SOLIGENIX, INC.
Form 424B3
September 30, 2013

Prospectus Supplement No. 1
(To Prospectus dated June 20, 2013)

Filed Pursuant to Rule 424(b)(3)
File No. 333-184762

SOLIGENIX, INC.

UP TO 9,523,809 UNITS, EACH CONSISTING OF
ONE SHARE OF COMMON STOCK,
A WARRANT TO PURCHASE UP TO AN ADDITIONAL 0.75 SHARE OF COMMON STOCK AND A
PREFERRED STOCK PURCHASE RIGHT

This Prospectus Supplement No. 1 (this "Prospectus Supplement") supplements the prospectus dated June 20, 2013 (the "Final Prospectus"), relating to the offer and sale by us of up to 9,523,809 units on a "best efforts" basis, with each unit consisting of (i) one share of our common stock, (ii) a warrant to purchase up to an additional 0.75 share of our common stock (collectively, the "Warrants"), and (iii) a preferred stock purchase right issuable in accordance with the Rights Agreement, dated June 22, 2007, between us and American Stock Transfer & Trust Company, which are attached to and trade with our common stock.

This Prospectus Supplement contains (i) the Quarterly Report on Form 10-Q that we filed with the Securities and Exchange Commission (the "SEC") on August 12, 2013, (ii) the Current Report on Form 8-K that we filed with the SEC on September 24, 2013 and (iii) the Current Report on Form 8-K that we filed with the SEC on September 30, 2013. This Prospectus Supplement should be read in conjunction with, and may not be utilized without, the Final Prospectus, which is to be delivered with this Prospectus Supplement. This Prospectus Supplement is qualified by reference to the Final Prospectus except to the extent that the information in this Prospectus Supplement updates and supersedes the information contained in the Final Prospectus, including any supplements or amendments thereto.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Placement Agent

Maxim Group LLC

Prospectus Supplement No. 1 dated September 30, 2013.

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

FORM 10-Q

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

For the Quarterly Period Ended June 30, 2013

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. 000-16929

SOLIGENIX, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 EMMONS DRIVE, SUITE C-10 PRINCETON, NJ	08540
(Address of principal executive offices)	(Zip Code)

(609) 538-8200
(Registrant's telephone number, including area code)

Indicate by check whether the registrant (1) 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 has submitted electronically and posted on its corporate Web Site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “accelerated filer” and “large accelerated filer” in Rule 112b-2 of the Exchange Act (Check one).

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company x

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 August 7, 2013, 19,030,487 shares of the registrant's common stock (par value, $.001 per share) were outstanding.

SOLIGENIX, INC.

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

Soligenix, Inc. and Subsidiaries
Consolidated Balance Sheets

	June 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$8,127,742	$3,356,380
Grants receivable	190,111	339,308
Prepaid expenses	194,971	140,693
Total current assets	8,512,824	3,836,381
Office furniture and equipment, net	16,139	12,995
Intangible assets, net	745,032	855,728
Total assets	$9,273,995	$4,705,104
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$1,364,841	$1,124,503
Warrant liability	5,177,831	-
Accrued compensation	276,613	29,495
Total current liabilities	6,819,285	1,153,998
Commitments and contingencies		
Shareholders' equity:		
Preferred stock; 350,000 shares authorized; none issued or outstanding	-	-
Common stock, $.001 par value; 50,000,000 shares authorized; 19,030,487 shares and 11,168,905 shares issued and outstanding in 2013 and 2012, respectively	19,030	11,169
Additional paid-in capital	129,208,632	125,820,318
Accumulated deficit	(126,772,952)	(122,280,381)
Total shareholders' equity	2,454,710	3,551,106
Total liabilities and shareholders' equity	$9,273,995	$4,705,104

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Operations
For the Three and Six Months Ended June 30, 2013 and 2012
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues, principally from grants	$632,278	$762,851	$1,532,632	$1,410,269
Cost of revenues	(527,948)	(616,330)	(1,271,605)	(1,172,901)
Gross profit	104,330	146,521	261,027	237,368
Operating expenses:				
Research and development	2,140,474	500,980	2,897,127	1,377,774
General and administrative	719,740	627,218	1,207,681	1,282,261
Total operating expenses	2,860,214	1,128,198	4,104,808	2,660,035
Loss from operations	(2,755,884)	(981,677)	(3,843,781)	(2,422,667)
Other income (expense):				
Change in fair value of warrant liability	(649,576)	-	(649,576)	-
Interest income, net	303	1,799	786	4,034
Net loss	$(3,405,157)	$(979,878)	$(4,492,571)	$(2,418,633)
Basic and diluted net loss per share	$(0.28)	$(0.09)	$(0.38)	$(0.22)
Basic and diluted weighted average common shares outstanding	12,259,394	11,124,359	11,720,066	11,121,814

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Changes in Shareholders' Equity
For the Six Months Ended June 30, 2013
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance, December 31, 2012	11,168,905	$11,169	$125,820,318	$(122,280,381)	$3,551,106
Common stock issued in Unit offering, net of offering cost of $895,933	6,773,995	6,774	6,209,988	-	6,216,762
Warrants issued in Unit offering	-	-	(4,528,255)	-	(4,528,255)
Issuance of common stock to collaboration partner	1,034,483	1,034	1,498,966	-	1,500,000
Issuance of common stock to vendors	28,104	28	35,860	-	35,888
Exercise of shares from options	25,000	25	7,475	-	7,500
Stock-based compensation expense	-	-	164,280	-	164,280
Net loss	-	-	-	(4,492,571)	(4,492,571)
Balance, June 30, 2013	19,030,487	19,030	129,208,632	(126,772,952)	2,454,710

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

Soligenix, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Six Months Ended June 30,
(Unaudited)

	2013	2012
Operating activities:		
Net loss	$(4,492,571)	$(2,418,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and depreciation	113,566	108,753
Common stock and warrants issued in exchange for services	1,535,888	3,000
Change in fair value of warrant liability	649,576	-
Restricted stock issued to employee	-	10,000
Stock-based compensation	164,280	235,002
Change in operating assets and liabilities:		
Grants receivable	149,197	122,874
Other receivable	-	574,157
Prepaid expenses	(54,278)	(54,216)
Accounts payable	240,338	(83,987)
Accrued compensation	247,118	(57,575)
Total adjustments	3,045,685	858,008
Net cash used in operating activities	(1,446,886)	(1,560,625)
Investing activities:		
Purchase of office equipment	(6,014)	(4,755)
Net cash used in investing activities	(6,014)	(4,755)
Financing activities:		
Proceeds from sale of common stock	6,216,762	-
Proceeds from exercise of options	7,500	-
Net cash provided by financing activities	6,224,262	-
Net increase / (decrease) in cash and cash equivalents	4,771,362	(1,565,380)
Cash and cash equivalents at beginning of period	3,356,380	5,996,668
Cash and cash equivalents at end of period	$8,127,742	$4,431,288
Supplemental disclosure of non cash investing and financing activities:		
Warrant issued in Unit Offering	$4,528,255	$-

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

Soligenix, Inc.
Notes to Consolidated Financial Statements

Note 1. Nature of Business

Basis of Presentation

Soligenix, Inc. (the "Company", "we" or "us") is a clinical stage biopharmaceutical company that was incorporated in 1987 and is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. The Company maintains two active business segments: BioTherapeutics and Vaccines/BioDefense. Soligenix's BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/ treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis. Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, and VeloThrax™, our anthrax vaccine, and OrbeShield™, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of these vaccine programs is currently supported by the Company's heat stabilization technology, known as ThermoVax™, under existing and on-going grant funding.

The Company generates revenues under four active grants primarily from the National Institutes of Health ("NIH").

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development of new technological innovations, dependence on key personnel, protections of proprietary technology, compliance with FDA regulations, litigation, and product liability. Results for the quarter ended June 30, 2013 are not necessarily indicative of results that may be expected for the full year.

Liquidity

As of June 30, 2013, the Company had cash and cash equivalents of $8,127,742 as compared to $3,356,380 as of December 31, 2012, representing an increase of $4,771,362 or 142%. As of June 30, 2013, the Company had working capital of $6,871,370, which excludes the non-cash warranty liability of $5,177,831, as compared to working capital of $2,682,283 as of December 31, 2012, representing an increase of $4,189,087, or 156%. The increase in cash and working capital was primarily the result of the receipt of net proceeds of $6,216,762 received from our registered public offering partially offset by cash used in operating activities during the six month period. For the six months ended June 30, 2013, the Company's cash used in operating activities was $1,446,886 as compared to $1,560,625 for the same period in 2012, representing a decrease of $113,739, or 7%.

Management's business strategy can be outlined as follows:

Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic GI GVHD;
Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology known as ThermoVax™ to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;

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Continue to apply for and secure additional government funding for each of our BioTherapeutics and Vaccines/BioDefense programs through grants, contracts and/or procurements;

Acquire or in-license new clinical-stage compounds for development; and

Explore other business development and acquisition strategies, an example of which is the recently announced collaboration with Intrexon Corporation.

Based on the Company's current rate of cash outflows, cash on hand, proceeds from grant programs and proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that its current cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter of 2015.

The Company's plans with respect to its liquidity management include, but are not limited to, the following:

The Company has approximately $2.3 million in active grant funding still available to support its associated research programs through 2014. The Company plans to submit additional grant applications for further support of its programs with various funding agencies.

The Company has continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expects to continue to do so for the foreseeable future.

The Company will pursue sale of Net Operating Losses ("NOLs") in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $521,458 in proceeds pursuant to NOL sales in 2012, the Company expects to participate in the program during 2013 and beyond; and

The Company may seek additional capital in the private and/or public equity markets to continue its operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. The Company evaluates equity financing opportunities on an ongoing basis and may execute them when appropriate. However, there can be no assurances that the Company can consummate such a transaction, or consummate a transaction at favorable pricing.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include Soligenix, Inc., and its wholly and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated as a result of consolidation.

Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment. The Company divides its operations into two operating segments: BioTherapeutics and Vaccines/BioDefense.

Grants Receivable

Grants receivable consist of unbilled amounts due from various grants from the NIH for costs incurred under reimbursement contracts prior to the period end. The amounts were billed to the NIH in the month subsequent to period end and collected shortly thereafter. Accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

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Intangible Assets

One of the most significant estimates or judgments that the Company makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, the Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for its current products in both the domestic and international markets. The Company believes that patent rights are one of its most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from Soligenix's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents and perhaps extending the lives of the patents. The Company capitalizes such costs and amortizes intangibles over their expected useful life – generally a period of 11 to 16 years.

The Company did not incur any capitalizable patent related costs during the six months ended June 30, 2013 and 2012.

Impairment of Long-Lived Assets

Office furniture, equipment and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company did not record any impairment of long-lived assets for the six months ended June 30, 2013 or 2012.

Fair Value of Financial Instruments

FASB ASC 820 — Fair Value Measurements and Disclosures, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of
all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us on June 30, 2013. Accordingly, the estimates presented in these financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).
The three levels of the fair value hierarchy are as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose value is based on quoted

market prices such as exchange-traded instruments and listed equities.

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2includes financial instruments that are valued using models or other valuation methodologies. These models consider various assumptions, including volatility factors, current market prices and contractual prices for the underlying financial instruments. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 — Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term maturity of these instruments. The Company recognizes all derivative financial instruments as assets or liabilities in the financial statements and measures them at fair value with changes in fair value reflected as current period income or loss unless the derivatives qualify as hedges. As a result, certain warrants issued in connection with the offering were accounted for as derivatives. See Note 4, Warrant Liabilities.

Revenue Recognition

Principally the Company's revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when the Company incurs internal expenses that are related to the grant.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, Research and Development. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries stock based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Stock-Based Compensation

Stock options are issued with an exercise price equal to the market price on the date of issuance. Stock options issued to directors upon re-election vest quarterly for a period of one year (new director issuances are fully vested upon issuance). Stock options issued to employees vest 25% immediately as of the grant date, then 25% each subsequent year for a period of three years. Stock options vest over each three month period from the date of issuance to the end of the three year period. These options have a ten year life for as long as the individuals remain employees or directors. In general when an employee or director terminates their position the options will expire within three months, unless otherwise extended by the Board.

Stock compensation expense for options, warrants and shares of common stock granted to non-employees has been determined in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employee directors is amortized as the options vest.

The Company issued 26,000 and 100,000 options during the six months ending June 30, 2013 and 2012, respectively.

The fair value of options granted are estimated using the Black-Scholes option pricing model utilizing the following assumptions and are amortized ratably over the option vesting periods, which approximates the service period:

a dividend yield of 0%;
an expected life of 4 years;
volatility of 167% and 160% for 2013 and 2012, respectively;
forfeitures at rate of 12%; and
risk-free interest rates of 1.09% and 0.51% in 2013 and 2012, respectively.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, and the length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through June 30, 2013 due to the net operating losses incurred by the Company since its inception. The Company recognizes accrued interest and penalties associated with uncertain tax positions, if any, as part of income tax expense. There were no tax related interest and penalties recorded for 2013 and 2012. Additionally, the Company has not recorded an asset for unrecognized tax benefits or a liability for uncertain tax positions at June 30, 2013 or 2012. Tax years beginning in 2010 for federal purposes are generally subject to examination by the taxing authorities, although net operating losses from those years are subject to examinations and adjustments for at least three years following the year in which the tax attributes are utilized.

Earnings Per Share

Basic earnings per share ("EPS") excludes dilution and is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period, Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that shared in the earnings of the entity. Since there is a significant number of options and warrants outstanding, fluctuations in the actual market price can have a variety of results for each period presented.

