BY _____ *(Signature of Contracting Officer)*	

NSN 7540-01-152-8069 26-107 STANDARD FORM 26 (REV. 4-85)
PREVIOUS EDITION UNUSABLE Computer Generated Prescribed by GSA

CONTRACT TABLE OF CONTENTS

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 overall objective of this contract is to advance the development and utility of ST-246 as a novel therapeutic agent for prevention and post-event therapeutic treatment of smallpox and related orthopoxviruses.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $52,424,101.

b. The fixed fee for this contract is $2,621,205. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and 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. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $55,045,306.

d. Total funds currently available for payment and allotted to this contract are $9,570,599, of which $9,114,856 represents the estimated costs, and of which $455,743 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through August 31, 2009.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. 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. Acquisition, by purchase or lease, of any interest in real property;

2. Special rearrangement or alteration of facilities;

3. 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.);

4. Travel to attend general scientific meetings;

5. Foreign travel - See subparagraph b. below;

6. Consultant costs;

7. Subcontracts;

8. Patient care costs;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property), regardless of acquisition value.

10. Light Refreshment and Meal Expenditures

    Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Project Officer, with a copy to the Contracting Officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held somewhere other than a government facility, provide an explanation of why the event is not being held at a government facility.

    Refer to NIH Manual Chapter 1160-1, Entertainment, for more information on NIH's policy on the use of appropriated funds for light refreshments and meals.

b. **Travel Costs**

1. Domestic Travel

    a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $141,600 without the prior written approval of the Contracting Officer.

    b. 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.

2. Foreign Travel

    Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of NIH contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.4. 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. **Overtime**

No overtime (premium) pay is authorized under the subject contract.

b. **Indirect Costs**

a. In no event shall the final amount reimbursable for General and Administrative expenses exceed a ceiling of 3% of $50,897,188.

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

c. Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

d. The Contractor shall complete all work in accordance with the Statement of Work, terms and conditions of this contract.

c. **Overhead**

In no event shall the final amount reimbursable for Overhead expenses exceed a ceiling of 50%.

d. **Subcontracts**

1. To negotiate a cost reimbursement type subcontract with Albemarle for an amount not to exceed $991,124. 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 cost reimbursement type subcontract with Amersham for an amount not to exceed $100,000. 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 cost reimbursement type subcontract with AZO Pharmarial for an amount not to exceed $1,618,800. 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 cost reimbursement type subcontract with Battelle for an amount not to exceed $5,219,262. 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 cost reimbursement type subcontract with Bioconvergence for an amount not to exceed $3,884,440. 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 cost reimbursement type subcontract with Catalent for an amount not to exceed $2,590,000. 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 cost reimbursement type subcontract with INC Research for an amount not to exceed $16,054,809. 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 cost reimbursement type subcontract with MPI Research for an amount not to exceed $3,928,200. 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 cost reimbursement type subcontract with Powdersize for an amount not to exceed $49,876. 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 cost reimbursement type subcontract with WGA for an amount not to exceed $80,000. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

e. **Consultants** Consultant agreements shall not proceed without the prior written approval of the Contracting Officer and are not to exceed $1,516,550. A copy of all signed approved consulting agreements shall be provided to the Contracting Officer.

Year 2008	Year 2009	Year 2010	Year 2011	Year 2012
$298,750	$298,750	$296,350	$286,350	336,350

f. **Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget**

1. The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

   a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.

   b. Fringe Benefits - Cite rate and amount

   c. Overhead - Cite rate and amount

   d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.

   e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

f. Consultant Fees - Identify individuals and amounts.

g. Subcontracts - Attach subcontractor invoice(s).

h. Equipment - Cite authorization and amount.

i. G&A - Cite rate and amount.

j. Total Cost

k. Fixed Fee

l. Total CPFF

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

2. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

g. **Confidential Treatment of Sensitive Information**

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

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

h. **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. HHSN272200800041C

i. **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 project officer 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.

Subcontracts/Consultant Agreements

j. It is understood that all subcontract and consultant agreements will be put in place after Contract Award. However, Contracting Officer review and approval is necessary before the Contractor can enter into agreement or before the subcontractor can start work.

Approval to Perform Work

k. The Contractor shall carry out activities within the contract Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Strategic Staged Product Development Plan following contract award, approval of Monthly and Annual Progress Reports, review and approval of a Clinical Trial Protocol and supporting materials, review and approval of protocols involving the use of vertebrate animals, and approval of Decision Gate Reports or Decision Gate Change or Deviation Requests (see reporting requirements for a description of these reports).

