UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from to

Commission file number: 001-33137
EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
400 Professional Drive, Suite 400 Gaithersburg, Maryland	**20879**
(Address of Principal Executive Offices)	*(Zip Code)*

(240) 631-3200
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

As of October 31, 2016, the registrant had 40,498,025 shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

Part I. Financial Information

Part II. Other Information

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the future earnings and performance of Emergent or any of its businesses, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. We generally identify forward-looking statements by using words like "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including, among others:

- appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed) and our other countermeasure products;
- our ability to perform under our contracts with the U.S. government related to BioThrax, including the timing of deliveries;
- our ability to obtain a new procurement contract for BioThrax on favorable terms;
- our ability to obtain Emergency Use Authorization pre-approval for NuThrax from the FDA;
- the availability of funding for our U.S. government grants and contracts;
- our ability to successfully execute our growth strategy and achieve our financial and operational goals;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- our ability to utilize the full manufacturing capacity of Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- whether the operational, marketing and strategic benefits of the spin-off of our biosciences business can be achieved and the timing of any such benefits;
- our ability to identify and acquire companies or in-license products or late-stage product candidates that satisfy our selection criteria;
- our ability to realize synergies and benefits from acquisitions or in-licenses within expected time periods or at all;
- our ability to successfully identify and respond to new development contracts with the U.S. government, as well as successfully maintain, through achievement of development milestones, current development contracts with the U.S. government;
- our ability to obtain and maintain intellectual property protection for our products and product candidates;
- our ability and plans to expand our manufacturing facilities and capabilities;
- our ability and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations;
- the results of regulatory inspections;
- the operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
- the outcome of the purported class action lawsuit filed against us and possible other future material legal proceedings;
- the rate and degree of market acceptance and clinical utility of our products;
- the success of our ongoing and planned development programs, non-clinical activities and clinical trials of our product candidates;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the success of our commercialization, marketing and manufacturing capabilities and strategy; and
- the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. New factors emerge from time to time and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. You should consider this cautionary statement, the risk factors identified in the section entitled "Risk Factors" in this quarterly report on Form 10-Q and the risk factors identified in our other periodic reports filed with the Securities and Exchange Commission when evaluating our forward-looking statements.

PART I. FINANCIAL INFORMATION

ITEM 1. *FINANCIAL STATEMENTS*

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 298,932	$ 308,304
Accounts receivable, net	69,633	113,906
Inventories	81,160	60,887
Income tax receivable, net	11,831	6,573
Prepaid expenses and other current assets	18,439	18,458
Current assets of discontinued operations	-	29,282
Total current assets	479,995	537,410
Property, plant and equipment, net	362,544	327,808
In-process research and development	-	701
Intangible assets, net	35,419	40,758
Goodwill	41,001	41,001
Deferred tax assets, net	11,286	11,286
Other assets	1,781	2,155
Non-current assets of discontinued operations	-	76,365
Total assets	$ 932,026	$ 1,037,484
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 46,342	$ 37,970
Accrued expenses and other current liabilities	4,279	6,207
Accrued compensation	32,102	31,998
Notes payable	20,000	-
Contingent consideration, current portion	2,759	2,109
Deferred revenue, current portion	4,824	3,979
Current liabilities of discontinued operations	-	17,348
Total current liabilities	110,306	99,611
Contingent consideration, net of current portion	20,169	23,046
Long-term indebtedness	247,793	246,892
Deferred revenue, net of current portion	4,695	3,426
Other liabilities	1,440	1,258
Non-current liabilities of discontinued operations	-	3,234
Total liabilities	384,403	377,467
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both September 30, 2016 and December 31, 2015	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized, 40,910,479 shares issued and 40,487,649 shares outstanding at September 30, 2016; 100,000,000 shares authorized, 39,829,408 shares issued and 39,406,578 shares outstanding at December 31, 2015	41	40
Treasury stock, at cost, 422,830 common shares at both September 30, 2016 and December 31, 2015	(6,420)	(6,420)
Additional paid-in capital	342,888	317,971
Accumulated other comprehensive loss	(3,572)	(2,713)
Retained earnings	214,686	351,139
Total stockholders' equity	547,623	660,017
Total liabilities and stockholders' equity	$ 932,026	$ 1,037,484

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

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales	$ 96,698	$ 117,512	$ 208,785	$ 204,563
Contract manufacturing	14,712	11,341	32,455	32,443
Contracts and grants	31,504	29,525	95,879	92,541
Total revenues	142,914	158,378	337,119	329,547
Operating expenses:				
Cost of product sales and contract manufacturing	39,560	35,240	93,025	73,083
Research and development	27,188	34,179	81,173	93,833
Selling, general and administrative	40,688	25,800	108,328	86,263
Income from operations	35,478	63,159	54,593	76,368
Other income (expense):				
Interest income	358	104	764	459
Interest expense	(2,049)	(1,635)	(5,082)	(4,923)
Other income (expense), net	(234)	519	(176)	669
Total other expense, net	(1,925)	(1,012)	(4,494)	(3,795)
Income from continuing operations before provision for income taxes	33,553	62,147	50,099	72,573
Provision for income taxes	13,165	20,059	19,861	23,648
Net income from continuing operations	20,388	42,088	30,238	48,925
Income (loss) from discontinued operations (net of tax)	952	(5,145)	(15,854)	(19,402)
Net income	$ 21,340	$ 36,943	$ 14,384	$ 29,523
Net income per share - basic:				
Income from continuing operations	$ 0.50	$ 1.08	$ 0.75	$ 1.28
Income (loss) from discontinued operations	0.02	(0.14)	(0.40)	(0.51)
Net income per share - basic	$ 0.52	$ 0.94	$ 0.35	$ 0.77
Net income per share - diluted (1):				
Income from continuing operations	$ 0.43	$ 0.90	$ 0.68	$ 1.11
Income (loss) from discontinued operations	0.02	(0.11)	(0.32)	(0.42)
Net income per share - diluted	$ 0.45	$ 0.79	$ 0.36	$ 0.69
Weighted-average number of shares - basic	40,465,423	38,831,341	40,071,730	38,423,715
Weighted-average number of shares - diluted	49,440,313	47,784,550	48,826,597	46,958,179

(1) See Note 10 "Earnings per share" for details on calculation.

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

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Comprehensive Income
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Net income	$ 21,340	$ 36,943	$ 14,384	$ 29,523
Foreign currency translations, net of tax	(492)	(495)	(859)	(1,144)
Comprehensive income	$ 20,848	$ 36,448	$ 13,525	$ 28,379

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

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:	(Unaudited)	
Net Income	$ 14,384	$ 29,523
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	14,527	11,802
Depreciation and amortization	28,155	25,859
Income taxes	4,814	15,904
Change in fair value of contingent obligations	(1,253)	(10,898)
Impairment of intangible assets (including IPR&D)	-	9,827
Abandonment of long-lived assets	3,749	-
Excess tax benefits from stock-based compensation	(10,825)	(8,002)
Other	2,467	197
Changes in operating assets and liabilities:		
Accounts receivable	45,035	1,749
Inventories	(16,183)	(14,396)
Income taxes	(14,662)	(22,707)
Prepaid expenses and other assets	(3,146)	1,010
Accounts payable	(1,305)	1,902
Accrued expenses and other liabilities	(1,699)	(2,060)
Accrued compensation	(152)	(1,688)
Provision for chargebacks	103	(296)
Deferred revenue	(1,348)	3,663
Net cash provided by operating activities	62,661	41,389
Cash flows from investing activities:		
Purchases of property, plant and equipment	(56,243)	(33,631)
Net cash used in investing activities	(56,243)	(33,631)
Cash flows from financing activities:		
Proceeds from long-term debt obligations	-	2,000
Issuance of common stock upon exercise of stock options	14,981	15,902
Excess tax benefits from stock-based compensation	10,825	8,002
Distribution of Aptevo	(45,000)	-
Contingent obligation payments	(1,226)	(5,427)
Net cash (used in) provided by financing activities	(20,420)	20,477
Effect of exchange rate changes on cash and cash equivalents	139	(16)
Net (decrease) increase in cash and cash equivalents	(13,863)	28,219
Cash and cash equivalents at beginning of period	312,795	280,499
Cash and cash equivalents at end of period	$ 298,932	$ 308,718

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

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Summary of significant accounting policies

Basis of presentation and consolidation

On August 6, 2015, Emergent BioSolutions Inc. (the "Company" or "Emergent"), announced its plan to separate into two independent publicly-traded companies. On August 1, 2016, the Company accomplished this plan through the completion of the spin-off of Aptevo Therapeutics Inc. ("Aptevo"), a biotechnology company focused on novel oncology and hematology therapeutics to meaningfully improve patients' lives. Emergent remains as a global specialty life sciences company focused on providing specialty products for civilian and military populations that address intentional and naturally emerging public health threats.

In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the Company's chief operating decision maker ("CODM") allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. Aptevo is now an independent public company trading under the symbol "APVO" on the NASDAQ Global Select Market ("NASDAQ"). The results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off. The historical financial statements and footnotes have been revised accordingly. See Note 2. "Discontinued operations" for further details regarding the spin-off. For periods following the spin-off, the Company reports financial results under one business segment.

The accompanying unaudited consolidated financial statements include the accounts of Emergent and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC.

During the nine months ended September 30, 2016 there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC. In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, except for the adjustments associated with the spin-off of Aptevo, and are necessary to present fairly the financial position of the Company as of September 30, 2016, specifically: the results of operations and comprehensive income for the three and nine months ended September 30, 2016 and 2015; and cash flows for the nine months ended September 30, 2016 and 2015. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

We analyze our multiple element revenue-generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in our control. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on the unit's relative selling price and is recognized in full when the appropriate revenue recognition criteria are met. We deem services to be rendered if no continuing obligation exists on our part. As of September 30, 2016, the Company has determined that its US Government contracts for Anthrasil™ (Anthrax Immune Globulin Intravenous (Human), BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine and VIGIV (Vaccinia Immune Globulin Intravenous (Human)) are multiple element arrangements.

Recent accounting standards

In April 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity* ("ASU No. 2014-08"). ASU No. 2014-08 limits discontinued operations reporting to disposals of components of an entity that represent strategic shifts that have (or will have) a major effect on an entity's operations and financial results. ASU No. 2014-08 also requires expanded disclosures for discontinued operations and disposals of individually significant components of an entity that do not qualify for discontinued operations reporting. ASU No. 2014-08 was effective for disposals and components classified as held-for-sale that occurred within annual periods beginning on or after December 15, 2014, and interim periods within those years. Early adoption was permitted. The new guidance is effective for the Company prospectively for all disposals of components of an entity that occurred after January 1, 2015. The spin-off of Aptevo by the Company on August 1, 2016 meets the definition of a discontinued operation under the new guidance and, as a result, the Company reflected the provisions of the new guidance in the third quarter of 2016.

In May 2014, the FASB issued ASU No. 2014-09, *Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40)*. ASU No. 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that it expects to receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements. The FASB has deferred ASU No. 2014-09 for one year, and with that deferral, the standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which for the Company will be its 2018 first quarter. The Company is permitted to use either the retrospective or the modified retrospective method when adopting ASU No. 2014-09. The Company is still assessing the potential impact that ASU No. 2014-09 will have on its financial statements and disclosures, but believes that there could be changes to the revenue recognition for government contracts.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30)*, which simplifies the presentation of debt issuance costs. ASU No. 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. Prior to the issuance of ASU 2015-03, debt issuance costs were required to be presented as an asset on the balance sheet. ASU No. 2015-03 is effective for interim and annual periods beginning after December 15, 2015. The Company has adopted the guidance and has applied the guidance on a retrospective basis.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)*. ASU No. 2016-09 simplifies several aspects of the accounting for share-based payment award transactions, including: (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. ASU No. 2016-09 is effective for the annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU No. 2016-09 will have on the consolidated financial statements and related disclosures.

2. Discontinued operations

On August 1, 2016, the Company completed the spin-off of Aptevo through the distribution of 100% of the outstanding shares of common stock of Aptevo to the Company's shareholders (the "Distribution"). The Distribution was made to the Company's shareholders of record as of the close of business on July 22, 2016 (the "Record Date"), who received one share of Aptevo common stock for every two shares of Emergent common stock held as of the Record Date. The Distribution was intended to qualify as a tax-free distribution for federal income tax purposes in the United States. In the aggregate, approximately 20.2 million shares of Aptevo common stock were distributed to the Company's shareholders of record as of the Record Date in the Distribution. After the Distribution, the Company no longer holds shares of Aptevo's common stock. In addition, on August 1, 2016, the Company entered into a non-negotiable, unsecured promissory note with Aptevo to provide an additional $20 million in funding within six to twelve months following the Distribution.

The historical balance sheet and statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements and prior periods have been restated. Discontinued operations include results of Aptevo's business except for certain allocated corporate overhead costs and certain costs associated with

transition services provided by the Company to Aptevo. These allocated costs remain part of continuing operations. Due to differences between the basis of presentation for discontinued operations and the basis of presentation as a stand-alone company, the financial results of Aptevo included within discontinued operations for the Company may not be indicative of actual financial results of Aptevo.

In conjunction with the spin-off, the Company entered into a Separation and Distribution Agreement with Aptevo to effect the separation of Aptevo from the Company (the "Separation"). The Company also entered into various other agreements to provide a framework for its relationship with Aptevo after the Separation, including a manufacturing services agreement, transition services agreement, a tax matters agreement and an employee matters agreement.

The Separation and Distribution Agreement with Aptevo sets forth, among other things, the assets that were transferred, the liabilities assumed, and the contracts that were assigned to each of Aptevo and the Company as part of the Separation of the Company into two companies, and provided for when and how these transfers, assumptions and assignments were to occur.

Under the terms of the manufacturing services agreement, the Company agreed to provide contract manufacturing services for certain of Aptevo's products commencing on the date of the Distribution. The contract has a term of ten years. For the three and nine months ended September 30, 2016, there has been no revenue under this agreement.

Under the terms of the transition services agreement, the Company agreed to provide on an interim, transitional basis, various services, including, but not limited to, accounts payable administration, information technology services, regulatory and clinical support, general administrative services and other support services commencing on the date of the Distribution and terminating up to two years following the date of the Distribution. During the three and nine months ended September 30, 2016, approximately $0.5 million of transition services revenue associated with the provision of services to Aptevo.

The tax matters agreement governs the respective rights, responsibilities and obligations of Aptevo and the Company with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the Distribution and certain related transactions to qualify as tax-free for U.S. federal income tax purposes), tax attributes, tax returns, tax proceedings and certain other tax matters.

The employee matters agreement governs certain compensation and employee benefit obligations and allocates liabilities and responsibilities relating to employment matters, employee compensation and benefit plans and programs and other related matters, including the transfer or assignment of employees from the Company to Aptevo.

