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 March 31, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

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 April 28, 2017, the registrant had 40,974,436 shares of common stock outstanding.

Emergent BioSolutions Inc.
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Part I. Financial Information

Part II. Other Information

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and the documents we incorporate by reference include 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 BioSolutions Inc. or any of our 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 countermeasures addressing public health threats;
- § our ability to perform under our contracts with the U.S. government related to BioThrax, including the timing of deliveries;
- § our ability to obtain Emergency Use Authorization pre-approval for NuThrax from the U.S. Food and Drug Administration;
- § 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 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 and utilize our manufacturing facilities and capabilities;
- § our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices 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 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)

	March 31, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 270,170	$ 271,513
Accounts receivable, net	128,082	138,478
Inventories	70,732	74,002
Income tax receivable, net	6,771	9,996
Prepaid expenses and other current assets	13,411	16,229
Total current assets	489,166	510,218
Property, plant and equipment, net	381,102	376,448
Intangible assets, net	32,311	33,865
Goodwill	41,001	41,001
Deferred tax assets, net	5,022	6,096
Other assets	3,037	2,483
Total assets	$ 951,639	$ 970,111
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 27,179	$ 34,649
Accrued expenses and other current liabilities	4,346	6,368
Accrued compensation	23,318	34,537
Notes payable	-	20,000
Contingent consideration, current portion	2,216	3,266
Deferred revenue, current portion	10,647	7,036
Total current liabilities	67,706	105,856
Contingent consideration, net of current portion	9,601	9,919
Long-term indebtedness	248,394	248,094
Deferred revenue, net of current portion	13,887	8,433
Other liabilities	1,632	1,604
Total liabilities	341,220	373,906
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both March 31, 2017 and December 31, 2016	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized, 41,380,108 shares issued and 40,954,615 shares outstanding at March 31, 2017; 40,996,890 shares issued and 40,574,060 shares outstanding at December 31, 2016	41	41
Treasury stock, at cost, 425,493 and 422,830 common shares at March 31, 2017 and December 31, 2016, respectively	(6,501)	(6,420)
Additional paid-in capital	355,661	352,435
Accumulated other comprehensive loss	(3,747)	(4,331)
Retained earnings	264,965	254,480
Total stockholders' equity	610,419	596,205
Total liabilities and stockholders' equity	$ 951,639	$ 970,111

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 March 31,	
	2017	2016
	(Unaudited)	
Revenues:		
Product sales	$ 81,969	$ 63,753
Contract manufacturing	17,628	7,587
Contracts and grants	17,261	31,624
Total revenues	116,858	102,964
Operating expenses:		
Cost of product sales and contract manufacturing	46,322	24,001
Research and development	20,476	26,093
Selling, general and administrative	35,150	31,713
Income from operations	14,910	21,157
Other income (expense):		
Interest income	373	186
Interest expense	(1,938)	(1,524)
Other income (expense), net	300	35
Total other expense, net	(1,265)	(1,303)
Income from continuing operations before provision for income taxes	13,645	19,854
Provision for income taxes	3,160	7,965
Net income from continuing operations	10,485	11,889
Net loss from discontinued operations	-	(7,898)
Net income	$ 10,485	$ 3,991
Net income from continuing operations - basic	$ 0.26	$ 0.30
Net loss from discontinued operations - basic	-	(0.20)
Net income per share - basic	$ 0.26	$ 0.10
Net income from continuing operations - diluted	$ 0.23	$ 0.27
Net loss from discontinued operations - diluted	-	(0.17)
Net income per share - diluted (1)	$ 0.23	$ 0.10
Weighted-average number of shares - basic	40,727,755	39,542,656
Weighted-average number of shares - diluted	49,718,426	48,359,892

(1) See "Earnings per share" footnote 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 March 31,	
	2017	2016
	(Unaudited)	
Net income	$ 10,485	$ 3,991
Foreign currency translations, net of tax	584	(1,439)
Comprehensive income	$ 11,069	$ 2,552

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

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

	Three Months Ended March 31,	
	2017	2016
Cash flows from operating activities:	(Unaudited)	
Net Income	$ 10,485	$ 3,991
Adjustments to reconcile to net cash provided by (used in) operating activities:		
Stock-based compensation expense	4,284	5,197
Depreciation and amortization	10,166	8,840
Income taxes	4,299	2,964
Change in fair value of contingent obligations	200	847
Excess tax benefits from stock-based compensation	-	(5,786)
Other	87	71
Changes in operating assets and liabilities:		
Accounts receivable	10,561	51,207
Inventories	3,270	(11,264)
Prepaid expenses and other assets	2,338	(5,555)
Accounts payable	81	385
Accrued expenses and other liabilities	(1,962)	(2,045)
Accrued compensation	(11,203)	(8,277)
Provision for chargebacks	-	(278)
Deferred revenue	9,065	1,874
Net cash provided by operating activities	41,671	42,171
Cash flows from investing activities:		
Purchases of property, plant and equipment	(20,304)	(18,214)
Net cash used in investing activities	(20,304)	(18,214)
Cash flows from financing activities:		
Issuance of common stock upon exercise of stock options	2,957	3,595
Excess tax benefits from stock-based compensation	-	5,786
Taxes paid on behalf of employees for equity activity	(4,015)	(4,377)
Payments of notes payable	(20,000)	-
Contingent obligation payments	(1,568)	(752)
Purchase of treasury stock	(81)	-
Net cash (used in) provided by financing activities	(22,707)	4,252
Effect of exchange rate changes on cash and cash equivalents	(3)	11
Net (decrease) increase in cash and cash equivalents	(1,343)	28,220
Cash and cash equivalents at beginning of period	271,513	312,795
Cash and cash equivalents at end of period	$ 270,170	$ 341,015

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

The accompanying unaudited consolidated financial statements include the accounts of Emergent BioSolutions Inc. ("Emergent" or the "Company") and its wholly owned and majority owned 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, 2016, as filed with the SEC.

During the three months ended March 31, 2017, 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, 2016, as filed with the SEC, except for revenue recognition associated with the new Biomedical Advanced Research and Development Authority ("BARDA") contract for BioThrax. On March 16, 2017, the Company entered into a contract with BARDA, valued at $100 million for the delivery of BioThrax to the Strategic National Stockpile over a two-year period of performance (the "BARDA BioThrax Contract"). In conjunction with the signing of this contract, the Company entered into a modification to its multi-year contract with BARDA for the advanced development and delivery of NuThrax (the "BARDA NuThrax Contract"). The modification to the BARDA NuThrax Contract increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also provides for a discount on the purchase price for doses to be procured during the option period by up to $100 million thereby reducing the total contract value up to $1.5 billion. Due to this modification of the BARDA NuThrax Contract, the Company has determined that these modifications are treated as discounts, and that a portion of the $100 million consideration to be received under the BARDA BioThrax Contract must be allocated to the future deliveries under the BARDA NuThrax Contract. This discount will result in a partial deferral of revenue recognized upon the delivery of BioThrax doses under the BARDA BioThrax Contract. This deferred revenue will then be recognized upon the delivery of NuThrax doses under the BARDA NuThrax Contract, or upon the future extinguishment of the Company's obligation to deliver NuThrax doses to which the discount applies. As of March 31, 2017, the Company has not delivered BioThrax under the BARDA BioThrax Contract.

The Company has classified the results of operations of Aptevo Therapeutics Inc. ("Aptevo") as discontinued operations for the three months ended March 31, 2016. 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.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of March 31, 2017. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Recently issued accounting standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606) ("*ASU No. 2014-09"). 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 standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. The Company has begun an initial assessment of the potential impact that ASU No. 2014-09 will have on its financial statements and disclosures and believes that there could be changes to the revenue recognition related to the Company's multiple element contracts, primarily those with the U.S. government.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)* (*"*ASU No. 2016-09"). 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. As of March 31, 2017, the Company adopted and performed the evaluation required by the standard and did not identify any conditions or events that would have a material impact on the current disclosures in the financial statements. The Company has retrospectively adjusted the operating and financing sections within the statement of cash flows for the classification of employee taxes paid associated with equity award activities for the three months ended March 31, 2016. In addition, the Company prospectively adopted the provisions related to the excess tax benefits, and as a result prior periods were not adjusted. If the Company had adopted this provision retrospectively, there would have been no change to the estimated effective annual tax rate for the period ended March 31, 2016, but there would have been a tax benefit associated with stock option activity of $2,300.0 million recorded in the provision for income taxes on the Company's statement of operations.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business ("*ASU No. 2017-01"). ASU No. 2017-01 provides clarification for the definition of a business with the objective of adding guidance and providing a more robust framework to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new standard will be effective for all annual periods beginning after December 15, 2017. Early adoption is permitted. The Company will assess the impact of this standard when a business combination arises.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 250): Simplifying the Test for Goodwill Impairment ("*ASU No. 2017-04"). The standard eliminates the second step in the goodwill impairment test, which requires an entity to determine the implied fair value of the reporting unit's goodwill. Instead, an entity should recognize an impairment loss if the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, with the impairment loss not to exceed the amount of goodwill allocated to the reporting unit. The standard is effective for annual and interim goodwill impairment tests conducted in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company does not believe that the new standard will have a material impact on its financial statements.

There are no other recently issued accounting pronouncements that are expected to have a material impact on the Company's financial position, results of operations or cash flows.

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"), and provided for such shareholders to receive 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, which the Company paid in January 2017.

The historical statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements and the prior period has 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 manufacturing services agreement, transition services agreement, a tax matters agreement and an employee matters agreement with Aptevo.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 and continues for 10 years. 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.

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

(in thousands)	**Three Months Ended March 31, 2016**
Revenues:	
Product sales	$ 7,952
Collaborations	85
Total revenues	8,037
Operating expense:	
Cost of product sales	4,502
Research and development	8,061
Selling, general and administrative	8,070
Loss from operations	(12,596)
Other income (expense), net:	81
Loss from discontinued operations before benefit from income taxes	(12,515)
Benefit from income taxes	(4,617)
Net loss from discontinued operations	$ (7,898)

The following table summarizes the cash flows of Aptevo included in the March 31, 2016 consolidated statements of cash flows:

(in thousands)	**Three Months Ended March 31, 2016**
Net cash used in operating activities	$ (6,021)
Net cash used in investing activities	(1,087)
Net cash provided by financing activities	5,689
Net decrease in cash and cash equivalents	$ (1,419)

3. Fair value measurements

Contingent consideration are liabilities measured at fair value on a recurring basis. As of March 31, 2017 and December 31, 2016, the fair value of contingent consideration was $11.8 million and $13.2 million, respectively.

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 Notes are subject to the fair value disclosure requirements and are classified as a Level 2 instrument. The estimated fair value of the Notes at March 31, 2017 was $299.6 million.

For the three months ended March 31, 2017, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program decreased by $0.2 million. For the three months ended March 31, 2016, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program increased by a nominal amount. The changes are primarily due to the estimated timing and probability of success for certain development and regulatory milestones of the EV-035 series of molecules and the broad spectrum antiviral platform program, which are inputs that have no observable market (Level 3). The decreases and increases in the contingent consideration are classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense.