Clilnical Trial Protocol Development and Implementation

l. The Contractor needs to be in compliance with all Section H. Clauses related to Clinical Trials and Human Subjects.

The Contractor shall develop all clinical trial protocols and shall have ultimate responsibility for the conduct of all clinical trials and adherence to Federal regulations and the DMID, NIAID, NIH policies and guidelines for the conduct of research involving human subjects. Copies of Department of Health and Human Services (DHHS) regulations for the protection of human subjects, 45 (CFR Part 46, are available from the Office for Human Research Protections (OHRP), Office of the Secretary (OS), DHHS - http://www.hhs.gov/ohrp/ humansubjects/guidance/45cfr46.htm DMID policies, guidelines, templates and other important information regarding performing human subjects research are available at: http://niaid.nih.gov/dmid/clinresearch/. It is required that the information contained in the DMID Serious Adverse Event (SAE) Report Form be included in the Contractor's SAE Report Form, and it is recommended that the Contractor use the DMID SAE Report Form located at http://niaid.nih.gov/dmid/clinresearch/. SAE Reports must be submitted to the DMID Office of Clinical Research Affairs, according to the Clinical Terms of Award (see below). In addition, the Contractor shall develop and implement a Clinical Trials Monitoring Plan as part of the DMID Clinical Protocol.

The Contractor shall be required to:

a. Comply with all Federal and NIAID Clinical Terms of Award (http://niaid.nih.gov/ncn/pdf/clinterm.pdf)

b. Submit clinical trial protocols and supporting documentation (e.g. sample informed consent forms and clinical investigators brochures at the time of protocol submission, and case report forms, manuals of procedures, site quality management plan, data management plan, safety oversight plan and local Institutional Review Board Committee approvals prior to study initiation) and amendments to the Project Officer for review and approval by the appropriate NIAID review committee (the Clinical Trials Monitoring Plan is part of the DMID protocol template and is also subject to approval by the Project Officer).

c. Obtain from the Project Officer, final approval of protocols to be undertaken prior to FDA IND submission and participant enrollment.

d. If approved by DMID, NIAID, serve as the product IND sponsor with responsibility for:

a. Preparing materials for and request, schedule and participate in all meetings with the CDER, FDA, including meetings to review IND, NDA, and BLA packages.

b. Submitting all documentation to the FDA in a timely manner, consistent with timeliness set out in the contract and by the FDA.

c. Including NIAID and BARDA staff, as designated by the Project Officer, in meetings and teleconferences with the FDA.

d. Providing copies of all FDA correspondence and meeting minutes that are relevant to the therapeutic candidate/product to the Project Officer.

Human Subjects

m. Research projects involving humans and/or human specimens can only be initiated with written approval by the NIAID Project Officer in conjunction with Contracting Officer approvals in accordance with Section H. clauses.

Publications

n. Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for NIAID Project Officer review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The NIAID Project Officer will review all manuscripts and abstracts in a period of time not to exceed thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstract from receipt, and will either agree to the publication/disclosure or recommend changes.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

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 1, 2008, set forth in SECTION J-List of Attachments, the statement of work is attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer and two (2) hard copies of each report shall be submitted to the Project Officer, unless otherwise specified.

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 October 15, 2008. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

The Contractor shall submit a Monthly Technical Progress Report on or before the 15th Calendar day following each reporting period and shall include the following:

A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

a. SECTION I-An Introduction covering the purpose and scope of the contract effort;

b. SECTION II-PROGRESS

- SECTION II Part A: OVERALL PROGRESS- A description of overall progress;
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE- A description of all meetings, conference calls, etc. that have taken place during the reporting period.

Include progress administration and management issues (e.g. evaluating, and managing subcontractor performance);

- SECTION II Part C: TECHNICAL PROGRESS- For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned, preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

- SECTION II Part D; PROPOSED WORK- A summary of work proposed for the next reporting period; and

- Preprint reprints of papers and abstracts.

A Monthly Technical Progress Report will not be required in the same month that the Annual Technical Progress Report is submitted.

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 1, 2008 through August 31, 2009 of this contract and shall be due on September 15, 2009. Thereafter, reports shall be due on or before the 15th Calendar day following the reporting period.