The following table represents the carrying value of Aptevo's assets and liabilities distributed as part of the Separation on August 1, 2016:

(in thousands)	**August 1, 2016**
Assets:	
Cash and cash equivalents	$ 45,000
Accounts receivable, net	4,465
Inventories	11,959
Other current assets	4,870
Current assets of discontinued operations	66,294
Property, plant and equipment, net	6,128
In-process research and development	41,800
Intangible assets, net	15,402
Goodwill	13,902
Non-current assets of discontinued operations	77,232
Total assets of discontinued operations	$ 143,526
Liabilities:	
Accounts payable	$ 6,285
Accrued expenses and other current liabilities	64
Accrued compensation	2,456
Contingent consideration	191
Provisions for chargebacks	2,341
Deferred revenue, current portion	433
Current liabilities of discontinued operations	11,770
Deferred revenue, net of current portion	3,232
Other liabilities	91
Non-current liabilities of discontinued operations	3,323
Total liabilities of discontinued operations	$ 15,093

The following table represents Aptevo's assets and liabilities presented as discontinued operations and classified as held-for-disposition as of December 31, 2015:

(in thousands)	**December 31, 2015**
Assets:	
Cash and cash equivalents	$ 4,492
Accounts receivable, net	6,861
Inventories	16,049
Prepaid expenses and other current assets	1,880
Current assets of discontinued operations	29,282
Property, plant and equipment, net	4,046
In-process research and development	41,800
Intangible assets, net	16,617
Goodwill	13,902
Non-current assets of discontinued operations	76,365
Total assets of discontinued operations	$ 105,647
Liabilities:	
Accounts payable	$ 8,134
Accrued expenses and other current liabilities	22
Accrued compensation	2,684
Contingent consideration, current portion	306
Provisions for chargebacks	2,238
Deferred revenue, current portion	3,964

Current liabilities of discontinued operations	17,348
Deferred revenue, net of current portion	3,163
Other liabilities	71
Non-current liabilities of discontinued operations	3,234
Total liabilities of discontinued operations	$ 20,582

The following table summarizes results from discontinued operations of Aptevo included in the consolidated statements of operations:

(in thousands)	Three Months Ended September 30, 2016	2015	Nine Months Ended September 30, 2016	2015
Revenues:				
Product sales	$ 3,019	$ 6,441	$ 21,183	$ 19,704
Collaborations	68	121	187	5,434
Total revenues	3,087	6,562	21,370	25,138
Operating expense:				
Cost of product sales	907	3,270	11,556	11,442
Research and development	2,509	7,689	18,024	27,678
Selling, general and administrative	7,499	5,756	23,792	16,239
Loss from operations	(7,828)	(10,153)	(32,002)	(30,221)
Other income (expense), net:	(116)	83	(41)	(464)
Loss from discontinued operations before benefit from income taxes	(7,944)	(10,070)	(32,043)	(30,685)
Benefit from income taxes	(8,896)	(4,925)	(16,189)	(11,283)
Net loss from discontinued operations	$ 952	$ (5,145)	$ (15,854)	$ (19,402)

The following table summarizes the cash flows of Aptevo included in the September 30, 2016 and 2015 consolidated statements of cash flows:

(in thousands)	Nine Months Ended September 30, 2016	2015
Net cash (used in) provided by operating activities	$ (17,813)	$ 1,414
Net cash used in investing activities	(1,925)	(970)
Net cash provided by (used in) financing activities	15,247	(679)
Net increase (decrease) in cash and cash equivalents	$ (4,491)	$ (235)

3. Fair value measurements

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

	September 30, 2016			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Investment in money market funds (1)	$ 10	$ -	$ -	$ 10
Total assets	$ 10	$ -	$ -	$ 10
Liabilities:				
Contingent consideration	$ -	$ -	$ 22,928	$ 22,928
Total liabilities	$ -	$ -	$ 22,928	$ 22,928

	December 31, 2015			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Investment in money market funds (1)	$ 3,323	$ -	$ -	$ 3,323
Total assets	$ 3,323	$ -	$ -	$ 3,323
Liabilities:				
Contingent consideration	$ -	$ -	$ 25,155	$ 25,155
Total liabilities	$ -	$ -	$ 25,155	$ 25,155

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

During the nine months ended September 30, 2016, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

For the three months ended September 30, 2016, the contingent consideration obligation associated with the EV-035 series of molecules increased by $0.1 million. For the nine months ended September 30, 2016, the contingent consideration obligation associated with the EV-035 series of molecules decreased by $0.3 million. For the three and nine months ended September 30, 2015, the contingent consideration obligation decreased by $9.9 million and $9.5 million, respectively. These changes are primarily due to the estimated timing and probability of success for certain development and regulatory milestones and the estimated timing and volume of potential future sales of the EV-035 series of molecules and the broad spectrum antiviral platform, which are inputs that have no observable market (Level 3), along with the novation of the Defense Threat Reduction Agency ("DTRA") contract for the EV-035 series of molecules. These decreases and increases in the contingent consideration were classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense. During the nine months ended September 30, 2015, the Company received novation of the DTRA contract and paid the $4.0 million milestone to Evolva in the second quarter of 2015.

For the three and nine months ended September 30, 2016, the contingent purchase consideration obligations associated with RSDL decreased by $2.3 million and $1.0 million, respectively. For the three and nine months ended September 30, 2015, the contingent consideration obligations associated with RSDL decreased by $1.9 million and $1.8 million, respectively. The fair value of the RSDL contingent consideration obligations decreased as a result of management's assessment of the assumed and actual achievement of future net sales, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as cost of product sales and contract manufacturing.

The following table is a reconciliation of the beginning and ending balance of the liabilities, consisting only of contingent consideration, measured at fair value using significant unobservable inputs (Level 3) during the nine months ended September 30, 2016.

(in thousands)	
Balance at December 31, 2015	$ 25,155
Income included in earnings	1,263
Settlements	(964)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at September 30, 2016	$ 22,928

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. As of September 30, 2016, the in-process research and development asset for the EV-035 series of molecules was measured at fair value on a non-recurring basis.

4. Inventories

Inventories consisted of the following:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials and supplies	$ 31,239	$ 21,275
Work-in-process	24,459	32,709
Finished goods	25,462	6,903
Total inventories	$ 81,160	$ 60,887

5. Property, plant and equipment

Property, plant and equipment consisted of the following:

(in thousands)	September 30, 2016	December 31, 2015
Land and improvements	$ 20,391	$ 16,520
Buildings, building improvements and leasehold improvements	141,322	108,908
Furniture and equipment	191,529	129,933
Software	52,744	39,683
Construction-in-progress	64,885	126,531
Property, plant and equipment, gross	470,871	421,575
Less: Accumulated depreciation and amortization	(108,327)	(93,767)
Total property, plant and equipment, net	$ 362,544	$ 327,808

6. Intangible assets and in-process research and development

Intangible assets consisted of the following:

(in thousands)	
Cost basis	
Balance at December 31, 2015	$ 57,099
Additions	-
Balance at September 30, 2016	$ 57,099
Accumulated amortization	
Balance at December 31, 2015	$ (16,343)
Amortization	(5,337)
Balance at September 30, 2016	$ (21,680)
Net balance at September 30, 2016	$ 35,419

In September 2015, the Company received data for the leading molecule in the EV-035 series of molecules, GC-072, that indicated a potential toxicity issue. The Company considered this information an indicator of impairment of the related EV-035 series of molecules in-process research and development ("IPR&D") asset, and completed an impairment assessment of this asset. Based on this assessment, the Company recorded a non-cash impairment charge of $9.8 million, which is included in the Company's statement of operations as research and development expense. The impairment assessment was performed using the income approach which discounts expected future cash flows to present value. The projected cash flows for the EV-035 series of molecules were based on key assumptions including: estimates of revenues and operating profits considering its stage of development; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets.

For the three months ended September 30, 2016 and 2015, the Company recorded amortization expense of $1.7 million and $1.8 million, respectively. For the nine months ended September 30, 2016 and 2015, the Company recorded amortization expense of $5.3 million and $5.5 million, respectively, for intangible assets, which has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of September 30, 2016, the weighted average amortization period remaining for intangible assets is 78 months.

7. Long-term debt

As of December 31, 2015, the Company reclassified debt issuance costs of $1.2 million and $4.9 million from prepaid expenses and other current assets and other assets, respectively, as a reduction to long-term debt.

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes mature on January 15, 2021, unless earlier purchased by the Company or converted. The original conversion rate was equal to 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $32.38 per share of common stock). The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. As of August 1, 2016, certain conversion features were triggered due to the completion of the Aptevo spin-off. The conversion rate under the Notes was adjusted in accordance with the terms of the indenture. Effective August 12, 2016, the conversion rate was adjusted to 32.3860 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $30.88 per share of common stock).

8. Equity

As of September 30, 2016, the Company had two stock-based employee compensation plans, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan"). The Company refers to both plans together as the "Emergent Plans." On May 19, 2016, at the Company's annual meeting, the Company's shareholders approved the Fourth Amended and Restated Emergent BioSolutions Inc.

2006 Stock Incentive Plan, and the issuance of 3.8 million shares thereunder. In addition, the Company's shareholders approved an increase in the number of authorized shares of common stock to 200 million shares from 100 million shares.

In connection with the Separation, on August 1, 2016 and in accordance with the employee matters agreement and the Emergent Plans, the Company made certain adjustments to the exercise price and number of equity awards. Continuing Emergent employees with equity awards issued prior to Distribution received an equitable adjustment reflecting a revised exercise price and number of equity awards granted. Continuing Aptevo employees who had been granted Emergent equity awards had their grants canceled and reissued as Aptevo equity awards with an adjusted exercise price.

The following is a summary of stock option award activity:

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2015	2,964,237	$ 22.73	29,699	$ 10.28	$ 52,119,607
Granted	403,978	33.70	-	-	
Exercised	(750,293)	19.56	(29,699)	10.28	
Forfeited	(62,441)	27.48	-	-	
Canceled	(146,986)	28.33	-	-	
Equitable adjustment	236,313	22.90	-	-	
Outstanding at September 30, 2016	2,644,808	22.84	-	-	22,976,804
Exercisable at September 30, 2016	1,558,840	$ 19.51	-	$ -	$ 18,732,937

The following is a summary of restricted stock unit award activity:

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2015	889,004	$ 26.86	$ 35,569,048
Granted	488,738	34.36	
Vested	(416,289)	24.68	
Forfeited	(46,994)	29.84	
Canceled	(107,514)	30.90	
Equitable adjustment	79,339	28.86	
Outstanding at September 30, 2016	886,284	$ 28.95	$ 24,922,306

On July 14, 2016, the Company's board of directors authorized management to repurchase, from time to time, up to an aggregate of $50 million of the Company's common stock under a board-approved share repurchase program. The timing, amount, and price of any repurchases will be made pursuant to one or more 10b5-1 plans. The term of the board authorization of the repurchase program is until December 31, 2017. The plan will permit shares to be repurchased when the Company might otherwise be precluded from doing so under insider trading laws. The repurchase program may be suspended or discontinued at any time. Any repurchased shares will be available for use in connection with the Company's stock plans and for other corporate purposes. As of September 30, 2016, the Company has neither implemented a repurchase plan nor repurchased any shares under this program.

9. Income taxes

The estimated effective annual tax rate for continued operations, which excludes discrete adjustments, was 37% and 29%, respectively, for the nine months ended September 30, 2016 and 2015. The increase in the estimated effective annual tax rate on continuing operations was primarily related to tax on the sale, within the Emergent consolidated group, of assets from Canadian subsidiaries to U.S. subsidiaries in preparation of the spin-off of Aptevo and a valuation allowance charge related to Aptevo net deferred tax assets prior to the Distribution, partially offset by a release of valuation allowances associated with Canadian Scientific Research and Experimental Development tax credits.

10. Earnings per share

The following table presents the calculation of basic and diluted net income (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2016	2015	2016	2015
Numerator:				
Net income from continuing operations	$ 20,388	$ 42,088	$ 30,238	$ 48,925
Interest expense, net of tax	934	786	2,234	2,378
Amortization of debt issuance costs, net of tax	183	215	569	671
Net income, adjusted from continuing operations	21,505	43,089	33,041	51,974
Income (loss) from discontinued operations	952	(5,145)	(15,854)	(19,402)
Net income, adjusted	$ 22,457	$ 37,944	$ 17,187	$ 32,572
Denominator:				
Weighted-average number of shares—basic	40,465,423	38,831,341	40,071,730	38,423,715
Dilutive securities—equity awards	878,390	1,232,684	658,367	813,939
Dilutive securities—convertible debt	8,096,500	7,720,525	8,096,500	7,720,525
Weighted-average number of shares—diluted	49,440,313	47,784,550	48,826,597	46,958,179
Net income per share-basic from continuing operations	$ 0.50	$ 1.08	$ 0.75	$ 1.28
Income (loss) per share-basic from discontinued operations	0.02	(0.14)	(0.40)	(0.51)
Net income per share-basic	$ 0.52	$ 0.94	$ 0.35	$ 0.77
Net income per share-diluted from continuing operations	$ 0.43	$ 0.90	$ 0.68	$ 1.11
Income (loss) per share-diluted from discontinued operations	0.02	(0.11)	(0.32)	(0.42)
Net income per share-diluted	$ 0.45	$ 0.79	$ 0.36	$ 0.69

For the three and nine months ended September 30, 2016 and 2015, basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period.

For the three and nine months ended September 30, 2016 and 2015, diluted earnings per share is computed using the "if-converted" method by dividing the net income adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the Company's Notes by the weighted average number of shares of common stock outstanding during the period. The weighted average number of shares is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, at the beginning of the period.

For the three months ended September 30, 2016, approximately 0.4 million stock options were excluded from the calculation of diluted earnings per share. For the three and nine months ended September 30, 2015, along with the nine months ended September 30, 2016, substantially all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share.

11. Restructuring

In August 2016, the Company adopted a plan to restructure and reprioritize the operations of one of our facilities at the Emergent BioDefense Operations Lansing LLC ("EBOL") site due to the Company's large-scale manufacturing facility at EBOL commencing manufacturing operations. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of income as a component of selling, general and administrative expense.

The Company has completed this restructuring. The costs of the restructuring as of September 30, 2016 are detailed below:

(in thousands)	Incurred in 2016	Inception to Date Costs Incurred	Total Expected to be Incurred
Termination benefits	$ 2,488	$ 2,488	$ 5,264
Abandonment of equipment	3,749	3,749	3,749
Other costs	691	691	691
Total	$ 6,928	$ 6,928	$ 9,704

During the nine months ended September 30, 2016, the Company abandoned certain equipment and associated assets at its EBOL facility related to the manufacturing process at Building 12 ("manufacturing process") asset group. The Company recorded a charge for the manufacturing process asset group of $3.7 million. The additional expense is classified in the Company's statements of operations as selling, general and administrative expense. As of September 30, 2016, the Company has determined that there were no indications of impairment for the remaining assets groups at the EBOL site.

The following is a summary of the activity for the liabilities related to the EBOL restructuring:

(in thousands)	Termination Benefits
Balance at December 31, 2015	$ -
Expenses incurred	2,488
Amount paid	-
Other adjustments	-
Balance at September 30, 2016	$ 2,488

In addition to the above restructuring costs, the Company also recorded a charge of $1.7 million during the nine months ended September 30, 2016 related to retention payments for certain employees at the EBOL site.

12. Related party transactions

In November 2015, the Company entered into a consulting arrangement with a member of the Company's Board of Directors, amended in July 2016, to provide assistance in connection with the planned spin-off of Aptevo. The total compensation under the agreement was approximately $0.2 million. The consulting agreement terminated on August 1, 2016.

13. Segment information

On August 6, 2015, the Company announced its plan to separate into two independent publicly-traded companies. In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the CODM allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. The results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off.

For financial reporting purposes, in the periods following the spin-off of Aptevo, the Company reports financial information for one business segment.

For the three and nine months ended September 30, 2016 and 2015, substantially all of the Company's revenues are from the United States government.

14. Litigation

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against the Company and certain of its senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that the Company made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts. Sponn is seeking unspecified damages, including legal costs. On October 25, 2016 the Court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robins Geller Rudman & Dowd LLP as Lead Counsel. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims. As of the date of this filing, the range of potential loss cannot be determined or estimated.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and financing, includes forward-looking statements that involve risks and uncertainties. You should carefully review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this quarterly report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

Emergent BioSolutions Inc., or Emergent, is a specialty biopharmaceutical business focused on countermeasures that address public health threats, specifically Chemical, Biological, Radiological, Nuclear and Explosive, or CBRNE, threats as well as emerging infectious diseases, or EID. The U.S. government is the primary purchaser of our products and historically provided us with substantial funding for the development of our product candidates. We develop, manufacture, and deliver a portfolio of medical countermeasures primarily for government agencies in the areas of biological and chemical threats and emerging infectious diseases. Operations include manufacturing, regulatory affairs, quality assurance, quality control, international sales and marketing, and domestic government affairs in support of our marketed products, as well as product development and manufacturing infrastructure in support of our investigational stage product candidates.

On August 1, 2016, we completed the spin-off of Aptevo Therapeutics Inc., or Aptevo. As a result of the spin-off, the operating results of Aptevo have been reflected as discontinued operations for the three and nine months ended September 30, 2016 and 2015. See Note 2. "Discontinued Operations" for further details regarding the spin-off. Unless otherwise stated, financial results herein reflect continuing operations.

Our portfolio consists of the following marketed products and investigational stage product candidates.

Our marketed products are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or the FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Anthrasil™ (Anthrax Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax;
- BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine), the only heptavalent therapeutic licensed by the FDA for the treatment of botulinum disease;
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination; and
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA for the removal or neutralization of chemical agents, T-2 toxin and many pesticide-related chemicals from the skin.

Our investigational stage product candidates are:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- UV-4B, a novel antiviral being developed for dengue and influenza infections;
- GC-072, the lead compound in the EV-035 series of broad spectrum antibiotics, being developed for *Burkholderia pseudomallei*;
- VAX161C, a recombinant pandemic influenza vaccine candidate being developed by VaxInnate, Inc. and for which we have an exclusive license agreement to manufacture and sell in the event of a surge order from the Biomedical Advanced Research and Development Authority, or BARDA; and
- Other product candidates that are focused on public health threats and emerging infectious diseases.

A unique attribute of our investigational stage product portfolio is that most of our candidates are under an active development contract with significant funding from the U.S. government. This allows our development pipeline, along with our marketed products, to be aligned with the strategic priorities of our U.S. and allied foreign government customers.

We also have programs that leverage our proven manufacturing infrastructure and expertise. We have responded to specific Task Order Requests issued by BARDA for the development and manufacture of specific countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program focused on imminent public health threats, including pandemic influenza and Ebola. On June 27, 2016, we received a task order from BARDA to develop and manufacture three cGMP lots of Zika vaccine for use in a Phase 1 clinical trial. Using a base vaccine candidate provided by BARDA, we will conduct technology transfer of process materials and information, process and analytical method development, execute small-scale production runs, and perform cGMP cell banking leading to cGMP manufacture of bulk drug substance and final drug product. The task order consists of a 30-month base period valued at $17.9 million and includes options that, if executed, will bring the total value to up to $21.9 million.