	Three Months Ended June 30,					
	2013			2012		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(3,405,157)	12,259,394	$(0.28)	$(979,878)	11,124,359	$(0.09)

	Six Months Ended June 30,					
	2013			2012		
	Net Loss	Shares	EPS	Net Loss	Shares	EPS
Basic & Diluted EPS	$(4,492,571)	11,720,066	$(0.38)	$(2,418,633)	11,121,814	$(0.22)

Shares issuable upon the exercise of options and warrants outstanding at June 30, 2013 and 2012 were 1,447,474 and 1,596,898 shares issuable upon the exercise of outstanding stock options, and 7,923,838 and 2,576,341 shares issuable upon the exercise of outstanding warrants, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2013 were $3.16 and $2.18 per share, respectively. The weighted average exercise price of the Company's stock options and warrants outstanding at June 30, 2012 were $3.50 and $4.32 per share, respectively. No options or warrants were included in the 2013 and 2012 computations of diluted earnings per share because their effect would be anti-dilutive as a result of losses in each of those years.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions such as the fair value of warrants and stock options and the recovery of the useful life of intangibles that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

Note 3. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Remaining Amortization Period (years)	Cost	Accumulated Amortization	Net Book Value
June 30, 2013				
Licenses	7.2	$462,234	$ 265,528	$196,706
Patents	3.0	1,893,185	1,344,859	548,326
Total	3.8	$2,355,419	$ 1,610,387	$745,032
December 31, 2012				
Licenses	7.7	$462,234	$ 252,019	$210,215
Patents	3.3	1,893,185	1,247672	645,513
Total	4.2	$2,355,419	$ 1,499,691	$855,728

Amortization expense was $55,654 and $55,208 for the three months ended June 30, 2013 and 2012, respectively and $110,696 and $101,845 for the six months ended June 30, 2013 and 2012, respectively.

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Based on the balance of licenses and patents at June 30, 2013, the expected annual amortization expense for each of the succeeding five years is estimated to be as follows:

	Amortization Expense
2013	$ 222,800
2014	$ 222,800
2015	$ 133,000
2016	$ 61,800
2017	$ 20,800

Note 4. Warrant Liabilities

Warrants issued in connection with the Company's registered public offering contain provisions that protect holders from a decline in the issue price of its common stock (or "down-round" provisions) and contain net settlement provisions. The Company accounts for these warrants as liabilities instead of equity. Down-round provisions reduce the exercise or conversion price of a warrant if a company issues equity shares for a price that is lower than the exercise or conversion price of the warrants. Net settlement provisions allow the holder of the warrant to surrender shares underlying the warrant equal to the exercise price as payment of its exercise price, instead of exercising the warrant by paying cash. The Company evaluates whether warrants to acquire its common stock contain provisions that protect holders from declines in the stock price or otherwise could result in modification of the exercise price and/or shares to be issued under the respective warrant agreements based on a variable that is not an input to the fair value of a "fixed-for-fixed" option.

The Company recognizes these warrants as liabilities at their fair value on the date of grant and remeasures them at fair value on each reporting date.

The Company recognized an initial warrant liability for the warrants issued in connection with the registered public offering completed in June 2013. The initial warrant liability recognized on the related warrants totaled $4,528,255, which was based on the June 25, 2013 closing price of a share of our common stock as reported on OTC Markets of $0.96. On June 30, 2013, the closing price of our common stock as reported on OTC Markets was $1.06. Due to the fluctuations in the market value of our common stock from June 25, 2013 through June 30, 2013, we recognized a non-cash charge of $649,576 for the change in the fair value of the warrant liability.

The assumptions used in connection with the valuation of warrants issued were as follows:

	June 30, 2013		Initial Measurement June 25, 2013	
Number of shares underlying the warrants	5,080,500		5,080,500	
Exercise price	$1.65		$ 1.65	
Volatility	140	%	140	%
Risk-free interest rate	1.49	%	1.49	%
Expected dividend yield	0		0	
Expected warrant life (years)	5		5	
Stock Price	$1.06		$ 0.96	

Recurring Level 3 Activity and Reconciliation

The table below provides a reconciliation of the beginning and ending balances for the liability measured at fair value using significant unobservable inputs (Level 3). The table reflects losses for the six months ended June 30, 2013 for the financial liability categorized as Level 3 as of June 30, 2013.

Fair Value Measurements Using Significant Unobservable Inputs (Level 3):

	March 31, 2013	Initial Measurement	Increase in Fair Value	June 30, 2013
2013 Warrant	-	$ 4,528,255	$649,576	$5,177,831

Note 5. Income Taxes

The Company had NOLs at December 31, 2012 of approximately $79,454,000 for federal tax purposes and approximately $9,478,000 of New Jersey NOL carry forwards remaining after the sale of unused NOL carry forwards, portions of which are currently expiring each year until 2031. In addition, the Company had $2,860,000 of various tax credits that started expiring in December 2012 and will continue to expire through December 2030. The Company may be able to utilize its NOLs to reduce future federal and state income tax liabilities. However, these NOLs are subject to various limitations under Internal Revenue Code (“IRC”) Section 382. IRC Section 382 limits the use of NOLs to the extent there has been an ownership change of more than 50 percentage points. In addition, the NOL carryforwards are subject to examination by the taxing authority and could be adjusted or disallowed due to such exams. Although the Company has not undergone an IRC Section 382 analysis, it is possible that the utilization of the NOLs, could be substantially limited.

The Company and one or more of its subsidiaries files income tax returns in the U.S. Federal jurisdiction, and various state and local jurisdictions. The Company is no longer subject to Federal income tax assessment for years before 2010 for federal and 2009 for New Jersey income tax assessment. However, since the Company has incurred net operating losses in every tax year since inception, all its income tax returns are subject to examination by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized.

The Company has no tax provision for the three and six month periods ended June 30, 2013 and 2012 due to losses incurred and full valuation allowances recorded against net deferred tax assets.

Note 6. Shareholders’ Equity

Preferred Stock

The Company has 350,000 shares of preferred stock authorized, none of which are issued or outstanding.

Common Stock

During the six months ended June 30, 2013, the Company issued the following shares of common stock:

On June 25, 2013, the Company completed a public unit offering consisting of one share of common stock and an additional warrant of 0.75 share of common stock. The Company issued 6,773,995 shares of common stock which included 5,080,500 five-year warrants at an exercise price of $1.65;
1,034,483 shares of common stock issued to Intrexon Corporation in connection with an exclusive channel collaboration;

25,000 shares of common stock issued upon the exercise of vested stock options;
28,104 shares of common stock issued to vendors as partial consideration for services performed.

Note 7. Commitments and Contingencies

The Company has commitments of approximately $362,500 as of June 30, 2013 for several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization success will occur.

On February 7, 2012, the Company entered into a lease agreement through March 31, 2015 for existing office space. The rent for the first 12 months is approximately $8,000 per month, or approximately $18.25 per square foot. This rent increases to approximately $8,310 per month, or approximately $19.00 per square foot, for the remaining 24 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following number of shares to each of Dr. Schaber and Dr. Brey immediately prior to the completion of a transaction, or series or a combination of related transactions negotiated by its Board of Directors whereby, directly or indirectly, a majority of its capital stock or a majority of its assets are transferred from the Company and/or its stockholders to a third party: 50,000 common shares to Dr. Schaber; and 10,000 common shares to Dr. Brey. The amended agreement with Dr. Schaber includes its obligation to issue such shares if such event occurs.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2013	$ 37,500	$ 53,000	$ 90,500
2014	100,000	101,100	201,100
2015	75,000	24,900	99,900
2016	75,000		75,000
2017	75,000	-	75,000
Total	$ 362,500	$ 179,000	$ 541,500

Note 8. Operating Segments

The Company maintains two active operating segments: BioTherapeutics and Vaccines/BioDefense. Each segment includes an element of overhead costs specifically associated with its operations, with its corporate shared services group responsible for support functions generic to both operating segments.

	Three Months Ended June 30,	
	2013	2012
Revenues, Principally from Grants		
Vaccines/BioDefense	$588,496	$710,237
BioTherapeutics	43,782	52,614
Total	$632,278	$762,851
Loss from Operations		
Vaccines/BioDefense	$(1,532,472)	$(2,144)
BioTherapeutics	(530,640)	(481,817)
Corporate	(692,772)	(497,716)
Total	$(2,755,884)	$(981,677)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$27,968	$24,954
BioTherapeutics	28,675	25,892
Corporate	424	562
Total	$57,067	$51,408
Other Income /(Expense), Net		
Corporate	$(649,273)	$1,799
Stock-Based Compensation		
Vaccines/BioDefense	$11,128	$2,130
BioTherapeutics	25,905	56,194
Corporate	47,755	59,064
Total	$84,788	$117,388

	Six Months Ended June 30,	
	2013	2012
Revenues, Principally from Grants		
Vaccines/BioDefense	$1,418,345	$1,307,842
BioTherapeutics	114,287	102,427
Total	$1,532,632	$1,410,269
Income (Loss) from Operations		
Vaccines/BioDefense	$(1,563,467)	$(130,509)
BioTherapeutics	(988,266)	(1,207,859)
Corporate	(1,292,048)	(1,084,299)
Total	$(3,843,781)	$(2,422,667)
Amortization and Depreciation Expense		
Vaccines/BioDefense	$55,635	$52,951
BioTherapeutics	57,070	54,733
Corporate	861	1,069
Total	$113,566	$108,753
Other Income /(Expense), Net		
Corporate	$(648,790)	$4,034
Stock-Based Compensation		
Vaccines/BioDefense	$22,249	$4,260
BioTherapeutics	46,941	112,614
Corporate	95,090	118,128
Total	$164,280	$235,002

	As of June 30, 2013	As of December 31, 2012
Identifiable Assets		
Vaccines/BioDefense	$470,414	$628,494
BioTherapeutics	466,498	566,111
Corporate	8,337,083	3,510,499
Total	$9,273,995	$4,705,104

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information to explain our results of operations and financial condition. You should also read our unaudited consolidated interim financial statements and their notes included in this Form 10-Q, and our audited consolidated financial statements and their notes, and Risk Factors and other information included in our Annual Report on Form 10-K for the year ended December 31, 2012. This report contains forward-looking statements. Forward-looking statements within this Form 10-Q are identified by words such as "believes," "anticipates," "expects," "intends," "may," "will" "plans" and other similar expressions, however, these words are exclusive means of identifying such statements. In addition, any statements that refer to expectations projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are subject to significant risks, uncertainties and other factors, which may cause actual results to differ materially from those expressed in, or implied by, these forward-looking statements. Except as expressly required by the federal securities laws, we undertake no obligation to publicly update or revise any forward-looking statements to reflect events, circumstances or developments occurring subsequent to the filing of this Form 10-Q with the U.S. Securities and Exchange Commission ("SEC") or for any other reason and you should not place undue reliance on these forward-looking statements. You should carefully review and consider the various disclosures the Company makes in this report and our other reports filed with the "SEC" that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

Overview:

Business Overview

We are a clinical stage biopharmaceutical company that is focused on developing products to treat serious inflammatory diseases and biodefense countermeasures where there remains an unmet medical need. We maintain two active business segments: BioTherapeutics and Vaccines/BioDefense.

Our BioTherapeutics business segment is developing proprietary formulations of oral beclomethasone 17,21-dipropionate ("BDP") for the prevention/treatment of gastrointestinal ("GI") disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), acute radiation enteritis, (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing our novel innate defense regulator ("IDR") technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine, VeloThraxTM, our anthrax vaccine, and OrbeShieldTM, our gastrointestinal acute radiation syndrome ("GI ARS") therapeutic. The advanced development of our vaccine programs is currently supported by our heat stabilization technology, known as ThermoVaxTM, under existing and on-going government grant funding. We also recently announced a global and exclusive channel collaboration with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize human monoclonal antibody therapies to treat melioidosis.

An outline for our business strategy follows:

- Initiate a Phase 2 clinical trial of SGX942 for the treatment of oral mucositis in head and neck cancer;
- Initiate a Phase 2/3 clinical trial of oral BDP, known as SGX203 for the treatment of pediatric Crohn's disease;
- Evaluate the effectiveness of oral BDP in other therapeutic indications involving inflammatory conditions of the GI tract such as prevention of acute radiation enteritis, prevention of acute radiation syndrome, and treatment of chronic graft-versus-host disease ("GI GVHD");

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Develop RiVax™ and VeloThrax™ in combination with our proprietary vaccine heat stabilization technology, known as ThermoVax™, to develop new heat stable vaccines in biodefense and infectious diseases with the potential to collaborate and/or partner with other companies in these areas;
Continue to apply for and secure additional government funding for each of our BioTherapeutics and BioDefense programs through grants, contracts and/or procurements; and
Explore other business development and merger/acquisition strategies, an example of which is our recently announced collaboration with Intrexon.

We were incorporated in Delaware in 1987. Our principal executive offices are located at 29 Emmons Drive, Suite C-10, Princeton, New Jersey 08540 and our telephone number is (609) 538-8200.

Our Products in Development

The following tables summarize the products that we are currently developing:

BioTherapeutic Products

Soligenix Product	Therapeutic Indication	Stage of Development
SGX942	Oral Mucositis in Head and Neck Cancer	IND clearance and Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014
SGX203	Pediatric Crohn's disease	Phase 1/2 clinical trial completed June 2013, data pharmacokinetic (PK)/pharmacodynamic (PD) profile and safety confirmed; Phase 2/3 clinical trial planned for the second half of 2013, with data expected in the second half of 2014
SGX201	Acute Radiation Enteritis	Phase 1/2 clinical trial complete; safety and preliminary efficacy demonstrated Phase 2 trial planned for the first half of 2014, with data expected in the first half of 2015
orBec®	Treatment of Chronic GI GVHD	Phase 2 trial planned for the second half of 2013, with data expected in the second half of 2014

Vaccine Thermostability Platform

Soligenix Product	Indication	Stage of Development
ThermoVax™	Thermostability of aluminum adjuvanted vaccines	Pre-clinical

Vaccines/BioDefense Products

Soligenix Product	Indication	Stage of Development
RiVaxTM	Vaccine against Ricin Toxin Poisoning	Phase 1B trial enrollment complete; safety and neutralizing antibodies for protection demonstrated

		Phase 2 trial planned for the first half of 2014
VeloThrax™	Vaccine against Anthrax Poisoning	Pre-clinical Phase 1 clinical trial planned for second half of 2014
OrbeShield™	Therapeutic against GI ARS	Follow-on pre-clinical study initiated; Initial pre-clinical study complete; successful protection observed in canine
SGX943/SGX101	Melioidosis	Pre-clinical

BioTherapeutics Overview

SGX94

In December 2012, we acquired a novel drug technology, we refer to as SGX94, representing what we believe is a novel approach to modulation of the innate immune system. SGX94 is an IDR that regulates the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. As part of the acquisition, we acquired all rights, including composition of matter patents, preclinical and Phase 1 clinical study datasets for SGX94. We also assumed a license agreement with the University of British Columbia ("UBC") to advance the research and development of the SGX94 technology. The license agreement with UBC provides us with exclusive worldwide rights to manufacture, distribute, market sell and/or license or sublicense products derived or developed from this technology.