For the three months ended March 31, 2017 and 2016, the contingent purchase consideration obligations associated with RSDL increased by $0.4 million and $0.8 million, respectively. The fair value of the RSDL contingent consideration obligations increased primarily due to the expected timing 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 three months ended March 31, 2017.

(in thousands)	
Balance at December 31, 2016	$ 13,185
Expense included in earnings	200
Settlements	(1,568)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at March 31, 2017	$ 11,817

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 March 31, 2017 and 2016, the Company had no assets or liabilities that were measured at fair value on a non-recurring basis.

4. Inventories

Inventories consisted of the following:

(in thousands)	March 31, 2017	December 31, 2016
Raw materials and supplies	$ 33,264	$ 30,687
Work-in-process	27,326	19,821
Finished goods	10,142	23,494
Total inventories	$ 70,732	$ 74,002

5. Property, plant and equipment

Property, plant and equipment consisted of the following:

(in thousands)	March 31, 2017	December 31, 2016
Land and improvements	$ 20,376	$ 20,340
Buildings, building improvements and leasehold improvements	147,481	147,130
Furniture and equipment	192,828	190,157
Software	53,059	52,564
Construction-in-progress	87,330	77,813
Property, plant and equipment, gross	501,074	488,004
Less: Accumulated depreciation and amortization	(119,972)	(111,556)
Total property, plant and equipment, net	$ 381,102	$ 376,448

As of March 31, 2017 and December 31, 2016, construction-in-progress primarily includes costs related to the build out of the Company's Center for Innovation in Advanced Development and Manufacturing ("CIADM") facility.

6. Intangible assets and in-process research and development

Intangible assets consisted of the following:

(in thousands)	
Cost basis	
Balance at December 31, 2016	$ 57,099
Additions	-
Balance at March 31, 2017	$ 57,099
Accumulated amortization	
Balance at December 31, 2016	$ (23,234)
Amortization	(1,554)
Balance at March 31, 2017	$ (24,788)
Net balance at March 31, 2017	$ 32,311

For the three months ended March 31, 2017 and 2016, the Company recorded amortization expense of $1.6 million and $1.8 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 March 31, 2017, the weighted average amortization period remaining for intangible assets is 73 months.

7. Equity

As of March 31, 2017, the Company had one equity awards plan, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan"), which includes both stock options and restricted stock units.

The following is a summary of stock option award activity under the 2006 Plan:

	2006 Plan		
	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2016	2,559,331	$ 22.94	$ 25,348,245
Granted	376,798	30.63	
Exercised	(162,642)	18.00	
Forfeited	(10,225)	27.38	
Outstanding at March 31, 2017	2,763,262	$ 24.17	$ 14,763,038

The following is a summary of restricted stock unit award activity under the 2006 Plan:

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2016	875,584	$ 28.94	$ 28,754,179
Granted	353,681	30.63	

Vested	(350,617)	30.39	
Forfeited	(13,989)	28.09	
Outstanding at March 31, 2017	864,659	$ 30.13	$ 25,109,698

8. Income taxes

The estimated effective annual tax rate for continued operations, which excludes discrete adjustments, was 31% and 34% for the three months ended March 31, 2017 and 2016, respectively. The increase in the estimated effective annual tax rate on continuing operations was primarily due to a change in the distribution of taxable income between U.S. and foreign jurisdictions.

9. Earnings per share

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

	Three Months Ended March 31,	
(in thousands, except share and per share data)	**2017**	**2016**
Numerator:		
Net income from continuing operations	$ 10,485	$ 11,889
Interest expense, net of tax	907	716
Amortization of debt issuance costs, net of tax	195	215
Net income, adjusted from continuing operations	11,587	12,820
Income (loss) from discontinued operations	-	(7,898)
Net income, adjusted	$ 11,587	$ 4,922
Denominator:		
Weighted-average number of shares—basic	40,727,755	39,542,656
Dilutive securities—equity awards	894,171	1,096,711
Dilutive securities—convertible debt	8,096,500	7,720,525
Weighted-average number of shares—diluted	49,718,426	48,359,892
Net income per share-basic from continuing operations	$ 0.26	$ 0.30
Income (loss) per share-basic from discontinued operations	-	(0.20)
Net income per share-basic	0.26	0.10
Net income per share-diluted from continuing operations	$ 0.23	$ 0.27
Income (loss) per share-diluted from discontinued operations	-	(0.17)
Net income per share-diluted	0.23	0.10

For the three months ended March 31, 2017 and 2016, 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 months ended March 31, 2017 and 2016, 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 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 March 31, 2017, approximately 0.8 million stock options were excluded from the calculation of diluted earnings per share due to the fact that the exercise prices were in excess of the average per share closing price during the period. For the three months ended March 31, 2016, all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share.

10. Restructuring

In August 2016, the Company adopted a plan to restructure and reprioritize the operations of one of its facilities at the Emergent BioDefense Operations Lansing LLC ("EBOL") site due to the Company's large-scale manufacturing facility at the EBOL site 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 substantially completed the EBOL restructuring. The costs of the restructuring as of March 31, 2017 are detailed below:

(in thousands)	**Incurred in 2017**	**Inception to Date Costs Incurred**	**Total Expected to be Incurred**
Termination benefits	$ 20	$ 5,266	$ 5,286
Abandonment of equipment	-	3,749	3,749
Other costs	-	691	691
Total	$ 20	$ 9,706	$ 9,726

During the year ended December 31, 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. During the third quarter of 2016, 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.

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

(in thousands)	**Termination Benefits**
Balance at December 31, 2016	$ 4,357
Expenses incurred	20
Amount paid	(2,122)

Other adjustments	-
Balance at March 31, 2017	$ 2,255

11. Segment information

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

12. 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 the U.S. Department of Health and Human Services 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. On December 27, 2016 the plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. The Company filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. 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

We are a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, intentional and naturally emerging public health threats. Our company is focused on developing, manufacturing and commercializing medical countermeasures, or MCM, that address public health threats, or PHTs. The PHTs we are addressing fall into two categories: Chemical, Biological, Radiological and Nuclear, or CBRN, and/or Explosives and Emerging Infectious Diseases, or EID. We have a portfolio of six revenue-generating products, as well as a pipeline of various investigational stage product candidates addressing select aspects of CBRN and EID threats. The U.S. government is the primary purchaser of our products and provides us with substantial funding for the development of many of our product candidates.

Our marketed MCMs 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. BioThrax is also licensed by the Paul-Ehrlich-Institut of the German Federal Ministry of Health for general use 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 and Health Canada for the treatment of botulinum disease;
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only therapeutic licensed by the FDA to address certain complications from smallpox vaccination;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA intended to remove or neutralize chemical warfare agents and T-2 toxin from the skin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, a nerve agent countermeasure. This product has not been approved by the FDA or any other regulatory agency, is not promoted or distributed in the U.S., and is only sold to non-U.S. authorized government buyers.

Our lead investigational stage MCMs 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*;
- FLU-IG (NP025), a human polyclonal antibody therapeutic being developed to treat seasonal influenza;
- ZIKA-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis for Zika infections; and
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat Ebola infections.

A unique attribute of our investigational stage product portfolio is that many of our candidates are under an active development contract with significant funding from the U.S. government.

We also have programs that leverage our proven manufacturing infrastructure and expertise. We have responded to specific Task Order Requests issued by the Biomedical Advanced Research and Development Authority, or 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 a Zika vaccine and an Ebola monoclonal therapeutic.

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 50 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 or inspected manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union.

Highlights and Recent Business Accomplishments for Three Months ended March 31, 2017

On March 31, 2017, we signed a modification to our contract with BARDA to manufacture and store bulk drug substance for our botulism antitoxin, BAT valued at approximately $53 million with a five-year period of performance. This modification to the contract is intended to enable future filling and deliveries of final drug product to the SNS. BAT is indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.

On March 16, 2017, we entered into a contract with the BARDA, valued at $100 million for the delivery of BioThrax to the Strategic National Stockpile, or SNS, over a two-year period of performance. In conjunction with the signing of the $100 million contract for delivery of BioThrax with BARDA, we entered into a modification to our previously disclosed multi-year contract with BARDA for the advanced development and delivery of NuThrax. The modification increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also reduces the purchase price for doses to be procured during the option period by $100 million thereby reducing the total contract value to be up to $1.5 billion.

On February 13, 2017, we received a task order from BARDA valued at up to $30.5 million to develop monoclonal antibody therapeutics for viral hemorrhagic fever. This task order will utilize our CIADM facility located in Baltimore, Maryland. Using monoclonal antibodies from Mapp Biopharmaceutical Inc., we will conduct technology transfer of process materials and information, perform process and analytical method development, execute small-scale production runs, and perform current good manufacturing practices, or cGMP, cell banking leading to cGMP, manufacture of bulk drug substance. The task order consists of a 36-month period of performance with a base task order valued at $7.4 million and options that, if executed, will bring the total task order value over three years to up to $30.5 million.

On January 27, 2017, we received from the Paul-Ehrlich-Institute, or PEI, the regulatory agency under the German Federal Ministry of Health, approval for our large-scale manufacturing facility, Building 55, located in Lansing, Michigan. This approval allows us to market BioThrax manufactured in Building 55 in Germany.

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, or the Court, 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. On December 27, 2016, the plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. We filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

Financial Operations Overview

Revenues

We have derived a majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are a party to a contract with the Centers for Disease Control and Prevention, or CDC, an operating division of the HHS, valued at up to $911 million, to supply approximately 29.4 million doses of BioThrax to the SNS through September 2021. Through March 31, 2017, we have delivered and recognized revenue on approximately 1.9 million doses, representing approximately $57 million in revenue under this contract. We are focused on increasing the sales of BioThrax as well as the other products in our product portfolio to U.S. government customers and expanding the market for our product portfolio to other customers domestically and internationally.

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

Development Programs	Funding Source	Award Date	Performance Period
Anthrasil	BARDA	09/2005	9/2005 — 4/2021
	BARDA	09/2013	9/2013 — 9/2018
BAT	BARDA	05/2006	5/2006 — 5/2026
CIADM	BARDA	06/2012	6/2012 — 6/2037
GC-072	DTRA	08/2014	8/2014 — 8/2017
Large-scale manufacturing for BioThrax	BARDA	07/2010	7/2010 — 7/2017
NuThrax	NIAID	08/2014	8/2014 — 10/2019
	BARDA	03/2015	3/2015 — 8/2017
	BARDA	09/2016	9/2016 — 9/2021
UV-4B	NIAID	09/2011	9/2011 — 9/2017
VIGIV	CDC	08/2012	8/2012 — 8/2017
Zika	BARDA	06/2016	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 our fulfilling orders for BioThrax and work done under new and existing grants and development contracts.