We also have multiple platform technologies, including the MVAtor™ (modified vaccinia virus Ankara vector) platform technology and Emergard™, a military-grade auto-injector device designed for intramuscular self-injection of antidotes and other emergency response medical treatments that can address exposure to certain chemical agents and other similar emerging threats and our hyperimmune specialty plasma product manufacturing platform. In February 2016, we announced that Emergard was selected by the U.S. Department of Defense, or DoD, and Battelle Memorial Institute to be tested against and developed to U.S. military specifications as a platform for nerve agent antidote delivery. Initial development and testing of Emergard is expected to be completed in 2016 and, if successful, could lead to Emergard's future procurement for U.S. military and emergency responder use. The testing and development of Emergard will be performed under a subcontract with Battelle, which in turn has a prime contract with the DoD.

In addition, we provide contract manufacturing services to third-party customers. The majority of these services are performed at our facilities located in Baltimore, Maryland. At these facilities we perform pharmaceutical product development and filling services for injectable and other sterile products, as well as process design, technical transfer, manufacturing validation, laboratory support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies. We manufacture both vial and pre-filled syringe formats for a wide variety of drug products - small molecule and biological - in all stages of development and commercialization, including 20 licensed products, which are currently sold in more than 40 countries. This facility produces finished units of clinical and commercial drugs for a variety of customers ranging from small biopharmaceutical companies to major multinationals. The facility is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union.

We have derived the majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are focused on increasing the sales of our products to U.S. government customers and expanding the market for our product portfolio to other customers domestically and internationally. We are currently a party to a contract with the Centers for Disease Control and Prevention, or the CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply up to 44.75 million doses of BioThrax for the placement into the Strategic National Stockpile, or SNS, over a five-year period, which was scheduled to expire on September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses under this contract, thereby committing to take delivery of the full 44.75 million doses and granted a no-cost extension to enable delivery of the remaining doses. We completed the delivery of doses under this no-cost extension in October 2016.

On June 21, 2016, HHS issued a Sole Source Notification indicating its intention to award Emergent a follow-on contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years. The solicitation does not state the number of doses expected to be procured per year, but represents a smaller annual procurement on average over the five-year period of the anticipated follow-on contract than under our current contract. The terms of the anticipated contract, including the price per dose and the timing of deliveries, remain subject to contract negotiation. In addition, the procurement of doses of BioThrax by the CDC remains subject to the availability of funding.

On August 10, 2016, the CDC exercised a contract option valued at $11.6 million over 12 months for the supply of Vaccinia Immune Globulin, or VIGIV, into the SNS. VIGIV is a therapeutic licensed by the FDA, for the treatment of complications arising from smallpox vaccinations. The contract option will require us to conduct manufacturing runs and additional activities in support of maintaining FDA licensure of VIGIV.

On September 30, 2016, we were awarded a multi-year contract with BARDA for the advanced development and delivery of NuThrax. The contract, valued at up to approximately $1.6 billion, consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses following Emergency Use Authorization, or EUA, pre-approval by the FDA. We anticipate that the FDA could authorize NuThrax for emergency use as early as 2018, triggering deliveries of NuThrax to the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which if both were to be exercised in full, would increase the total contract value to up to $1.6 billion.

Litigation

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of our common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against us and certain of our senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that we made materially false and misleading statements about the government's demand for BioThrax and expectations that our five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts. Sponn is seeking unspecified damages, including legal costs. On October 25, 2016 the Court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robins Geller Rudman & Dowd LLP as Lead Counsel.

Financial Operations Overview

Revenues

Effective September 30, 2011, we entered into a contract with the CDC to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period from September 30, 2011 through September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses, thereby committing to take delivery of the full 44.75 million doses under this contract and granted a no-cost extension to enable delivery of the remaining doses to be completed by November 30, 2016. Through September 30, 2016, we have approximately 1.0 million doses remaining to deliver under this contract, which were delivered in October 2016.

We have received contract and grant funding from BARDA, the CDC, Defense Threat Reduction Agency, or DTRA, and National Institute of Allergy and Infectious Diseases, or NIAID, for the following development programs:

Development Programs	Funding Source	Award Date	Performance Period
Anthrasil	BARDA	Sep-05	9/2005 — 4/2021
	BARDA	Sep-13	9/2013 — 9/2018

BAT	BARDA	May-06	5/2006 — 5/2026
CIADM	BARDA	Jun-12	6/2012 — 6/2037
GC-072	DTRA	Aug-14	8/2014 — 8/2017
Large-scale manufacturing for BioThrax	BARDA	Jul-10	7/2010 — 7/2016
NuThrax	NIAID	Aug-14	8/2014 — 10/2019
	BARDA	Mar-15	3/2015 — 8/2017
	BARDA	Sep-16	9/2016 — 9/2021
VIGIV	CDC	Aug-12	8/2012 — 8/2017
Zika	BARDA	Jun-16	6/2016 — 12/2018

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily due to the timing of sales of our products and timing of work completed under existing and new grants, development contracts and collaborative relationships.

Cost of Product Sales and Contract Manufacturing

The primary expense that we incur to deliver to our customers our marketed vaccines and therapeutics and to perform for our customers our contract manufacturing operations is manufacturing costs consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expense that we incur to deliver our medical devices to our customers is the cost per unit of production from our third-party contract manufacturers. Other associated expenses include sales-based royalties, amortization of intangible assets, shipping, logistics and the cost of support functions.

Research and Development Expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

We intend to focus our product development efforts on promising late-stage candidates that we believe satisfy well-defined criteria and seek to utilize collaborations or non-dilutive funding. We plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executive, sales and marketing, business development, government affairs, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales and contract manufacturing or research and development expense.

Critical Accounting Policies and Estimates

There have been no significant changes to our Critical Accounting Policies and Estimates during the nine months ended September 30, 2016,. Refer to the Critical Accounting Policies and Estimates section in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission.

Results of Operations

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

Revenues

	Three Months Ended September 30,			
(in thousands)	**2016**	**2015**	**Change**	**% Change**
Product sales:				
BioThrax	$ 94,116	$ 109,785	$ (15,669)	(14%)
Other	2,582	7,727	(5,145)	(67%)
Total product sales	96,698	117,512	(20,814)	(18%)
Contract manufacturing	14,712	11,341	3,371	30%
Contracts and grants	31,504	29,525	1,979	7%
Total revenues	$ 142,914	$ 158,378	$ (15,464)	(10%)

Product Sales:

The decrease in BioThrax sales was primarily due to the timing of deliveries to the SNS. The decrease in other product sales was primarily due to the timing of BAT sales to the SNS.

Contract Manufacturing:

The increase in Contract manufacturing is primarily due to the timing of fill/finish services provided to third parties.

Contracts and grants:

The increase in Contracts and grants was primarily due to:

- increased development funding of $6.9 million related to our CIADM program, including $3.2 million from new CIADM task orders;
- increased development funding of $3.8 million for NuThrax related to non-clinical studies and manufacturing activities; and
- increased development funding of $3.3 million for VIGIV related to plasma collection.

These increases were partially offset by:

- decreased development funding of $5.7 million for Anthrasil related to the timing of plasma collection; and
- decreased development funding of $5.2 million for large scale manufacturing of BioThrax due to our Building 55 facility receiving FDA approval in August 2016.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $4.4 million, or 13%, to $39.6 million for the three months ended September 30, 2016 from $35.2 million for the three months ended September 30, 2015. The increase was attributable to an increase in BioThrax sales to the SNS along with an increase in the BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced, partially offset by a decrease in BioThrax sales to the SNS. In addition, the increase is due to an increase in costs associated with underutilized manufacturing capacity at our Winnipeg site.

Research and Development Expenses

Research and development expenses decreased by $7.0 million, or 20%, to $27.2 million for the three months ended September 30, 2016 from $34.2 million for the three months ended September 30, 2015. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, our research and development expenses were fully funded during the three months ended September 30, 2016. Net of contracts and grants revenues, we incurred net research and development expenses of $4.7 million during the three months ended September 30, 2015.

Our principal research and development expenses for the three months ended September 30, 2016 and 2015 are shown in the following table:

	Three Months Ended September 30,			
(in thousands)	**2016**	**2015**	**Change**	**% Change**
Biodefense:				
Large-scale manufacturing for BioThrax	$ 1,491	$ 3,577	$ (2,086)	(58%)
BioThrax related programs	1,012	1,449	(437)	(30%)
PreviThrax	294	1,972	(1,678)	(85%)
NuThrax	6,182	3,764	2,418	64%
Pandemic influenza	201	5,243	(5,042)	(96%)
Anthrasil	178	3,923	(3,745)	(95%)
BAT	814	578	236	41%
EV-035 series of molecules	1,331	4,357	(3,026)	(69%)
CIADM task orders	2,600	375	2,225	593%
VIGIV	1,475	(828)	2,303	278%
Emergard	2,475	1,207	1,268	105%
Other	9,135	8,562	573	7%
Total	$ 27,188	$ 34,179	$ (6,991)	(20%)

The decrease in expense for large-scale manufacturing of BioThrax was primarily due to the completion of development work and the licensure of the large-scale manufacturing facility in August 2016. The decrease in expense for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in expense for PreviThrax was primarily due to the timing of non-clinical studies. In light of reduced funding by the U.S. government for this product candidate, we determined to cease further development work on our PreviThrax vaccine and expect the spending for PreviThrax will be minimal in the future. The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The decrease in spending for Pandemic influenza was primarily for a $5.0 million milestone payment to VaxInnate Corporation in the third quarter of 2015. The decrease in expense for our Anthrasil program was primarily due to the timing of plasma collection services. The spending for our BAT program was primarily related to stability testing and plasma collection. The decrease in expense for our EV-035 series of molecules was primarily due to pharmacologic and formulation activities and a third quarter 2015 non-cash impairment charge of $9.8 million due to toxicity related issues, partially offset by a third quarter 2015 $6.7 million reduction of contingent consideration associated with the estimated timing and probability of achievement for certain development and regulatory milestones. The increase in expense for CIADM task orders was primarily for manufacturing development for Ebola monoclonal antibodies. The increase in expense for VIGIV was primarily due to the timing of plasma collection partially offset by a reduction in 2015 of a liability to BARDA associated with 2013 manufacturing activities. The increase in expense for Emergard was primarily for formulation development. The spending for our Other activities was primarily for our funded pre-clinical product candidates and manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $14.9 million, or 58%, to $40.7 million for the three months ended September 30, 2016 from $25.8 million for the three months ended September 30, 2015. The increase includes costs associated with the Aptevo spin-off, restructuring activities at our Lansing, Michigan site, along with increased professional services to support our strategic growth initiatives, and increased information technology investments. In addition, during the third quarter of 2015, we recorded a $3.3 million reduction in contingent consideration related to the estimated timing and probability of potential future sales of EV-035.

Provision for Income Taxes

Provision for income taxes decreased by $6.9 million, or 34%, to $13.1 million for the three months ended September 30, 2016 from $20.1 million for the three months ended September 30, 2015. The decrease was primarily due to a $28.5 million decrease in income before provision for income taxes, partially offset by an increase in the effective tax rate related to one-time, non-cash charges to complete the Aptevo spin-off.

Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

Revenues

	Nine Months Ended September 30,			
(in thousands)	**2016**	**2015**	**Change**	**% Change**
Product sales:				
BioThrax	$ 193,255	$ 182,026	$ 11,229	6%
Other	15,530	22,537	(7,007)	(31%)
Total product sales	208,785	204,563	4,222	2%
Contract manufacturing	32,455	32,443	12	0%
Contracts and grants	95,879	92,541	3,338	4%
Total revenues	$ 337,119	$ 329,547	$ 7,572	2%

Product Sales:

The increase in BioThrax sales was primarily due to the timing of deliveries to the SNS. The decrease in Other product sales was primarily due to the timing of a $6.7 million decrease in BAT sales to the SNS and a one-time payment of $7.0 million for Anthrasil associated with FDA approval in the first quarter of 2015.

Contracts and grants:

The increase in Contracts and grants was primarily due to:

- § increased development funding of $25.5 million related to our CIADM program, including $13.0 million from new CIADM task orders;
- § increased development funding of $7.2 million for NuThrax related to non-clinical animal studies and manufacturing activities;and
- § increased development funding of $18.8 million for VIGIV related to plasma collection.

These increases were partially offset by:

- § decreased development funding of $36.9 million for Anthrasil related to the timing of plasma collection; and
- § decreased development funding of $8.5 million for large scale manufacturing of BioThrax due to our Building 55 facility receiving FDA approval in August 2016.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $19.9 million, or 27%, to $93.0 million for the nine months ended September 30, 2016 from $73.1 million for the nine months ended September 30, 2015. The increase was attributable to an increase in BioThrax sales to the SNS along with an increase in the BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced. In addition, the increase is due to an increase in costs associated with underutilized manufacturing capacity at our Winnipeg site.

Research and Development Expenses

Research and development expenses decreased by $12.6 million, or 13%, to $81.2 million for the nine months ended September 30, 2016 from $93.8 million for the nine months ended September 30, 2015. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, our research and development expenses were fully funded during the nine months ended September 30, 2016. Net of contracts and grants revenues, we incurred net research and development expenses of $1.3 million during the nine months ended September 30, 2015.

Our principal research and development expenses for the nine months ended September 30, 2016 and 2015 are shown in the following table:

	Nine Months Ended September 30,			
(in thousands)	**2016**	**2015**	**Change**	**% Change**
Biodefense:				
Large-scale manufacturing for BioThrax	$ 4,870	$ 8,526	$ (3,656)	(43%)
BioThrax related programs	2,701	2,732	(31)	(1%)
PreviThrax	1,369	5,772	(4,403)	(76%)
NuThrax	15,847	9,098	6,749	0%
Pandemic influenza	1,260	6,469	(5,209)	(81%)
Anthrasil	626	25,533	(24,907)	(98%)
BAT	2,964	4,277	(1,313)	(31%)
EV-035 series of molecules	2,973	6,076	(3,103)	(51%)
CIADM task orders	7,899	375	7,524	2,006%
VIGIV	7,428	(106)	7,534	7,108%
Emergard	7,645	2,405	5,240	218%
Other	25,591	22,676	2,915	13%
Total	$ 81,173	$ 93,833	$ (12,660)	(13%)

The decrease in expense for large-scale manufacturing of BioThrax was primarily due to the timing of manufacturing development activities due to the licensure of the large-scale manufacturing facility in August 2016. The spending for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in expense for PreviThrax was primarily due to the timing of non-clinical studies, and in light of reduced funding by the U.S. government for this product candidate, we determined to cease further development work on our PreviThrax vaccine and expect the spending for PreviThrax will be minimal in the future. The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The decrease in spending for Pandemic influenza was primarily for a $5.0 million milestone payment to VaxInnate Corporation in the third quarter of 2015. The decrease in expense for our Anthrasil program was primarily due to the timing of plasma collection services. The decrease in expense for our BAT program was primarily related to stability testing and plasma collection. The decrease in expense for EV-035 series of molecules was primarily due to pharmacologic and formulation activities and a third quarter 2015 non-cash impairment charge of $9.8 million due to toxicity related issues, partially offset by a third quarter 2015 $6.7 million reduction of contingent consideration associated with the estimated timing and probability of achievement for certain development and regulatory milestones. The increase in expense for CIADM task orders awarded was primarily for manufacturing development of Ebola monoclonal antibodies. The increase in expense for VIGIV was primarily due to the timing of plasma collection partially offset by a reduction in 2015 of a liability to BARDA associated with 2013 manufacturing activities. The increase in expense for Emergard was primarily for formulation development. The increase in spending for our Other activities was primarily for manufacturing development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $22.0 million, or 25%, to $108.3 million for the three months ended September 30, 2016 from $86.3 million for the nine months ended September 30, 2015. The increase includes costs associated with the Aptevo spin-off, restructuring activities at our Lansing, Michigan site, along with increased professional services to support our strategic growth initiatives, and increased information technology investments. In addition, during the third quarter of 2015 we recorded a $3.3 million reduction in contingent consideration related to the estimated timing and probability of potential future sales of EV-035.

Provision for Income Taxes

Provision for income taxes decreased by $3.7 million, or 16%, to $19.9 million for the nine months ended September 30, 2016 from $23.6 million for the nine months ended September 30, 2015. The decrease was primarily due to a $22.2 million decrease in income before provision for income taxes, partially offset by an increase in the effective tax rate related to one-time, non-cash charges to complete the Aptevo spin-off.

Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 2016, we have funded our cash requirements principally with a combination of revenues from sales of BioThrax, debt financing, development funding from government entities, non-government and philanthropic organizations, and collaborative partners, the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2015. As of September 30, 2016, we had cash and cash equivalents of $298.9 million.