SGX94 is the research name for the active ingredient in SGX942, which is the research name for the finished drug product being studied in oral mucositis. It is a new class of short, synthetic peptides known as IDRs that have a novel mechanism of action in that it is simultaneously anti-inflammatory and anti-infective. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. IDRs provide a novel approach to the control of infection and tissue damage via highly selective binding to an intracellular adaptor protein, sequestosome-1, also known as p62, which has a pivotal function in signal transduction during activation and control of the innate defense system. Preclinical data indicate that IDRs are active in models of a wide range of therapeutic indications including life-threatening bacterial infections as well as the severe side-effects of chemo- and radiation-therapy.

We have a strong worldwide IP position on SGX94 and related analogs including composition of matter. SGX94 was developed pursuant to discoveries made by Professors B. Brett Finlay and Robert Hancock of UBC and approximately $40 million has been invested towards its development to date, inclusive of government grants.

SGX94 has demonstrated efficacy in numerous animal disease models including mucositis, colitis, skin infection and other bacterial infections and has been evaluated in a double-blind, placebo-controlled Phase 1 clinical trial in 84 healthy volunteers with both single ascending dose and multiple ascending dose components. SGX94 showed a strong safety profile when administered by IV over 7 days and was consistent with safety results seen in pre-clinical studies. SGX94 is the subject of an open Investigational New Drug ("IND") application which has been cleared by the FDA. Market opportunities include, but are not limited to, mucositis, acute bacterial skin and skin structure infections, acinetobacter, melioidosis, acute radiation syndrome and as a vaccine adjuvant, with potential opportunities for non-dilutive funding to support the development.

We believe the potential worldwide market for SGX942 is in excess of $500 million for all applications, including oral mucositis.

SGX942 – for Treating Oral Mucositis in Head and Neck Cancer

SGX942 is poised to start a Phase 2 clinical study in oral mucositis in head and neck cancer patients. Oral mucositis in this patient population is an area of unmet medical need where there are currently no approved drug therapies. Accordingly, we received Fast Track designation for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients from the FDA in the first half of 2013. Fast Track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast Track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, we will be eligible to submit a New Drug Application ("NDA") for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for Fast Track development programs ordinarily will be eligible for priority review, which implies an abbreviated review time of six months.

About Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the U.S. per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastro-intestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis is a subpopulation of approximately 90,000 patients in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (>80% incidence of severe mucositis) and is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral BDP

Oral BDP (beclomethasone 17,21-dipropionate) represents a first-of-its-kind oral, locally acting therapy tailored to treat gastrointestinal inflammation. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. Oral BDP is specifically formulated for oral administration as a single product consisting of two tablets. One tablet is intended to release BDP in the upper sections of the GI tract and the other tablet is intended to release BDP in the lower sections of the GI tract.

Based on its pharmacological characteristics, oral BDP may have utility in treating other conditions of the gastrointestinal tract having an inflammatory component. We have an issued U.S. patent 8,263,582 claiming the use of oral BDP as a method of treating inflammatory disorders of the gastrointestinal tract, including Crohn's disease, and an issued U.S. patent 6,096,731 claiming the use of oral BDP as a method for preventing and treating the tissue damage that is associated with both GI GVHD following hematopoietic cell transplantation, as well as GVHD which also

occurs following organ allograft transplantation. We also have European Patent EP 1392321 claiming the use of topically active corticosteroids in orally administered dosage forms that act concurrently to treat inflammation in the upper and lower gastrointestinal tract. We are planning to pursue development programs in the treatment of pediatric Crohn's disease, acute radiation enteritis, chronic GI GVHD, and GI ARS pending further grant funding. We are also exploring the possibility of testing oral BDP for local inflammation associated with Ulcerative Colitis, among other indications.

We believe the potential worldwide market for oral BDP is in excess of $500 million for all GI applications, namely, pediatric Crohn’s disease, radiation enteritis, GI ARS, and chronic GI GVHD.

In addition to issued patents and pending worldwide patent applications held by or exclusively licensed to us, oral BDP would benefit from orphan drug designations in the U.S. and in Europe. Orphan drug designations provide for 7 and 10 years of market exclusivity upon approval in the U.S. and Europe, respectively.

SGX203 –for Treating Pediatric Crohn’s Disease

SGX203 is a two tablet delivery system of BDP specifically designed for oral use that allows for administration of immediate and delayed release BDP throughout the small bowel and the colon. The FDA has awarded SGX203 Orphan Drug designation as well as Fast Track designation for the treatment of pediatric Crohn's disease.

About Pediatric Crohn's Disease

Crohn's disease is an ongoing disorder that causes inflammation of the GI tract. Crohn's disease can affect any area of the GI tract, from the mouth to the anus, but it most commonly affects the lower part of the small intestine, called the ileum. The swelling caused by the disease extends deep into the lining of the affected organ. The swelling can induce pain and can make the intestines empty frequently, resulting in diarrhea. Because the symptoms of Crohn's disease are similar to other intestinal disorders, such as irritable bowel syndrome and ulcerative colitis, it can be difficult to diagnose. People of Ashkenazi Jewish heritage have an increased risk of developing Crohn's disease.

Crohn's disease can appear at any age, but it is most often diagnosed in adults in their 20s and 30s. However, approximately 30% of people with Crohn's disease develop symptoms before 20 years of age. We estimate, based upon our review of historic published studies and reports and an interpolation of data on the incidence of Pediatric Crohn’s disease,, that Pediatric Crohn's disease is a subpopulation of approximately 80,000 patients in the U.S. with a comparable number in Europe. Crohn’s disease tends to be both severe and extensive in the pediatric population and a relatively high proportion (~40%) of pediatric Crohn’s patients have involvement of their upper gastrointestinal tract.

Crohn's disease presents special challenges for children and teens. In addition to bothersome and often painful symptoms, the disease can stunt growth, delay puberty, and weaken bones. Crohn's disease symptoms may sometimes prevent a child from participating in enjoyable activities. The emotional and psychological issues of living with a chronic disease can be especially difficult for young people.

SGX201 – for Preventing Acute Radiation Enteritis

SGX201 is a delayed-release formulation of BDP specifically designed for oral use. We completed a Phase 1/2 clinical trial testing SGX201 in prevention of acute radiation enteritis. Patients with rectal cancer scheduled to undergo concurrent radiation and chemotherapy prior to surgery were randomized to one of four dose groups. The objectives of the study were to evaluate the safety and maximal tolerated dose of escalating doses of SGX201, as well as the preliminary efficacy of SGX201 for prevention of signs and symptoms of acute radiation enteritis. The study demonstrated that oral administration of SGX201 was safe and well tolerated across all four dose groups. There was also evidence of a potential dose response with respect to diarrhea, nausea and vomiting and the assessment of enteritis according to National Cancer Institute Common Terminology Criteria for Adverse Events for selected gastrointestinal events. In addition, the incidence of diarrhea was lower than that seen in recent published historical control data in this patient population. This program was supported in part by a $500,000 two-year Small Business Innovation and Research (“SBIR”) grant awarded by the National Institutes of Health (“NIH”). We are currently working with our Radiation Enteritis medical advisory board to determine potential next steps forward with the clinical

development program.

We have received Fast Track designation from the FDA for SGX201 for acute radiation enteritis.

About Acute Radiation Enteritis

External radiation therapy is used to treat most types of cancer, including cancer of the bladder, uterine, cervix, rectum, prostate, and vagina. During delivery of treatment, some level of radiation will also be delivered to healthy tissue, including the bowel, leading to acute and chronic toxicities. The large and small bowels are very sensitive to radiation and the larger the dose of radiation the greater the damage to normal bowel tissue. Radiation enteritis is a condition in which the lining of the bowel becomes swollen and inflamed during or after radiation therapy to the abdomen, pelvis, or rectum. Most tumors in the abdomen and pelvis need large doses, and almost all patients receiving radiation to the abdomen, pelvis, or rectum will show signs of acute enteritis.

Patients with acute enteritis may have nausea, vomiting, abdominal pain and bleeding, among other symptoms. Some patients may develop dehydration and require hospitalization. With diarrhea, the gastrointestinal tract does not function normally, and nutrients such as fat, lactose, bile salts, and vitamin B 12 are not well absorbed.

Symptoms will usually resolve within 2-6 weeks after therapy has ceased. Radiation enteritis is often not a self-limited illness, as over 80% of patients who receive abdominal radiation therapy complain of a persistent change in bowel habits. Moreover, acute radiation injury increases the risk of development of chronic radiation enteropathy, and overall 5% to 15% of the patients who receive abdominal or pelvic irradiation will develop chronic radiation enteritis.

We estimate, based upon our review of historic published studies and reports, and an interpolation of data on the treatment courses and incidence of cancers occurring in the abdominal and pelvic regions, there to be over 100,000 patients annually in the U.S., with a comparable number in Europe, who receive abdominal or pelvic external beam radiation treatment for cancer, and these patients are at risk of developing acute and chronic radiation enteritis.

orBec® –for Treating Chronic GI GVHD

orBec® is a two tablet delivery system of BDP specifically designed for oral use that allows for delivery of immediate and delayed release BDP to treat the gastrointestinal manifestation of chronic GVHD, the organ system where GVHD is most frequently encountered and highly problematic. orBec® is intended to reduce the need for systemic immunosuppressive drugs such as prednisone to treat chronic GI GVHD. The active ingredient in orBec® is BDP, a highly potent, topically active corticosteroid that has a local effect on inflamed tissue. BDP has been marketed in the U.S. and worldwide since the early 1970s as the active pharmaceutical ingredient in a nasal spray and in a metered-dose inhaler for the treatment of patients with allergic rhinitis and asthma. orBec® has been awarded orphan drug designations in the U.S. and in Europe for the treatment of GI GVHD. In September 2012, we received a $300,000 two-year SBIR grant awarded by the NIH to support a Phase 2 study for the treatment of chronic GI GVHD.

About Chronic GVHD

GVHD is a major complication of allogeneic hematopoietic cell transplantation. GVHD is an inflammatory disease initiated by T cells in the donor graft that recognize histocompatibility and other tissue antigens of the host, and is mediated by a variety of effector cells and inflammatory cytokines. GVHD presents in both acute and chronic forms. The symptoms of chronic GVHD typically present at between 100 days and three years post-transplant.

Chronic GVHD has features resembling autoimmune and other immunologic disorders such as scleroderma, Sjögren syndrome, primary biliary cirrhosis, wasting syndrome, bronchiolitis obliterans, immune cytopenias and chronic immunodeficiency. The manifestations of chronic GVHD may be restricted to a single organ or tissue or may be widespread. Chronic GVHD can lead to debilitating consequences, e.g., joint contractures, loss of sight, end-stage lung disease, or mortality resulting from profound chronic immune suppression leading to recurrent or life-threatening infections.

Treatment of chronic GVHD is a challenge because it can be refractory to frontline immunosuppression. High-dose systemic corticosteroids are used with some success but carry significant toxicity. The risks of prolonged immunosuppression include local and disseminated infections; Epstein-Barr virus associated lymphoproliferative disease, hypothalamic-pituitary-adrenal ("HPA") axis suppression, myopathy, glucose intolerance, neuropsychiatric disease and bone demineralization.

We estimate, based upon our review of historic published studies and reports and an interpolation of data on the incidence of chronic GVHD, there to be 6,000 patients annually in the U.S., with a comparable number in Europe that suffer from chronic GVHD.

Vaccines/BioDefense Overview

ThermoVax™ – Thermostability Technology

Our thermostability technology, ThermoVax™, is a novel method of rendering aluminum salt, (known colloquially as Alum), adjuvanted vaccines stable at elevated temperatures. Alum is the most widely employed adjuvant technology in the vaccine industry. The value of ThermoVax™ lies in its potential ability to eliminate the need for cold-chain production, transportation, and storage for Alum adjuvanted vaccines. This would relieve companies of the high costs of producing and maintaining vaccines under refrigerated conditions. Based on historical reports from the World Health Organization and other scientific reports, a meaningful proportion of vaccine doses globally are wasted due to excursions from required cold chain temperature ranges. This is due to the fact that most Alum adjuvanted vaccines need to be maintained at between 2 and 8 degrees Celsius ("C") and even brief excursions from this temperature range (especially below freezing) usually necessitates the destruction of the product or the initiation of costly stability programs specific for the vaccine lots in question. The savings realized from the elimination of cold chain costs and related product losses would in turn significantly increase the profitability of vaccine products. Elimination of the cold chain would also further facilitate the use of these vaccines in the lesser developed parts of the world. ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency settings.