Each Annual Progress Report shall include:

a. A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

b. SECTION I: EXECUTIVE SUMMARY -A brief overview of the work completed, and the major accomplishments achieved during the current reporting period;

c. SECTION II: PROGRESS

i) SECTION II Part A: OVERALL PROGRESS-A description of overall progress;

ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE-A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits);

iii) SECTION II Part C: TECHNICAL PROGRESS-A detailed description of the work performed structured to follow the activities and decision gates outlined

in the approved Strategic Staged Product Development Plan. Any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved;

iv) SECTION II Part D; PROPOSED WORK-A summary of work proposed for the next year period;

v) Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

vi) A summary of any inventions developed during the course 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, “Inclusion Enrollment Report,” which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

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

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

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

4. **Final Report**

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

The Contractor shall provide the Contracting Officer with copies of the Final Report in draft form (in accordance with the DELIVERIES Article in SECTION F of this contract/120 Calendar days prior to the expiration date of this contract.) The Project Officer will review the draft report and provide the Contracting Officer with comments within 45 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.

This report shall be submitted fifteen (15) calendar days before the completion date of the contract. The report shall conform to the following format:

(a) Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date;

(b) SECTION I: EXECUTIVE SUMMARY- Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

(c) SECTION II: RESULTS- A detailed description of the work performed, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

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. This report will be required on or before the expiration date of the contract.

6. **Report 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* 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 description of the work that will be done with each new or additional *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*;

    c. The title 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.

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. Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the approved Strategic Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or

conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project.

Decision Gate Reports shall include the following specific information:

a) Cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, telephone number, fax number, email address, and the date of submission;

b) An introduction covering the purpose, the scope of the contract effort, and the specific Decision Gate that has been reached;

c) Document and summarize the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision -making;

d) Actual costs incurred in relation to costs estimated in the original approved budget; and

e) A description of the next stage of product development to be initiated and a request for NIAID approval to proceed to the next stage of product development.

2. Decision Gate Change or Deviation Request

The Contractor shall submit a written request for a change in the agreed time lines and/or decision gate as approved in the Strategic Staged Product Development Plan. This request shall include the following:

a) A discussion of the justification/rationale for the request based on current data and a description of those data;

b) Options for addressing the needed change/deviation from the approved time lines and/ or decision gates, including a cost-benefit analysis of each option; and

c) A recommendation for the preferred option that includes a full analysis and discussion of the effects of the change on the entire product development program, time lines, and budget.

3. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

4. Clinical Trial Protocols

The NIAID/BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID/BARDA-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the NIAID Project Officer. Protocols must be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subjects research are available at (http://www.niaid.nih.gov/dmid/clinresearch/). The updates are to be included in the Monthly Technical Progress Report.

5. Final Clinical Study Report

The Final Clinical Study Report shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm). Final Clinical Study

Reports shall be provided within thirty (30) calendar days of the completion of the analysis of all data generated in the clinical trial.

6. Draft and Final Animal Efficacy Study Report

The Final Animal Efficacy Study Report shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought.

7. Strategic Staged Product Development Plan and Workplan

Within fourteen (14) calendar days of contract award and prior to initiation of product development activities, unless otherwise negotiated with NIAID Project Officer and the NIAID Contracting Officer, the Contractor shall submit for approval the Strategic Staged Product Development Plan. This Plan shall include:

a)Clearly defined goals, product development stages and product development activities;

b) Go/No Go decision gates;

c) Quantitative and qualitative criteria for assessing the scientific merit and feasibility of moving to the next stage of product development; and

d) A detailed time line for each stage covering the initiation, conduct and completion of product development activities, the analysis of outcomes and findings, and the preparation of detailed reports summarizing the results of work completed and an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision-making.

8. External Advisory Group Approval Request

Contractors shall submit the following to the NIAID Project Officer and NIAID Contracting Officer to request approval of External Advisory Group membership within 6 months of contract award:

a) a short biosketch for each member being proposed;

b) a description of the roles and duties of each member; and

c) the proposed compensation for each member.

9. Annual Review Meeting Report

A report of the post-award kick off meeting and the annual review meetings shall be prepared by the contractor within twenty-one (21) calendar days following the date of the meeting. This report shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

10. FDA Communications, Correspondence and Meeting Summaries

a) Within two (2) calendar days of the submission of any communication to the FDA, copies of the communication shall be submitted to the NIAID Project Officer.

b) Within thirty (30) calendar days of receiving correspondence or meeting with the FDA, submit copies of the correspondence or meeting minutes/summaries to the NIAID Project Officer.