At the closing of the spin-off of Aptevo from Emergent,we provided to Aptevo cash of $45 million from our cash reserves, along with a commitment in the form of a promissory note to provide another $20 million due within six to 12 months after the separation.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
(in thousands)	**2016**	**2015**
Net cash provided by (used in):		
Operating activities(i)	$ 62,800	$ 41,373
Investing activities	(56,243)	(33,631)
Financing activities	(20,420)	20,477
Net increase in cash and cash equivalents	$ (13,863)	$ 28,219

(i) Includes the effect of exchange rates on cash and cash equivalents.

Net cash provided by operating activities of $62.8 million for the nine months ended September 30, 2016 was primarily due to our net income of $14.4 million, a $45.0 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC along with non-cash charges of $28.2 million for depreciation and amortization and a $14.5 million increase in stock-based compensation expense, partially offset by an increase in inventories of $16.2 million, primarily due to the timing of deliveries of BioThrax to the CDC.

Net cash provided by operating activities of $41.4 million for the nine months ended September 30, 2015 was primarily due to our net income of $29.5 million and non-cash charges of $25.9 million for depreciation and amortization along with a $9.8 million impairment charge for EV-035, partially offset by an increase in inventories of

$14.4 million primarily due to the timing of deliveries of BioThrax to the CDC and a $10.9 million decrease in contingent consideration to Evolva for regulatory, development and sales-based royalty contingencies.

Net cash used in investing activities of $56.2 million for the nine months ended September 30, 2016 was due to infrastructure and equipment investments, including the construction of a third manufacturing suite at our Baltimore CIADM manufacturing facility.

Net cash used in investing activities of $33.6 million for the nine months ended September 30, 2015 was due to infrastructure and equipment investments.

Net cash used in financing activities of $20.4 million for the nine months ended September 30, 2016 was primarily due to $15.0 million in proceeds from the issuance of common stock pursuant to employee equity plans and $10.4 million in excess tax benefits from exercise of stock options that is partially offset by $45.0 million in cash provided to Aptevo on date of distribution, August 1, 2016.

Net cash provided by financing activities of $20.5 million for the nine months ended September 30, 2015 was primarily due to $15.9 million in proceeds from the issuance of common stock pursuant to employee equity plans, $8.0 million in excess tax benefits from the exercise of stock options and $2.0 million in proceeds from long-term indebtedness, partially offset by $5.4 million in contingent obligation payments.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources: existing cash and cash equivalents; revenues from product sales; development contracts and grants funding; contract manufacturing services and our revolving credit facility and any other lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- our ability to secure a new BioThrax procurement contract on favorable terms;
- the level, timing and cost of product sales;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase our common stock under our share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured revolving credit facility, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our credit facility restricts our ability to incur additional indebtedness, including secured indebtedness.

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations and financial condition would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Share Repurchase Program

On July 14, 2016, our board of directors authorized our management to repurchase, from time to time, up to an aggregate of $50 million of our common stock under a board-approved share repurchase program. The timing, amount, and price of any repurchases will be made pursuant to one or more 10b5-1 plans. The term of the board authorization of the repurchase program is until December 31, 2017. The plan will permit shares to be repurchased when we might otherwise be precluded from doing so based upon insider trading laws. The repurchase program may be suspended or discontinued at any time. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of September 30, 2016, we have neither implemented a repurchase plan nor repurchased any shares under this program.

ITEM 3. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

Our exposure to market risk is currently confined to our cash and cash equivalents. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates would likely increase the interest expense associated with our debt.

ITEM 4. ***CONTROLS AND PROCEDURES***

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During 2016, we completed the implementation of an enterprise resource planning ("ERP") system. In connection with the implementation, we updated the processes that constitute our internal control over financial reporting, as necessary, to accommodate related changes to our business processes and accounting procedures.

Although the processes that constitute our internal control over financial reporting have been materially affected by the implementation of this system and will require testing for effectiveness as the implementation progresses, we do not believe that the implementation has had or will have a material adverse effect on our internal control over financial reporting.

Except as otherwise described above, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the nine months ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

From time to time, we may be involved in various legal proceedings and claims that arise in or outside the ordinary course of our business. We believe that the outcome of these pending legal proceedings in the aggregate is unlikely to have a material adverse effect on our business, financial condition or results of operations.

Purported Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against the Company and certain of its senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that the Company made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts. Sponn is seeking unspecified damages, including legal costs. On October 25, 2016 the Court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robins Geller Rudman & Dowd LLP as Lead Counsel.

The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

ITEM 1A. RISK FACTORS

You should carefully consider, among other matters, the following risk factors in addition to the other information in this Quarterly Report on Form 10-Q when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flow. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flow. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flow.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

We may not realize some or all of the anticipated benefits of the spin-off of Aptevo due to a number of factors.

On August 1, 2016, we completed the spin-off of Aptevo Therapeutics Inc. Aptevo is now an independent public company trading under the symbol "APVO" on the NASDAQ Global Select Market. We may not realize some or all of the anticipated strategic, financial or other benefits from the spin-off. We are now smaller, less diversified with a narrower business focus and may be more vulnerable to changing market conditions, which could materially and adversely affect our business, financial condition and results of operations. Further, the combined value of the common stock of the two publicly-traded companies may not be equal to or greater than what the value of our common stock would have been had the spin-off not occurred.

If our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders, together with certain related transactions, does not qualify as a tax-free transaction for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

It is intended that our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders, or the Distribution, together with certain related transactions, qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended, or the Code. In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service, or the IRS, regarding certain U.S. federal income tax matters relating to the Distribution and certain related transaction and an opinion of counsel substantially to the effect that, for U.S. federal income tax purposes, the Distribution, together with certain related transactions, will qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code. A "private letter ruling," is a written statement issued to a taxpayer by an Associate Chief Counsel Office of the Office of Chief Counsel that interprets and applies the tax laws to a specific set of facts. Our private letter ruling is based on certain facts and representations submitted by us to the IRS and the opinion of counsel was based upon and relied on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of Emergent and Aptevo contained in a tax matters agreement and certain representations contained in representation letters provided by Emergent, Aptevo and certain stockholders to such counsel, including representations and covenants relating to the past and future conduct of Emergent, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants are, or become, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized and, as a result, the Distribution, together with certain related transactions, could fail to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code for U.S. federal income tax purposes.

In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the Distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of counsel only represents the judgment of such counsel, which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of counsel, there can be no assurance that the IRS will not assert that the Distribution, together with certain related transactions, should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the Distribution, together with certain related transactions, fails to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) we would recognize taxable gain on the Distribution equal to the amount by which the fair market value of the Aptevo shares distributed to our shareholders exceeded our tax basis in the Aptevo shares and (ii) each of our shareholders who received Aptevo shares in the Distribution would be treated as receiving a taxable distribution equal to the fair market value of the Aptevo shares received by such shareholder.

Under the tax matters agreement that we entered into with Aptevo in connection with the spin-off, Aptevo may be required to indemnify us against any tax liabilities and related expenses resulting from the failure of the Distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to our counsel for purposes of their opinion. Any such indemnity obligations could be material, and there can be no assurance that Aptevo will be able to pay any such indemnification.

To preserve the tax-free treatment of the Distribution, together with certain related transactions, and in addition to Aptevo's indemnity obligation, the tax matters agreement restricts Aptevo from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for the two-year period following the Distribution, Aptevo is restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the Distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. There can be no assurance that Aptevo will comply with these restrictions. Failure of Aptevo to satisfy its obligations could have a substantial impact on our tax obligations, consolidated financial condition and cash flows.

GOVERNMENT CONTRACTING RISKS

We currently derive the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If we are unable to secure a new procurement contract for BioThrax on favorable terms, or the U.S. government's demand for and funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow could be materially harmed.

We have derived and currently expect to derive the majority of our revenue from sales of BioThrax, our anthrax vaccine licensed by the U.S. Food and Drug Administration, or the FDA, to the U.S. government. We are currently party to a contract with the Centers for Disease Control and Prevention, or the CDC, for the supply of up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or the SNS, over a five-year period, which was scheduled to expire on September 30, 2016. On September 21, 2016, the CDC exercised an option to procure all remaining BioThrax doses, thereby committing to take delivery of the full 44.75 million doses and granted a no-cost extension to enable delivery of the remaining doses under this contract to be completed by November 30, 2016.

On June 21, 2016, the U.S. Department of Health and Human Services, or HHS, issued a Sole Source Notification indicating its intention to award Emergent a follow-on contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years. The solicitation does not state the number of doses expected to be procured per year, but represents a smaller annual procurement on average over the five-year period of the anticipated contract than under our current contract. As of the date hereof, we remain in active negotiations with respect to this anticipated contract. The terms of the anticipated contract, including the price per dose and the timing of deliveries, remain subject to contract negotiation, and there can be no assurance that we will reach agreement on the terms of a follow-on BioThrax procurement contract.

In addition, the procurement of doses of BioThrax by the CDC remains subject to the availability of funding. Our existing contract with the CDC for BioThrax does not, and any follow-on procurement contract for BioThrax will not, guarantee that funding for the procurement of doses will be made available. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available, and our business, financial condition and operating results could be materially harmed. The success of our business and our operating results for the foreseeable future are significantly dependent on the level of funding for the procurement of BioThrax and the terms of our BioThrax sales to the U.S. government, including the price per dose, the number of doses and the timing of deliveries. If we are unable to secure a new contract for

procurement of BioThrax on acceptable terms, or if the U.S. government's demand for and level of funding for procurement of BioThrax is reduced, our business, financial condition, operating results and cash flows could be materially harmed.

Our submission of NuThrax for Emergency Use Authorization pre-approval and eventual FDA licensure may not be approved by the FDA in a timely manner or at all. Delays in our ability to achieve such pre-approval and licensure could prevent us from realizing the full potential value of our BARDA contract for the advanced development and delivery of NuThrax.

On September 30, 2016, we entered into a contract with HHS, through the Biomedical Advanced Research and Development Authority, or BARDA, for the advanced development and delivery of NuThrax, our next generation anthrax vaccine candidate. The contract, valued at up to approximately $1.6 billion, consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses, following receipt of Emergency Use Authorization, or EUA, pre-approval by the FDA. Although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early as 2018, triggering deliveries of NuThrax to the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at approximately $48 million, which if both were to be exercised in full, would increase the potential total contract value to up to approximately $1.6 billion.

We currently intend to submit an application in 2017 with the FDA for EUA pre-approval, so that NuThrax may be delivered to the SNS for use in an emergency situation as early as 2019. However, the FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any approval of an EUA pre-approval submission is uncertain. We cannot guarantee that the FDA will review our data in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for EUA pre-approval and require additional pre-clinical, clinical or other studies and refuse to approve our application. If we are unsuccessful in obtaining EUA pre-approval for NuThrax and eventual FDA licensure in a timely manner or at all, we may not be able to realize the full potential value of the contract, which could have a material adverse effect on our future business, financial condition, operating results and cash flow.

In addition, if the SNS priorities change, funding to procure any future doses of NuThrax may be limited or not available, and our future business, financial condition and operating results could be materially harmed.

Our U.S. government procurement and development contracts require ongoing funding decisions by the U.S. government. Reduced or discontinued funding of these contracts could cause our business, financial condition, operating results and cash flow to suffer materially.

Our principal customer for BioThrax, BAT, Anthrasil, VIGIV and RSDL products and our primary source of funds for the development of our NuThrax product candidate is the U.S. government. We anticipate that the U.S. government will also be a principal customer for other Biodefense products that we successfully acquire or develop. Additionally, a significant portion of our revenue comes from U.S. government development contracts and grants. Over its lifetime, a U.S. government procurement or development program may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. For example, sales of BioThrax supplied under our current procurement contract with the CDC as well as sales of BioThrax to be supplied under our expected follow-on procurement contract with the CDC and any future sales of NuThrax that may be supplied under our contract with BARDA for the development and delivery of NuThrax to the SNS are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, in April 2016, we were notified by BARDA that, after prioritization of its development funding, BARDA would not be exercising the clinical trial option for our PreviThrax rPA vaccine development program. As a consequence of this decision, we determined to cease further development work on our PreviThrax vaccine product candidate. Additionally, our government-funded development contracts typically give the U.S. government the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the contract with BARDA we were awarded in September 2016 for the development and delivery to the SNS of NuThrax for post-exposure prophylaxis of anthrax disease consists of a five-year base period of performance valued at approximately $200 million to develop NuThrax to deliver to the SNS an initial two million doses, following receipt of EUA pre-approval by the FDA, includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax to the SNS, valued from approximately $255 million to up to $1.4 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which if both were to be exercised in full, would increase the total contract value to up to $1.6 billion. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under our contracts, our business, revenues and operating results would suffer.

The government contracting process is typically a competitive bidding process and involves unique risks and requirements.

Our business involves government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks and requirements, including:

- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- in the event our competitors protest or challenge contract or grant awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development of our Biodefense product candidates or for the procurement of our Biodefense products, and may instead award such contracts to our competitors. If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those contracts. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs or resources that we will be required to secure and, if applicable, perform under such contract awards, our growth strategy and our business, financial condition and operating results could be materially and adversely affected.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws could result in significant civil and criminal penalties and materially damage our relationship with the U.S. government.

We must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. Among the most significant government contracting regulations that affect the business of our Biodefense division are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the Defense Federal Acquisition Regulations, or DFARs, and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of U.S. Department of Defense, or DoD, government contracts;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- export and import control laws and regulations, including but not limited to ITAR (International Traffic in Arms Regulations); and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

U.S. government agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. If we are audited and such audit was to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting and significant reputational harm.

The amount we are paid under our fixed price government procurement contracts is based on estimates we have made of the time, resources and expenses required for us to perform under those contracts. If our actual costs exceed our estimates, we may not be able to earn an adequate return or may incur a loss under these contracts, which could harm our operating results and materially reduce our net income.

Some of our current contracts with HHS and the DoD for the procurement of our Biodefense products are fixed price contracts. We expect that our potential future contracts with the U.S. government for our Biodefense products also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

Unfavorable provisions in government contracts, some of which may be customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our financial condition and operating results.

Government contracts customarily contain provisions that give the U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the U.S. government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders, if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract;
- decline to renew a procurement contract;
- § claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our contract for procurement of BioThrax and our contract for the development and delivery of NuThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. Our CDC contract for the procurement of BioThrax and our contract with BARDA for the development and delivery of NuThrax to the SNS are, and our expected follow-on contract for the procurement of BioThrax and our future U.S. government procurement and development contracts are likely to be, terminable at the U.S. government's convenience with these potential consequences.

Our U.S. government contracts grant the U.S. government the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the U.S. government. Under our U.S. government contracts, we might not be able to prohibit third parties, including our competitors, from accessing such technology or data, including intellectual property, in providing products and services to the U.S. government.

COMMERCIALIZATION RISKS

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future from other companies and governments, universities and other non-profit research organizations. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may devote greater resources to market or sell their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, initiate or withstand substantial price competition more successfully than we can, or more effectively negotiate third-party licensing and collaborative arrangements.

There are a number of companies with biodefense products or product candidates competing with us for both U.S. government procurement and development resources. For example, in terms of additional procurement of anthrax countermeasures, HHS awarded an SNS procurement contract to GlaxoSmithKline plc for ABThrax™ (raxibacumab), an FDA-approved anthrax monoclonal antibody therapeutic, and recently awarded an SNS procurement contract to Elusys Therapeutics, Inc. for Anthim (obiltoxaximab), an FDA-approved anthrax monoclonal antibody therapeutic.

Any reduction in demand for our products as a result of a competing product could lead to reduced revenues, reduced margins, reduced levels of profitability and loss of market share for our products. These competitive pressures could adversely affect our business and operating results.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, BAT, Anthrasil, and VIGIV or our "Biologic Products," may be affected by follow-on biologics, or "biosimilars" in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars, although the European Medicines Agency has expressly excluded blood or plasma-derived products and their recombinant alternatives from the biosimilar pathway for a period of time. Vaccine and allergen products are considered on a case-by-case basis. The specific regulatory framework for this new approval pathway, whether the FDA will permit biosimilars for blood products and vaccines, and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors that are currently unknown. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business and operating results.

Political or social factors may delay or impair our ability to market our products and may require us to spend significant management time and financial resources to address these issues.

Products developed to treat diseases caused by or to combat Chemical, Biological, Radiological, Nuclear and Explosives, or CBRNE, threats are subject to changing political and social environments. The political responses and social awareness of the risks of biowarfare and bioterrorism attacks on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk of bioterrorism may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which could negatively affect our revenues.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our Biodefense products and thereby limit the demand for our Biodefense products, which would adversely affect our revenues.

REGULATORY AND COMPLIANCE RISKS

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates and, if we are not successful, our business and operating results may suffer.