Critical Accounting Policies and Estimates

During the three months ended March 31, 2017, there have been no significant changes to our Critical Accounting Policies and Estimates contained in our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission, except for revenue recognition associated with the new BARDA contract for BioThrax. On March 16, 2017, we entered into a contract with BARDA, valued at $100 million for the delivery of BioThrax to the SNS over a two-year period of performance, or the BARDA BioThrax Contract. In conjunction with the signing of the $100 million contract for delivery of BioThrax with BARDA, we entered into a modification to our previously disclosed multi-year contract with BARDA for the advanced development and delivery of NuThrax, or the BARDA NuThrax Contract. The modification to the BARDA NuThrax Contract increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also provides for a discount on the purchase price for doses to be procured during the option period by up to $100 million thereby reducing the total contract value up to $1.5 billion. Due to this modification of the BARDA NuThrax Contract, we have determined that these modifications are treated as discounts, and that a portion of the $100 million consideration to be received under the BARDA BioThrax Contract must be allocated to the future deliveries under the BARDA NuThrax Contract. This discount will result in a partial deferral of revenue recognized upon the delivery of BioThrax doses under the BARDA BioThrax Contract. This deferred revenue will then be recognized upon the delivery of NuThrax doses under the BARDA NuThrax Contract, or upon the future extinguishment of our obligation to deliver NuThrax doses to which the discount applies. As of March 31, 2017, the Company has not delivered BioThrax under the BARDA BioThrax Contract.

Results of Operations

Three Months Ended March 31, 2017 Compared to Three Months Ended March 31, 2016

Revenues

Three Months Ended March 31,

(in thousands)	2017	2016	Change	% Change
Product sales:				
BioThrax	$ 43,815	$ 59,100	$ (15,285)	(26%)
Other	38,154	4,653	33,501	720%
Total product sales	81,969	63,753	18,216	29%
Contract manufacturing	17,628	7,587	10,041	132%
Contracts and grants	17,261	31,624	(14,363)	(45%)
Total revenues	$ 116,858	$ 102,964	$ 13,894	13%

Product Sales:

The increase in Product sales was primarily due to the timing of BAT sales to the SNS, partially offset by a decrease in BioThrax sales primarily due to the timing of deliveries to the SNS.

Contract Manufacturing:

The increase in Contract manufacturing is primarily due to the timing of fill/finish services provided to third parties, along with manufacturing of products for Aptevo.

Contracts and grants:

The decrease in Contracts and grants was primarily due to:

- § decreased development funding of $8.2 million for VIGIV related to the timing of plasma collection;
- § decreased development funding of $3.9 million related to our CIADM program, which includes a decrease of $2.4 million for CIADM task orders; and
- § decreased development funding of $2.2 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 $22.3 million, or 93%, to $46.3 million for the three months ended March 31, 2017 from $24.0 million for the three months ended March 31, 2016. The increase was attributable to increased costs associated with the increase in Other product sales and increased costs associated with the expansion of our contract manufacturing business, as well as costs for routine maintenance shutdown activities.

Research and Development Expenses

Research and development expenses decreased by $5.6 million, or 22%, to $20.5 million for the three months ended March 31, 2017 from $26.1 million for the three months ended March 31, 2016. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, we incurred net research and development expenses of $3.2 million during the three months ended March 31, 2017. Net of contracts and grants revenues, our research and development expenses were fully funded during the three months ended March 31, 2016, resulting in a net contribution from funded development programs of $5.5 million.

Our principal research and development expenses for the three months ended March 31, 2017 and 2016 are shown in the following table:

	Three Months Ended March 31,			
(in thousands)	2017	2016	Change	% Change
NuThrax	$ 6,403	$ 4,386	$ 2,017	46%
UV-4B	1,849	1,153	696	60%
CIADM task orders	1,115	2,824	(1,709)	(61%)
FLU-IG (NP025)	1,028	-	1,028	N/A
BAT	934	1,055	(121)	(11%)
Auto-injector platform	658	2,672	(2,014)	(75%)
Large-scale manufacturing for BioThrax	626	2,380	(1,754)	(74%)
Pandemic influenza	621	741	(120)	(16%)
VIGIV	610	2,587	(1,977)	76%
EV-035 series of molecules	606	802	(196)	24%
Anthrasil	212	283	(71)	-25%
BioThrax related programs	9	791	(782)	(99%)
Other	5,805	6,419	(614)	(10%)
Total	$ 20,476	$ 26,093	$ (5,617)	(22%)

The increase in expense for NuThrax was primarily due to the timing of non-clinical animal studies and manufacturing activities. The increase in expense for UV-4B was primarily due to clinical trial activity to evaluate safety and tolerability. The decrease in expense for CIADM task orders was due to the timing of manufacturing development for Ebola monoclonal antibodies. The expense for FLU-IG (NP025) was primarily due to clinical trial preparation. The spending for our BAT program was primarily related to stability testing. The decrease in expense for our Auto-injector platform was due to the timing of device and formulation development activities. 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 spending for Pandemic influenza was primarily for non-clinical development activities. The decrease in expense for VIGIV was primarily due to the timing of plasma collection. The spending for our EV-035 series of molecules was primarily for formulation development activities. The spending for our Anthrasil program was primarily for post-licensure development activities. The decrease in expense for BioThrax related programs was primarily related to the timing of clinical and non-clinical studies to support applications for label expansion for BioThrax. 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 $3.5 million, or 11%, to $35.2 million for the three months ended March 31, 2017 from $31.7 million for the three months ended March 31, 2016. The increase includes costs of $1.4 million associated with restructuring activities within the general and administrative functional groups. The increase is also attributable to professional services to support our strategic growth initiatives.

Provision for Income Taxes

Provision for income taxes decreased by $4.8 million, or 60%, to $3.2 million for the three months ended March 31, 2017 from $8.0 million for the three months ended March 31, 2016. The decrease was primarily due to a $1.1 million tax benefit in 2017 associated with stock option activity and a one-time non-cash charge of $1.2 million associated with tax planning and restructuring activities in the first quarter of 2016.

Liquidity and Capital Resources

Sources of Liquidity

From inception through March 31, 2017, we have funded our cash requirements principally with a combination of product sales revenues, debt financing, development funding, 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, 2016. As of March 31, 2017, we had cash and cash equivalents of $270.2 million.

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
(in thousands)	**2017**	**2016**
Net cash provided by (used in):		
Operating activities(i)	$ 41,668	$ 42,182
Investing activities	(20,304)	(18,214)
Financing activities	(22,707)	4,252
Net (decrease) increase in cash and cash equivalents	$ (1,343)	$ 28,220

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

Operating Activities:

Net cash provided by operating activities of $41.7 million for the three months ended March 31, 2017 was primarily due to our net income of $10.5 million, non-cash charges of $10.2 million for depreciation and amortization and $4.3 million in stock-based compensation expense, a $10.6 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC, a $9.1 million increase in deferred revenue, and a $3.3 million decrease in inventories primarily due to the timing of deliveries of BioThrax to the CDC, partially offset by a decrease in accrued compensation of $11.2 million primarily related to the payment of 2016 annual bonuses.

Net cash provided by operating activities of $42.2 million for the three months ended March 31, 2016 was primarily due to our net income of $4.0 million and a $51.2 million decrease in accounts receivable related to the timing of collection of amounts billed primarily to the CDC, along with non-cash charges of $8.8 million for depreciation and amortization, partially offset by an increase in inventories of $11.3 million primarily due to the timing of deliveries of BioThrax to the CDC, a decrease in accrued compensation of $8.3 million primarily related to the payment of 2015 annual bonuses and an increase of $5.6 million in prepaid expenses and other assets.

Investing Activities:

Net cash used in investing activities of $20.3 million and $18.2 million for the three months ended March 31, 2017 and 2016, respectively, was due to infrastructure and equipment investments, including the construction of a third manufacturing suite at our Baltimore CIADM manufacturing facility.

Financing Activities:

Net cash used in financing activities of $22.7 million for the three months ended March 31, 2017 was primarily due to the payment of a $20.0 million note payable to Aptevo in conjunction with the spin-off, $4.0 million associated with the taxes paid on behalf of employees for equity activity and $1.6 million in contingent obligation payments, partially offset by $3.0 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

Net cash provided by financing activities of $4.3 million for the three months ended March 31, 2016 was primarily due to $5.8 million in excess tax benefits from the exercise of stock options and $3.6 million in proceeds from the issuance of common stock pursuant to our employee equity award plans, that is partially offset by $4.4 million associated with the taxes paid on behalf of employees for equity activity.

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 the Securities and Exchange Commission, or 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.

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 March 31, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, 1934, or 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 March 31, 2017, 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

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. ***LEGAL PROCEEDINGS***

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. On December 27, 2016 the plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. On February 27, 2017 the Company filed a motion to dismiss the Plaintiff's amended complaint. The Plaintiffs filed an opposition brief on April 28, 2017.

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 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.

GOVERNMENT CONTRACTING RISKS

We currently derive the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow would be materially harmed.

We have derived, and expect for the foreseeable future 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. In December 2016, we signed a follow-on procurement contract with the Centers for Disease Control and Prevention, or the CDC, for the delivery of approximately 29.4 million doses of BioThrax for placement into the Strategic National Stockpile, or the SNS, over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million, if all procurement options are exercised. In March 2017, we signed a procurement contract with the Biomedical Advanced Research and Development Authority, or BARDA, a division within the Office of the Assistant Secretary of Preparedness and Response at the U.S. Department of Health and Human Services, or HHS, for the delivery of approximately $100 million of BioThrax into the SNS over a two-year period. This contract is separate from and in addition to the follow-on procurement contract with the CDC.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. We have no certainty that funding will be made available for the procurement of doses under the CDC contract. 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 would be materially harmed. The success of our business and our operating results for the foreseeable

future are significantly dependent on 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.

Our submission of NuThrax for Emergency Use Authorization, or EUA, 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.

In September 2016, we entered into a contract with HHS through BARDA for the advanced development and delivery of NuThrax, our next generation anthrax vaccine candidate. The contract, as modified in March 2017, is valued at up to approximately $1.5 billion.

We intend to submit an application in 2018 with the FDA for EUA pre-approval of NuThrax, and 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 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.

The U.S. government is the principal customer for our public health threat-focused medical countermeasures BioThrax, BAT, Anthrasil, VIGIV and RSDL, and is the primary source of funds for the development of our product candidates in our development pipeline, most notably our NuThrax product candidate. We anticipate that the U.S. government will also be a principal customer for those medical countermeasures that we successfully develop within our existing product development pipeline, as well as those we successfully acquire. 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 to be supplied under our procurement contract with the CDC is subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations and stringent budgetary constraints.

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 September 2016 contract award from BARDA 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. The contract award also includes options for the delivery of additional doses of NuThrax to the SNS and options for an additional clinical study and post-marketing commitments which if both were to be exercised in full, would increase the total contract value to up to $1.5 billion. If levels of government expenditures and authorizations for public health countermeasure preparedness 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 existing 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 possibility that we may be ineligible to respond to a request for proposal issued by the government;
- 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 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 could 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 either the development of our new product candidates or for the procurement of our existing products addressing public health threats, 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, which could have a material adverse effect on our financial condition and operating results.

As a manufacturer and supplier of medical countermeasures addressing public health threats to 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 our business 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 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 were 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 procurement contracts with HHS and the DoD are fixed price contracts. We expect that future procurement contracts we successfully secure with the U.S. government would also 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 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. All of our contracts, both development and procurement, with the U.S. government, are terminable at the U.S. government's convenience with these potential consequences.