ThermoVax™ development is being supported pursuant to our $9.4 million National Institute of Allergy and Infectious Diseases ("NIAID") grant enabling development of thermo-stable ricin (RiVax™) and anthrax (VeloThrax™) vaccines. Proof-of-concept preclinical studies with ThermoVax™ indicate that it is able to produce stable vaccine formulations using adjuvants, protein immunogens, and other components that ordinarily would not withstand long temperature variations exceeding customary refrigerated storage conditions. These studies were conducted with our aluminum-adjuvanted ricin toxin vaccine, RiVax™, made under precise lyophilization conditions using excipients that aid in maintaining native protein structure of the ricin A chain, the immunogenic compound of the vaccine. When

RiVax™ was kept at 40 degrees C for six months, all of the animals vaccinated with the lyophilized RiVax™ vaccine developed potent and high titer neutralizing antibodies. Confirmatory results have extended the stability to six months when the vaccine is kept at 40 degrees C. In contrast, animals that were vaccinated with the liquid RiVax™ vaccine kept at 40 degrees C did not develop neutralizing antibodies and were not protected against ricin exposure. The ricin A chain is extremely sensitive to temperature and rapidly loses the ability to induce neutralizing antibodies when exposed to temperatures higher than 8 degrees C.

Near term progress with ThermoVax™ will allow us to seek out potential partnerships with companies marketing FDA/ex-U.S. health authority approved Alum adjuvanted vaccines that are interested in eliminating the need for cold chain for their products. ThermoVax™ will further enable Soligenix to expand its vaccine development expertise beyond biodefense into the infectious disease space and also has the potential to allow for the development of multivalent vaccines (e.g., combination ricin-anthrax vaccine).

ThermoVax™ is the subject of U.S. patent application number 8,444,991 issued on May 22, 2013 titled “Method of Preparing an Immunologically-Active Adjuvant-Bound Dried Vaccine Composition” and also U.S. patent application number 13/474,661 filed May 17, 2012 titled “Thermostable Vaccine Compositions and Methods of Preparing Same.” These patents and their corresponding foreign filings are pending and licensed to Soligenix by the University of Colorado (“UC”) and they address the use of adjuvants in conjunction with vaccines that are formulated to resist thermal inactivation. The license agreement covers thermostable vaccines for biodefense as well as other potential vaccine indications.

RiVax™ – Ricin Toxin Vaccine

RiVax™ is our proprietary vaccine developed to protect against exposure to ricin toxin, and is the first ricin vaccine. With RiVax™, we are a world leader in ricin toxin vaccine research. The immunogen in RiVax™ induces a protective immune response in animal models of ricin exposure and functionally active antibodies in humans. The immunogen consists of a genetically inactivated subunit ricin A chain that is enzymatically inactive and lacks residual toxicity of the holotoxin. Two Phase 1 human clinical trials have been completed. The development of RiVax™ has been sponsored through a series of overlapping challenge grants, UC1, and cooperative grants, U01, from the NIH, granted to Soligenix and to the University of Texas Southwestern Medical Center (“UTSW”) where the vaccine originated. The second clinical trial was supported by a grant from the FDA's Office of Orphan Products to UTSW. Soligenix and UTSW have collectively received approximately $25 million in grant funding from the NIH for RiVax™. Results of the first Phase 1 human trial of RiVax™ established that the immunogen was safe and induced antibodies anticipated to protect humans from ricin exposure. The antibodies generated from vaccination, concentrated and purified, were capable of conferring immunity passively to recipient animals, indicating that the vaccine was capable of inducing functionally active antibodies in humans. The outcome of this study was published in the Proceedings of the National Academy of Sciences (Vitetta et al., 2006, A Pilot Clinical Trial of a Recombinant Ricin Vaccine in Normal Humans, PNAS, 103:2268-2273). The second trial, sponsored by UTSW, evaluated a more potent formulation of RiVax™ that contained an aluminum adjuvant (Alum), was completed in September 2012. The results of the Phase 1B study indicated that Alum adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. The outcomes of this second study were published in the Clinical and Vaccine Immunology (Vitetta et al., 2012, Recombinant Ricin Vaccine Phase 1B Clinical Trial, Clin. Vaccine Immunol. 10:1697-9). We have adapted the original manufacturing process for the immunogen contained in RiVax™ for large scale manufacturing and are further establishing correlates of the human immune response in non-human primates.

RiVax™ is the subject of three issued U.S. patent numbers 6,566,500, 6,960,652, and 7,829,668, all titled "Compositions and methods for modifying toxic effects of proteinaceous compounds." This patent family includes composition of matter claims for the modified ricin toxin A chain which is the immunogen contained in RiVax™, and issued in 2003, 2005 and 2010 respectively. The initial filing date of these patents is March 2000 and they are expected to expire in March 2020. The issued patents contain claims that describe alteration of sequences within the ricin A chain that affect vascular leak, one of the deadly toxicities caused by ricin toxin. Another U.S. patent number 7,175,848 titled “Ricin A chain mutants lacking enzymatic activity as vaccines to protect against aerosolized ricin,” was filed in October of 2000 and is expected to expire in October 2020. RiVax™ has also been granted Orphan Drug designation by the FDA for the prevention of ricin intoxication.

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Assuming development efforts are successful for RiVax™, we believe potential government procurement contract(s) could reach $200 million.

About Ricin Toxin

Ricin toxin can be cheaply and easily produced, is stable over long periods of time, is toxic by several routes of exposure and thus has the potential to be used as a biological weapon against military and/or civilian targets. As a bioterrorism agent, ricin could be disseminated as an aerosol, by injection, or as a food supply contaminant. The potential use of ricin toxin as a biological weapon of mass destruction has been highlighted in a Federal Bureau of Investigations Bioterror report released in November 2007 titled Terrorism 2002-2005, which states that "Ricin and the bacterial agent anthrax are emerging as the most prevalent agents involved in WMD investigations" (http://www.fbi.gov/stats-services/publications/terrorism-2002-2005/terror02_05.pdf).

The Centers for Disease Control has classified ricin toxin as a Category B biological agent. Ricin works by first binding to glycoproteins found on the exterior of a cell, and then entering the cell and inhibiting protein synthesis leading to cell death. Once exposed to ricin toxin, there is no effective therapy available to reverse the course of the toxin. The recent ricin threat to government officials has heightened the awareness of this toxic threat. Currently, there is no FDA approved vaccine to protect against the possibility of ricin toxin being used in a terrorist attack, or its use as a weapon on the battlefield, nor is there a known antidote for ricin toxin exposure.

In January of 2012, a Request for Information ("RFI") was issued by the Chemical Biological Medical Systems – Joint Vaccine Acquisition Program of the Department of Defense ("DoD"). This RFI was titled "Development of a Ricin Toxin Vaccine to FDA Approval", and marks the first time any agency of the U.S. government has specifically indicated an interest in development of a vaccine against ricin toxin. We intend to pursue this avenue of funding to the fullest extent.

VeloThrax™ – Anthrax Vaccine

VeloThrax™ is our newly acquired proprietary vaccine based on a recombinant Protective Antigen ("rPA") derivative intended for use against anthrax. Soligenix has entered into an exclusive license option with Harvard College to license VeloThrax™ (also known as DNI for dominant negative inhibitor) for a vaccine directed at the prevention of anthrax infection of humans. VeloThrax™ is a translocation-deficient mutant of PA with double mutations of K397D and D425K that impede the conformational changes necessary for endosomal membrane translocation into the cell cytoplasm. In the absence of that PA translocation step, anthrax toxin trafficking and function cease. VeloThrax™ is also considered a more immunogenic candidate than native rPA. This apparent increase in immunogenicity suggests that the DNI rPA is processed and presented to the immune system more efficiently by cellular antigen processing pathways, which is consistent with known properties of the molecule.

DNI versions of rPA such as VeloThrax™ are also capable of inducing antibodies that neutralize the activity of the anthrax toxin complex. Unlike fully-functional rPA, VeloThrax™ might be given to a patient post-exposure without risk of enhancing intoxication during an infection, although clinical tests involving intravenous administration of potentially therapeutic levels of DNI rPA resulted in serious adverse events and so further development of this product as a therapeutic biological for blocking the effects of infection by B. anthracis was discontinued. Soligenix intends to test VeloThrax™ at a 1,000 fold lower dose than previously tested for an intramuscular or intradermal vaccine.

VeloThrax™'s greater immunogenicity could lead to a vaccine that can be administered in the fewest possible doses to induce the highest level of toxin neutralizing antibodies. Utilizing ThermoVax™, we believe that we will be able to develop VeloThrax™ into a vaccine with an improved stability profile, an issue that has proven challenging in the development of other anthrax vaccines. Extended stability at ambient temperatures would be a significant improvement for stockpiled vaccines and one which is not expected from conventional vaccines. Further, a large-scale, cGMP production methodology has already been completed. Assuming long-term stability can be met, VeloThrax™ could be stockpiled for general prophylactic as well as a post exposure use.

The overall objective of the VeloThrax™ program is to rapidly and efficiently develop a next generation anthrax vaccine which combines a well-established, safe and relatively low risk vaccine development and dosing approach with targeted, proven innovative strategies. VeloThrax™ will potentially be a combination of a stable, readily manufactured mutant rPA subunit antigen with next generation, clinically compatible adjuvants which have been demonstrated to enhance potency and reduce the time and number of vaccine doses required to achieve protective titer using a variety of vaccine antigens. This blend of proven yet innovative technologies will provide the Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE") and the DoD with a safe and stable alternative to the existing licensed anthrax vaccine product. Soligenix also proposes to adapt newly developed glassification technology (initially developed under an ongoing NIAID grant to stabilize exceptionally unstable ricin toxin/adjuvant formulations) to enable a thermostable, dried, single vial, pre-formulated adjuvanted rPA vaccine which is suitable for both long term storage and field use without typical cold chain constraints.

Assuming development efforts are successful for VeloThrax™, we believe potential government procurement contract(s) could reach $500 million.

About Anthrax

Anthrax is an acute infectious disease that is easily transmitted to humans by environmentally durable spores that are produced by Bacillus anthracis. Because the spores are robust and contagious, anthrax is considered a Category A bioterror threat. Anthrax infection can occur in three forms: cutaneous (skin), inhalation, and gastrointestinal. Inhaled spores can cause a rapidly progressing form of anthrax since the spores are transported to lymph nodes near the lungs where they germinate, releasing vegetative bacteria into the bloodstream. Bacteria synthesize a complex series of toxin components that make up anthrax toxin, resulting in overwhelming toxemia that causes shock and organ failure. Treatment of anthrax involves long-term antibiotic therapy, since ungerminated spores can lie dormant in the lungs for up to 60 days. Only a few inhaled spores can cause inhalational anthrax. Once the toxin has entered the bloodstream, antibiotics are ineffective, and only toxin-specific therapy is effective. Passively transferred antibodies can neutralize anthrax toxins and can be used post-exposure in conjunction with antibiotics. Because of the long residence time of spores in the lung, it is possible to vaccinate post-exposure, but the onset of neutralizing antibodies must occur during the period of antibiotic therapy.

OrbeShield™ – for Treating GI ARS

OrbeShield™ (an oral immediate and delayed release formulation of the topically active corticosteroid BDP) is being developed for the treatment of GI ARS. Corticosteroids are the best understood and most widely used class of anti-inflammatory drugs. BDP is a corticosteroid with predominantly topical activity that is approved for use in asthma, psoriasis and allergic rhinitis.

OrbeShield™ has demonstrated positive preclinical results in a canine GI ARS model which indicate that dogs treated with OrbeShield™ demonstrated statistically significant (p=0.04) improvement in survival with dosing at either two hours or 24 hours after exposure to lethal doses of total body irradiation ("TBI") when compared to control dogs. OrbeShield™ appears to significantly mitigate the damage to the GI epithelium caused by exposure to high doses of radiation using a well-established canine model of GI ARS.

The GI tract is highly sensitive to ionizing radiation and the destruction of epithelial tissue is one of the first effects of radiation exposure. The rapid loss of epithelial cells leads to inflammation and infection that are often the primary cause of death in acute radiation injury. This concept of GI damage also applies to the clinical setting of oncology, where high doses of radiation cannot be administered effectively to the abdomen because radiation is very toxic to the intestines. This is the same type of toxicity that occurs in Soligenix's acute radiation enteritis clinical program with SGX201. As a result, there is a dual avenue of development for Soligenix, and OrbeShield™ is potentially a "dual use" compound, a desirable characteristic which is a specific priority of Biomedical Advanced Research and Development Authority ("BARDA") for ARS and other medical countermeasure indications. BARDA recently invited Soligenix to submit a full contract proposal for a potential multi-year, multi-million dollar contract to develop OrbeShield™ from its current level of technical readiness to potential FDA approval. In response, Soligenix submitted its contract proposal in February 2013. We expect a response in the second half of 2013.

The FDA has cleared the IND application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS. Previously, development of OrbeShield™ had been largely supported by a $1 million NIH grant to Soligenix's academic partner, the Fred Hutchinson Cancer Research Center. In July 2012, we received an SBIR grant from NIAID of approximately $600,000 to support further preclinical development of OrbeShield™ for the treatment of acute GI ARS. The FDA has awarded OrbeShield™ Orphan Drug and Fast Track designation for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

Assuming development efforts are successful for OrbeShield™, we believe potential government procurement contract(s) could reach as much as $450 million.

About GI ARS

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to >2 Gy are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death in 5-15 days. The GI tract is highly sensitive due to the requirement for incessant proliferation of crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. Therefore, there is an urgent need to develop specific medical counter measures against the lethal pathophysiological manifestations of radiation-induced GI injury.

SGX943/SGX101– for Treating Melioidosis

SGX943 is the research name for the finished drug product, containing the active ingredient SGX94, which is being studied in melioidosis. A preliminary study with SGX943 has demonstrated efficacy. Further preclinical studies are planned with the pursuit of grant applications funding. Because SGX943 directly targets the innate immune system (and does not attempt to kill the bacteria directly), it is particularly relevant for antibiotic-resistant bacteria. The bacteria which causes melioidosis, Burkholderia pseudomallei, is known to be resistant to most antibiotics and to require prolonged treatment with the few antibiotics that do work. Thus, SGX943 may represent a much-needed

novel and additive therapy for melioidosis.