Our product candidates and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Except under limited circumstances related to certain government sales, failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

In the United States, to obtain approval from the FDA to market any of our future biologic products, we will be required to submit a biologics license application, or BLA, to the FDA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, NuThrax or any of our Biodefense product candidates, for example, is subject to a different regulatory approval pathway. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant efficacy for these product candidates cannot be demonstrated in humans. Instead, efficacy must be demonstrated, in part, by utilizing animal models instead of testing in humans. This is known as the FDA's "Animal Rule." We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax or any Biodefense product candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, the FDA may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. For example, to the extent feasible and ethical, manufacturers of products approved pursuant to the Animal Rule must conduct post-

marketing studies, such as field studies, to verify and describe the product candidate's clinical benefit and to assess its safety when used as indicated. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process may cause delays in the approval or rejection of an application.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current good manufacturing practices, or cGMP, requirements relating to quality control, quality assurance, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Our regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our facilities where Canadian marketed products are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other world regulatory agencies conduct periodic inspections of our facilities. For example, our Lansing Building 55 facility was inspected most recently by the FDA in June 2016, our Lansing Building 12 facility was inspected most recently by the FDA in April 2016, our Winnipeg manufacturing facility was inspected most recently by the FDA in January 2015 and Health Canada in March 2015, and our Baltimore (Camden) facility was most recently inspected by Health Canada in October 2016 and the FDA in August 2015. Following each of these inspections, both the FDA and Health Canada have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, the FDA or Health Canada find that we are not in substantial compliance with cGMP requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

- warning letters and other communications;
- product seizure or withdrawal of the product from the market;
- restrictions on the marketing or manufacturing of a product;
- suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;
- fines or disgorgement of profits or revenue; and
- injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

Failure to obtain or maintain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could limit the growth of our business.

We currently sell and intend to sell certain of our products outside the United States that are currently sold only in the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax, which would harm our business, financial condition and operating results.

We have completed the transition to moving BioThrax manufacturing from our Building 12 manufacturing facility on our Lansing, Michigan campus to Building 55, our large-scale manufacturing facility on our Lansing, Michigan campus. Any interruption in manufacturing operations at Building 55 could result in our inability to produce BioThrax for delivery to satisfy the product demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flow. A number of factors could cause interruptions, including:

- § equipment malfunctions or failures;
- § technology malfunctions;
- § cyber-attacks;
- § work stoppages or slow-downs;
- § protests, including by animal rights activists;
- § injunctions or the imposition of civil or criminal penalties.
- § damage to or destruction of the facility; or
- § product contamination or tampering.

Providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our Biodefense Baltimore facility as facilities requiring additional security. Although we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect our facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facility in Winnipeg, Manitoba, Canada. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our biologic products, our product candidates and our ability to produce products for external customers, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition and operating results.

We may not be able to utilize the full manufacturing capacity of Building 55, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

On August 15, 2016, we received FDA approval for the manufacture of BioThrax in Building 55, our large-scale manufacturing facility on our Lansing, Michigan campus and have moved BioThrax manufacturing to Building 55, which significantly increases our BioThrax manufacturing capacity compared to the capacity of our Building 12 licensed facility. Although we recently secured FDA approval for the manufacture of BioThrax in Building 55 and have begun to utilize Building 55, we may not secure procurement contracts for BioThrax or other products or product candidates sufficient to utilize its full manufacturing capacity. For example, on June 21, 2016, HHS issued a Sole Source Notification indicating its intention to award Emergent a contract for the purchase of 29.4 million doses of BioThrax with a period of performance of five years.

As of the date hereof, we remain in active negotiations with respect to this solicitation. Although the notification does not state the number of doses expected to be procured per year, the 29.4 million doses represents a smaller annual procurement on average over the five-year period of the anticipated contract than under our current contract. An inability to utilize the full manufacturing capacity of Building 55 could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

Our biologic products and product candidates are complex to manufacture and ship, which could cause us to experience delays in product manufacturing or development and resulting delays in revenues.

BioThrax, BAT, Anthrasil, VIGIV, and many of our current product candidates, including NuThrax, are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from, among other things, particulates, filtration, filling, labeling, packaging, storage and shipping, and quality control testing, may result in lot (as defined below) failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, including warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business.

For example, FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 186,000 doses. We are not able to sell any lots that fail to satisfy the release testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax is performed against a qualified control lot that we maintain. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. We continually monitor the status of our control lot and periodically produce and qualify a new control lot to replace the existing control lot. If we are not able to produce and qualify a new control lot or otherwise satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet the FDA's requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly impact our revenues. Delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

If we are unable to obtain supplies for the manufacture of BioThrax or our other products and product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our other products and product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise harm our business.

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of BioThrax and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and NuThrax. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL and the specialty plasma in our hyperimmune specialty plasma products. A disruption in the availability of such materials or services from these suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise harm our business, financial condition and operating results.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

PRODUCT DEVELOPMENT RISKS

Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant efforts and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the U.S. government's interest in providing development funding for or procuring certain of our Biodefense product candidates, and the commercial viability of our acquired or developed product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of manufacturing that meets FDA requirements;
- successful program partnering;
- successful completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
- receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
- establishment of commercial manufacturing processes and product supply arrangements;
- training of a commercial sales force for the product, whether alone or in collaboration with others;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government customers.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners where applicable must conduct extensive preclinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

For certain of our Biodefense product candidates, we expect to rely on the Animal Rule to obtain regulatory approval. The Animal Rule permits, in certain limited circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. We have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans. Under the Project BioShield Act of 2004, or Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an Emergency Use Authorization. If our Biodefense product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms.

We may experience unforeseen events or issues during, or as a result of, preclinical testing, clinical trials or animal efficacy studies. These issues and events, which could delay or prevent our ability to receive regulatory approval for a product candidate, include, among others:

- our inability to manufacture sufficient quantities of materials for use in trials;
- the unavailability or variability in the number and types of subjects for each study;
- safety issues or inconclusive or incomplete testing, trial or study results;
- drug immunogenicity;
- lack of efficacy of product candidates during the trials;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and, as a result, our business may suffer.

We do not have the ability to independently conduct the clinical and non-clinical trials required to obtain regulatory approval for our product candidates. We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. For example, in April 2016, we were notified by BARDA that, after prioritization of its development funding, BARDA would not be exercising the clinical trial option for our PreviThrax rPA vaccine program. As a consequence of this decision, we determined to cease further development work on our PreviThrax vaccine product candidate. As a result of changes in our strategy or in government development funding decisions, we may change or refocus our existing product development, commercialization and manufacturing activities. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, our business could be harmed.

Our success, particularly with respect to our small molecule product candidates, will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology, products and product candidates. Obtaining and maintaining this protection is very costly. The patentability of technology in the biopharmaceutical field generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. In the past, we have abandoned the prosecution and/or maintenance of patent applications related to patent families in the ordinary course of business. In the future we may choose to abandon such prosecution and/or maintenance in a similar fashion. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defensive measures.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subject to opposition proceedings. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by or incorporating them. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license from Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our anthrax vaccine product candidate NuThrax.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

Third parties may choose to file patent infringement claims against us; defending ourselves from such allegations would be costly, time-consuming, distracting to management and could materially affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold sufficient licenses or other rights. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the United States and abroad. These third parties may have substantially greater financial resources than us and could bring claims against us that could cause us to incur substantial expenses to defend against these claims and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biopharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, if at all, or if an injunction is granted against us, which could harm our business significantly.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license and/or sue us for breach, which could cause us to not be able to market any product that is covered by the licensed patents and may be subject to damages.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for any of our current products, our only intellectual property protection for these products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and unique starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, through agreements with our employees, consultants and third parties as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known, including through a potential cyber security breach, or may be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

Our strategy of generating growth through acquisitions may not be successful.

Our business strategy includes growing our business through acquisition and in-licensing transactions. We may not be successful in identifying, effectively evaluating, structuring, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in the biopharmaceutical field. These companies may have a competitive advantage over us due to their size, cash resources, cost of capital, effective tax rate and greater clinical development and commercialization capabilities.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. For example, in part to fund our acquisition of Cangene Corporation, we issued $250 million of senior convertible notes in January 2014. If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our financial results.

Our failure to successfully integrate acquired assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

We may not be able to integrate any acquired business successfully or operate any acquired business profitably. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

Issues that could delay or prevent successful integration or cost synergies of an acquired business include, among others:

- retaining existing customers and attracting new customers;
- retaining key employees;
- diversion of management attention and resources;
- conforming internal controls, policies and procedures, business cultures and compensation programs;
- consolidating corporate and administrative infrastructures;
- consolidating sales and marketing operations;
- identifying and eliminating redundant and underperforming operations and assets;
- assumption of known and unknown liabilities;
- coordinating geographically dispersed organizations; and
- managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business.

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our operations to pay our substantial debt.

As of September 30, 2016, our total consolidated indebtedness was $253 million, including $250 million of obligations under our senior convertible notes. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

In addition to our current debt, we also have a senior secured revolving credit facility with available capacity of up to $100 million, effective until December 11, 2018 (or such earlier date to the extent required by the terms of this facility). We may seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
- subjecting us, as under our senior secured revolving credit facility, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
- requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
- limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

We may not have sufficient funds or be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under other debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests, if any, in our assets securing our indebtedness.

We may require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our ability to grow our business, results of operations and financial condition.

We may require significant additional funding to grow our business, including to acquire other companies or products, in-license and develop additional products, enhance our manufacturing capacity, support commercial marketing activities or otherwise provide additional financial flexibility. We may also require additional funding to support our ongoing operations in the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, reducing our BioThrax revenues and decreasing our cash balances.

As of September 30, 2016, we had approximately $298.9 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including, among others:

- the level, timing and cost of product sales;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from government entities for our development programs; and
- the costs of commercialization activities, including product marketing, sales and distribution.

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured revolving credit facility, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us. We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on our indebtedness. However, our credit facility restricts our ability to incur additional indebtedness, including secured indebtedness.

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations and financial condition would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

We may not maintain profitability in future periods or on a consistent basis.

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. For example, we incurred a net loss in the first and second quarters of 2016 and in each of the first quarters of 2015, 2014, 2013 and 2012. Our profitability has been substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the U.S. government. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

OTHER BUSINESS RISKS

Pending litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact the company and its financial condition and results of operations.

From time to time, we may be named as a defendant in various legal actions or other proceedings. Certain of these actions include and future actual or threatened legal actions may include claims for substantial and indeterminate amounts of damages, or may result in other results adverse to us.

For example, as more fully described under Part II, "ITEM 1 – LEGAL PROCEEDINGS," on July 19, 2016, a purported class action lawsuit was filed against us and several of our senior officers and directors in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between January 11, 2016 and June 21, 2016. The complaint alleges, among other things, that we made false and misleading statements about the government's demand for BioThrax and expectations that our five-year exclusive procurement contract with HHS would be renewed.

The results of this lawsuit and possible other future legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses, if any. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the purported class action lawsuit or in other future legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that may adversely affect our business, financial condition and results of operations, possibly materially.

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005. The PREP Act creates immunity for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide immunity from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, BAT, Anthrasil and VIGIV as covered countermeasures. These declarations expire in 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

Additionally, BioThrax and RSDL are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002, or SAFETY Act. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from claims made against us.

If we cannot successfully defend ourselves against future claims that our products or product candidates caused injuries and if we are not entitled to indemnity by the U.S. government, or the U.S. government does not honor its obligations to us under the PREP Act or SAFETY Act, or if the indemnification under the PREP Act and SAFETY Act is not adequate to cover all claims, we may incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand or withdrawal of a product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- an inability to commercialize products that we may develop.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, BAT, Anthrasil and VIGIV and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could adversely affect our business, financial condition and operating results.

Our success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we are unable to retain the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including equity incentive awards. If we cannot offer a competitive compensation package to attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our common stock, including an ability to influence the election of the members of our Board of Directors, or delay or prevent a change of control of us.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of October 31, 2016, Mr. El-Hibri was the beneficial owner of approximately 14% of our outstanding common stock. As a result, Mr. El-Hibri could delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial influence over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;
- advance notice requirements for stockholder nominations of candidates for election to the Board of Directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue a new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a corporation from engaging in a business combination with an interested stockholder, generally a person which, together with its affiliates, owns or within the last three years has owned 15% or more of the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Our stockholder rights plan could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests.

Under our stockholder rights plan, we issue to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of $150 in cash, subject to adjustments.

Our stockholder rights plan is intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests or those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

Our stock price is volatile and purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 31, 2016, our common stock has traded as high as $44.38 per share and as low as $4.40 per share. The stock market in general as well as the market for biopharmaceutical companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- contracts, decisions and procurement policies by the U.S. government affecting BioThrax and our other biodefense products and product candidates;
- the success of competitive products or technologies;
- results of clinical and non-clinical trials of our product candidates;
- announcements of acquisitions, financings or other transactions by us;
- announcements relating to litigation or legal proceedings;
- public concern as to the safety of our products;
- termination or delay of a development program;
- the recruitment or departure of key personnel;
- variations in our product revenue and profitability; and
- the other factors described in this "Risk Factors" section.

Because we currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We currently do not pay dividends on our common stock. Our senior secured credit facility and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of October 28, 2016, have the right to require us to register these shares of common stock under specified circumstances. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, would provide for a secondary offering of these shares from time to time.

ITEM 2. ***UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS***

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. ***DEFAULTS UPON SENIOR SECURITIES***

Not applicable.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

ITEM 5. ***OTHER INFORMATION***

Not applicable.

ITEM 6. ***EXHIBITS***

The exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto.

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2016

By: /s/ROBERT G. KRAMER
Robert G. Kramer
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: November 8, 2016

EXHIBIT INDEX

Exhibit Number	Description
2.1	Contribution Agreement, dated July 29, 2016, by and among Emergent BioSolutions Inc., Aptevo Therapeutics Inc., Aptevo Research and Development LLC and Aptevo BioTherapeutics LLC (incorporated by reference to Exhibit 2.1 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016).
2.2	Separation and Distribution Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 2.2 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016).
10.1	Promissory Note, dated July 29, 2016, made by Emergent BioSolutions Inc. in favor of Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on August 5, 2016).
10.2#††	Award/Contract, effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc.
10.3#††	Modification No. 16 to the Solicitation, Offer and Award, effective September 30, 2011, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (the "CDC BioThrax Procurement Contract"), effective March 22, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.4#	Modification No. 17 to the CDC BioThrax Procurement Contract, effective April 19, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.5#††	Modification No. 18 to the CDC BioThrax Procurement Contract, effective May 6, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.6#††	Modification No. 19 to the CDC BioThrax Procurement Contract, effective August 11, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.7#††	Modification No. 20 to the CDC BioThrax Procurement Contract, effective September 7, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.8#††	Modification No. 21 to the CDC BioThrax Procurement Contract, effective September 8, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.9#	Modification No. 22 to the CDC BioThrax Procurement Contract, effective September 20, 2016, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
12#	Ratio of Earnings to Fixed Charges.
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101. INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linksbase Document.
101.DEF	XBRL Taxonomy Definition Linksbase Document.
101.LAB	XBRL Taxonomy Label Linksbase Document.
101.PRE	XBRL Taxonomy Presentation Linksbase Document.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language):

(i) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015;
(ii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2016 and 2015;
(iii) Condensed Consolidated Balance Sheets at September 30, 2016 and December 31, 2015;
(iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015; and
(v) Notes to Consolidated Financial Statements.

Filed herewith.

†† Confidential treatment requested with the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

EXHIBIT 12

Ratio of Earnings to Fixed Charges

(in thousands)	Year to Date September 30, 2016	Year Ended December 31, 2015	2014	2013	2012	2011
Pretax income (loss) from continuing operations (1)	$ 50,099	$ 89,769	$ 53,062	$ 44,243	$ 37,446	$ 38,849
Fixed charges						
Interest expense	5,787	7,834	7,480	1,973	2,177	1,719
Debt issuance cost	1,145	1,564	3,290	319	67	135
Total fixed charges (2)	6,932	9,398	10,770	2,292	2,244	1,854
Noncontrolling interest in pretax income (3)	-	-	-	876	5,381	6,906
Capitalized interest (4)	1,850	2,875	2,530	1,973	2,177	1,713
Earnings ((1) + (2) -(3) -(4))	55,181	96,292	61,302	43,686	32,132	32,084
Fixed charges	6,932	9,398	10,770	2,292	2,244	1,854
Ratio of earnings to fixed charges	8.0	10.2	5.7	19.1	14.3	17.3
Coverage deficiency	-	-	-	-	-	-

EXHIBIT 31.1

CERTIFICATION

I, Daniel J. Abdun-Nabi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;

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

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

4. The registrant's other certifying officer 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.

Date: November 8, 2016

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Robert G. Kramer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions Inc.;

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

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

4. The registrant's other certifying officer 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.

Date: November 8, 2016

/s/ROBERT G. KRAMER
Robert G. Kramer
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Abdun-Nabi, Chief Executive Officer of the Company, 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.

Date: November 8, 2016

/s/DANIEL J. ABDUN-NABI
Daniel J. Abdun-Nabi
Chief Executive Officer

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Kramer, Chief Financial Officer of the Company, 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.