In addition, 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 products or product candidates addressing public health threat preparedness and therefore are competing with us for both U.S. government procurement and development resources. Many of our competitors have greater financial, technical and marketing resources than we do.

Any reduction in demand for our products as a result of a competing product could lead to a loss of market share for our products and therefore reduced revenues, reduced margins and reduced levels of profitability for us, which 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, otherwise referred to as 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 path, 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 counter the potential impact of public health threats, whether Chemical, Biological, Radiological and Nuclear, or CBRN, threats, or Explosives and Emerging Infectious Diseases, or EID, are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our marketed 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 public health threat countermeasures and thereby limit the demand for our products, which would adversely affect our business and operating results.

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 company 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 medical countermeasure product candidates, for example, is subject to a different regulatory approval pathway. Specifically, in the case of anthrax-related product development, 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 rather than 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 of our public health threat countermeasure 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, 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 foreign 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 November 2016, and our Baltimore (Camden) facility was most recently inspected by the Health Products Regulatory Authority of Ireland in February 2017, FDA in January 2017 and Health Canada in October 2016. Following several of these inspections, regulatory authorities 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, regulatory authorities find that we are not in substantial compliance with all applicable 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.

Additionally, companies may not promote drugs for "off-label" uses, that is, uses that are not described in the product's labeling and that differ from those approved by the applicable regulatory agencies. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the U.S. government), as well as criminal sanctions. If our employees or agents engage in "off-label" marketing of any of our products, we could be subject to civil or criminal investigations, monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our results of operations and damage our reputation.

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 intend to sell certain of our products outside 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. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

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 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 or our other products, which would harm our business, financial condition and operating results.

Any interruption in manufacturing operations at Building 55, our FDA-approved large-scale manufacturing facility on our Lansing, Michigan campus, 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;
- § damage to or destruction of the facility; and
- § product contamination or tampering.

Providers of public health threat countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our bulk manufacturing facility in Baltimore, Maryland 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 our manufacturing facilities, including Building 55, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

If we are unable to utilize the full manufacturing capacities of our manufacturing facilities, our future revenues, financial condition, operating results and cash flows could be adversely affected. For example, in August 2016, we received FDA approval for the manufacture of BioThrax in Building 55, our large-scale manufacturing facility at our Lansing, Michigan campus and have transitioned BioThrax manufacturing to Building 55, which significantly increases our BioThrax manufacturing capacity compared to the capacity of our Building 12 licensed facility. Despite this recent success with FDA approval and the initiation of manufacturing of BioThrax in Building 55, we may not secure procurement contracts for BioThrax or other products or product candidates sufficient to utilize its full manufacturing capacity. The procurement volume of our current CDC and BARDA contracts for BioThrax and our manufacturing of NuThrax for development work will not fully utilize the manufacturing capacities of Building 55, and we may be unable to utilize the remaining manufacturing capacities.

Our marketed products and our 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 during manufacturing may arise 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.

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.

Manufacturing 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.

We are required to obtain FDA approval prior to the release of each lot of BioThrax, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 181,000 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 reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are not able to produce and qualify a new reference 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.

If we are unable to obtain supplies for the manufacture of our marketed products and product candidates in sufficient quantities, at an acceptable cost and in acceptable quality, our ability to manufacture or to develop and commercialize our marketed 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 as well as the specialty plasma in our hyperimmune specialty plasma products. A disruption in the availability of such materials or services from these suppliers or in the quality of the material provided by such 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 growth 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 effort 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 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 or other foreign regulatory 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 and other 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 product candidates addressing CBRN threats, 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 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 March 31, 2017, 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 efforts 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 March 31, 2017, we had approximately $270.2 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 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, 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.

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 second quarter 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.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

If our spin-off distribution on August 1, 2016 of all of the outstanding shares of Aptevo Therapeutics Inc. 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 was our intention 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 transactions 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.

In connection with Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters. This indemnity may not be sufficient to hold us harmless from the full amount of losses that we may incur in connection with these matters, and Aptevo may not be able to satisfy its indemnification obligations to us.

Pursuant to the agreements that we entered into with Aptevo at the time of Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters, including liabilities related to Aptevo's business or for which Aptevo otherwise agreed to be responsible in the separation. This indemnity from Aptevo may not be sufficient to protect us against the full amount of losses that we may incur in connection with these matters, including if third parties assert claims against us for liabilities that were allocated to Aptevo in the separation. Moreover, Aptevo may dispute its indemnification obligation to us or have insufficient resources to satisfy its indemnification obligations to us. Even if we ultimately succeed in recovering from Aptevo the amount of any losses that we incur in connection with these matters, the recovery could take a substantial amount of time and we may be required to bear these losses ourselves while we seek recovery. Each of these risks could negatively affect our business, results of operations and financial condition.

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, 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, as amended on December 27, 2016, 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.

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.

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 certain of our products, namely 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, certain of our products, namely 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.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could impact our financial information and disclosures, require significant resources to remediate the lapse or deficiency, and expose us to legal or regulatory proceedings.

We regularly review and update our internal controls and disclosure controls and procedures. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed, can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the price of our common stock could be negatively affected.

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 April 28, 2017, Mr. El-Hibri was the beneficial owner of approximately 14% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over all corporate actions requiring board or stockholder approval, including a change of control, or 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;
- § 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, we are subject to Section 203 of the Delaware General Corporation Law, or Section 203. In general and subject to certain exceptions, Section 203 prohibits a publicly-held 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 Board of Directors may reinstate our stockholder rights plan or implement a new stockholder rights plan without stockholder approval, which 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.

Our Board of Directors may implement a stockholder rights plan without stockholder approval. We previously implemented a stockholder rights plan, which expired on November 14, 2016. Under our prior stockholder rights plan, we issued to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, would have entitled 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 was 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.

Our Board of Directors may reinstate the prior stockholder rights plan or implement a new stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could 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 April 28, 2017, 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 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 limits 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 April 28, 2017, 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: May 4, 2017

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

Date: May 4, 2017

EXHIBIT INDEX

Exhibit Number	Description
10.1*	Form of Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2017).
10.2#††	Modification No. 1 to the Award/Contract (the "BARDA NuThrax Contract"), effective March 16, 2017, between the BioMedical Advanced Research and Development Authority and Emergent Product Development Gaithersburg Inc.
10.3#††	Award/Contract (the "BARDA BioThrax Contract"), effective March 16, 2017, between the BioMedical Advanced Research and Development Authority and Emergent Biodefense Operations Lansing LLC.
10.4#	Sixth Amendment to Credit Agreement, dated as of April 4, 2017, among the Company, as borrower, certain of its subsidiaries party thereto, as guarantors, Bank of America, N.A., as administrative agent, and certain financial institutions party thereto as lenders.
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 months ended March 31, 2017 and 2016;
(ii) Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2017 and 2016;
(iii) Condensed Consolidated Balance Sheets at March 31, 2017 and December 31, 2016;
(iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and 2016; 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.

* Management contract or compensatory plan or arrangement filed herewith in response to Item 15(c) of Form 10-Q.

EXHIBIT 12

Ratio of Earnings to Fixed Charges

(in thousands)	Year to Date March 30, 2017	Year Ended December 31, 2016	2015	2014	2013	2012
Pretax income from continuing operations (1)	$ 13,645	$ 99,221	$ 135,716	$ 84,194	$ 83,439	$ 68,011
Fixed charges						
Interest expense	1,957	8,270	7,834	7,480	1,973	2,177
Debt issuance cost	382	1,526	1,564	3,290	319	67
Total fixed charges (2)	2,339	9,796	9,398	10,770	2,292	2,244
Noncontrolling interest in pretax income (3)	-	-	-	-	876	5,381
Capitalized interest (4)	401	2,179	2,875	2,530	1,973	2,177
Earnings ((1) + (2) -(3) -(4))	15,583	106,838	142,239	92,434	82,882	62,697
Fixed charges	2,339	9,796	9,398	10,770	2,292	2,244
Ratio of earnings to fixed charges	6.7	10.9	15.1	8.6	36.2	27.9
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: May 4, 2017

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

EXHIBIT 31.2

CERTIFICATION

I, Robert G. Kramer, Sr., 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: May 4, 2017

/s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
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 March 31, 2017 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: May 4, 2017

/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 March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Kramer, Sr., 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: May 4, 2017

/s/ROBERT G. KRAMER, SR.
Robert G. Kramer, Sr.
Chief Financial Officer

SIXTH AMENDMENT TO CREDIT AGREEMENT

This **SIXTH AMENDMENT TO CREDIT AGREEMENT**, dated as of April 4, 2017 (this "Amendment"), modifies that certain Credit Agreement, dated as of December 11, 2013 (as amended, restated, extended, supplemented or otherwise modified in writing from time to time, the "Credit Agreement"), among **EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation (the "Borrower"), each Domestic Subsidiary of the Borrower from time to time party thereto as a Guarantor, each lender from time to time party thereto (collectively, the "Lenders" and individually, a "Lender"), and **BANK OF AMERICA, N.A.**, as administrative agent (in such capacity, the "Administrative Agent"), Swing Line Lender and L/C Issuer. Capitalized terms used herein and not defined shall have the meaning assigned to such terms in the Credit Agreement.

RECITALS

WHEREAS, the Borrower has requested that the Administrative Agent and the Lenders agree to amend certain of the terms and provisions of the Credit Agreement, as specifically set forth in this Amendment; and

WHEREAS, the Administrative Agent and each of the undersigned Lenders are prepared to amend the Credit Agreement, in each case, on the terms, subject to the conditions and in reliance on the representations set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual agreements contained here, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

Section 1. Amendment to Credit Agreement.

(a) Section 1.01 (Defined Terms) is hereby amended by restating the following definitions contained in such Section in its entirety as follows:

"L/C Issuer" means each of (a) Bank of America, N.A., or any successor issuer thereof, (b) JPMorgan Chase Bank, N.A. or any successor issuer thereof ("JPM"), (c) PNC Bank, National Association, or any successor issuer thereof ("PNC"), (d) such other Lender selected by the Borrower pursuant to Section 2.03(n) from time to time to issue Letters of Credit (provided that no Lender shall be required to become an L/C Issuer pursuant to this subclause (d) without such Lender's consent), or any successor issuer thereof or (e) any Lender selected by the Borrower (with the prior consent of the Administrative Agent) to replace a Lender who is a Defaulting Lender at the time of such Lender's appointment as an L/C Issuer (provided that no Lender shall be required to become an L/C Issuer pursuant to this subclause (e) without such Lender's consent), or any successor issuer thereof, in each case, in their respective capacities as an issuer of Letters of Credit hereunder. References herein to "L/C Issuer" or "the L/C Issuer" shall mean, as applicable, and as the context may require (as reasonably determined by Administrative Agent), each L/C Issuer, each applicable or relevant L/C Issuer with respect to any Letter of Credit and/or all L/C Issuers with respect to all Letters of Credit.