11. Samples of Therapeutics:

The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. At the time of manufacturing, the Contractor will advise the

Project Officer concerning the type of material. The Contractor will be advised by the Project Officer how samples are to be packaged and where samples are to be shipped.

12. Animal Model:

Technology Transfer packages that include complete protocols and critical reagents for animal models developed and/or improved with contract funding will be submitted at the request of the Project Officer.

13. Copies of Other Reports Generated:

Copies of other reports generated during the contract period related to performance of the contract, including: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/ Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis at the request of the Project Officer.

14. Institutional Biosafety Approval:

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the Project Officer.

15. Data:

Provide raw data or specific analysis of data generated with contract funding at the request of the Project Officer.

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 Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, 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
Office of Acquisition
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 3214
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 designated Project Officer is the authorized representative of the Contracting Officer.

Inspection and acceptance will be performed at:

Office of Biodefense Research Affairs
National Institute of Allergy and Infectious Diseases, NIH
6610 Rockledge Drive, Room 5068
Bethesda, Maryland 20892

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

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

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

Type of Report	No. of Copies	Distribution	Due Date
Monthly Technical Progress Report	3 Paper 2 Electronic	Original hard copy and one (1) electronic copy: Contracting Officer (CO), Two (2) paper and one (1) electronic: Project Officer (PO)	The 15th of each month.
Annual Technical Progress Report	3 Paper 2 Electronic	Same as CO and PO above.	15th of the month following the end of each 12 months of the performance period.
DRAFT Final Technical Progress Report	3 Paper 2 Electronic	Same as CO and PO above.	120 Calendar days prior to completion date of the contract.
Final Technical Progress Report	3 Paper 2 Electronic	Same as CO and PO above.	15 Calendar days before completion date of the Contract.
Summary of Salient Results	3 Paper 2 Electronic	Same as CO and PO above.	On or before the expiration date of the contract.
Invention Report	2 Paper 2 Electronic	Original hard copy and one (1) electronic copy: Contracting Officer (CO), Original hard copy and one (1) electronic copy: Extramural Inventions and Technology Resources Branch, OPERA, NIH 6705 Rockledge Drive, Room 1040-A Bethesda, Maryland 20892-7980	Contract Expiration date
TECHNICAL			
Decision Gate Report	3 Paper 2 Electronic	Same as CO and PO above	Following completion of a pre-defined stage of product development and prior to initiation of a new stage.

Type of Report	No. of Copies	Distribution	Due Date
Decision Gate Change or Deviation Request	3 Paper 2 Electronic	Same as CO and PO above	As soon as the Contractor has sufficient data to support the need for a change from the approved Strategic Staged Product Development Plan.
Audit Reports	3 Paper 2 Electronic	Same as CO and PO above	Within 30 calendar days of the audit.
Clinical Trials Protocols	3 Paper 2 Electronic	Same as CO and PO above	To be negotiated with the NIAID Project Officer and prior to IND submission or enrollment of human subjects.
Final Clinical Study Report	3 Paper 2 Electronic	Same as CO and PO above	30 calendar days after completion of analysis clinical trial data.
Draft Animal Efficacy Study Reports	3 Paper 2 Electronic	Same as CO and PO above	30 calendar days after completion of all analysis of animal efficacy study data, otherwise approved by the PO.
Final Animal Efficacy Study Reports	3 Paper 2 Electronic	Same as CO and PO above	60 calendar days after completion of all analysis of animal efficacy study data, unless otherwise approved by the CO.
OTHER REPORTS			
Strategic Staged Product Development Plan and Workplan	3 Paper 2 Electronic	Same as CO and PO above	Within 14 calendar days after contract award and prior to initiation of product development activities.
External Advisory Group Approval Request	3 Paper 2 Electronic	Same as CO and PO above	Within 6 months after contract award.
Annual Review Meeting Report	3 Paper 2 Electronic	Same as CO and PO above	Within 21 calendar days following the date of the Annual Review Meeting.
FDA Communications, Correspondence, and Meeting Summaries	1 Paper 1 Electronic	Same as PO above	Within 2 calendar days of the submission of any communication to FDA, send copies of the communication to PO; Within 30 calendar days or receiving correspondence or meeting with the FDA, submit copies of correspondence or minutes/summaries to PO.