SGX 101 is the research name for the human monoclonal antibody therapy for the treatment of melioidosis based upon Intrexon's advanced human antibody discovery, isolation, and production technologies.

About Melioidosis

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, Burkholderia pseudomallei ("Bp"). Highly resistant to many antibiotics, Bp can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. Therefore, there is a significant medical need for improved prevention and therapy.

Bp infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. Moreover, the organism has a worldwide distribution and the full extent of global spread is likely underestimated. In Northeast Thailand, which has the highest incidence of melioidosis recorded in the world, the mortality rate associated with Bp infection is over 40 percent, making it the third most common cause of death from infectious disease in that region after HIV/AIDS and tuberculosis. Bp activity is seen in Southeast Asia, South America, Africa, the Middle East, India, and Australia. The highest pockets of disease activity occur in Northern Australia and Northeast Thailand with increasing recognition of disease activity in coastal regions of India. Melioidosis has been under recognized and is likely to be under-reported in China.

Beyond its public health significance, Bp and the closely-related Burkholderia mallei ("Bm") are considered possible biological warfare agents by the DHHS because of the potential for widespread dissemination through aerosol. Bp like its relative Bm, the cause of Glanders, was studied by the U.S. as a potential biological warfare agent, but was never weaponized. It has been reported that the Soviet Union was also experimenting with Bp as a biological warfare agent. Both Bp and Bm have been designated high priority threats by the DHHS in its PHEMCE Strategy released in 2012 and are classified as Category B Priority Pathogens by NIAID.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosure of contingent assets and liabilities. We evaluate these estimates and judgments on an on-going basis.

Intangible Assets

One of the most significant estimates or judgments that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 730, Research and Development. Based on this consideration, we capitalized payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. We believe that patent rights are one of our most valuable assets. Patents and patent applications are a key component of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives us access to key product development rights from our academic and industrial partners. These rights can also be sold or sub-licensed as part of our strategy to partner our products at each stage of development as the intangible assets have alternative future use. The legal costs incurred for these patents consist of work associated with filing new patents designed to protect, preserve, maintain and perhaps extending the lives of the patents. We capitalize such costs and amortize intangibles over their expected useful life - generally a period of 11 to 16 years.

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These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable or if the underlying program is no longer being pursued. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and carrying value of the related asset or group of assets.

Research and Development Costs

Research and development costs are charged to expense when incurred in accordance with FASB ASC 730, Research and Development. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries stock based compensation, employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Revenue Recognition

Principally our revenues are generated from NIH grants and revenues from licensing activities and the achievement of licensing milestones (in prior periods). Recording of revenue is applied in accordance with FASB ASC 605, Revenue Recognition, ASC 605-25 and/or Accounting Standard Update, ASU, 2009-13, Revenue Recognition – Multiple Element Arrangements. The revenue from NIH grants is based upon subcontractor costs and internal costs incurred that are specifically covered by the grants, plus a facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized when expenses have been incurred by subcontractors or when we incur internal expenses that are related to the grant.

Stock-Based Compensation

We determine stock-based compensation expense for options, warrants and shares of common stock granted to non-employees in accordance with FASB ASC 718, Stock Compensation, and FASB ASC 505-50, Equity-Based Payments to Non-Employees, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest. The option’s price is remeasured using the Black-Scholes model at the end of each quarterly reporting period. Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period.

Material Changes in Results of Operations

Three and Six Months Ended June 30, 2013 Compared to June 30, 2012

For the three months ended June 30, 2013, we had a net loss of $3,405,157 as compared to a net loss of $979,878 for the same period in the prior year, representing an increase in the net loss of $2,425,279 or 248%. For the six months ended June 30, 2013, we had a net loss of $4,492,571 as compared to a net loss of $2,418,633 for the same period in the prior year, representing an increase of $2,073,938 or 86%. Included in the net loss for the three months and six months ended June 30, 2013, is a non-cash charge of $649,576 which represents the change in the fair value of the warrant liability related to warrants issued in connection with our recent registered public offering.

For the three and six months ended June 30, 2013, revenues and associated costs related to NIH grants awarded which supported development of our thermostable vaccines and orBec®. For the three months ended June 30, 2013, we had revenues of $632,278 as compared to $762,851 for the same period in the prior year, representing a decrease of $130,573 or 17%. For the six months ended June 30, 2013, we had revenues of $1,532,632 as compared to $1,410,269 for the same period in the prior year, representing an increase of $122,363 or 9%. The changes in revenues during both periods were a result of timing of grant activity impacting our NIH grant drawdowns and the associated development work underlying them.

We incurred costs related to those revenues for the three months ended June 30, 2013 and 2012 of $527,948 and $616,330, respectively, representing a decrease of $88,382, or 14%. For the six months ended June 30, 2013, costs related to revenues were $1,271,605 as compared to $1,172,901 for the same period in the prior year, representing an increase of $98,704, or 8%. These costs relate to payments made to subcontractors in connection with research performed pursuant to the grants. The fluctuations are due to the development activity performed on the NIH grants discussed above.

Our gross profit for the three months ended June 30, 2013 was $104,330 as compared to $146,521 for the same period in 2012, representing a decrease of $42,191 or 29%. The decrease in gross profit is directly related to a decrease in grant revenue. For the six months ended June 30, 2013, gross profit was $261,027 as compared to $237,368 for the same period in the prior year representing an increase of $23,659 or 10%. The increase in gross profit is attributable to our increase in grant revenue.

Research and development expenses increased by $1,639,494 to $2,140,474 for the three months ended June 30, 2013 as compared to $500,980 for the same period in 2012. For the six months ended June 30, 2013, research and development expenses were $2,897,127 compared to $1,377,774 for the same period in 2012, reflecting an increase of $1,519,353. The significant increase for both the three months and six months ended June 30, 2013, was a result of the exclusive channel collaboration agreement entered into with Intrexon Corporation under which we issued common stock with a value of $1,500,000 and costs related to the Phase 1/2 trial for Pediatric Crohn’s.

Financial Condition

Cash and Working Capital

As of June 30, 2013, we had cash and cash equivalents of $8,127,742 as compared to $3,356,380 as of December 31, 2012, representing an increase of $4,771,362 or 142%. As of June 30, 2013, we had working capital of $6,871,370, which excludes a non cash warranty liability of $5,177,831, as compared to working capital of $2,682,383 as of December 31, 2012, representing an increase of $4,188,987 or 156%. The increase in cash and working capital was primarily the result of net proceeds of $6,216,762 received from our registered public offering partially offset by $1,446,886 of cash used in operating activities over the six month period ended June 30, 2013.

Based on cash on hand, our current rate of cash outflows, proceeds from our grant-funded programs, and expected proceeds from the State of New Jersey Technology Business Tax Certificate Transfer Program, management believes that our cash will be sufficient to meet the anticipated cash needs for working capital and capital expenditures into the first quarter 2015.

Our plans with respect to our liquidity management include, but are not limited to, the following:

We have approximately $2.3 million in active grant funding still available to support our associated research programs into 2014. We plan to submit additional grant applications for further support of these programs with various funding agencies.

We have continued to use equity instruments to provide a portion of the compensation due to vendors and collaboration partners and expect to continue to do so for the foreseeable future.

We will pursue sale of Net Operating Losses ("NOLs") in the State of New Jersey, pursuant to its Technology Business Tax Certificate Transfer Program. Based on the receipt of $521,458 in proceeds from the sale of NJ NOL in 2012, we expect to participate in this expanded program during 2013 and beyond as the program is available; and

We may seek additional capital in the private and/or public equity markets to continue our operations, respond to competitive pressures, develop new products and services, and to support new strategic partnerships. We are currently evaluating additional equity financing opportunities and may execute them when appropriate. However, there can be no assurances that we can consummate such a transaction, or consummate a transaction at favorable pricing.

Expenditures

Under our budget and based upon our existing product development agreements and license agreements pursuant to letters of intent and option agreements, we expect our total research and development expenditures for the next 12 months to be approximately $5.8 million before any grant reimbursements, of which $4.4 million relates to the BioTherapeutics business and $1.4 million relates to the Vaccines/BioDefense business. We anticipate grant revenues in the next 12 months of approximately $2.0 million to offset research and development expenses, primarily for the development of our ThermoVax™ vaccine technology.

The table below details our costs for research and development by program and amounts reimbursed under grants for the six months ended June 30:

	2013	2012
Research & Development Expenses		
Oral BDP	$635,730	$516,982
RiVax™ and ThermoVax™ Vaccines	598,155	743,918
SGX 94	94,052	-
SGX 943/SGX101	1,500,000	-
Other	69,190	116,874
Total	$2,897,127	$1,377,774
Reimbursed under NIH Grants		
Oral BDP	$101,176	$98,828
RiVax™ and thermostable vaccines	1,170,429	1,074,073
Total	1,271,605	1,172,901
Grand Total	$4,168,732	$2,550,675

Contractual Obligations

The Company has commitments of approximately $362,500 as of June 30, 2013 relating to several licensing agreements with consultants and universities, which upon clinical or commercialization success may require the

payment of milestones and/or royalties if and when achieved. However, there can be no assurance that clinical or commercialization milestones will occur.

On February 7, 2012, we entered into a lease agreement through March 31, 2015 for our existing office space. The rent for the first 12 months is approximately $8,000 per month, or approximately $18.25 per square foot on an annualized basis. This rent increases to approximately $8,310 per month, or approximately $19.00 per square foot on an annualized basis, for the remaining 24 months.

In February 2007, the Company's Board of Directors authorized the issuance of the following shares to Dr. Schaber and Dr. Brey, upon the completion of a transaction, or series or a combination of related transactions negotiated by our Board of Directors whereby, directly or indirectly, a majority of our capital stock or a majority of its assets are transferred from us and/or our stockholders to a third party: 50,000 common shares to Dr. Schaber and 10,000 common shares to Dr. Brey. The employment agreement with Dr. Schaber has been amended to reflect this obligation.

As a result of the above agreements, the Company has future contractual obligations over the next five years as follows:

Year	Research and Development	Property and Other Leases	Total
2013	$ 37,500	$ 53,000	$ 90,500
2014	100,000	101,100	201,100
2015	75,000	24,900	99,900
2016	75,000	-	75,000
2017	75,000	-	75,000
Total	$ 362,500	$ 179,000	$ 541,500

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

ITEM 4 - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the Company's controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the possible controls and procedures.

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Based upon that evaluation, our management, including our principal executive officer and principal financial officer has concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls

There was no change in our internal control over financial reporting identified in connection with the evaluation of such internal controls that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION.

ITEM 1A – RISK FACTORS

We have identified no additional risk factors other than those included in Part I, Item 1A of our Form 10-K for the fiscal year ended December 31, 2012. Readers are urged to carefully review our risk factors because they may cause our results to differ from the "forward-looking" statements made in this report. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations. We do not undertake to update any of the "forward-looking" statements or to announce the results of any revisions to these "forward-looking" statements, except as required by law.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On April 12, 2013, the Company issued 2,041 shares of common stock to a consultant as partial consideration for services performed. The per share closing price of the Company's common stock on March 28, 2013 was $1.47, which was the date on which the liability was recognized.

The issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

ITEM 6 - EXHIBITS

EXHIBIT NO.	DESCRIPTION
31.1	Certification of Chief Executive Officer pursuant to Exchange Act rule 13(a)-14(a) (under Section 302 of the Sarbanes-Oxley Act of 2002).
31.2	Certification of Chief Financial Officer pursuant to Exchange Act rule 13(a)-14(a) (under 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

SIGNATURES

In accordance with 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.

SOLIGENIX, INC.

August 12, 2013

By /s/ Christopher J. Schaber
Christopher J. Schaber, PhD
President and Chief Executive Officer
(Principal Executive Officer)

August 12, 2013

By /s/ Joseph M. Warusz
Joseph M. Warusz, CPA
Vice President, Finance and Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Christopher J. Schaber, Ph.D., certify that:

1. I have reviewed this Form 10-Q of the Soligenix, Inc. for the quarter period ended June 30, 2013;

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

b.

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

Auguts 12, 2013

/s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Joseph M. Warusz, certify that:

1. I have reviewed this Form 10-Q of the Soligenix, Inc. for the quarter perid ended June 30, 2013;

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

b.

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

Auguts 12, 2013

/s/ Joseph M. Warusz
Joseph M. Warusz, CPA
Vice Presient of Finance, Acting Chief Financial Officer
(Principal Financial and Accounting 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 this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended June 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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.

Auguts 12, 2013

/s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal 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 this Form 10-Q of Soligenix, Inc. (the "Company") for the fiscal quarter ended June 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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.

Auguts 12, 2013

/s/ Joseph M. Warusz
Joseph M. Warusz, CPA
Vice Presient of Finance, Acting Chief Financial Officer
(Principal Financial and Accounting Officer)

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 18, 2013

Commission File No. 000-16929

Soligenix, Inc.
(Exact name of small business issuer as specified in its charter)

DELAWARE	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 Emmons Drive, Suite C-10 Princeton, NJ	08540
(Address of principal executive offices)	(Zip Code)

(609) 538-8200
(Issuer's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry Into a Material Definitive Agreement.

On September 18, 2013, Soligenix, Inc. (the "Company") entered into a contract (the "Contract") with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA") for the advanced preclinical and manufacturing development of OrbeShield™ (oral beclomethasone 17,21-dipropionate or oral BDP) as a medical countermeasure for the treatment of gastrointestinal acute radiation syndrome (GI ARS).

The Contract consists of a guaranteed base period and two optional segments that can be initiated solely at the discretion of BARDA. The two contract options would extend the contract term to up to five years if both of the options are exercised. The total funding amount to be paid by BARDA under the Contract would be up to $26.3 million if the two options are exercised by BARDA, the occurrence of which the Company can provide no assurance. The total award will support the preclinical and manufacturing development activities necessary to successfully complete the Food and Drug Administration approval process for use of OrbeShield™ to treat GI ARS.