(b) Section 1.01 (Defined Terms) is hereby amended by inserting the following new definitions in the appropriate alphabetical order:

"L/C Issuer Sublimits" means, as of the Closing Date, (i) $8,333,333, in the case of Bank of America, (ii) $8,333,333, in the case of JPM, (iii) $8,333,333, in the case of PNC, and (iv) such amount as shall be designated to the Administrative Agent and the Borrower in writing by an L/C Issuer; provided that any L/C Issuer shall be permitted at any time to increase its L/C Issuer Sublimit upon providing five (5) days' prior written notice thereof to the Administrative Agent and the Borrower to an amount not exceeding the Letter of Credit Sublimit.

"Letter of Credit Report" means a certificate in substantially a form approved by the Administrative Agent.

"Notice of Additional L/C Issuer" means a certificate substantially in a form approved by the Administrative Agent.

(a) Section 2.03(a)(i) (The Letter of Credit Commitment) is hereby amended by inserting the following sentence at the end of such Section 2.03(a)(i):

Notwithstanding the foregoing or anything to the contrary contained herein, no L/C Issuer shall be obligated to issue. amend or extend any Letter of Credit if, immediately after giving effect thereto, the outstanding L/C Obligations in respect of all Letters of Credit issued by such L/C Issuer would exceed such Person's L/C Issuer Sublimit.

(b) Section 2.03 (Letters of Credit) is hereby amended by inserting the following new subsections (n) and (o) in the appropriate alphabetical order:

(n) L/C Issuer Reports to the Administrative Agent. Unless otherwise agreed by the Administrative Agent, each L/C Issuer (other than Bank of America, N.A.) shall, in addition to its notification obligations set forth elsewhere in this Section, provide the Administrative Agent a Letter of Credit Report, as set forth below:

(i) reasonably prior to the time that such L/C Issuer issues, amends, renews, increases or extends a Letter of Credit, the date of such issuance, amendment, renewal, increase or extension and the stated amount of the applicable Letters of Credit after giving effect to such issuance, amendment, renewal or extension (and whether the amounts thereof shall have changed);

(ii) on each Business Day on which such L/C Issuer makes a payment pursuant to a Letter of Credit, the date and amount of such payment;

(iii) on any Business Day on which the Borrower fails to reimburse a payment made pursuant to a Letter of Credit required to be reimbursed to such L/C Issuer on such day, the date of such failure and the amount of such payment;

(iv) on any other Business Day, such other information as the Administrative Agent shall reasonably request as to the Letters of Credit issued by such L/C Issuer; and

(v) for so long as any Letter of Credit issued by an L/C Issuer is outstanding, such L/C Issuer shall deliver to the Administrative Agent (A) on the last Business Day of each calendar month, (B) at all other times a Letter of Credit Report is required to be delivered pursuant to this Agreement, and (C) on each date that (1) an L/C Credit Extension occurs or (2) there is any expiration, cancellation and/or disbursement, in each case, with respect to any such Letter of Credit, a Letter of Credit Report appropriately completed with the information for every outstanding Letter of Credit issued by such L/C Issuer.

(o) Additional L/C Issuers. Any Lender hereunder may become an L/C Issuer upon receipt by the Administrative Agent of a fully executed Notice of Additional L/C Issuer which shall be signed by the Borrower, the Administrative Agent and each L/C Issuer.

Section 2. New L/C Issuer. By its signature below, each of JPM and PNC hereby acknowledges and agrees that, from and after the effectiveness of this Amendment, each of JPM and PNC shall be an L/C Issuer under the Credit Agreement, with all rights and obligations of an L/C Issuer thereunder.

Section 3. Conditions Precedent. This Amendment shall become effective as of the date first written above (the "Effective Date") upon the satisfaction of the following conditions precedent:

(a) Documentation. Administrative Agent shall have received all of the following, in form and substance satisfactory to Administrative Agent:

(i) a fully-executed and effective Amendment executed by the Borrower, the Guarantors, the Administrative Agent and the Required Lenders; and

(ii) such additional documents, instruments and information as Administrative Agent may reasonably request in connection with the transactions contemplated hereby.

(b) No Default. On the Effective Date and after giving effect to this Amendment, no event shall have occurred and be continuing that would constitute a Default or an Event of Default.

Section 4. Representations and Warranties; Reaffirmation of Grant. Each Loan Party hereby represents and warrants to the Administrative Agent and the Lenders that, as of the date hereof and after giving effect to this Amendment: (a) all representations and warranties of the Borrower and each other Loan Party set forth in the Credit Agreement and in any other Loan Document are true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof) on and as of the date hereof, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects as of such earlier date (except that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof), (b) no Default or Event of Default has occurred and is continuing, (c) the Credit Agreement and all other Loan Documents are and remain legally valid, binding obligations of the Loan Parties party thereto, enforceable against each such Loan Party in accordance with their respective terms, subject to bankruptcy, insolvency, reorganization, moratorium and other laws applicable to creditors' rights generally and subject to general principles of equity, and (d) the provisions of the Collateral Documents to which such Loan Party is a party are effective to create in favor of the Administrative Agent for the benefit of the Secured Parties a legal, valid and enforceable first priority Lien (subject only to Liens permitted by Section 7.01 of the Credit Agreement) on all right, title and interest of the respective Loan Parties in the Collateral described therein and do and shall continue to secure the payment of all Obligations as set forth in such respective Collateral Documents. Each Loan Party hereby reaffirms its grant of a security interest in the Collateral to the Administrative Agent for the benefit of the Secured Parties, as security for the payment and performance in full of the Obligations.

Section 5. Survival of Representations and Warranties. All representations and warranties made in this Amendment or any other Loan Document shall survive the execution and delivery of this Amendment, and no investigation by the Administrative Agent or the Lenders shall affect the representations and warranties or the right of the Administrative Agent and the Lenders to rely upon them.

Section 6. Amendment as Loan Document. This Amendment constitutes a "Loan Document" under the Credit Agreement. Accordingly, it shall be an immediate Event of Default under the Credit Agreement if any representation, warranty, certification or statement of fact made by any Loan Party under or in connection with this Amendment shall have been incorrect or misleading in any material respect when made or deemed made.

Section 7. Costs and Expenses. The Borrower shall pay not later than ten (10) Business Days after invoiced all reasonable out-of-pocket costs and expenses of the Administrative Agent (including the reasonable fees, charges and disbursements of counsel to the Administrative Agent)

incurred in connection with the preparation, negotiation, execution and delivery of this Amendment, in each case, in accordance with Section 10.04 of the Credit Agreement.

Section 8. Governing Law. THIS AMENDMENT AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AMENDMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

Section 9. Execution. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by telecopier (or electronic mail (including in PDF format)) shall be effective as delivery of a manually executed counterpart of this Amendment.

Section 10. Limited Effect. This Amendment relates only to the specific matters expressly covered herein, shall not be considered to be an amendment or waiver of any rights or remedies that the Administrative Agent or any Lender may have under the Credit Agreement or under any other Loan Document (in each case, except as expressly set forth herein) or under Law, and shall not be considered to create a course of dealing or to otherwise obligate in any respect the Administrative Agent or any Lender to execute similar or other amendments, consents, or waivers or grant any amendments, consents or waivers under the same or similar or other circumstances in the future.

Section 11. Ratification by Guarantors. Each of the Guarantors acknowledges that its consent to this Amendment is not required, but each of the undersigned nevertheless does hereby agree and consent to this Amendment and to the documents and agreements referred to herein. Each of the Guarantors agrees and acknowledges that (i) notwithstanding the effectiveness of this Amendment, such Guarantor's Guaranty shall remain in full force and effect without modification thereto and (ii) nothing herein shall in any way limit any of the terms or provisions of such Guarantor's Guaranty or any other Loan Document executed by such Guarantor (as the same may be amended from time to time), all of which are hereby ratified, confirmed and affirmed in all respects. Each of the Guarantors hereby agrees and acknowledges that no other agreement, instrument, consent or document shall be required to give effect to this Section 11.

[*Signature Pages Follow*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered as of the date first above written.

BORROWER:

EMERGENT BIOSOLUTIONS INC.

By: /s/ROBERT G. KRAMER
Name: Robert G. Kramer
Title: Chief Financial Officer and Treasurer

GUARANTORS:

EMERGENT BIODEFENSE OPERATIONS LANSING LLC

EMERGENT COMMERCIAL OPERATIONS FREDERICK INC.

EMERGENT INTERNATIONAL INC.

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.

EMERGENT EUROPE INC.

EMERGENT PROTECTIVE PRODUCTS USA INC.

EMERGENT VIROLOGY LLC

By: /s/ROBERT G. KRAMER
Name: Robert G. Kramer
Title: Treasurer

GUARANTORS (cont'd):

400 PROFESSIONAL LLC

By: /s/ROBERT G. KRAMER
Name: Robert G. Kramer
Title: Vice President

CANGENE BIOPHARMA LLC

By: /s/MICHAEL R. DARLING
Name: Michael R. Darling
Title: Treasurer

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC

By: /s/ROBERT G. KRAMER
Name: Robert G. Kramer
Title: Executive Manager

ADMINISTRATIVE AGENT:

BANK OF AMERICA, N.A.

By: /s/ERIK M. TRUETTE
Name: Erik M. Truette
Title: Vice President

LENDERS:

BANK OF AMERICA, N.A., as a Lender, a L/C Issuer and Swing Line Lender

By: /s/LORI JOU EGAN
Name: Lori Jou Egan
Title: Senior Vice President

LENDERS (cont'd):

JPMORGAN CHASE BANK, N.A. as a Lender and a L/C Issuer

By: /s/ANTHONY GALEA
Name: Anthony Galea
Title: Executive Director

LENDERS (cont'd):

PNC BANK, NATIONAL ASSOCIATION, as a Lender and L/C Issuer

By: /s/ERIC H. WILLIAMS
Name: Eric H. Williams
Title: Vice President

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 OF PAGES 1 6

2. AMENDMENT/MODIFICATION NO. 0001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. *(If applicable)*

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA
ASPR-BARDA 200 Independence Ave., S.S. Room 640-G Washington, DC 20201		ASPR-BARDA 200 Independence Ave., S.S. Room 638-G Washington, DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., Street, county, State and ZIP Code)*	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR # 100 GAITHERSBURG MD 208793419		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201600030C
		10B. DATED *(SEE ITEM 13)* 09/30/2016
CODE 1365869	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 Schedule

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 52.243-2 Changes – Cost Reimbursement

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

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

Tax ID Number: [**]

DUNS Number: [**]

The purpose of this modification is to modify ARTICLES B.2 BASE PERIOD, B.3. OPTION PRICES, B.5. ADVANCE UNDERSTANDINGS, and SECTION 1 - CONTRACT CLAUSES.

Funds Obligated Prior to this Modification: $198,705,042
Funds Obligated with Mod #1: $0
Total Funds Obligated to Date: $198,705,042

Expiration Date: September 29,2021
Period of Performance: 09/30/2016 to 09/29/2021

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 CHRISTOPHER SCOTT	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA By *(Signature of Contracting Officer)*	16C. DATE SIGNED

ARTICLE B.2. BASE PERIOD is hereby modified as follows:

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**	**3,000,000**	[**]	[**]
Total CLINS 1&2	09/30/2016 – 09/29/2021	See Above Descriptions			$198,705,042 (Funded)

[**]

ARTICLE B.3. OPTION PRICES is hereby modified as follows:

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.5. ADVANCE UNDERSTANDINGS is hereby modified as follows:

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.