Type of Report	No. of Copies	Distribution	Due Date
Samples of Therapeutics, non-GMP and GMP	Equivalent of 50 doses of drug substance, 50 courses of treatment and/ or prevention of ST-246 drug product	Same as PO above	Contact PO for delivery.
Animal Model development Package including technology transfer, protocols and critical reagents.	3 Paper 2 Electronic	Same as CO and PO above	Contact PO for delivery.
Other Reports including Process Development Reports, Assay Qualification Plan/Report, Assay Technology transfer Report, Batch Records, SOP's, Master Production Records and Certificate of Analysis	3 Paper 2 Electronic	Same as CO and PO above	Contact PO for delivery.
Institutional Biosafety Approval	3 Paper 2 Electronic	Same as CO and PO above	Contact PO for delivery.
Raw Data	2 Paper 1 Electronic	Same as PO above	Upon PO's request.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

(to be determined at time of award)

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

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; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (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	Title
Dennis E. Hruby, Ph.D.	Principal Investigator

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

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

1. Payment requests shall be submitted as follows:

a. One original 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

One copy to the following approving official:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 3214
Bethesda, MD 20892-7612

E-Mail (address to be supplied upon contract award):

The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH, e.g. MS Word, MS Excel, or Adobe Portable Document Format (PDF). 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 Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases.

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

   c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26.

   d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

   e. Identification of whether payment is to be made using a two-way or three-way match. **This contract requires a Two-Way match.**

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 the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H 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 the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

   E-Mail:

   The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH [e.g., MS

Word, MS Excel, or Adobe Portable Document Format (PDF). ***[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."]***

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
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

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

ARTICLE G.5. 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 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted every two (2) years.

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 that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. 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.2. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-14 (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 receipt by the Contracting Officer 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.

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.3. 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.4. 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.5. REGISTRATION OF CLINICAL TRIALS IN THE GOVERNMENT DATABASE (ClinicalTrials.gov)

Pursuant to Public Law 110-85, Food and Drug Administration Amendments Act of 2007, Title VIII-Clinical Trial Databases, the Contractor shall register the clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov) by the later of December 27, 2007, or 21 days after the first patient is enrolled.

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

ARTICLE H.6. 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.7. 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.8. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.html) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and/or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Project Officer and Contracting Officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for Contracting Officer prior approval of any or all Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836).

ARTICLE H.9. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to the current HHS annual appropriations act, 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.10. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, 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.11. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, 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.12. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.13. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

> "(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.14. RESTRICTION ON ABORTIONS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for any abortion.

ARTICLE H.15. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

ARTICLE H.16. PRIVACY ACT, HHSAR 352.270-11 (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 HHS employees. These provisions also apply to all subcontracts awarded 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 to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

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/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.17. 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. This policy may be accessed at:

http://grants1.nih.gov/grants/olaw/references/phspol.htm.

ARTICLE H.18. 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://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.19. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

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

ARTICLE H.20. OMB CLEARANCE

In accordance with HHSAR 352.270-7, 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 Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.21. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the “Facility Standards for Records Storage Facilities Inspection Checklist,” self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.archives.gov/about/regulations/part-1228/k.html

Sixty (60) days prior to contract end date, the Contractor shall submit to the Project Officer and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

ARTICLE H.22. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

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, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http:// www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

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 order/contract exceeding $100,000 when the order/contract 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 in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and 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 and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://508.hhs.gov.

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment 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 Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance withthe following schedule. Instructions for completing the Report are available at: http://508.hhs.gov/ 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 incremental funding, as applicable.

ARTICLE H.23. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor 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 principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

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

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular 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 Contractor has not managed, reduced, or eliminated the conflict of interest. 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 conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.24. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, 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 Biomedical Advanced Research and Development Authority (BARDA), Department of Health and Human Services, and the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272200800041C"

ARTICLE H.25. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector

General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

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

ARTICLE H.26. 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.