The foregoing is only a brief description of the material terms of the Contract and does not purport to be a complete description of the rights and obligations of the parties thereunder. The foregoing description is qualified in its entirety by reference to the Contract, which is filed as Exhibit 10.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Contract HHSO100201300023C dated September 18, 2013 by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority. *
99.1	Press Release issued by the Company on September 19, 2013.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

SIGNATURE

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 hereunto duly authorized.

Soligenix, Inc.

By: /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

September 24, 2013

EXHIBIT INDEX

Exhibit No.	Description
10.1	Contract HHSO100201300023C dated September 18, 2013 by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority. *
99.1	Press Release issued by the Company on September 19, 2013.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

EXHIBIT 10.1

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The work plan will detail the key studies in the OrbeShieldTM (oral beclomethasone 17,21- dipropionate or BDP) development program. The focus of the work plan is the evaluation of OrbeShieldTM in pre-clinical and non-clinical studies. [*****]

ARTICLE B.2. ESTIMATED COST

a. The total estimated cost of the base period of the contract excluding fee is [*****]

b. The total fixed fee for the base period of performance is [*****]

c. The fixed fee for the base period of performance (CLIN 0001 in the table below) and any exercised contract options (CLINs 0002 and 0003) shall be paid at a rate equal to [** ***] of actual costs incurred per invoicing period, with the balance of the maximum fee payable upon successful completion of all work under each non-severable discrete work segment covered under each CLIN. Payment of the maximum fee is subject to the following limitations:

- The government may withhold the payment of fee if necessary to protect the government's interest as set forth in Federal Acquisition Regulation (FAR) 52.216-8, Fixed Fee.

- Fixed Fee amounts listed under CLIN 0001 for the Base Segment [*****], CLIN 0002 for the Option 1 Segment [*****] and CLIN 0003 for Option 2 Segment [*****] represent the maximum amount of fee that can be earned for completing all work required to complete each discreet non-severable work segment.

d. The total estimated ceiling cost of the base period of the contract, CLIN 0001 in the table below, represented by the sum of the total estimated cost plus fixed fee is [*****]. The Government will not be responsible for any Contractor incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting Officer which expressly increases the cost ceiling pursuant to the Limitation of Cost Clause (FAR Clause 52.232-20) incorporated into this contract.

e. It is estimated that the monies currently obligated will cover performance of the contract through September 17, 2015.

f. The Contractor shall maintain records of all contract costs and such records shall be subject to the FAR 52.215-2, Audit and Records-Negotiation, and Health and Human Services Acquisition Regulation (HHSAR) 352.242-74, Final Decisions on Audit Findings clauses incorporated by reference into this contract in SECTION I.

g.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

ARTICLE B. 3. OPTION PRICES

Unless the government exercises contract options pursuant to Federal Acquisition Regulation (FAR) 52.217-9, Option to Extend the Term of the Contract, the contract consists only of the base work specified in the Statement of Work as defined in SECTIONS C and F, with estimated costs set forth in ARTICLE B.2 of the contract.

Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract, set forth in full in ARTICLE I.3., the Government may, by unilateral contract modification, require the Contractor to perform discrete packages of additional work as specified in the Statement of Work. The Government must give the Contractor a preliminary written notice of its intent to exercise any contract option at least 60 days prior to the beginning of the period of performance of that contract option. The estimated cost of this contract would then be increased as set forth below:

ARTICLE B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

a.Items Unallowable Unless Otherwise Provided

Notwithstanding the clause FAR 52.216-7, Allowable Cost and Payment, incorporated in this contract, the costs of the following items or activities shall be unallowable as direct costs unless authorized in writing in advance by the Contracting Officer:

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

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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. Unapproved foreign travel;

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 available athttp://fast.faa.gov/archive/v0702/docs/html_version/contractor_guide/chapter1.htm, regardless of acquisition value.)

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

11. 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 Contracting Officer’s Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to “HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meeting, Food and Promotional Items and Printing and Publications.” 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 refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

12. Meeting room or conference space used for face to face meetings with USG staff in the performance of this contract. Justification for why the meeting cannot be held at a government facility must be provided. COA requests must be made at least (2) two weeks prior to meeting date.

13. Purchasing of animals and/or other supplies for non-clinical studies

b. Travel Costs

Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses such as taxis or airport parking) incurred by the Prime Contractor in direct performance of this contract during the base period shall not exceed [****] without the prior written approval of the Contracting Officer. Total expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses such as taxis or airport parking) incurred by the Prime Contractor in direct performance of this contract during the base period shall not exceed [****]without the prior written approval of

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the Contracting Officer. (Please refer to Item 3., below, for guidelines regarding approval for foreign travel.) The Prime Contractor shall notify the Contracting Officer in writing when travel has exceeded the amounts allowed for domestic and/or foreign travel within the base period. Cost must be consistent with FAR 52.247-63 – Preference for U.S.-Flag Air Carriers

1. If, pursuant to FAR Clause 52.217-9 (Option to Extend the Term of the Contract), the Government exercises an option, domestic and foreign travel costs for each CLIN shall not exceed the following schedule:

Option 1 (CLIN 0002) - [****]
Option 2 (CLIN 0003) - [****]

2. Subject to the dollar limitation of[****] , the Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.703.

3. Requests for foreign travel and attendance at any general scientific meetings must be submitted at least six weeks in advance and shall contain the following:

(i) meeting(s) and place(s) to be visited, with costs and dates;
(ii) names(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
(iii) contract purpose to be served by the travel;
(iv) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of AMCG contract funds;
(v) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
(vi) what additional functions may be performed by the travelers to accomplish other purpose of the contact and thus further benefit the project.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

a. A Security Plan is currently not required at the initial point for this effort. However, a security waiver for the security plan will be requested. In the event a security waiver cannot successfully be obtained and approved, a security plan must subsequently be delivered to the Government.

Security Reporting Requirement –Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The Contracting Officer in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the Contracting Officer.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

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b. Subcontracts and Consultants

Prior written consent from the Contracting Officer in the form of a Contracting Officer Authorization (COA) is required for any subcontract or consultant agreement/subcontract that:

- Is of the cost-reimbursement type;
- Is Fixed-Price and exceeds $150,000 or 5% of the total estimated cost of the Contract, whichever value is greater.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract or consulting agreement/subcontract by the Contracting Officer, a copy of the signed, executed subcontract or consulting agreement/subcontract shall be provided to the Contracting Officer.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

The Contractor will negotiate [****] type subcontracts with the following subcontractors in the base period of the contract with total costs not to exceed the amounts listed in the chart below. Award of the following subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the draft subcontract as required by the FAR Clause 52.244-2, Subcontracts. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

c. Reference FAR 52.244-2(e) Subcontracts

FAR 52.244-2, Subcontracts (Oct 2010)

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (d) of this clause, including the following information:

(i). A description of the supplies or services to be subcontracted.
(ii). Identification of the type of subcontract to be used.
(iii). Identification of the proposed subcontractor.
(iv). The proposed subcontract price.
(v). The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.
(vi). The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting standards when such data are required by other provisions of this contract.
(vii). A negotiation memorandum reflecting-

(A). The principal elements of the subcontract price negotiations;
(B). The most significant considerations controlling establishment of initial or revised prices;
(C). The reason cost or pricing data were or were not required;
(D). The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective and in negotiating the final price;
(E). The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any

such defective data on the total price negotiated;

(F). The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G). A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

d. Site Visits, Inspections and Audits

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours notice to the contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held by the contractor, or subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowed costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, and cGMP/GLP/GCP compliance.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR within 10 business days detailing the finding and corrective action(s) of the audit.
    - COR and CO will review the report and provide a response to the Contractor within 10 business days.
    - Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

e. Quality Assurance Audit:

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications; and
    - Contractor shall notify the COR and CO within 5 business days of report completion.

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

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 (actual hours or % 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. Cite appropriate COA
g. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
h. Equipment - Cite authorization and amount. Cite appropriate COA
i. Other Direct Costs - Include detailed breakdown when total amount is over $1,000.
j. G&A - Cite rate and amount.
k. Fee
l. Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government. In order to verify allowability, further breakdown of costs may be requested at the Government's discretion.

See Attachment 6, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, for additional instructions.

g. Confidential Treatment of Sensitive Information

The Contractor shall, to the extent permitted by law, guarantee strict confidentiality of the information/data that 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.

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

The Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction (b) otherwise required by law, (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data

h. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

i. Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract. Billing of actual hours should be limited to total productive hours in a month.

j. Contract Number Designation

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

HHSO100201300023C

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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 August 22, 2013 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

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

ARTICLE C.3. SUBJECT 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, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the Contracting Officer to the address set forth in SECTION G – CONTRACT ADMINISTRATION DATA.

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.

ARTICLE C.4. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Representative and designees and the Contractor's Project Leader/delegate and designees shall occur twice-monthly or as directed by the Contracting Officer's Representative. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

ARTICLE C.5. PROJECT MEETINGS

The contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG/BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor will provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities.

ARTICLE C.6. FACE-TO-FACE PROJECT REVIEW MEETING

The contractor shall, at a time to be determined later but estimated to be the 23rd month of contract performance, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC. The contractor will be responsible for updating BARDA leadership on technical progress under the Statement of Work.

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 date, contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Report Deliverables

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to BARDA electronically along with a concurrent email notification to the Contracting Officer, Contract Specialist, and COR (as defined in SECTION G, CONTRACT ADMINISTRATION) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

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

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The contractor is advised to review FAR 52.243-2, Changes-Cost reimbursement contracts Alternative V, which is incorporated by reference into this contract in ARTICLE I.1.

Inspection and acceptance will be performed at:

Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Avenue, S.W., Room G644
Washington, D.C. 20201

The 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 52.246-9, Inspection of Research and Development – Short Form (Apr 1984)

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. ESTIMATED PERIOD OF PERFORMANCE

Under CLIN 0001 the estimated technical period of performance for the base period of this contract shall be from September 18, 2013 through September 17, 2015. The period of performance encompasses the review of the Draft Final Report and the submission of the Final Report 30 days after the technical period of performance to allow for completion of the Final Report(s), as specified in the REPORTING REQUIREMENTS Article in SECTION C.2 of this contract.

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated August 22, 2013 set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative, of each of the deliverables described in SECTION C, SECTION F and SECTION J, Attachment 2 of this contract. Each deliverable must be delivered electronically to the Contracting Officer or Contract Specialist, Contracting Officer's Representative, and Alternate Contracting Officer's Representative in accordance with the Deliverable Schedule set forth below:

Item	Description	Quantity	Addresses	Deliverable Schedule
		Technical Progress Reports		
1)	Monthly Progress Report	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	The 15th calendar day of each month following the first full month of the contract award. The Monthly Progress Report will not be required on months when an Annual or Final Technical Progress Report is due.
2)	Annual Progress Report	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	The 15th calendar day of the month following the end of each 12 month performance period. The Monthly Progress Report will not be required on months when an Annual Progress Report is due.
3)	Draft Final Technical Progress Report	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	45 Calendar days before the completion date of the contract.
5)	Summary of salient Results	3 electronic	CO: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	On or before the expiration date of the contract.
Other Technical Reports				
6)	Audit Reports	3 electronic		

			CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	Within 30 Calendar days of the audit.
7)	FDA/ Regulatory Agency Correspondence and Meeting Summaries	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	Within 5 business days of each meeting for Contractor's minutes and upon receipt of minutes from FDA/ regulatory agency.
8)	FDA/ Regulatory Agency Submissions	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	BARDA shall provide comment within 10 business days after receipt. BARDA reserves the right to request more than 10 business days for review of any regulatory submission that is of significant length. The Contractor shall inform BARDA of the anticipated submission length so BARDA can make a determination if more than 10 business days will be needed to complete its review of the document.

Other Reports

9)	Invention Report Annual Utilization Report	3 electronic	CO or CS: (1) electronic copy COR or CS: (1) electronic copy Alternate COR: (1) electronic copy	Due on or before the 30th of the month following each anniversary date of the contract.
10)	Final Invention Report	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	Due on or before the completion date of the contract.
Other Deliverables				
11)	Kickoff Meeting	N/A	N/A	Within a month of contract award.
12)	Twice monthly Teleconference and meeting minutes	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	Twice monthly or as otherwise agreed by the parties or determined by the Contracting Officer. Electronic copy of conference call meeting minutes/summaries to be provided within seven (7) calendar days after the conference call is held.
13)	Face-to-Face progress review meeting presentation	3 electronic	CO or CS: (1) electronic copy COR: (1) electronic copy Alternate COR: (1) electronic copy	Within the 23nd month of the period of performance of the contract, unless otherwise agreed by the parties. Presentation must be delivered 30 days prior to the scheduled meeting.

Unless otherwise specified by the Contracting Officer, the above items #1-13 shall be delivered electronically along with a concurrent email notification email sent to the Contracting Officer or Contract Specialist, COR, and Alternate COR stating delivery has been made.

Please refer to Attachment 2, Milestone and Deliverables, for a list of additional deliverables.

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:.

A.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 Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of 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;

SECTION I - An introduction covering the purpose and scope of the contract effort; 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 significant meetings, conference calls, etc., including those between Contractor and any federal agency, subcontractor or collaborator that have taken place during the reporting period and relate to the Contract of the Statement of Work. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);

SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Gantt chart, document the results of work completed and costs 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 preprints/reprints of papers and abstracts, and a current/updated Gantt chart.

A Monthly Progress Report will not be required in the same month that the Annual or Final Technical Progress Reports are submitted.

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B. Annual Progress Reporting Requirement

This report shall include a summation 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 year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 15th calendar day following the last day of 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.

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

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 on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);

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 preprints/reprints of papers, abstracts and a current Gantt chart.

A Monthly and Annual Progress Report will not be required for the period when the Final Technical Progress Report is due and a Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

C. Draft Final Technical Progress Report and Final Technical Progress Report

These reports are 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 Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. The Draft Final Technical Progress Report shall be submitted forty-five (45) calendar days before completion date of the contract and the Final Technical Progress Report shall be submitted 30 days post technical period of performance. 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, e-mail 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 related to the Gantt chart, 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.