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998) is hereby modified to add FAR 52.219-9 as follows:

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	**52.219-9**	**Nov 2016**	**Small Business Subcontracting Plan**
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

All other terms and conditions of this contract remain unchanged.

End of Modification #1

EXHIBIT 10.3

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

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) **AWARD/CONTRACT**		RATING	PAGE OF PAGES 1 42
2. CONTRACT (*Proc. Inst. Indent.*) NO. HHSO100201700007C	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS194860	

5. ISSUED BY CODE HHS/OS/ASPR/BARDA HHS/OS/ASPR/BARDA 330 Independence Ave., SW Room 640-G Washington, DC 20201		6. ADMINISTERED BY *(if other than Item 5)* CODE ASPR-BARDA01 ASPR-BARDA 330 Independence Ave, SW, Rm G644 Washington DC 20201	
7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303 EMERGENT BIODEFENSE OPERATIONS LANS 3500 N MARTIN LUTHER KING, JR BLVD # LANSING, MI 489062933		8. DELIVERY FOB ORIGIN Other *(See below)* 9. DISCOUNT FOR PROMPT PAYMENT	
CODE 330303	FACILITY CODE		
10. SHIP TO/MARK FOR CODE HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201		12. PAYMENT WILL BE MADE BY CODE PSC PSC 330 Independence Ave, SW, Rm G644 Washington DC 20201	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: 10 U.S.C. 2304(c) ( ) 41 U.S.C. 253(c) ( )		14. ACCOUNTING AND APPROPRIATION DATA 2017.1990008.26402	

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	TITLE: AVA FOR THE SNS Continued				
15G. TOTAL AMOUNT OF					$99,941,719.80

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4	PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	7	X	J	LIST OF ATTACHMENTS	42
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X	E	INSPECTION AND ACCEPTANCE	16		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	17		L	INSTRS, CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	21		M	EVALUATION FACTORS FOR AWARD	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return* __2__ *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications as are attached or incorporated by reference herein. *(Attachments are listed herein.)*	18. AWARD *(Contractor is required to sign this document.) Your bid on* Solicitation Number 17-100-SOL-00010, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's soliciation 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)*	20A. NAME OF CONTRACTING OFFICER [**]
19B. NAME OF CONTRACTOR BY *(Signature of person authorized to sign)*	19C. DATE SIGNED 20B. UNITED STATES OF AMERICA BY *(Signature of Contracting Officer)* 20C. DATE SIGNED 3/16/2017

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STANDARD FORM 26 (REV. 5/2011)
Prescribed by GSA – FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR
EMERGENT BIODEFENSE OPERATIONS LANSING LLC 330303

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: [**] DUNS Number: [**] HHSO100201700007C Anthrax Vaccine for SNS IGF::XX::IGF Appr. Yr.: 2017 CAN: 1990008 Object Class: 26402 FOB: Destination Period of Performance: 03/16/2017 to 03/15/2019				
1	ASPR-17-01726 -- Procurement of [**] does of Bio Thrax (AVA) (CLIN0001) Obligated Amount: $[**]				99,450,000.00
2	ASPR-17-01726 -- Logistics – Safe and secure shipment of product to SNS (CLIN0002) Obligated Amount: $[**]				491,719.80

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES

Anthrax is an acute infectious disease caused by the spore-forming bacterium Bacillus anthracis, which can cause human disease via gastrointestinal, cutaneous, or inhalation (pulmonary) routes. The 2014 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan identifies anthrax as a high-priority threat as determined by the Secretary of Homeland Security. Strategies to mitigate anthrax as a biothreat against civilian populations include anthrax vaccine suitable for Post-Exposure Prophylaxis (PEP) when given concomitantly with antibiotics. Currently, BioThrax® is the only licensed and FDA approved vaccine for both General- Use Prophylaxis (GUP) and PEP capable of eliciting a protective immune response when administered as a three-dose post-exposure prophylactic regimen. BioThrax® is currently procured and stockpiled by the USG in the Strategic National Stockpile.

B.2. PRICES/COSTS

Below are the agreed upon price/cost provisions and Contract Line Item Numbers (CLINs) between the Government and the Contractor.

B.2.1. BASE PERIOD OF PERFORMANCE: The base period is 24 months from date of award.

B.2.2. FIRM FIXED PRICE

ITEM	SUPPLIES/SERVICES	QTY/UNIT	UNIT PRICE	Total Fixed Price
0001	BioThrax®/AVA BioThrax® [**] product [**] upon date of delivery [**]	[**] Dose	$ [**]	$ [**]
0002	Logistics – Safe and secure shipment of product to SNS Delivery Address: TBD	[**] Trucks	$ [**]	$ [**]
TOTAL				$ 99,941,719.80

B.2.3. OPTION PERIODS

This contract consists only of the base award period. No option CLINs are included in this award.

B.2.4. RESERVED

B.2.5. PRICE PROTECTIONS

Should the Contractor be unable to deliver product with [**] within [**] days of a scheduled delivery date the pricing for such lots shall be based upon the contract unit price for the number of delivered doses in the lot that have a [**] as of the actual delivery date. This does not apply if the shipment is rescheduled at the Government's request. Further, this does not apply if there are unresolved issues with the quality, safety, and/or efficacy of the delivered product.

B.2.6. COSTS UNALLOWABLE UNLESS AUTHORIZED BY THE CONTRACTING OFFICER

This section prohibits or restricts the use of contract funds for the following items (costs unallowable unless otherwise approved by the Contracting Officer):

(a) Acquisition, by purchase or lease, of any interest in real property;
(b) Rearrangement or alteration of facilities;
(c) Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
(d) Accountable Government Property;
(e) Overtime;
(f) General scientific meetings/conferences;
(g) Travel costs including foreign travel;
(h) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
(i) Costs to be paid for the performance of a fixed-price subcontract that exceeds $150,000.00;

(j) Refreshments and Meal Expenditures;
(k) Promotional Items
(l) Printing

B.2.7. 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 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 will be provided to the Contracting Officer within [**] days.

This Advanced Understanding may be modified in subsequent task orders.

B.2.8. CONFIDENTIAL TREATMENT OF SENSITIVE INFORMATION

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

Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer. (See also HHSAR clause 352.224-71).

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

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least two (2) business days prior to the Contractor's disclosure of the information/data; or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data.

B.2.9. SHARING OF CONTRACT DELIVERABLES WITHIN THE UNITED STATES GOVERNMENT

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government 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 Portfolio Advisory Committee (PAC) Charter, Technology Transfer Agreements (TTA) between BARDA and the Defense Threat Reduction Agency and the National Institute of Allergies and Infectious Diseases (NIAID), the Government may share technical deliverables set forth in Section F with colleagues within the Integrated Portfolio. This advance understanding does not authorize the government to share financial information outside HHS. This clause does not limit the Government's ability to use or disclose data or information in accordance with the terms or conditions of this contract. The Contractor is advised to review the terms of FAR Clause 52.227-14 regarding the Government's rights to deliverables submitted during performance as well as the Government's rights in data.

B.2.10. CONTRACT NUMBER DESIGNATION

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number on the face page of the contract.

B.2.11. DEFINITION OF DAYS

In this contract, it is intended that the term "days" refers to calendar days. If this results in a deliverable becoming due on a weekend, the due date shall be assumed to be the soonest business day thereafter, inclusive of holidays.

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

C.1. VACCINE PRODUCTION AND CGMP COMPLIANCE:

1. The Contractor shall manufacture BioThrax® in accordance with current Good Manufacturing Practices (cGMP) guidelines

2. BioThrax® must be delivered on any business day, except Federal holidays, within the scheduled month in accordance with the targeted delivery schedule. The Contractor shall notify the Government promptly upon becoming aware of any deviations from the targeted delivery schedule. All changes to the targeted delivery schedule must be approved by the Contracting Officer and/or the Contracting Officer's Representative (COR).

3. Quantities for each scheduled delivery shall be of a specific quantity.

4. The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the Food Drug Administration (FDA) approved Biologic License Application (BLA-License Number 1755, STN 103821, and any approved change).

5. All BioThrax® delivered under this contract must be labeled with an expiration date consistent with its current product license at the time of manufacture.

6. The Contractor shall provide primary and secondary points of contact that shall be available 24 hours per day, seven days per week to be notified in case of a public health emergency.

7. The Contractor shall report to the Government material correspondence from the FDA regarding the quality, safety, or efficacy of BioThrax®.

8. The Contractor shall provide the Government with access to and/or provide copies of the following documents: (1) Form 483s form FDA inspections of Contractor's Lansing facility, (2) Establishment Inspection Reports (EIRs) from FDA inspections of Contractor's Lansing facility; (3) W arning Letters relating to BioThrax®; and Contractor's Annual Safety Report to FDA regarding BioThrax®. These documents will be provided to the Contracting Officer within 2 business days of receipt.

9. The Contractor shall notify the Government of any issues with the safety and efficacy of BioThrax® and/or manufacturing or quality of the FDA-licensed production lines at the Contractor's Lansing facility within [**] business days of the determination of potential to be reported to FDA.

10. The Government will have the option to conduct site inspections of the Contractor's Lansing facility during the period of performance of the contract. Such inspections will be performed by the COR or the COR's designee(s).

11. If the contractor should obtain FDA approval for the manufacture and production of BioThrax® having [**] while under this contract, the Government will accept delivery of those doses with the [**] in addition to doses with a [**]. The Contractor may invoice only for those doses actually delivered under this contract in accordance with Section B.

12. The product must be delivered in accordance with cGMP guidelines.

13. The Contractor shall notify BARDA at least [**] days' prior of estimated shipment of product. At least [**] business days prior to the product being ready for shipment to DSNS, the Contractor shall obtain delivery address from the Contracting Officer and provide to the Contracting Officer and COR the following:

    (a) The date the product will be ready for loading on the truck(s) and the intended delivery date of product to the DSNS

    (b) Number of pallets, vials, and doses to be loaded and delivered to DSNS

14. At least [**] hours before each scheduled delivery, the Contractor shall provide the following to the Contracting Officer and COR:

(a) Packing Slip

(b) Certificate(s) of Analysis c. FDA Lot Release(s)

(c) Actual number of pallets, vials and doses to be loaded

(d) Diagram of product shipment pallet (how many vials per box, per pallet)

15. TempTale monitors supplied with each delivery must be returned to Contractor per instructions provided with each shipment within [**] business days after product delivery. Within [**] hours of receipt of TempTale monitors, the Contractor shall provide to the Contracting Officer and COR a letter for each delivered lot from the Contractor's Quality Department containing the following information:

(a) The remaining ambient exposure time letter disclosing accumulated ambient temperature exposure until the point that BARDA (or DSNS-designated personnel) assumed responsibility for temperature control, per Section F, for each lot from the Contractor's Quality Department. The letter must indicate that the product was manufactured and released in accordance with cGMP and has met all acceptance criteria to allow for Government distribution.

16. Funds provided shall be paid on a price per doses basis only on those products delivered and accepted to DSNS under contract.