2. **Noncommercial Supply Items Warranty**
YEAR 2000 WARRANTY—NONCOMMERCIAL SUPPLY ITEMS

The Contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below 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, when used in accordance with the item documentation provided by the Contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

Hardware and Software

3. **Commercial Supply Products Warranty**
YEAR 2000 WARRANTY—COMMERCIAL SUPPLY ITEMS

The Contractor warrants that each hardware, software and firmware product delivered under this contract and listed below 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, when used in accordance with the product documentation provided by the Contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the Contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

Hardware and Software

ARTICLE H.27. 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, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

ARTICLE H.28. SHARING RESEARCH DATA

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.29. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

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

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using NIH/BARDA funds for work involving a *Select Agent or Toxin*. **No NIH/BARDA 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/BARDA 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 inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. **No NIH/BARDA funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http:// www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf.

Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and:
http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html

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

ARTICLE H.30. POSSESSION, USE OR TRANSFER OF A HIGHLY PATHOGENIC AGENT

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

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

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

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

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

ARTICLE H.31. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.32. 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.33. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

Beginning April 7, 2008, 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.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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 at this address: http://www.arnet.gov/far/.

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

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Jul 2004*	*Definitions (Over $100,000)*
52.203-3	*Apr 1984*	*Gratuities (Over $100,000)*
52.203-5	*Apr 1984*	*Covenant Against Contingent Fees (Over $100,000)*
52.203-6	*Sep 2006*	*Restrictions on Subcontractor Sales to the Government (Over $100,000)*
52.203-7	*Jul 1995*	*Anti-Kickback Procedures (Over $100,000)*
52.203-8	*Jan 1997*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)*
52.203-10	*Jan 1997*	*Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)*
52.203-12	*Sep 2007*	*Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)*
52.204-4	*Aug 2000*	*Printed or Copied Double-Sided on Recycled Paper (Over $100,000)*
52.204-7	*Apr 2008*	*Central Contractor Registration*
52.204-10	*Sep 2007*	*Reporting Subcontract Awards ($500,000,000 or more)*
52.209-6	*Sep 2006*	*Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
52.215-2	*Jun 1999*	*Audit and Records - Negotiation (Over $100,000)*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Oct 1997*	*Price Reduction for Defective Cost or Pricing Data (Over $650,000)*
52.215-12	*Oct 1997*	*Subcontractor Cost or Pricing Data (Over $650,000)*
52.215-14	*Oct 1997*	*Integrity of Unit Prices (Over $100,000)*
52.215-15	*Oct 2004*	*Pension Adjustments and Asset Reversions*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*Oct 1997*	*Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications*
52.216-7	*Dec 2002*	*Allowable Cost and Payment*
52.216-8	*Mar 1997*	*Fixed Fee*
52.219-8	*May 2004*	*Utilization of Small Business Concerns (Over $100,000)*
52.219-9	*Apr 2008*	*Small Business Subcontracting Plan (Over $550,000, $1,000,000 for Construction)*

FAR CLAUSE NO.	*DATE*	*TITLE*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $550,000, $1,000,000 for Construction)*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Sep 2006*	*Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)*
52.222-36	*Jun 1998*	*Affirmative Action for Workers with Disabilities*
52.222-37	*Sep 2006*	*Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)*
52.222-50	*Aug 2007*	*Combating Trafficking in Persons*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-14	*Aug 2003*	*Toxic Chemical Release Reporting (Over $100,000)*
52.225-1	*Jun 2003*	*Buy American Act - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*Dec 2007*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-14	*Dec 2007*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*Jun 1996*	*Interest (Over $100,000)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*Jan 1986*	*Assignment of Claims*
52.232-25	*Oct 2003*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Oct 2003*	*Payment by Electronic Funds Transfer—Central Contractor Registration*
52.233-1	*Jul 2002*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2001*	*Penalties for Unallowable Costs (Over $650,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over $100,000)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Jun 2007*	*Subcontracts, Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over $100,000)*
52.244-6	*Mar 2007*	*Subcontracts for Commercial Items*

FAR CLAUSE NO.	*DATE*	*TITLE*
52.245-1	*Jun 2007*	*Government Property*
52.245-9	*Jun 2007*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over $100,000)*
52.249-6	*Sep 1996*	*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)*
352.216-72	*Jan 2006*	*Additional Cost Principles*
352.228-7	*Dec 1991*	*Insurance - Liability to Third Persons*
352.232-9	*Jan 2006*	*Withholding of Contract Payments*
352.233-70	*Jan 2006*	*Litigation and Claims*
352.242-71	*Apr 1984*	*Final Decisions on Audit Findings*
352.270-5	*Jan 2006*	*Key Personnel*
352.270-6	*Jan 2006*	*Publications and Publicity*
352.270-10	*Jan 2006*	*Anti-Lobbying (Over $100,000)*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 08/2008].