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Representative and Contracting Officer. This report is due 45 calendar days before the completion date of the contract. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments within 15 calendar days after receipt.

Final Technical Progress Report: The contractor shall address all BARDA comments in the Final Technical Progress Report. The Contractor will deliver the final version of the Final Technical Progress Report 30 days post technical period of performance.

D. Summary of Salient Results

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

E. Copies of FDA/ Regulatory Agency Correspondence and Meeting Summaries

a. Within five business days of any formal meeting with the FDA or other regulatory agency, the contractor shall forward the initial draft minutes to BARDA. The contractor shall forward final draft minutes when available.
b. Within five business days of any informal meeting with the FDA or other regulatory agency, the contractor shall forward the final draft minutes to BARDA.
c. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA and make arrangements for appropriate BARDA staff to attend the meetings.
d. The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the contractor prior to the contractor’s submission to the FDA.
e. The contractor shall forward Standard Operating Procedures (SOPs) upon request from Project Officer/Contracting Officer.
f.

The contractor shall provide upon request animal study and/or other technology packages developed under this contract. Packages shall include complete protocols and critical reagents for animal models developed and/or improved with contract funding.

g. The contractor shall provide upon request raw data and/or specific analysis of data generated with USG funds.

F.Other Reports/Deliverables

a. Technology Transfer

Technology packages developed under the contract that include complete protocols and critical reagents developed and/or improved with contract funding must be submitted at the request of the BARDA Contracting Officer's Representative. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data.

b. 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 BARDA Contracting Officer's Representative.

c. Experimental Protocols

The Contractor shall submit all study/experiment/test plans, designs, and protocols upon request by the COR.

d. Data

The Contractor shall provide data or specific analysis of data generated with contract funding at the request of the BARDA Contracting Officer's Representative.

e. Meeting Minutes

The Contractor shall provide an electronic copy of conference call meeting minutes/summaries to the BARDA Contracting Officer's Representative and Contracting Officer within seven (7) calendar days after the conference call is held.

Additional Addresses Listed for Reference, if needed:

AMCG/BARDA Security Specialist	Office of the Assistant Secretary for Preparedness and Response Office of Public Health Emergency Medical Countermeasures 409 3rd Street, S.W. Suite 320 Washington, DC 20201 E-mail: [****]

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W. Room G640
Washington, D.C. 20201

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

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

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b.The Contracting Officer (CO) is the only person with authority to act as agent of the Government under this contract. Only the CO 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.

c.No information, other than that which may be contained in an authorized modification to this contract duly issued by the CO, shall be considered grounds for deviation from this contract.

d.The Government may unilaterally change its CO designation.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

[****]

Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[****]
[****]

Mailing Address:
330 Independence Avenue, S.W. Room 640G
Washington, D.C. 20201

Alternate PO/COR:
[****]

Alternate Project Officer (PO), Alternate Contracting Officer’s Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[****]
[****]

Mailing Address:
330 Independence Avenue, SW
Washington, D.C. 20201

The COR is responsible for:

a.Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

b.Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

c.Performing technical evaluation as required;

d.Performing technical inspections and assisting the Contracting Officer in acceptances of deliverables required by this contract; and

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

e. Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR designation(s).

ARTICLE G.3. KEY PERSONNEL

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 individuals are considered to be essential to the work being performed hereunder:

ARTICLE G.4. QUARTERLY CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within the Attachment entitled, "Financial Report of Individual Project/Contract," located in SECTION J and made a part of this contract.

f. The Government may unilaterally revise the “Financial Report of Individual Project/Contract” to reflect the allotment of additional funds.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

a. The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer as defined above, in ARTICLE G of this contract.

b. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract at Section J, Attachment 5.

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

d. 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 estimated costs for the base period or any option period(s) (See estimated costs under Articles B.2) and the reasons for the variance. Also refer to the requirements of FAR Clause 52.232-20, Limitation of Cost.

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

f. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment.

ARTICLE G.6. INDIRECT COST RATES

1. The following interim provisional indirect rates will be utilized for billing purposes during the period of performance, pending the establishment if final rates covering each fiscal year of the contractor’s performance.: Fringe benefits at [****], and Overhead (G&A) at [****] of Total Direct Costs Excluding Subcontractor Costs. Final rate proposals must be sent to the Contracting Officer, within 6 months of the fiscal year end. See FAR Clause 52.216-7, Allowable Cost and Payment.

ARTICLE G.7. REIMBURSEMENT OF COST

1) The Government shall reimburse the Contractor those costs determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

i. Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1 Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted at least once during the contract period of performance.

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.

2 Electronic Access to Contractor Performance Evaluations

The Government is undergoing a conversion to a new website for reporting. This website is http://www.cpars.gov. When the website goes active, Contractors may access evaluations through a secure website for review and comment by completing the online registration form.

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 that 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.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number HHSO100201300023C from Page 1 of the contract.

ARTICLE G.10. GOVERNMENT PROPERTY

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

ARTICLE G.11. EXERCISE OF OPTIONS

Unless the Government exercises its option pursuant to the Option Clause set forth in Section I, Article I.2, the contract will consist only of CLIN 0001 of the Statement of Work, Deliverables and Requirements as defined in Sections C, F and J of the contract. Pursuant to FAR Clause 52.217–9 (Option to Extend the Term of the Contract) set forth in Section I of this contract, under Article I.2, the Government may, by unilateral contract modification, require the Contractor to perform the additional CLINs listed in Section B, Article B.3., and as also defined in Sections C, F and J of this contract. If the Government exercises an option, written notice must be given to the Contractor within 30 days after the Government has completed its analysis of the deliverables; and the Government must give the Contractor a preliminary written notice of its intent to exercise the option at least 30 days before the contract expires. The amount of the contract may then be increased as set forth in Section B, Article B.3 provided that funds are available.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. CLINICAL AND NON-CLINICAL RESEARCH

H.1.1. Non-Clinical Research

These Non-Clinical Terms apply to all grants and contracts that involve non-clinical research. Draft protocols for each nonclinical study will be submitted to the Government for evaluation and comment. The Government shall have rights to all protocols, data resulting from execution of these protocols, and final reports, funded by the Government under this contract, as defined in FAR Clause 52.227-14, Rights in Data – General. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

H.1.1.1. Safety and Monitoring Issues

PHS Policy on Humane Care and Use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to the Government a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW- National Institutes of Health) Federal Wide Assurance (FWA) number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol. They must also provide the Government initial documentation and documentation of continuing review and approval and FWA number.

The Contractor must ensure that the applications as well as all protocols are reviewed by the performing institution’s IACUC.

To help ensure the safety of animals used in BARDA funded studies, the Contractor must provide the Government copies of documents related to all major changes in the status of ongoing protocols, including the following:

a) All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.

b) All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).

c) Termination or temporary suspension of the study(ies) for regulatory issues

d) Termination or temporary suspension of the protocol.

e) Any change that is made in the specific IACUC approval for the indicated study(ies).

f) Any other problems or issues that could affect the scientific integrity of the study(ies), i.e. fraud, misrepresentation, misappropriation of funds, etc.

Contractors must notify the Government by email of any of the above changes within three business days from the time Contractor becomes aware of such changes, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

H.1.1.2. Non-Clinical Data and Safety Monitoring Requirements

The Contractor shall continue safety monitoring for all non-clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. The Contractor should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies.

BARDA will work with the Contractors on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform the Government of any upcoming site visits and/or audits of CRO facilities funded under this effort. The Government reserves the right to accompany the Contractor on site visits and/or audits of CROs as the Government deems necessary.

H.1.1.3. BARDA Review Process of Non-Clinical Trials

The Government is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.

2. Documentation of IACUC approval, including OLAW FWA number, IACUC registration number, and IACUC name.

3. Contractor should reduce the number of animals required for a study using power of statistics.

4. Plans for the management of side effects, rules for interventions and euthanasia criteria.

5. Procedures for assessing and collecting safety data.

6. If a study is contracted through CRO(s), work orders and service agreements the Contractor shall assure that an integrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).

7. Documentation that the Contractor or CRO and all staff responsible for the conduct of the research have received required training in the protection and handling of animals.

8. Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer. The Contractor must have the ability to return/re-sell animals, at purchase price, to distributor or a third party, in the event that the protocols do not obtain approval.

9. Provide justification for whether studies require good laboratory practice (GLP) conditions.

10. Provide justification for whether studies will be classified as non-pivotal or pivotal studies.

BARDA comments will be forwarded to the Contractor within one week (5 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the Government staff to the satisfaction of the Government before study execution. After receiving the updated documentation that satisfies the Government, a written Contract Officer Authorization (COA) Letter will be provided to the Contractor. This COA will provide authorization to the Contractor to execute the specific nonclinical study funded in part or in whole by BARDA.

In case of problems or issues, the BARDA COR will contact the Contractor within two weeks (10 business days), with copy to the principal investigator and the institution’s office of sponsored programs, listing issues and appropriate actions to be discussed.

Final decisions regarding ongoing safety reporting requirements for research not performed under an Investigational New Drug Application (IND) or investigational device exemption (IDE) must be made jointly by the Government and the Contractor.

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ARTICLE H.2. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5 (October 2009)

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

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

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

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

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

ARTICLE H.3. 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

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ARTICLE H.4. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS

Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

ARTICLE H.5. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the Government to provide assurances for the humane care of such animals.

ARTICLE H.6. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.7. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should 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.8. 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.9. IDENTIFICATION AND DISPOSITION OF DATA

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

ARTICLE H.10. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

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ARTICLE H.11. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.12. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest.

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

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

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was managed or reported by the Institution, the Contracting Officer shall

require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.13. NEEDLE DISTRIBUTION

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

ARTICLE H.14. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.15. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

ARTICLE H.16. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.17. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.18. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Offeror performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Offeror shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under a contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

ARTICLE H.19. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written notice to the Contracting Officer, whose response shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any Government entity' for submission to any securities exchange on which the Offeror's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

ARTICLE H.20. EPA ENERGY STAR REQUIREMENTS

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

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

ARTICLE H.21. ACKNOWLEDGMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents.

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

B. Publication and Publicity

Publications: Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for BARDA COR review no less than fourteen (14) calendar days for manuscripts and seven (7) 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 Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201300023C."

C. Press Releases

(1) The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) if applicable, the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

(2) The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. 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.

H.22. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables may be required when the IPRs are conducted. The Contractor’s success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F.

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Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

ARTICLE H.23. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (March 2012)

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

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.203-70 "Anti-Lobbying" (March 2012), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

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

ARTICLE H.24. PRIVACY ACT APPLICABILITY

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

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ARTICLE H.25. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

ARTICLE H.26. QA AUDIT REPORTS

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. The Contractor shall notify the CO and COR reasonably in advance of upcoming QA audit so that Government personnel may participate in person at BARDA's discretion.
    - Contractor shall notify the COR and CO within 5 business days of report completion.

ARTICLE H.27. BARDA AUDITS

Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

ARTICLE H.28. SECURITY REPORTING REQUIREMENT

Violations of established security protocols shall be reported to the CO and COR upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system have been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the CO.

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ . HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

General Clauses for Cost-Reimbursement Research and Development Contract

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

FAR CLAUSE	DATE	TITLE
52.202-1	Jan 2012	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	Apr 1984	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
52.203-7	Oct 2010	Anti-Kickback Procedures
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
52.203-14	Dec 2007	Display of Hotline Posters.
52.204-4	May 2011	Printed or Copied Double-Sided on Recycled Paper
52.204-7	Jul 2013	System for Award management
52.204-10	Aug 2012	Reporting Executive Compensation and First-Tier Subcontract awards
52.204-13	Jul 2013	System for Award Maintenance
52.209-6	Aug 2013	Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Feb 2012	Updates of Publicly Available Information Regarding Responsibility Matters
52.210-1	Apr 2011	Market Research
52.215-2	Oct 2010	Audit and Records – Negotiation

52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
52.215-15	Oct 2010	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 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Jan 2011	Utilization of Small Business Concerns
52.219-9	Jan 2011	Small Business Subcontracting Plan, Alternate II
52.219-28	Jul 2013	Post-Award Small Business Program Representation
52.222-2	Jul 1990	Payment for Overtime Premiums
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2010	Equal Opportunity for Veterans
52.222-36	Oct 2010	Affirmative Action for Workers with Disabilities
52.222-37	Sep 2010	Employment Reports on Veterans
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Feb 2009	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases

52.227-1	Dec 2007	Authorization and Consent, Alternate I
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, Alternate II
		Completed portion as follows:
		Limited Rights Notice (Dec 2007)
		(a) These data are submitted with limited rights under Government Contract No. HHSO100201300023C. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, provided that the Government makes such disclosure subject to prohibition against further use and disclosure: (i) Use (except for manufacture) by support service contractors. (ii) Evaluation by nongovernment evaluators. (b) This Notice shall be marked on any reproduction of these data, in whole or in part.
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Oct 2010	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer-System for Award Management
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (June 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.234-4	Jul 2006	Earned Value Management System
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.242-15	Aug 1989	Stop Work Order, Alternate I (Aug 1984)

52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	June 2007	Subcontracts, Alternate I
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Dec 2010	Subcontracts for Commercial Items
52.245-1 Alt. II	Apr 2012	Government Property, Alternate II
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability
52.246-25	Feb 1997	Limitation of Liability – Services
52.247-63	Jun 2003	Preference for U.S.-Flag Air Carriers
52.247-67	Feb 2006	Submission of Transportation Documents for Audit
52.249-6	May 2004	Termination (Cost-Reimbursement)
52-249-14	Apr 1984	Excusable Delays
52.251-1	Apr 2012	Government Supply Sources
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.201-70	Jan 2006	Paperwork Reduction Act
352.202-1	Jan 2006	Definitions, with Alternate paragraph (h)
352.203-70	Mar 2012	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Jan 2006	Safety and Health
352.224-70	Jan 2006	Privacy Act
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.231-70	Mar 2012	Salary Rate Limitation
352.231-71	Jan 2001	Pricing of Adjustments

352.233-71	Jan 2006	Litigation and Claims
352.234-3	Oct 2008	Full Earned Value Management System
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings
352.270-4	Jan 2006	Protection of Human Subjects
352.270-6	Jan 2006	Restrictions on Use of Human Subjects

ARTICLE I.2. 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 52.215-17, Waiver of Facilities Capital Cost of Money (October 1997).
2. FAR 52.227-16, Additional Data Requirements (June 1987).