Date: November 8, 2016

/s/ROBERT G. KRAMER
Robert G. Kramer
Chief Financial Officer

EXHIBIT 10.2

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions. **AWARD/CONTRACT**	1.THIS CONTRACT IS A RATED ORDER UNDER OPAS (15 CFR 700) RATING	PAGE OF PAGE 1 46

2. CONTRACT *(Proc Inst Ident.)* NO. HHSO100201600030C	3. EFFECTIVE DATE See Block 20C	4. ACQUISITION (PURCHASE REQUEST NO. OS165547

5. ISSUED BY CODE ASPR-BARDA	6. ADMINISTERED BY *(If other than ASPR-BARDA by)CODE* ASPR BARDA
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR *(No., Street, City Country, State and ZIP Code)* EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869 EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419	8. DELIVERY FOB ORIGIN	x OTHER *(See below)*
	9. DISCOUNT(FOR PROMPT PAYMENT	
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN }	ITEM

CODE 1365869	FACILITY CODE

11. SHIP TO/MARK FORCODE HHS/OS/ASPR	12. PAYMENT WILL BE MADE BY CODE PSC
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201	Program Support Center 330 Independence Avenue SW Washington DC 20201
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION 10 USC 2304(c)( ) 41 USC 253(c) ( )	14. ACCOUNTING AND APPROPRIATION DATA 2016.1990007.26201

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT }				$198,705,042.00

16. TABLE OF CONTENTS

(X)	SEC	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	
PART 1 – THE SCHEDULE					PART II – CONTRACT CLAUSES		
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	42
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3		PART III –LIST OF DOCUMEMTS, EXHIBITS AND OTHER ATTACH		
X	C	DESCRIPTION/SPECS/WORK STATEMENT	10	X	J	LIST OF ATTACHMENTS	46
X	D	PACKAGING AND MARKING	11		PART IV – REPRESENTATIONS AND INSTRUCTIONS		
X	E	INSPECTION AND ACCEPTANCE	12		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	13		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	22		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	26				

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED BID PROCUREMENT) AS APPLICABLE

17. X CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return 2 copies to issuing office.)* Contractor agrees to furnish and deliver all items to perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. SEALED BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)* Adam Havey		20A. NAME OR CONTRACTING OFFICER BROOKE T. BERNOLD	
19B. NAME OF CONTRACTOR Emergent BioSolutions BY */s/ Adam Havey* *(Signature of person authorized to sign)*	19C. DATE SIGNED Sep 28, 2016	20B. UNITED STATES OF AMERICA BY */s/ Brooke Bernold* *(Signature of the Contracting Officer)*	20C. DATE SIGNED 9/30/2016

NAME OF OFFEROR OR CONTRACTOR
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: [**] DUNS Number: [**] Next Generation Anthrax Vaccine Delivery: 09/27/2016 Appr. Yr.: 2016 CAN: 1990007 Object Class: 26201 FOB: Destination Period of Performance: 09/30/2016 to 09/29/2021				
1	ASPR-16-06550 – CLIN 0001 and CLIN 0002 – Base contract to Emergent for the Manufacturing Development and Procurement of AV7909 (FDA Licensure and Approval/Initial Purchase, Storage, and Delivery of Product Obligated Amount: $198,705,042.00				198,705,042.00
2	CLIN 0001A – Phase II [**] Study of Studies Required by the FDA [**] Amount: $[**] (Option Line Item)				0.00
3	CLIN 0003 Post IV Marketing Commitments Amount: $[**] (Option Line Item)				0.00
4	CLIN 0004 (A-H) for Additional Surge Capacity (Based on [**] doses at the licensure price of $[**]) Amount: $[**] (Option Line Item)				0.00

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Emergent Product Development Gaithersburg Inc. is developing NuThrax vaccine as a next generation anthrax vaccine. This vaccine is intended to mitigate anthrax as a bio threat against civilian populations suitable for Post-Exposure Prophylaxis (PEP) as a priority medical countermeasure.

Under the base period-of-performance, Emergent will complete remaining development activities necessary to achieve licensure of the vaccine and manufacture and deliver vaccine product into the Strategic National Stockpile (SNS). The contract options may be exercised to perform additional studies necessary for licensure, support post-licensure commitments as required by the FDA, and procure additional treatment courses for the SNS.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and several options, if necessary, as specified in this contract. The period of performance for the base period is 60 months.

ARTICLE B.2. BASE PERIOD

CLIN	Period of Performance	Supplies/ Services	Total Est. Cost	Fixed Fee (7%)	Total Cost Plus Fixed Fee
COST REIMBURSEMENT					
0001 (Base)	**09/30/2016 – 09/29/2021**	**Licensure, approval, and clearance of product through the FDA**	**[**]**	**[**]**	**[**]**
FIRM FIXED PRICE					
CLIN	**Period of Performance**	**Supplies/ Services**	**Units (# of Doses)**	**Unit Price ($)**	**Total ($)**
0002 (Base)	**09/30/2016 – 09/29/2021**	**Initial Purchase, Storage, and Delivery of Product**	**2,000,000**	**[**]**	**[**]**
Total CLINS 1&2	**09/30/2016 – 09/29/2021**	**See Above Descriptions**			**$198,705,042 (Funded)**

ARTICLE B.3. OPTION PRICES

CLIN	Period of Performance	Supplies/ Services	Total Est. Cost	Fixed Fee	Total Cost Plus Fixed Fee ($)
		COST REIMBURSEMENT			
0001A (Option Quantity)	[**]	Phase II [**] Study or studies required by the FDA [**]	[**]	[**]	[**]

CLIN	Period of Performance	Supplies/ Services	Total Est. Cost	Fixed Fee	Total Cost Plus Fixed Fee ($)
		FIXED PRICE			
0003 (Option Quantity)	[**]	Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA)	N/A	N/A	[**]

CLIN	Period of Performance	Supplies/ Services	Units (# of Product)	FY 2018 Unit Price ($)	Total ($)
0004A (Option Quantity)	[**]	Additional Surge Capacity (EUA)	7,500,000 to [**]	[**]	[**]
0004B (Option Quantity)	[**]	Additional Surge Capacity (Licensure)	7,500,000 to [**]	[**]	[**]
0004C (Option Quantity)	[**]	Additional Surge Capacity (EUA)	[**]	[**]	[**]
0004D (Option Quantity)	[**]	Additional Surge Capacity (Licensure)	[**]	[**]	[**]
0004E (Option Quantity)	[**]	Additional Surge Capacity (EUA)	[**]	[**]	[**]
0004F (Option Quantity)	[**]	Additional Surge Capacity (Licensure)	[**]	[**]	[**]
0004G (Option Quantity)	[**]	Additional Surge Capacity (EUA)	[**]	[**]	[**]
0004H (Option Quantity)	[**]	Additional Surge Capacity (Licensure)	[**]	[**]	[**]

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:

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

2. Special rearrangement or alteration of facilities;

3. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of

personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings;

5. 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 as items of personal property, supplies and equipment that are highly desirable and easily converted to personal use), 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. Clinical Trial Insurance

b. Travel Costs

1. During the Base Period total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract shall not exceed **$[**]** without prior advance written approval by the Contracting Officer. Costs must be consistent with FAR 52.247-63 – Preference for U.S.- Flag Air Carriers.

2. The Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.205-46, Contracts with Commercial Organizations, Travel Costs.

3. Requests for foreign travel 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.5. ADVANCE UNDERSTANDINGS

a. Subcontracts and Consultants

Award of **any FFP subcontract or FFP consulting agreement in excess of $150,000 or any cost reimbursement subcontract or consulting agreement** shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued 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 and consulting agreement shall be provided to the Contracting Officer within ten (10) calendar days of full execution.

b. Site Visits, Inspections and General 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. In case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable 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.
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 an issue 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 issues 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 within a time frame negotiated with the COR in writing after review of the issues report.

c. QA Audits

BARDA reserves the right to participate in QA audits. Upon completion of the QA audit the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and 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.

- Contractor shall notify the COR and CO within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

d. Man-in-Plant

At the discretion of the Government and seven calendar (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in- plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

e. Emergency Use Authorization (EUA)

The Contractor shall be responsible for generating the data to support the USG's filing of a Pre-Emergency Use Authorization (Pre-EUA) package for use of the product prior to FDA licensure or approval during a declared emergency, declared potential emergency, or identification of material threat under an Emergency Use Authorization (EUA).

The Contractor commits to supporting the potential use of the product under a pre-EUA package as submitted by BARDA or the CDC/SNS. The Contractor shall supply BARDA or the CDC/SNS with the data needed to support such a submission, including expanded access INDs, right to hold product, right of reference to the Contractor's Investigational New Drug (IND), or other application that contains the supporting data. The Contractor shall address any FDA comments on all pre-EUA packages as applicable. The Contractor shall maintain and update, as required by the FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.), that will be used to support use under EUA and approval/licensure.

Any product which has not received FDA approval or licensure, but has completed submission of a Pre-EUA package deemed acceptable by the FDA and has met the two

(2) criteria listed below may be considered for procurement at the discretion of the USG. The Contractor would be required to demonstrate the two (2) essential criteria listed below for consideration of procurement of any unapproved products by seeking a COA. The COA shall include a product delivery schedule for consideration and documentation of the following:

- Substantial evidence, including a validated process, of the Contractor's ability to manufacture a product that would be identical to the commercial scale as required for product approval or licensure. A clear understanding of the outstanding risks, if any, for approval or licensure must be demonstrated.

- Completion of non-clinical and clinical studies with substantial evidence of safety and efficacy for the indicated use. A list of outstanding activities and targets for completion, adverse events/safety profile which do not pose unusual risks or challenges for FDA approval or licensure shall be provided.

A tentative delivery schedule of product delivery to the inventory (acceptable as in the Quality Agreement) shall be required as part of the COA. The delivery schedule shall be updated periodically as necessary.

For information concerning EUA, please consult http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127 and http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

f. 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.

g. 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.

h. Option CLINS

If procurement for CLIN 4 occurs after FY 2018, the following chart illustrates the dose prices to be used:

Units (# of Doses)	FY 2019 Unit Price ($)	FY 2020 Unit Price ($)	FY 2021 Unit Price ($)
7,500,000 to [**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

The USG reserves the right to re-negotiate the option CLINS based on availability of funds and feedback received from the FDA.

i. 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:

HHSO100201600030C

j. Quality Agreement

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. – CDC/SNS-Quality Control and BARDA) for event- driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement.

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 September 30, 2016 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

See Section F for specific 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. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Representative (COR) and the Contractor's Project Leaders/delegates and designees shall occur twice-monthly or as directed by the Contracting Officer and Contracting Officer's Representative. During this call the Contractor's Project Leaders/delegates 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 Leaders/delegates 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.4. 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 and Contracting Officer's Representative in order to facilitate review of contract activities.

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.

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 52.243-1 Changes – Fixed Price Contracts Alternate V and 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 200 C St. SW
Washington, D.C. 20024

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

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 52.246-4, Inspection of Services - Fixed Price (August 1996)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984) FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance for this contract shall be from September 30, 2016 through September 29, 2021. The period of performance for the base period of this contract shall be consistent with the dates set forth in SECTION B. If the Government exercises option(s), the period of performance will be extended as described under in SECTION B of this contract.

ARTICLE F.2. REPORTING REQUIREMENTS

In all cases the reports are intended to provide sufficient detail to understand the Contractor's approach and progress to addressing the technical requirements. The reports supplement, and do NOT replace, routine (i.e. daily) communication between the COR and project manager and/or their designee(s) regarding project plans and progress.

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:

Title Page: The title page for this report shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort. SECTION II Part A: SUMMARY - A description or table

summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section
shall include 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).
Please include all Quality Management System, Quality Control, and Quality Assurance updates as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section 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; and if a project activity is delinquent, then what corrective action steps are planned.
Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This
section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

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

B. Annual Progress Report

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 30th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort. SECTION II Part A: SUMMARY - A description or table

summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section
shall include 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).
Please include all Quality Management System, Quality Control, and Quality Assurance updates as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall 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.

SECTION II Part D: ISSUES – This section 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; and if a project activity is delinquent, then what corrective action steps are planned.
Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as an annual forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This
section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

C. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report is due on or before the expiration date of the contract. The report shall conform to the following format:

Title Page: The title for these reports shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

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.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

D. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.

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 the final minutes when available.

b. Within five business days of any informal meeting with the FDA or other regulatory agency, the Contractor shall provide a formal contact report to BARDA. The Contractor shall forward the final minutes when available and if applicable.

c. The Contractor shall forward the dates and times of any formal meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known 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 make Standard Operating Procedures (SOPs) available upon request from COR.

f. The Contractor shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

g. The Contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all site visits/audits conducted by the FDA or any other regulatory agency. The Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

E. Other Requirements/Deliverables

a. Integrated Master Project Plan
The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and CDC) for review of critical documentation. The Contractor shall integrate to demonstrate interdependencies among all CLINS. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor performance of the contract. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

i. Critical Path Milestones
The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

ii. Work Breakdown Structure
The USG has provided a Contract Work Breakdown Structure (CWBS) template (See http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) and the Contractor shall further delineate the CWBS to Level 5 as part of their Integrated Master Project Plan. The WBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

iii. Risk Mitigation Plan/Matrix
The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx**) to be completed by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

b. Technology Packages
Technology packages developed under the contract that includes complete protocols 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. This report shall be due upon request from the COR or Alternate COR.

c. Experimental Protocols
The Contractor shall submit to the COR all protocols and associated study/experiment/test plans prior to the execution of any non-clinical animal study or clinical study for BARDA approval or upon request by the COR or Alternate COR when required. Approval must be provided in writing by the COR or Alternate COR prior to the execution of the study.

d. Annual/Final Invention Report
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. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention

Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. 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.

e. Publications

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.
Publications are due within 10 business days for manuscripts and 5 business days for abstracts prior to public release.

f. Press Releases

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

g. Incident Security Report

The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

h. Security Plan

The Contractor shall submit a draft security plan within 90 days of contract award. A detailed security plan with any updates shall be submitted for approval at least three (3) months prior to the initiation of product procurement with proper documentation. The Contractor shall cooperate with USG representatives to develop a sustainable security plan to ensure continued security of the premises. Security plan updates are required when an incident security report has been filed.

F. Earned Value Management System Plan

a. Earned Value Management System Plan:

Subject to the requirements under HHSAR Clause 352.234-3, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Seven Principles are:

I. Plan all work scope for the program to completion.

II. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

III. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control changes to the baseline.

IV. Use actual cost incurred and recorded in accomplishing the work performed.

V. Objectively assess accomplishments at the work performance level.

VI. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

VII. Use earned value information in the company's management processes.

VIII. Elements of EVMS shall be applied to all CLINs as part of the Integrated Master Project Plan, the Contractor shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

b. Performance Measurement Baseline Review (PMBR):

The Contractor shall submit a PMBR plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. **The goals of the PMBR are as FOLLOWS**:

I. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks.

II. Confirm the integrity of the Performance Measurement Baseline (PMB).

III. Foster the use of EVM as a means of communication.

IV. Provide confidence in the validity of Contractor reporting

V. Identify risks associated with the PMB.

VI. Present any revised PMBs for approval.

VII. Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI- MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).

VIII. Present the Risk Management Plan.

c. Integrated Master Schedule

The Contractor shall provide a program Integrated Master Schedule (IMS) with monthly status updates (e.g. % complete with program tasks).

Initial IMS due thirty (30) days after award. Monthly status updates are due the 20th day of the month after the end of each month.

The Integrated Master Schedule shall be incorporated into the contract, and shall be used to monitor performance of the contract. The Contractor shall include the key milestones and Go/No Go decision gates. The Contractor shall include BARDA Portfolio Management Milestones (See the AMCG Business Toolkit for a description and sample (http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) in their IMS and provide monthly updates within their IMS. This IMS shall include the following fields at a minimum; baseline start and finish,

forecast start and finish, actual start and finish, predecessor and/or successor. The Contractor shall deliver the Integrated Master Schedule, viewed at the work package level in MS Project file format

d. Earned Value Contract Performance Report (EV-CPR)

a. The Offeror shall deliver an Earned Value Contract Performance Report (CPR) on a monthly basis per the instruction in DI-MGMT-81466A (see http://www.acq.osd.mil/pm/). The Contractor shall provide Format 1, Format 3, and Format 5 only. Format 1 will be reported at the Work Breakdown Structure level 3 agreed to by BARDA and the Contractor.

b. EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be (+/- 10% and $30,000). In conjunction with the CPR, the Contractor shall provide a monthly update to the IMS with up to date performance data and shall include actual start/finish and projected start / finish dates.

c. The supplemental monthly CAP report shall contain, at the work package level, time phased budget (budgeted cost of work scheduled (BCWS)), earned value (budgeted cost of work performed (BCWP)), and actual costs of work performed (ACWP) as captured in the Contractor's EVM systems.

d. The Contractor and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the COR. Such meetings may include, but are not limited to, site visits to the Contractor's and/or subcontractor's facilities, meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and Government-contracted subject matter experts as required by the BARDA COR in order to facilitate review of contract activities.

e. The Contractor shall provide a list of individuals to serve as primary and secondary points of contact who will be available 24 hours a day, seven days a week, to be notified in case of a public health emergency.