17. Under CLIN 0001 of this contract the products shall have an [**] product. The Contractor shall target ≥[**] of the total [**] remaining when the Government takes delivery of the product.

C.2. RESERVED

C.3. MEETINGS/SITE VISITS/AUDITS

The Contractor and the Government shall participate in regular meetings to coordinate and oversee the work performed as requested by the Contracting Officer (CO) or Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meeting or teleconferences, site visits to the Contractor's and/or subcontractor's facilities and 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 USG-contracted subject matter experts as required by the CO/COR facilitating review of activities. The Government reserves the right to conduct a pre-award site visit of the manufacturing plant. Pre-award site visits may be made with short notice. Contractors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit. The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award. Bi-weekly or monthly status update meetings/teleconferences will be held throughout the life of the contract. The schedule for these meetings will be established by the CO and COR. The Government reserves the right to visit the contractor's site for purposes of assessing quality as deemed necessary by the Government throughout the period of performance of the contract. The Contractor shall provide data, reports and presentations to groups of outside experts and USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities. The contractor shall facilitate cGMP site-visit or inspection as requested by FDA/Center for Biologics Evaluation and Research (CBER) at the time of production of product lots destined for the SNS. Periodic site visits will occur on an ad hoc basis (at least twice a year).

Within [**] calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

Other U.S. Government Audits

The United States Government (USG) reserves the right to conduct unannounced audits of the Contractor without advance notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits or audits of subcontractor(s). At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Contractor and subcontractors. Finally, BARDA reserves the right to conduct unannounced site visits with justification and critical need. All audits will be conducted between normal business hours, i.e. 8 a.m. through 6 p.m., Monday through Friday.

C.4. PRODUCT DELIVERIES

C.4.1. TEMPERATURE CONTROL AND MONITORING

FOB Destination Deliveries:

The Contractor shall be responsible for maintaining product temperature control until the product arrives at the DSNS and has completed product acceptance by the USG. The Contractor shall provide the Government with an ambient exposure letter that covers the time the product leaves the Contractor's validated [**]°C storage facility until arrival at DSNS. Upon Government acceptance of the product to the Government, the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between [**]°C). The Contractor will provide and place TempTale(s) on each pallet of product while the product is inside the Contractor's validated [**]°C storage facility prior to placing the product onto the truck(s) of the designated carrier. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

C.4.2. DSNS QUALITY CONTROL UNIT (QCU) ACCEPTANCE PROCEDURE FOR BIOTHRAX (AVA)

At the time the product is delivered to a designated DSNS delivery location, all product will be placed into DSNS Quarantine pending receipt of the required lot distribution documentation and the remaining ambient exposure time letter from the Contractor. The Contractor shall supply the Government:

1. Notification of practices that may impact DSNS shipping procedures, if applicable

2. All items outlined for delivery of product.

C.4.3. ACCEPTANCE PROCESS AND TIMEFRAME (FOB DESTINATION DELIVERY)

1. Contractor shall deliver to the Government, via e-mail or facsimile:

   (a) All required documentation outlined for delivery of product

   (b) Notification of the date and time that the product was delivered.

2. Acceptance Timeframe: The Government will have [**] full business days, after receipt of all documentation required to establish that the requirements have been satisfied and provide Contractor notice that DSNS accepts the lot(s).

   (a) For purposes of this acceptance timeframe, business days are defined as 9:00AM to 5:00PM Eastern Time, Monday through Friday, excluding U.S. Government Holidays.

   (b) For the avoidance of doubt, BARDA will provide the Contractor with a written acceptance or refusal of BioThrax® lot(s) no later than 5:00PM on the [**] business day after receipt of the documentation.

C.4.4. BARDA RELEASE FOR BioThrax

The DSNS Quality Control Unit (QCU) recommends that the temperature acceptance range for BioThrax, using the temperature monitoring device accuracy of [**]°C, would be [**]°C to [**]°C. This temperature is consistent with licensed label specifications ([**]°C to [**]°C) and takes into account the contractor's rounding practices (memo dated 8/12/09), and the accuracy of the temperature monitoring device (TempTale Bio).

TempTale device alarms will be set for shipments to alert for possible temperature deviations for further evaluation. BARDA will review the temperature data for DSNS internal processes. As a clarification and guide, the table below outlines temperature limits acceptable during the period that the Contractor is responsible for maintaining product temperature control and the resulting actions under each scenario. This table is based on the TempTale with an accuracy of [**]°C. If any of the following changes occur while the Government is responsible for temperature monitoring and control, DSNS QCU will seek guidance from the Contractor:

Temperature Range	Action
< [**]°C	☐ AVA Pallet will be placed into DSNS quarantine pending further disposition
[**]°C – [**]°C	☐ Acceptable for use by the SNS
≥[**]°C – [**]°C	☐ AVA Pallet will be placed into DSNS quarantine ☐ Release of product by BARDA will be pending quality disposition investigation, and remaining ambient exposure for the lot
>[**]°C	☐ AVA Pallet will be placed into DSNS quarantine pending further disposition

Temperature deviations during shipping are the responsibility of the Contractor for FOB Destination deliveries. Deviations during shipping shall not delay the Government's acceptance of the lots when deliveries are FOB Destination and shall be evaluated and fully documented by the Party responsible for temperature control and monitoring in accordance with standard procedures. The Contractor shall include an Event Description and Contractor's Product Impact Assessment in the Contractor's Certification Letter), for each lot impacted by such deviations. The Contractor shall state in the Certification Letter

that, "A Full Deviation Report, including root cause analysis and corrective and preventative actions shall be submitted to the Government within [**] business days of report completion." The Party responsible for temperature control and monitoring is also responsible for root cause analysis and defining appropriate corrective and preventative actions.

C.5. REPORTING REQUIREMENTS

See SECTION F.4 for specific reporting requirements. The Contractor shall submit to the CO and the COR technical progress reports as identified in any potential resultant contract. These reports shall be subject to the technical inspection and requests for clarification by the COR. These reports shall be brief, factual, and prepared in accordance with the following format:

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 [**] 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 Plans 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 [**] 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 month Annual Progress Reports or a Final Report 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 [**] 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 Plans 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 a rolling [**] 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. 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 [**] 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 USG reserves the right to comment on the draft report. Any comments on the draft report made by the USG must be included in the final report submitted by the Offeror. 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

The Contractor shall provide a copy of any regulatory communications (e.g., meeting minutes, submissions, etc.) that occur during the contract period of performance pertaining to the product being procured (i.e. BioThrax). Any pertinent regulatory communications of issues that may impact the product or ability of the Contractor to complete delivery of the product on this particular contract shall be made known to ACMG/BARDA until delivery of all [**] doses are completed.

E. OTHER REQUIREMENTS/DELIVERABLES

(a) 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 [**] 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.

(b) 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 [**] business days prior to the issuance of any potential press release.

(c) 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 [**] hours after occurrence of an activity or incident.

SECTION D - PACKAGING, MARKING AND SHIPPING

Packaging shall be consistent with the FDA approved labeling and packaging for this product at the time of manufacture. In addition, the product will be labeled and packaged with FDA approved components and in accordance with the criteria (e.g. Palletization) set forth by the CDC SNS. This configuration will include product label, product insert, individual vial carton, and other components deemed necessary to appropriately identify and control the product throughout the supply chain and eventual use.

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email as described in SECTION F.

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

SECTION E - INSPECTION AND ACCEPTANCE

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more 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.

E.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.246-2	Aug 1996	Inspection of Supplies - Fixed Price
FAR	52.246-16	Apr 1984	Responsibility for Supplies

E.2. INSPECTION AND ACCEPTANCE (NON-PRODUCT DELIVERABLES)

Inspection and acceptance of materials, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance will take place at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
200 C Street, S.W.
Washington, D.C. 20024

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duty authorized representative within [**] days of receipt.

E.3. INSPECTION AND ACCEPTANCE (PRODUCT DELIVERABLES)

Performance of the contract will be monitored by the CO/COR on a regular basis. The Contracting Officer will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Contractor.

SECTION F - DELIVERIES OR PERFORMANCE

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more 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.

F.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.246-15	Aug 1989	Stop Work Order
FAR	52.246-15, Alternate 1	Apr 1984	Alternate 1

F.2. PERIOD OF PERFORMANCE

The base period of performance under this contract shall be for twenty-four (24) months from date of award. There are no option periods under this contract and therefore no options will be exercised during the life of this contract.

F.3. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C of this contract and upon delivery and acceptance of the items by the Contracting Officer or their duly authorized representative as described in F.5.2.2.

F.4. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.4.1. SUBMISSION OF CONTRACT DELIVERABLES (NON-PRODUCT DELIVERABLES)

Documents shall be delivered electronically via email to the Contracting Officer (CO) and the Contracting Officer's Representative (COR). When electronic deliverables are not preferable by the Contracting Officer, all deliverables and reports furnished to the Government under any potential resultant contract (including invoices) shall be addressed as follows:

UPS/FedEx/Courier	USPS Mail Packages
[**] Contracting Officer HHS/ASPR/AMCG 200 C St. SW Washington, DC 20024 Email: [**]	[**] Contracting Officer HHS/ASPR/AMCG 200 C St. SW Washington, DC 20024

UPS/FedEx/Courier	USPS Mail Packages
[**] Contracting Officer Representative HHS/ASPR/BARDA 200 C St. SW Washington, DC 20024 Email: [**]	[**] Contracting Officer Representative HHS/ASPR/BARDA 200 C St. SW Washington, DC 20024

F.4.2. DELIVERABLE SCHEDULE

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 [**] 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 [**] 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 [**] 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	CO: (1) electronic copy COR: (1) electronic copy	Reports are due with the next applicable report from Items 1 through 4 above.
6	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the [**] calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract.
7	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than [**] business days prior to the issuance of any potential press release.
8	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within [**] hours after occurrence of an activity or incident.

F.5. PRODUCT DELIVERIES

F.5.1. USE OF PRODUCT BY THE U.S. GOVERNMENT

To the extent that third parties contact BARDA to obtain doses of BioThrax®, BARDA will notify such third parties that Emergent sells BioThrax commercially.

F.5.2. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.5.2.1. DELIVERY SCHEDULE

The offeror shall propose a delivery schedule of products to include number of doses and dates. Delivery is estimated to occur by [**]. The forecasted schedule, subject to revisions per Section F.5.2.3 below, is:

[**]

F.5.2.2. PRODUCT DELIVERY – PRODUCT DROP OFF BY CONTRACTOR (FOB DESTINATION DELIVERIES)

(a) The delivery of BioThrax® product shall be F.O.B Destination at the USG designated drop off location.

(b) At least [**] days prior to an estimated shipment vendor will provide the COR with the notices required under Section C.1.13 above and F.5.2.3 below.

(c) The place of product drop off by the Contractor will be provided by the USG to the Contractor at least [**] business days prior to scheduled pick up by the designated carrier.

F.5.2.3. DELIVERY DOCUMENTATION

For product delivered FOB Destination, the Contractor shall deliver, within the specified timeframes, and submit the following documents to the Contracting Officer and COR:

(a) At least [**] days prior to an estimated shipment the contractor shall notify the COR and receive the DSNS shipment delivery address from the COR.