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

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

ARTICLE I.3. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT

FAR 52.217-9 Option to Extend the Term of the Contract

OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

FAR 52.219-1 Small Business Program Representations

SMALL BUSINESS PROGRAM REPRESENTATIONS (MAY 2004)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is 541711.

(2) The small business size standard is 500 employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) Representations.

(1) The offeror represents as part of its offer that it [X] is, [_] is not a small business concern.

(2) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, for general statistical purposes, that it [_] is, [X] is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents as part of its offer that it [ ] is, [X] is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The offeror represents as part of its offer that—

(i) It [_] is, [X] is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [_] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture:_____ .] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The offeror represents as part of its offer that--

(i) It [_] is, [X] is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [_] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture:_____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents as part of its offer that it [_] is, [X] is not a veteran-owned small business concern.

(7) [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.] The offeror represents as part of its offer that is [_] is, [X] is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that –

(i) It [_] is, [X] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

(ii) It [_] is, [X] is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture:_____ .] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(c) Definitions. As used in this provision--

“Economically disadvantaged women-owned small business (EDWOSB) concern” means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

“Service-disabled veteran-owned small business concern”—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

“Small business concern,” means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

“Veteran-owned small business concern” means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

“Women-owned small business concern,” means a small business concern --

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

“Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127),” means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm’s status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall --

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

FAR 52.219-28, Post-Award Small Business Program Representation

POST-AWARD SMALL BUSINESS PROGRAM REPRESENTATION (JUL 2013)

(a) Definitions . As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, which is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/contractingopportunities/officials/size/index.html.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [X] is, [ ] is not a small business concern under NAICS Code 541711 assigned to contract number HHSO100201300023C.

FAR 52.232-99, Providing Accelerated Payment to Small Business Subcontractors (DEVIATION)

PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS (DEVIATION) (AUG 2013)

This clause implements the temporary policy provided by OMB Policy Memorandum M-12−16, Providing Prompt Payment to Small Business Subcontractor, dated July 11, 2012, and the extension to that policy provided by OMB Policy Memorandum M-13-15, Extension of Policy to Provide Accelerated Payment to Small Business Subcontractors, dated July 11, 2013.

(a) Upon receipt of accelerated payments from the Government, the contractor is required to make accelerated payments to small business subcontractors to the maximum extent practicable after receipt of a proper invoice and all proper documentation from the small business subcontractor.

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

(c) The acceleration of payments under this clause does not provide any new rights under the Prompt payment Act

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, dated August 22, 2013, 8 pages
2. Milestone and Deliverables Chart, dated August, 2013, 5 pages
3. Work Breakdown Structure Gantt Chart, dated August 22, 2013, 3 pages
4. Financial Report of Individual Project/Contract, 1 page
5. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages
6. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, 8 pages
7. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
8. Report of Government Owned, Contractor Held Property, 1 page, available at http://rcb.cancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1) Annual Representations and Certifications completed on the System for Award Management (SAM) website.

2) Animal Welfare Assurance Numbers (OLAW/PHS):

[****]

End of Contract No. HHSO100201300023C

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Exhibit 99.1

Soligenix Awarded BARDA Contract Valued up to $26.3 Million for Advanced Development of OrbeShield™ in GI ARS

Princeton, NJ – September 19, 2013 – Soligenix, Inc. (OTCQB: SNGX) (Soligenix or the Company), a clinical stage biopharmaceutical company focused on developing products to treat inflammatory diseases and biodefense medical countermeasures (MCMs) where there remains an unmet medical need, announced today that it has been awarded a contract valued at up to $26.3 million by the US Department of Health and Human Service's Biomedical Advanced Research and Development Authority (BARDA). The contract is for the advanced preclinical and manufacturing development of OrbeShield™ (oral beclomethasone 17,21-dipropionate or oral BDP) as a MCM for the treatment of gastrointestinal acute radiation syndrome (GI ARS).

The potential five year contract contains a two year base period, with two contract options that would extend the contract an additional three years. The total award will support the preclinical and manufacturing development activities necessary to successfully navigate and complete the FDA approval process for use of OrbeShield™ to treat GI ARS.

"Securing a highly competitive BARDA contract provides important recognition as to the innovative quality and potential therapeutic impact of our technology," stated Christopher J. Schaber, PhD, President & Chief Executive Officer of Soligenix. "This contract award provides the comprehensive funding necessary to continue development of OrbeShield™ while building upon the growing body of compelling scientific evidence supporting its use as a potential MCM for GI ARS. We thank BARDA for their support and look forward to collaborating closely with them as we advance this technology."

About GI ARS

ARS occurs after toxic radiation exposure and involves several organ systems, notably the bone marrow the GI tract and later the lungs. In the event of a nuclear disaster or terrorist detonation of a nuclear bomb, casualties exposed to >2 Gy are at high risk for development of clinically significant ARS. Exposure to high doses of radiation exceeding 10-12 Gy causes acute GI injury which can result in death in 5-15 days. The GI tract is highly sensitive due to the requirement for incessant proliferation of crypt stem cells and production of mucosal epithelium. The extent of injury to the bone marrow and the GI tract are the principal determinants of survival after exposure to TBI. Although the hematopoietic syndrome can be rescued by bone marrow transplantation or growth factor administration, there is no established treatment or preventive measure for the GI damage that occurs after high-dose radiation. Therefore, there is an urgent need to develop specific MCMs against the lethal pathophysiological manifestations of radiation-induced GI injury.

About OrbeShield™

OrbeShield™ is formulated for oral administration in GI ARS patients as a single product consisting of two tablets; one tablet releases BDP in the proximal portions of the GI tract and the other tablet releases BDP in the distal portions of the GI tract. BDP has been marketed in the US and worldwide since the early 1970s as the active pharmaceutical ingredient in inhalation products for the treatment of patients with allergic rhinitis and asthma. To date, oral BDP has been safely administered to more than 350 human subjects in multiple clinical studies. Oral BDP is also being developed in other GI disorders characterized by severe inflammation such as pediatric Crohn's disease, radiation enteritis and chronic Graft-versus-Host disease (cGVHD).

The FDA has cleared the Investigational New Drug (IND) application for OrbeShield™ for the mitigation of morbidity and mortality associated with GI ARS. OrbeShield™ has also been granted Orphan Drug and Fast Track designations by the FDA for the prevention of death following a potentially lethal dose of total body irradiation during or after a radiation disaster.

About BARDA

The Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response in the US Department of Health and Human Services, provides an integrated, systematic approach to the development and procurement of critical products needed for public health emergencies. In collaboration with the National Institutes of Health, Department of Homeland Security, and other federal agencies, BARDA plays a key role in the government's efforts to develop MCMs needed to prevent or mitigate potential health effects from exposure to chemical, biological, radiological and nuclear (CBRN) agents and other terrorist threats. Support for OrbeShield™ product development is being provided under a CBRN program to advance technologies and products to treat acute radiation syndrome (ARS). Funding for BARDA's MCM development programs is authorized under the Pandemic and All Hazards Preparedness Act of 2006 (PAHPA) and reauthorized under the Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). Additional MCM programs are funded by BARDA under the Project BioShield Act of 2004.

About Soligenix, Inc.

Soligenix is a clinical stage biopharmaceutical company developing products to treat serious inflammatory diseases where there remains an unmet medical need, as well as developing several biodefense vaccines and therapeutics. Soligenix is developing proprietary formulations of oral BDP (beclomethasone 17,21-dipropionate) for the prevention/treatment of gastrointestinal disorders characterized by severe inflammation, including pediatric Crohn's disease (SGX203), acute radiation enteritis (SGX201) and chronic Graft-versus-Host disease (orBec®), as well as developing its novel innate defense regulator (IDR) technology SGX942 for the treatment of oral mucositis.

Through its BioDefense Division, Soligenix is developing countermeasures pursuant to the Biomedical Advanced Research and Development Authority (BARDA) Strategic Plan of 2011-2016 for inclusion in the US government's Strategic National Stockpile. Soligenix's lead biodefense products in development are a recombinant subunit vaccine called RiVax™, which is designed to protect against the lethal effects of exposure to ricin toxin and VeloThrax™, a vaccine against anthrax exposure. RiVax™ has been shown to be well tolerated and immunogenic in two Phase 1 clinical trials in healthy volunteers. Both RiVax™ and VeloThrax™ are currently the subject of a $9.4 million National Institute of Allergy and Infectious Diseases (NIAID) grant supporting development of Soligenix's new vaccine heat stabilization technology known as ThermoVax™. Soligenix is also developing OrbeShield™ for the treatment of gastrointestinal acute radiation syndrome (GI ARS) under a $600,000 NIAID Small Business Innovation Research (SBIR) grant. OrbeShield™ has previously demonstrated statistically significant preclinical survival results in two separate canine GI ARS studies funded by the NIAID. Recently, Soligenix announced a worldwide exclusive collaboration with Intrexon Corporation that will focus on the joint development of a treatment for Melioidosis, a high priority biothreat and an area of unmet medical need.

For further information regarding Soligenix, Inc., please visit the Company's website at www.soligenix.com.

This press release contains forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "intends," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance, enter into any biodefense procurement contracts with the US Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the US Congress may not pass any legislation that would provide additional funding for the Project BioShield program. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission, including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

For more information regarding Soligenix, Inc., contact:

Joe Warusz, CPA
Acting Chief Financial Officer
(609) 538-8200 | www.soligenix.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 24, 2013

Commission File No. 000-16929

Soligenix, Inc.
(Exact name of small business issuer as specified in its charter)

DELAWARE	41-1505029
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
29 Emmons Drive, Suite C-10 Princeton, NJ	08540
(Address of principal executive offices)	(Zip Code)

(609) 538-8200
(Issuer's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry Into a Material Definitive Agreement.

On September 24, 2013, Soligenix, Inc. (the "Company") entered into a contract (the "Contract") with the National Institutes of Health (the "NIH"), which Contract will be funded by the National Institute of Allergy and Infectious Diseases. The Contract is for the advanced preclinical development of OrbeShield™ (oral beclomethasone 17,21-dipropionate or oral BDP) as a medical countermeasure for the treatment of gastrointestinal acute radiation syndrome ("GI ARS").

The Contract consists of a base period of one year and two optional guaranteed segments that can be initiated solely at the discretion of the NIH. The two contract options would extend the Contract term to up to one year each, for a total Contract term of three years if both of the options are exercised. The total funding amount to be paid by the NIH under the Contract would be up to $6.4 million if the two options are exercised by the NIH, the occurrence of which the Company can provide no assurance. The total award will support the development activities necessary to evaluate OrbeShield™ as a potential medical countermeasure to treat GI ARS.

The foregoing is only a brief description of the material terms of the Contract and does not purport to be a complete description of the rights and obligations of the parties thereunder. The foregoing description is qualified in its entirety by reference to the Contract, which is filed as Exhibit 10.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Contract HHSN272201300030C dated September 24, 2013 by and between the Company and the National Institutes of Health. *
99.1	Press Release issued by the Company on September 25, 2013.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment

SIGNATURE

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 hereunto duly authorized.

Soligenix, Inc.

By: /s/ Christopher J. Schaber
Christopher J. Schaber, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

September 30, 2013

EXHIBIT INDEX

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Exhibit 10.1

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

Contract Number : HHSN272201300030C

CONTRACT TABLE OF CONTENTS

Contract Number : HHSN272201300030C

PART I - THE SCHEDULE

SECTION B - SERVICES AND COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

NIAID's Division of Allergy, Immunology, and Transplantation funds applied and translational research and development of radiation/nuclear medical countermeasures (MCMs) to mitigate and/or treat radiation gastrointestinal tissue damaged when administered at least 24 hours after radiation exposure. OrbeShield will be evaluated as a MCM for Gastrointestinal-Acute Radiation Syndrome (GI-ARS).

ARTICLE B.2. ESTIMATED COST – OPTION

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

b. The fixed fee for the Base Period of this contract is [*****] . The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

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

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

ARTICLE B.3. ADVANCE UNDERSTANDINGS

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

a. Indirect Costs

1. In no event shall the final amount reimbursable for G&A costs exceed a ceiling of indirect costs, and for Fringe costs exceed a ceiling of [*****] of [*****] of salary costs. These rates shall be fixed for the life of the contract.

2. The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates.

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

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed

separately with the Securities and Exchange Commission.

b. Subcontract

To negotiate a [*****] type subcontract with [*****] for non-human primate studies for an amount not to exceed $(as negotiated) for the period 9/30/2013 through 9/29/2014. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

c. Consultants Consultant fees to be paid to the following individuals:

d. 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.

Portions herein identified by [*****] have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A complete copy of this document has been filed separately with the Securities and Exchange Commission.

e. 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.

f. Special Copyright Provisions

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

g. 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. HHSN272201300030C

h. Advance Copies of Press Releases

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

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

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

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

1. Conferences and Meetings

2. Food for Meals, Light Refreshments, and Beverages

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

4. Special rearrangement or alteration of facilities;

5. 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.);

6. Travel to attend general scientific meetings;

7. Foreign travel;

8. Consultant costs;

9. Subcontracts;

10. Patient care costs;

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

b. Travel Costs

1. Domestic Travel

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

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

Contract Number : HHSN272201300030C

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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 7/5/2013, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. All electronic reports submitted shall be compliant with Sectio