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

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

a. **Alternate I** (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 1997) is added.

b. FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

c. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

d. **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.

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).

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://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply** (July 2004).

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

5. FAR Clause **52.217-2, Cancellation Under Multiyear Contracts** (October 1997).

6. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

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

7. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).

8. FAR Clause **52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services--Requirements** (November 2007).

9. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

10. FAR Clause **52.223-17, Affirmative Procurement of EPA-designated Items in Service and Construction Contracts** (May 2008).

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

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

13. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).

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

15. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).

16. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).

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

18. FAR Clause **52.246-23, Limitation of Liability** (February 1997).

19. FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).

20. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

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

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

2. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

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

4. *HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).*

5. *HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).*

6. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*

7. *HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).*

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

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

1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

2. ***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.

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

a. *FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees**(December 2004)*

(a) Definition. As used in this clause —

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

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

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

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

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint

Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

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

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that—

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

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

(End of Clause)

b. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (February 2006).

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid—

(1) By Contractor under a cost-reimbursement contract; and

(2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding $100. Bills under $100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to:

Contracting Officer
Office of Acquistions
National Institute of Allergy and Infectious Diseases, NIH
6700-B Rockledge Drive, Room 3214
Bethesda, Maryland 20892-7612

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 1, 2008, 8 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, (5/07), 6 pages.

3. Inclusion Enrollment Report

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

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. Procurement of Certain Equipment

Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.

7. Research Patient Care Costs

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

8. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 3 pages.

9. Commitment To Protect Non-Public Information

Commitment To Protect Non-Public Information, 1 page. Located at:
http://irm.cit.nih.gov/security/Nondisclosure.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website.

Human Subjects Assurance Identification Number FWA00002255 (SIGA)

Animal Welfare Assurance Number is A3034-01 (Battelle)

Animal Welfare Assurance Number is A3181-01 (MPI Research, Inc.)

END of the SCHEDULE

Exhibit 10.2

OMB Approval 2700-0042

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE 1	OF PAGES 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
Four (4)	See block 16C.	722925	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions Room 3214, MSC 7612 6700-B Rockledge Drive Bethesda, MD 20892-7612		MID RCB-A	

8. NAME AND ADDRESS OF CONTRACTOR *(No. Street, County, State and ZIP: Code)*	(o)	9A. AMENDMENT OF SOLICITATION NO.
SIGA Technologies 4575 SW Research Way, Suite 230 Corvallis, OR 97333		9B. DATED ***(SEE ITEM 11)***
		10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN266200600014C
CODE / FACILITY CODE	X	10B. DATED ***(SEE ITEM 13)*** September 29, 2006

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required*

EIN: 1-133864870-AI SOC: 25.55 **CAN: 8-8470038 Obligates $2,984,928** **BARDA CAN: 8-8475593 Obligates $8,500,000**

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

(o) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
41 U.S.C. 253(c) (1), as set forth in FAR 6.302-1

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return **2** copies to the issuing office.

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

PURPOSE: 1) extend contract performance for two additional years; 2) increase the estimated cost; 3) provide funding; 4) update two existing and add six new subcontracts; 5) update the Statement of Work; and 6) update Public Law clauses under Section H.

	Total Funds Currently Allotted			Total Estimated Cost Plus Fixed Fee		
	Cost	Fee	Total	Cost	Fee	Total
Prior to this Mod	$15,903,262	$636,327	$16,539,589	$15,908,190	$636,327	$16,544,517
This Mod #4	$11,484,928	$0	$11,484,928	$19,999,803	$0	$19,999,803
Revised Total	$27,388,190	$636,327	$28,024,517	$35,907,993	$636,327	$36,544,320

FUNDED THROUGH DATE: December 31, 2010 (Changed) COMPLETION DATE: September 28, 2011 (Changed)

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Yvette R. Brown, Contracting Officer, OA, NIAID, NIH, DHHS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY *(Signature of Contracting Officer)*	

The following changes are hereby made to the Standard Form 26 dated September 29, 2006:

Under **Block 15A.**, the period is hereby revised to read as follows:

Period: September 29, 2006 through **September 28, 2011**

Under **Block 15G. TOTAL AMOUNT OF CONTRACT**, the total amount of the contract is hereby increased by $19,999,803 from $16,544,517 to **$36,544,320**.