ARTICLE F.3. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated September 30, 2016, set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

Item No.	Description	Addresses	Deliverable Schedule
1	Monthly Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
2	Annual Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
3	Draft Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due 45 Calendar days prior to the expiration date of the contract.
4	Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due on or before the expiration date of the contract.
5	FDA/ Regulatory Agency Correspondence and Meeting Summaries	COR: (1) electronic copy	Reports are due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR or Alternate COR.
6	Integrated Master Project Plan -Critical Path Milestones -Work Breakdown Structure -Risk Mitigation Plan/Matrix	COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR or Alternate COR.
7	Technology Packages	COR: (1) electronic copy	Upon request from the COR or Alternate COR.
8	Experimental Protocols for non-clinical animal studies or clinical studies	COR: (1) electronic copy	Upon request from the COR or Alternate COR. Written approval from the COR or Alternate COR is required prior to the execution of the study.
9	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract.
10	Publications	COR: (1) electronic copy	Reports are due within 10 business days for manuscripts and 5 business days for abstracts.
11	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Incident Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after occurrence of an activity or incident.
13	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Draft report is due within 90 days of contract award. Updates are due at least 3 months prior to product procurement or as requested by the COR or Alternate COR.
14	Earned Value Management Requirements	CO: (1) electronic copy COR: (1) electronic copy	As detailed in Section F.2 Reporting Requirements, subpart -F.

Email Addresses: CO – [**]
COR – [**]

ARTICLE F.4. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/far.

FAR 52.242-15, Stop Work Order (August 1989)
FAR 52.242-15, Alternate 1 (April 1984) is applicable to this contract.

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:

[**] DHHS/OS/ASPR/AMCG 200 C St.
Washington, D.C. 20024

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.

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: 200 C St.

Washington, D.C. 20024

Alternate COR:

[**]
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: 200 C St.
Washington, D.C. 20024

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

e. Assisting in the resolution of technical problems encountered during performance.

f. 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:

Name	Title
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

ARTICLE G.4. INVOICE SUBMISSION

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 made a part of the contract at Section J, Attachments 2 & 3.

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 options for additional quantities (See estimated costs under Articles B.2 and B.3) 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.

g. Invoices shall be delivered electronically to the Contracting Officer (CO), the Contracting Officer's Representative (COR), PSC, and e-Room electronically. Unless otherwise specified by the Contracting Officer, all deliverables, invoices, and reports furnished to the Government under the resultant contract shall be addressed as follows:

[**] Contracting Officer HHS/ASPR/AMCG 200 C Street, S.W. Washington, DC 20024 Email: [**]	[**] Contracting Officer Representative HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 **Email:** [**]	Email invoices to: PSC_Invoices@psc.hhs.gov e-Room

ARTICLE G.5. INDIRECT COST RATES

The established provisional billing rates are based on rates approved by NIH-DFAS and adjustments made for consumable materials, which are specific to this contract HHSO100201600030C, per 2016 Provisional Billing Rate letter dated September 15, 2016. The following interim provisional indirect rates will be utilized for billing purposes during the period of performance: Fringe benefits at [**]%, Development O/H at [**]%, G&A at [**]% and Material and Subcontracting Handling at [**]%. Final rate proposals must be sent to the Contracting Officer upon immediate notification from the cognizant audit agency. See FAR Clause 52.216-7, Allowable Cost and Payment.

ARTICLE G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

(c) Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

ARTICLE G.7. 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, interim evaluation(s) will be prepared annually as to coincide with the Anniversary date of the contract.

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

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

2. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure website for review and comment at the following:

http://cpars.gov

ARTICLE G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number HHSO100201600030C from Page 1 of the contract.

ARTICLE G.9. 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.

Section H – Special Contract Requirements

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS

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

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

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

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

ARTICLE H.2. NON-CLINICAL RESEARCH

PHS Policy on Humane Care and Use of Laboratory Animals

Before initiation of research 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.

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.

BARDA Review Process Before Non-Clinical Study Execution Begins

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. Non-clinical research protocol to be submitted for IACUC approval identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria. Contractor should reduce the number of animals required for a study using power of statistics

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

3. Procedures for assessing and collecting safety data

4. 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).

5. 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

6. 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

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

BARDA comments will be forwarded to the Contractor within two weeks (10 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 BARDA COR to the satisfaction of the Government before study execution. After the Government receives the corrected documentation, a written protocol approval will be provided by the COR to the Contractor. This written approval provides authorization to the Contractor to execute the specific non-clinical animal study funded in part or in whole by the Government.

Documentation of IACUC approval, including OLAW FWA number, IACUC registration number, and IACUC name, must be provided to the BARDA COR within 24 hours of receipt by the Contractor.

In case of problems or issues, the BARDA COR will contact the Contractor within two weeks (10 business days) by email or fax, followed within 30 calendar days by an official letter to the principal investigator, with a copy to 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) must be made jointly by the Government and the Contractor.

ARTICLE H.3. CLINICAL RESEARCH

These Clinical Terms apply to all contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. 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.3.1 Safety and Monitoring Issues

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval
Before initiation of research and then with Annual Progress Reports, the Contractor shall submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) and Contracting Officer (CO) of any of the above changes within 24 hours from the time the Contractor becomes aware of the change by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety 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.3.2. Data and Safety Monitoring Requirements

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.
The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

H.3.3. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. Clinical research protocol to be submitted for approval by the IRB or IEC, identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;
2. Informed consent document, identified by version number, date, or both and date it is valid;
3. Plans for the management of side effects;
4. Procedures for assessing and reporting adverse events;
5. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;
6. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 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 BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written protocol approval will be provided by the COR and CO to the Contractor. This written approval provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB and IEC name, must be provided to the BARDA COR within 24 hours of receipt by the Contractor.

H.3.4. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the Contracting Officer's Representative within 24 hours of FDA notification.

2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

4. *Expedited safety reports* – shall be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial shall be included in the annual IND report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

Safety reporting for research not performed under an IND.

Ongoing safety reporting requirements for research not performed under an IND shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

ARTICLE H.4. HUMAN MATERIALS

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

ARTICLE H.5. CARE OF LIVE VERTEBRATE ANIMALS

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; W eb site: (http://www.aphis.usda.gov/animal_welfare).

ARTICLE H.6. ANIMAL WELFARE

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

ARTICLE H.7. 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.8. 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.9. 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 initiation of research 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.10. NEEDLE EXCHANGE

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

ARTICLE H.11. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

ARTICLE H.12. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN OF FUNDING OF HUMAN EMBRYO RESEARCH

a. The Contractor shall not use any funds obligated under this contract for any abortion.

b. The Contractor shall not use any funds obligated under this contract for the following:
    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 of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c. The term "human embryo or embryos'" includes any organism, not protected as a human subject under 45 CFR part 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 of human diploid cells.

d. The Contractor shall not use any Federal funds for the cloning of human beings.

ARTICLE H.13. 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.14. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.15. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.16. 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 is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

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

ARTICLE H.17. 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.18. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.19. CERTIFICATION OF FILING AND PAYMENT OF TAXES

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

ARTICLE H.20. ELECTRONIC INFORMATION AND TECHNOLOGY ACCESSIBILITY NOTICE

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows Offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues.
Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

ARTICLE H.21. FULL EARNED VALUE MANAGEMENT SYSTEM

a. The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

b. If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

c. HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

d. HHS will conduct a Performance Measurement Baseline Review (PMBR). If a pre-award PMBR has not been conducted, a post-award PMBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require a PMBR as part of the exercise of an option or the incorporation of a major modification.

e. Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

f. Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

g. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform to the requirements referenced in paragraph (a) of this clause.

ARTICLE H.22. 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 shall 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.23. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTERESTS

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. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/text- idx?
c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51
&idno=45

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

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

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions

   made in these vehicles.

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

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

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

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

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

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

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

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

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

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the 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 not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.24. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the Department of Health and Human Services, 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. HHSO100201600030C"

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 five (5) working days prior to the issuance of the press release.

ARTICLE H.25. 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 Contractor 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 Contractor commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence with the FDA, within 5 business days 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.26. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval 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 Contractor'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.27. 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.28. 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 (HHS). HHS reserves the right to review any other data determined by HHS 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.29. 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.30. 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. 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.31. 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/COR 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

ARTICLE H.32. 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.33. 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.34. 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 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 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/Fixed Price Research and Development Contract

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Jul 2013	System for Award Management
FAR	52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Jul 2013	System for Award Management Maintenance
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Jun 2013	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Oct 2014	Utilization of Small Business Concerns
FAR	52.219-28	July 2013	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	Jul 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2015	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-43	May 2014	Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.224-1	April 1984	Privacy Act Notification
FAR	52.224-2	April 1984	Privacy Act
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General
FAR	52.227-16	Jun 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.230-6	June 2010	Administration of Cost Accounting Standards
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jul 2013	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243.6	Apr 1984	Change Order Accounting
FAR	52.243-7	Apr 1984	Notification of Changes
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)

FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Apr 2015	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-7	Apr 1996	Inspection of Research and Development – Fixed-Price
FAR	52.246-8	May 2001	Inspection of Research and Development – Cost-Reimbursement
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.248-1	Oct 2010	Value Engineering
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.270-4a	Dec 2015	Protection of Human Subjects
HHSAR	352.270-5b	Dec 2015	Care of Live Vertebrate Animals
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects

ARTICLE I.2. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT

FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within **30 days.** Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

FAR 52.217-9 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 **30 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 8 years.

ARTICLE I.3. ADDITIONAL HHSAR CLAUSES – IN FULL TEXT

352.231-70 Salary rate limitation (December 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that
an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule salary levels.

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 September 30, 2016, 10 pages
2. Invoice/Financing Instructions for Cost-Reimbursement Type Contracts
3. Invoice Instructions for Fixed-Priced Type Contracts
4. Sample Invoice Form
5. Research Patient Care Costs
6. Report of Government Owned, Contractor Held Property, 1 page.
7. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages

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

ATTACHMENT 1: STATEMENT OF WORK

NEXT GENERATION ANTHRAX VACCINE RFP 16-100-SOL-0015 AV7909 Anthrax Vaccine

1.1 Contractual Statement of Work

Preamble to the Statement of Work
Independently and not as an agent of the Government, the Contractor shall be required to 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 submitted in response to RFP 16-100-SOL-00015.

1.2 Scope
The scope of work for this contract includes AV7909 development activities through licensure that fall into the following areas: program management, nonclinical, clinical, regulatory, and chemistry, manufacturing, and controls (CMC). The scope of work also includes activities to support post-marketing requirements.

1.3 Objective
The objective of this Statement of Work (SOW) is to conduct all necessary activities to advance the development of AV7909 through Biologics License Application (BLA) submission and approval and post- marketing requirements. Activities to meet the objective of this SOW fall in three separate contract line item number (CLIN):

- CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
- CLIN 0001A – Conduct of a Phase 2 clinical [**] study or other studies required by the FDA [**] (Option)
- CLIN 0002 - Initial purchase, storage, and delivery of product (Base)
- CLIN 0003 – Phase 4 post marketing requirements (Option)
- CLIN 0004 - Surge Capacity – Additional procurement of product (Option)

1. 3 CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
This section identifies representative tasks and sub-tasks for CLIN 0001 with associated WBS code for each task or subtask.

[**] Program Management
Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No-Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
    - Submit an updated Integrated Master Schedule in an approved format.
    - Use principles of Earned Value Management System (EVMS) in the management of this contract.
    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

[**] Non-Clinical Toxicology
Emergent shall conduct safety and toxicology of AV7909 using animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21CFR Part 58), as appropriate. The activities shall include but are not limited to:

[**]

[**] **Non-Clinical Efficacy**
Emergent shall conduct efficacy, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the medical countermeasure using both in vitro and animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations, 21 CFR Part 58), as appropriate. The activities shall include but are not limited to:

[**]

[**] **Clinical Evaluation**
Emergent shall design and conduct Phase 2 and Phase 3 clinical studies in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines. The activities shall include but are not limited to:

[**]

[**] **Regulatory Activities**

Emergent shall conduct all required regulatory activities to support submission of BLA licensure for AV7909. The activities shall include but are not limited to:

[**]

[**] - **Chemistry and Manufacturing Controls (CMC)**
Emergent shall complete the manufacturing activities necessary to support BLA submission. The activities shall include but are not limited to:

[**]

1.4 CLIN 0001A - Conduct of a Phase 2 clinical [**] study or other studies required by the FDA [**] (Option)

This section identifies representative tasks and sub-tasks for CLIN 0001A with associated WBS code for each task or subtask.

[**] Program Management
Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/ No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
    - Submit an updated Integrated Master Schedule in an approved format.
    - Use principles of Earned Value Management System (EVMS) in the management of this contract.
    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

[**] Clinical Evaluation
Emergent shall design and conduct a Phase 2 clinical study in accordance with all Federal regulations and Good Clinical Practice (GCP) guidelines unless other studies are required by the FDA [**]. The activities shall include, but are not limited to:

- [**] - AVA.214 Phase 2 [**] Study

[**] - Chemistry and Manufacturing Controls (CMC)
Emergent shall complete the manufacturing activities necessary to support AVA.214 Phase 2 [**] Study. The activities below are specific to conducting a Phase 2 [**] clinical study. If the FDA requires an alternate strategy for [**], the activities below may no longer be applicable. Upon new guidance from the FDA, Emergent will update the SOW accordingly.

[**]

1.5 CLIN 0002 - Initial purchase, storage, and delivery of product (Base)
Emergent shall deliver 2,000,000 doses of AV7909 within [**] after EUA pre-authorization approval by FDA.

1. 6 CLIN 0003 - Phase 4 post marketing requirements (Option)
[**].

Program Management
Emergent shall provide program management activities. The activities shall include but are not limited to:

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.
- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative (COR).
    - Submit an updated Integrated Master Schedule in an approved format.

- Use principles of Earned Value Management System (EVMS) in the management of this contract.
- Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.

· Develop and maintain a risk management plan.
· Participate in regular meetings to coordinate and oversee the contracting effort.

[**]

1.7 CLIN 0004 - Surge Capacity – Additional procurement of product (Option)

Emergent shall deliver up to 25 million dose regimens (equivalent to 50 million doses of AV7909). This option may be triggered after EUA pre-authorization approval by FDA, which is currently linked to release of PPQ lots, and deliveries will start within [**] after trigger.

1.8 Reporting Requirements and Deliverables Reports

As part of the work to be performed under this contract, Emergent will prepare and deliver the following reports throughout the period of performance.

Monthly Technical Progress Reports
On the fifteenth (15) day of each month for the previous calendar month, Emergent will submit to the COR and the CO a Technical Progress Report covering the previous calendar month. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period will consist of each calendar month. The frequency of Technical Progress Reporting will be determined by the CO and COR during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the COR. The Technical Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. A Technical Progress Report will not be required for the period when the same month Annual Progress Reports or a Final Report are due. Emergent will submit one copy of the Technical Progress Report electronically via e-mail to the CO and COR.

Annual Progress Reports
On the thirtieth (30th) calendar day following the last day of each reporting period, Emergent will submit to the COR and the CO an Annual Progress Report. 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. Annual Progress Reports will summarize progress for the reporting period, such as: management and administrative updates, technical progress, issues, proposed work, manufacturing and supply chain management, and a summary of invoices. An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

Draft Final Report and Final Report
Emergent will submit the Draft Final Progress Report forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report on or before the expiration date of the contract. These reports will include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report will be in sufficient detail to describe comprehensively the results achieved. An electronic copy of the Draft Final Report and Final Report will be submitted to the COR and CO.

FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions
With regard to interactions with the FDA, Emergent shall:

· Forward the initial draft minutes to BARDA within five business days of any formal meeting with the FDA or other regulatory agency, and forward the final minutes when available.
· Forward the initial draft minutes to BARDA within five business days of any informal meeting with the FDA or other regulatory agency, and forward the final minutes when available and if applicable.
· Forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.
· Provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. Emergent will provide BARDA with five (5) business days in which to review and provide comments prior to Emergent's submission to the FDA.