The following updates are hereby made under **SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS**:

ARTICLE B.2. ESTIMATED COST AND FIXED FEE – paragraphs a., c., d. and e. are hereby modified to read as follows:

a. The estimated cost of this contract is hereby increased by $19,999,803 from $15,908,190 to $35,907,993.

c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee is hereby increased by $19,999,803 from $16,544,517 to $36,544,320.

d. Total funds currently available for payment and allotted to this contract are increased by $11,484,928 from $16,539,589 to $28,024,517, of which $27,388,190 represents the estimated costs, and of which $636,327 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, Article I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through December 31, 2010.

ARTICLE B.4. ADVANCE UNDERSTANDINGS, paragraph a., is hereby modified to update two existing and add six new subcontracts as follows. Award of these subcontracts shall not proceed without the prior written approval of the Contracting Officer. After written approval of the subcontracts by the Contracting Officer, a copy of each of the signed, approved subcontracts shall be provided to the Contracting Officer:

(4) To negotiate a subcontract with Metrics for an amount not to exceed $235,994.
(5) To negotiate a subcontract with MPI Research for an amount not to exceed $1,343,320.
(6) To negotiate a subcontract with Albemarle for an amount not to exceed $6,817,166.
(7) To negotiate a subcontract with Battelle for an amount not to exceed $3,000,000.
(8) To negotiate a subcontract with Catalent for an amount not to exceed $5,634,917.
(9) To negotiate a subcontract with INC Research for an amount not to exceed $923,451.
(10) To negotiate a subcontract with Powdersize for an amount not to exceed $62,950.
(11) To negotiate a subcontract with WGA for an amount not to exceed $134,000.

The following updates are hereby made under **SECTION C – DESCRIPTION/SPECIFICATION/WORK STATEMENT:**

ARTICLE C.1. STATEMENT OF WORK, paragraph a. is hereby revised to read as follows:

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 July 9, 2008, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

The following updates are hereby made under **SECTION H – SPECIAL CONTRACT REQUIREMENTS**, in compliance with Public Paw (P.L.) 110-161**:**

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, is deleted in its entirety and replaced with the following:

Pursuant to the current HHS annual appropriations act, 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.6. NEEDLE EXCHANGE, is deleted in its entirety and replaced with the following:

Pursuant to the current HHS annual appropriations act, 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.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS, is deleted in its entirety and replaced with the following:

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as “indirect costs” or “facilities and administrative (F&A) costs”). Direct salary has the same meaning as the term “institutional base salary.” An individual’s direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual’s appointment whether that individual’s time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual’s salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.*

ARTICLE H.12. PRESS RELEASES, is deleted in its entirety and replaced with the following:

Pursuant to the current HHS annual appropriations act, 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.14. ANTI–LOBBYING, is deleted in its entirety and replaced with the following:

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

THE FOLLOWING NEW PROVISIONS ARE HEREBY ADDED TO THIS CONTRACT IN COMPLIANCE WITH THE CONTINUING LEGISLATIVE MANDATES FOR FY2008 (P.L. 110-161).

ARTICLE H.23. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.24. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien.-As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

The following update is hereby made under **SECTION J – LIST OF ATTACHMENTS**:

1. Statement of Work, dated July 9, 2008, 6 pages

END OF MODIFICATION No. 4

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric A. Rose, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of SIGA Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 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 quarterly 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 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 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 registrant's board of directors (or persons performing the equivalent functions);

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2008

By: /s/ *Eric A. Rose*

Eric A. Rose, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas N. Konatich, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SIGA Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 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 quarterly 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 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 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 registrant's board of directors (or persons performing the equivalent functions);

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2008

By: /s/ *Thomas N. Konatich*

Thomas N. Konatich
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of SIGA Technologies, Inc. (the "Company") for the period ending September 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eric A. Rose, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §§.1350, as adopted pursuant to §§.906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

November 6, 2008

/s/ *Eric A. Rose*

Eric A. Rose, M.D.
Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of SIGA Technologies, Inc. (the "Company") for the period ending September 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas N. Konatich, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §§.1350, as adopted pursuant to §§.906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(3) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

November 6, 2008

/s/ *Thomas N. Konatich*

Thomas N. Konatich
Chief Financial Officer