Emergent will notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency and provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). Emergent will provide the COR and CO copies of the plan for addressing areas of non-conformance to FDA regulations for Good Laboratory Practice (GLP) guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. Emergent will also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. Emergent will make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

Key Deliverables

A summary of Key Deliverables for this contract follow

No.	Deliverable	Description	Due Date
01	Monthly Progress 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.	Due on or before the 15th day of each month following the end of each reporting period. Monthly progress reports are not required in the same month Annual Progress reports or a Final Report are due.
02	Annual Progress 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.	Due on or before the 30th calendar day following the end of each reporting period.
03	Draft Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due 45 Calendar days prior to the expiration date of the contract.
04	Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due on/before the expiration date of the contract.
	FDA/Regulatory Agency	The Contractor shall forward initial draft minutes and final draft minutes of any formal or informal meeting with the FDA or other regulatory agency. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the	Due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes

05	Correspondence and Meeting Minutes	FDA or other regulatory agency. The Contractor shall forward SOPs upon request from the COR. The contractor shall notify the COR and CO within 24 hours of all FDA arrivals to conduct sitevisits/audits by any regulatory agency, and provide copies of any associated reports, documentation, or communication.	from FDA/ regulatory agency, and upon request from the COR or Co-COR.
06	Integrated Master Project Plan (Critical Path Milestones, Work Breakdown Structure, Risk Mitigation Plan/ Matrix)	The contractor shall provide an Integrated Master Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables (key, critical path milestones, with "Go/No Go" decision criteria) and Work Breakdown Structure (WBS) elements that shall be discernable and consistent. The contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans.	Due within 90 days of contract award. Updates are due as requested by the COR or Co-COR.
07	Technology Packages	Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA COR.	Due upon request from the COR or Co-COR.

No.	Deliverable	Description	Due Date
08	Experimental Protocols	The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Co-COR when required.	Due upon request from the COR or Co-COR.
09	Annual/Final Invention Report	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. 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 CO.	Annual Invention Report Due on or before the 30th calendar day after the completion of each reporting period. Final Invention Report due on or before the expiration of the contract.
10	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.	Due within 30 calendar days for manuscripts prior to publication and 15 calendar days for abstracts.
11	Press Releases	The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the CO has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.	Reports/Notices due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Due within 24 hours after occurrence of an activity or incident.
13	Earned Value Management System Requirements	Subject to the requirements under FAR 52.234-4 Earned Value Management System, the Contract shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Contractor shall also submit a Performance Measurement Baseline Review plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award, and an Integrated Master Schedule electronically via email as outlined in a format agreed upon by BARDA to the COR and CO. The Offeror shall deliver an Earned Value Contract Performance Report on a monthly basis.	As detailed in Section F.3.2 Subpart F.

.

	Milestone #	WBS #	Milestone	Deliverables Summary (Details as specified in the Deliverables)	Quantity	Estimated Completion Date
CLIN 0001	1	[**]	[**]	[**]	1 Electronic Copy to Contract Officer Representative (COR); 1 Electronic Copy to Contracting Officer (CO)	[**]
	2	[**]	[**]	[**]	See Above	[**]
	3	[**]	[**]	[**]	See Above	[**]
	4	[**]	[**]	[**]	See Above	[**]
	5	[**]	[**]	[**]	See Above	[**]
	6	[**]	[**]	[**]	See Above	[**]
	7	[**]	[**]	[**]	See Above	[**]
	8	[**]	[**]	[**]	See Above	[**]
	9	[**]	[**]	[**]	See Above	[**]
	10	[**]	[**]	[**]	See Above	[**]
	11	[**]	[**]	[**]	See Above	[**]
	12	[**]	[**]	[**]	See Above	[**]
CLIN 0002	16	-	Completion of delivery of 2 million doses of AV7909	Delivery of 2 million doses of AV7909	See Above	[**]

ATTACHMENT #2

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

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

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

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

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

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

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

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

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

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

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

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

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

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

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

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

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

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed- fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

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

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

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

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

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately

priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract

Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

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

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

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

- COA number, if the equipment is not covered by the Property Schedule.

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

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

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

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

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

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

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

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

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

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

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

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

ATTACHMENT #3

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address: HHS/ASPR/BARDA

330 Independence Ave, Room G640 Washington DC 20201

ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

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

ATTACHMENT #4 - SAMPLE INVOICE FORM

Company Name

This invoice represents reimbursable costs for the period from

		Amount Billed		
Expenditure Category		**Current**	**Cumulative**	**Contract Value**
Direct Costs:				
Direct Labor				
Fringe Benefits	**0.00%**			
Total Labor Costs:				
Overhead	**0.00%**			
Travel				
Subcontracts				
Consultant Fees				
Materials and Supplies				
Other				
Total Direct Costs				
G&A Rate	**0.00%**			
Subtotal:				
Fixed Fee	**0.0**			
Total Amount Claimed				
Adjustments				
Grand Total		**$-**		

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

Name/signature of signatory authority for invoicing

ATTACHMENT #5

RESEARCH PATIENT CARE COSTS

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

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

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

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

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

chargeable to this contract.

Attachment 6

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:	**CONTRACT NUMBER:**
ADDRESS:	**REPORT DATE:**
ADDRESS1:	
ADDRESS2:	**FISCAL YEAR:**
CITY:	
STATE:	
ZIP:	

CLASSIFICATION	**BEGINNING OF PERIOD**		**ADJUSTMENTS**			**END OF PERIOD**	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=$25K							
LAND <$25K							
OTHER REAL >=$25K							
OTHER REAL <$25K							
PROPERTY UNDER CONST >=$25K							
PROPERTY UNDER CONST <$25K							
PLANT EQUIP >=$25K							
PLANT EQUIP <$25K							
SPECIAL TOOLING >=$25K							
SPECIAL TOOLING <$25K							
SPECIAL TEST EQUIP >=$25K							
SPECIAL TEST EQUIP <$25K							
AGENCY PECULIAR >=$25K							
AGENCY PECULIAR <$25K							
MATERIAL >=$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=$25K							
PROPERTY UNDER MFR <$25K							

SIGNED BY:			
SIGNATURE		DATE SIGNED:	
NAME PRINTED		Email	
TITLE		TELEPHONE	

Report of Government Owned, Contractor Held Property (Rev 10/2014)

_____

_____

Attachment 7

DISCLOSURE OF LOBBYING ACTIVITIES Approved by OMB

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

0348-0046

_____

_____

_____

(See reverse for public burden disclosure.)

1. Type of Federal Action: a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	**2. Status of Federal Action:** a. bid/offer/application b. initial award c. post-award	**3. Report Type:** a. initial filing b. material change **For Material Change Only:** year quarter date of last report
4. Name and Address of Reporting Entity: **Prime** **Subawardee** Tier , *if known* : **Congressional District**, *if known* :	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:** **Congressional District**, *if known* :	
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable* :_____	
8. Federal Action Number, *if known* **:**	**9. Award Amount,** *if known* **:** $	

10. a. Name and Address of Lobbying Registrant **Services** (*including address if* (*if individual, last name, first name, MI*):	b. Individuals Performing *different from No. 10a*) (*last name, first name, MI*):
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: Print Name: Title: Telephone No.: Date:
Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

PRINT

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

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

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

2. Identify the status of the covered Federal action.

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

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

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

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

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

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

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

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

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

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

Cumulative Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native										0
Asian										0
Native Hawaiian										

or Other Pacific Islander										**0**
Black or African American										**0**
White										**0**
More Than One Race										**0**
Unknown or Not Reported										**0**
Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

EXHIBIT 10.3

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions. **AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**	1. CONTRACT ID CODE	PAGE 1	OF PAGES 2

2. AMENDMENT/MODIFICATION NO. 00016	3. EFFECTIVE DATE 03/22/2016	4. REQUISITION/PURCHASE REQ. NO. 0000HCGE-2016-95388	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE	8219	7. ADMINISTERED BY *(If other than Item 6)* CODE	8219
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539		Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)* EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933	(√)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
		10B. DATED *(SEE ITEM 13)* 09/30/2011
CODE 026489018	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
939ZWUX 2642 2016 75-X-0956 5664711101 Increase $17906329.32

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

(√)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-6, Option for Increased Quantity
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
The purpose of this modification is to:

a. Increase and fund [**] doses on CLIN 0005 in the amount of $17,906,329.32;

b. As a result of the modification, total contract value and funding are increased by $17,906,329.32 from $1,055,309,076.28 to $1,073,215,405.60

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

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Christine N Godfrey	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By /s/ Christine N Godfrey *(Signature of Contracting Officer)*	16C. DATE SIGNED 3/22/16

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE 30-105 STANDARD FORM 30 (Rev. 10-83)

Prescribed by GSA
FAR (48 CFR) 53.24

Option 4 Option for Additional Items Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0005	BioThrax [**] product BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below (attached per SOW) Line(s) Of Accounting: 939ZWUX 2642 2016 75-X-0956 5664711101 $17,906,329.32	[**] Doses	$ [**]	$ [**]

EXHIBIT 10.4

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

2. AMENDMENT/MODIFICATION NO. 00017	3. EFFECTIVE DATE 04/19/2016	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE	8219	7. ADMINISTERED BY *(If other than Item 6)* CODE	8219
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539		Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
CODE 026489018 FACILITY CODE		10B. DATED *(SEE ITEM 13)* 09/30/2011

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

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

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

E. IMPORTANT: Contractor is not, is required to sign this document and return ___1____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to add FAR Clause 52.232-40 Providing Accelerated Payments to Small Business Subcontractors to Section I-2 – Clauses Incorporated In Full Text. Please see a description of the clause on Page 2.

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Michael Mann Sr. Manager, Commercial Operations		Sherrie N Randall	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ J. Michael Mann *(Signature of person authorized to sign)*	20 APR 16	By *(Signature of Contracting Officer)*	

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE 30-105 STANDARD FORM 30 (Rev. 10-83)

Prescribed by GSA
FAR (48 CFR) 53.243

Section 1-2 - Clauses Incorporated In Full Text

FAR 52.232-40 Providing Accelerated Payments to Small Business Subcontractors.

As prescribed in 32.009-2, insert the following clause:

PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013)

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

1. CONTRACT ID CODE	PAGE 1	OF PAGES 2

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00018	05/06/2016	0000HCGE-2016-97151	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219	Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
		10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
CODE 026489018 FACILITY CODE	X	10B. DATED *(SEE ITEM 13)* 09/30/2011

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
939ZWUX 2642 2016 75-X-0956 5664711101 Increase $39999996.00

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

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

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

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER *(Specify type of modification and authority)*
FAR 52.217-6, Option for Increased Quantity

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to:

1. Increase and fund [**] doses on CLIN 0005 in the amount of $39,999,996.00
2. The total funding and value for this contract has been increased by $39,999,996.00 from $1,073,215,406.60 to $143,740,431.60

All other terms and conditions remain the same

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Christine N. Godfrey	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By /s/ Christine N. Godfrey *(Signature of Contracting Officer)*	16C. DATE SIGNED 5/6/16

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE **30-105** **STANDARD FORM 30**
(Rev. 10-83)

Prescribed by GSA
FAR (48 CFR) 53.24

SECTION B - Supplies Or Services And Prices/Costs

Option 4 Option for Additional Items Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0005	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below (attached per SOW) POP: 05/06/16 to 09/30/16.	[**]Doses	$ [**]	$ 143,740,431.60
	Line(s) Of Accounting: 939ZWUX 2642 2016 75-X-0956 5664711101 $39,999,996.00			

EXHIBIT 10.6

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

1. CONTRACT ID CODE	PAGE 1	OF PAGES 2

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00019	08/11/2016	0000HCGE-2016-02664	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219	Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
		10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
		10B. DATED *(SEE ITEM 13)* 09/30/2011
CODE 026489018	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Section B

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

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
(√)	D. OTHER *(Specify type of modification and authority)* FAR 52.217-6, Option for Increased Quantity

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to:
1. Increase and fund [**] additional doses on CLIN 0005 in the amount of $24,430,484.40
2. The total funding and value for this contract has been increased by $24,430,484.40 from $143,740,431.60 to $168,170,916.00
All other terms and conditions remain the same
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Sherrie N. Randall	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By /s/ Sherri N. Randall *(Signature of Contracting Officer)*	16C. DATE SIGNED 08/11/2016

NSN 7540-01-152-8070 STANDARD FORM 30 (Rev. 10-83)
PREVIOUS EDITION UNUSABLE 30-105 Prescribed by GSA
FAR (48 CFR) 53.24

SECTION B - Supplies Or Services And Prices/Costs

Option 4 Option for Additional Items Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0005	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below (attached per SOW) Delivery Peiod – 08/10/16 - 09/30/16	[**] Doses	$ [**]	$ 168,170,916
	Line(s) Of Accounting: 939ZQPD 2642 2016 75-X-0956 5664711101 $[**] 939ZWUX 2642 2016 75-X-0956 5664711101 $[**] 939ZXXW 2642 2016 75-X-0956 5664711101 $[**]			

EXHIBIT 10.7

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.	1. CONTRACT ID CODE	PAGE 1	OF PAGES 2

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00020	09/07/2016	0000HCGE-2016-03591	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219	Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
		10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
	X	10B. DATED *(SEE ITEM 13)* 09/30/2011
CODE 026489018	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Section B

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

(√)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER *(Specify type of modification and authority)* FAR 52.217-6, Option for Increased Quantity

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to:

1. Increase and fund [**] additional doses on CLIN 0005 in the amount of $[**]
2. Increase and fund [**] additional doses on CLIN 000502 in the amount of $[**]
3. The total funding and value for this contract has been increased by $97,040,755.20 from $168,170,916.00 to $265,211,671.20

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Christine N. Godfrey	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By /s/ Christine N. Godfrey *(Signature of Contracting Officer)*	16C. DATE SIGNED 9/7/16

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE 30-105 STANDARD FORM 30 (Rev. 10-83)

Prescribed by GSA
FAR (48 CFR) 53.24

SECTION B - Supplies Or Services And Prices/Costs

Option 4 Option for Additional Items Items:

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0005	BioThrax [**] product [**] upon date of delivery [**] To be delivered in accordance with the delivery schedule below (attached per SOW) POP: 09/07/16 to 09/30/16. Delivery Peiod – 09/07/2016 - 09/30/16	[**] Doses	$ [**]	$ [**]
	Line(s) Of Accounting: 939062V 2642 2016 75-16-0943 5623RF1101 $[**] 93907BF 2642 2016 75-16-0943 5623RF1101 $[**] 93907BF 2642 2016 75-16-0943 5623RF1101 $[**] 93907EW 2642 2016 75-16-0943 5623RF1101 $[**] 939ZWUX 2642 2016 75-X-0956 5664711101 $[**]			

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
000502	BioThrax [**] product [**] upon date of delivery [**] Corresponds to Line Item 0005B in the contract. To be delivered in accordance with the delivery schedule schedule below (attached per SOW) Delivery Peiod – 09/07/2016 -09/30/16	[**] Doses	$ [**]	$ [**]
	Line(s) Of Accounting: 939ZWUX 2642 2016 75-X-0956 5664711101 $[**]			

EXHIBIT 10.8

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.	1. CONTRACT ID CODE	PAGE 1	OF PAGES 2

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00021	09/08/2016		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219	Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(√)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(SEE ITEM 11)*
		10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084
CODE 026489018 FACILITY CODE	X	10B. DATED *(SEE ITEM 13)* 09/30/2011

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

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

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

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
This modification is issued to correct an administrative error on Mod 20 in Section 14.
Section 14 for Mod 00020 has been corrected to read:
"This modification is issued to:

1. Increase and fund [**] additional doses on CLIN 0005 in the amount of $[**]
2. Increase and fund [**] additional doses on CLIN 000502 in the amount of $[**]
3. The total funding and value for this contract has been increased by $97,040,755.20 from $1,137,645,886.00 to $1,234,686,641.20."

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME OF CONTRACTING OFFICER Sherrie N. Randall	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By /s/ Sherrie N. Randall *(Signature of Contracting Officer)*	16C. DATE SIGNED 9/13/16

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE 30-105 STANDARD FORM 30 (Rev. 10-83)

Prescribed by GSA
FAR (48 CFR) 53.24

EXHIBIT 10.9

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
00022	09/20/2016	0000HCGE-2016-03922	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
(Ö) Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219	Centers for Disease Control and Prevention (CDC) Procurement and Grants Office (PGO) 2920 Brandywine Road Atlanta, GA 30341-5539	8219

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 3500 N MARTIN LUTHER KING JR BLVD # 1 LANSING, MI 48906-2933		9B. DATED *(See Item 11)* 10A. MODIFICATION OF CONTRACT/ORDER NO. 200-2011-42084 10B. DATED *(See Item 13)*
CODE 026489018	FACILITY CODE	X 09/30/2011

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
N/A

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

(O)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.243-1, Changes Firm Fixed Price
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, X is required to sign this document and return __1__copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
The purpose of this modification is to extend the final delivery date for CLIN 0005 and 0005 02 through November 30, 2016 at no additional cost to the Government.
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME OF CONTRACTING OFFICER
J. Michael Mann Sr. Manager, Commercial Operations & Analytics	Christine N Godfrey

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ J. Michael Mann *(Signature of person authorized to sign)*	20 SEPT 2016	BY /s/ Christine N. Godfrey *(Signature of Contracting Officer)*	9/21/2016

NSN 7540-01-152-8070 STANDARD FORM 30 (REV. 10-83)
PREVIOUS EDITION UNUSABLE 30-105
GSA 53.24 Prescribed by FAR (48 CFR)