(b) At least [**] business days prior to each product shipment by the Contractor, the Contractor shall provide to the Contracting Officer and COR:

(i) The delivery date: For FOB Destination deliveries, shall be the date the product will be scheduled for delivery by the Contractor

(ii) Actual number of 40"x48" pallets, number of vials, and doses to be loaded

(c) At least [**] hours before each scheduled shipment by the Contractor, the Contractor shall provide the following to the Contracting Officer and COR:

(i) Packing Slip

(ii) Certificate(s) of Analysis iii. FDA Lot Release(s)

(iii) Confirm the number of pallets, vials and doses to be loaded

(iv) Diagram of product shipment pallet (how many vials per box, per pallet)

(d) On the shipment date, the Contractor shall provide a shipment confirmation including the TempTale ID#(s) associated with each pallet being delivered.

(e) TempTale monitors supplied with each delivery must be returned to Contractor per instructions provided with each shipment within [**] business days upon product receipt. Within [**] hours of receipt of TempTale monitors, the Contractor shall provide to the Contracting Officer and COR a letter for each delivered lot from the Contractor's Quality Department containing the following information:

(i) The remaining ambient temperature exposure time for the lot until the point that BARDA (or DSNS-designated personnel) assumed responsibility for temperature control, per Section C.4.1.

(ii) This letter shall also indicate that the product was manufactured and released in accordance with cGMP and has met acceptance criteria to allow for Government distribution.

SECTION G - CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

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

[**]
Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W., Room G640
Washington, D.C. 20201
E-mail: [**]

The following Contracting Specialist (CS) will represent the Government for the purpose of this contract:

[**]
Contracting Specialist
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W., Room G640
Washington, D.C. 20201
E-mail: [**]

The Contracting Officer is the only individual who can legally commit and bind the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

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

1. direct or negotiate any changes in the statement of objectives;

2. modify or extend the period of performance;

3. change the delivery schedule;

4. authorize reimbursement to the Contractor for any costs incurred during the performance of this contract;

5. obligate or de-obligate funds into the contract;

6. sign written licensing agreements; or

7. otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

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

The Government's Contracting Officer's Representative (COR) is:

[**]
Contracting Officer's Representative (COR)
DHHS/OS/ASPR/BARDA
Independence Avenue, S.W., Room G640
Washington, D.C. 20201
E-mail: [**]

The Government's Alternate Contracting Officer's Representative (COR) is:

[**]
Contracting Officer's Representative (COR)
DHHS/OS/ASPR/BARDA
Independence Avenue, S.W., Room G640
Washington, D.C. 20201
E-mail: [**]

As delegated by the CO, the COR is responsible for:

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

2. assisting the CO in interpreting the statement of work and any other technical performance requirements;

3. performing technical evaluation as required;

4. performing technical inspections required by this contract; and

5. assisting in the resolution of technical problems encountered during performance.

G.3. CONTRACTOR'S POINTS OF CONTACT

The Contractor shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency. If there are any changes to these points of contact, the Contractor shall notify the CO and COR immediately.

Technical Contacts:

[**]
Emergent Biodefense Operations Lansing LLC
3500 N. Martin Luther King Jr. Blvd.
Lansing, MI 48906
Phone: [**]
Email: [**]

[**]
Emergent Biodefense Operations Lansing LLC
3500 N. Martin Luther King Jr. Blvd.
Lansing, MI 48906
Phone: [**]
Email: [**]

Administrative Business Contact:

[**]
Emergent BioSolutions, Inc.
400 Professional Dr, Suite 400
Gaithersburg, MD 20879
Phone: [**]
Email: [**]

G.4. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least [**] calendar days prior to the Contractor voluntarily 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 are considered key personnel for this contract:

· [**]

G.5. INVOICE SUBMISSION

(a) The Contractor shall submit invoices electronically to the Contracting Officer (CO), the Contract Specialist (CS), the Contracting Officer's Representative (COR), and PSC (PSC_Invoices@psc.hhs.gov). The payment request shall be transmitted as an attachment via email. Invoice composition instructions are provided in Attachment #2 (Fixed Price Type Contracts). A sample invoice form is provided as Attachment #3.

(b) The Contractor agrees to include (as a minimum) the following information on each invoice:

1. Contractor's Name & Address
2. Contractor's Tax Identification Number (TIN)
3. Contract Number
4. Invoice Number
5. Invoice Date
6. Contract Line Item Number
7. Quantity
8. Unit Price & Extended Amount for each line item
9. Total Amount of Invoice
10. Name, title and telephone number of person to be notified in the event of a defective invoice
11. Payment Address, if different from the information in (b)(1).

(c) The invoice shall be signed by a person authorized to bind the Contractor.

(d) The Contractor shall not submit an invoice prior to delivery of goods or services.

(e) 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 current HHS Salary Rate Limitation Provisions in Section I of the contract."

G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (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, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

G.7. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

(a) *Purpose*: In accordance with FAR Subpart 42.15, the Contractor's performance will be periodically evaluated by the government in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period*: The Contractor's performance will be evaluated at least [**].

(c) *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(d) *Performance Evaluation Factors*: The Contractor's performance will be evaluated in accordance with FAR Subpart 42.15.

(e) *Contractor Review*: A copy of the evaluation will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within [**] calendar days after receipt of the evaluation.

(f) *Resolving Disagreements between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be

reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of [**] years after completion of contract performance for the purpose of providing source selection

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1. NEEDLE DISTRIBUTION

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

H.2. ACKNOWLEDGEMENT OF FEDERAL FUNDING

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that:

(1) the percentage of the total costs of the program or project which will be financed with Federal money;

(2) the dollar amount of Federal funds for the project or program; and

(3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

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

Subcontractors - Contractors shall require subcontractors to adhere to these requirements for HHS acknowledgement of support.

H.3. RESTRICTIONS ON ABORTIONS

The Contractor shall not use funds for any abortion.

H.4. GUN CONTROL

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

H.5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.6. CARE OF LIVE VERTEBRATE ANIMALS

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (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 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 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 Animal Welfare 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 (Email: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

H.7. ANIMAL WELFARE

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

H.8. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act of 1995 (44 U.S.C. section 3501), 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.

H.9. 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.

H.10. CERTIFICATION OF FILING AND PAYMENT OF TAXES

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

H.11. SUBCONTRACTING PROVISIONS

A. SMALL BUSINESS SUBCONTRACTING PLAN

1. The Small Business Subcontracting Plan, dated February 1, 2017 is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

B. SUBCONTRACTING REPORTS

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   · [**]

   · [**]

   · Expiration Date of Contract

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   · [**]

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address defined in SECTION F.

H.12. CONFIDENTIALITY OF INFORMATION

(a) Confidential information, as used in this article, means information or data of a personal nature about 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. (See HHSAR Clause 352.224-70).

(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.

H.13. 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. HHSO100201700007C."

Press Releases:

Pursuant to Section 508 of Public Law 105-78, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non- Governmental sources.

H.14. 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

H.15. 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 Pub. 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.

H.16. 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. The Contractor shall provide the Government with an electronic copy of all correspondence with the FDA within [**] hours of receipt. The Government shall acquire unlimited rights to all data funded under this contract awarded in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.17. 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.

H.18. 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.

H.19. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.20. INCORPORATION OF TECHNICAL PROPOSAL

The Contractor's Final Technical Proposal dated February 1, 2017 submitted in response to RFP-17-100-SOL-00010 is hereby incorporated into the Contract as Attachment #2 in Section J, List of Attachments. The Contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

B.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

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	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Recession, and Recovery of Funds for Illegal or Improper Activity
FAR	25.203-10	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	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	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	52.204-13	Jul 2013	System for Award Management Maintenance
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.212-1	Oct 2016	Instructions to Offerors – Commercial Items
FAR	52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
FAR	52.218-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.219-8	Oct 2015	Utilization of Small Business Concerns
FAR	52.219-9	Oct 2015	Small Business Subcontracting Plan
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-29	Apr 2015	Notification of Visa Denial
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.224-1	Apr 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises
FAR	52.227-1	Dec 2007	Authorization and Consent
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.229-3	Feb 2013	Federal, State, and Local Taxes
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	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-39	June 2013	Unenforceability of Unauthorized Obligations
FAR	52.233-3	Aug 1996	Protest after Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes—Fixed Price
FAR	52.244-6	Jan 2017	Subcontracts for Commercial Items
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.248-1	Oct 2010	Value Engineering

B.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at
http://www.hhs.gov/grants/contracts/contract- policies-regulations/hhsar/index.html

HHSAR	352.203-70	December 2015	Anti-Lobbying
HHSAR	352.208-70	December 2015	Printing and Duplication
HHSAR	352.215-70	December 2015	Late Proposals and Revisions
HHSAR	352.216-70	December 2015	Additional Cost Principles
HHSAR	352.222-70	December 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	December 2015	Safety and Health
HHSAR	352.224-70	December 2015	Privacy Act
HHSAR	352.224-71	December 2015	Confidential Information
HHSAR	352.227-70	December 2015	Publications and Publicity
HHSAR	352.233-71	December 2015	Litigation and Claims
HHSAR	352-239.73	December 2015	Electronic Information and Technology Accessibility Notice
HHSAR	352.270-9	December 2015	Non-Discrimination for Conscience

B.3. ADDITIONAL CONTRACT CLAUSES

B.3.1. ADDITIONAL HHS ACQUISITION REGULATION (HHSAR) CLAUSES – IN FULL TEXT

HHSAR 352.211-3 Paperwork Reduction Act (Dec 2015)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C 3501 et seq.) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Technical Representative shall be guided by the provisions of 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until OMB Clearance is received. Once OMB Clearance is received from the Contracting Officer's Technical Representative, the Contracting Officer shall provide the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

B.3.2. ADDITIONAL FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES – IN FULL TEXT

FAR 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements – Representation (January 2017)

(a) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), Government agencies are not permitted to use funds appropriated (or otherwise made available) under that or any other Act for contracts with an entity that requires employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The prohibition in paragraph (a) of this provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(c) Representation. By submission of its offer, the Contractor represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(End of provision)

FAR 52.212-4 -- Contract Terms and Conditions -- Commercial Items (January 2017)

(a) *Inspection/Acceptance*. See required procedures under FAR clause 52.246-2.

(b) *Assignment*. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C.3727). However, when a third party makes payment (e.g., use of the Government-wide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) *Changes*. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) *Disputes*. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) *Definitions*. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

(f) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) *Invoice*.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include
--

(i) Name and address of the Contractor;
(ii) Invoice date and number;
(iii) Contract number, contract line item number and, if applicable, the order number;
(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
(vi) Terms of any discount for prompt payment offered;
(vii) Name and address of official to whom payment is to be sent;
(viii) Name, title, and phone number of person to notify in event of defective invoice; and
(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.
(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer— System for Award Management, or 52.232-34, Payment by Electronic Funds Transfer—Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) *Patent indemnity*. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment*.

(1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) Prompt Payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR Part 1315.

(3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected contract line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period at fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final decisions. The Contracting Officer will issue a final decision as required by 33.211 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) *Risk of loss*. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(k) *Taxes*. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause*. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title*. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty*. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability*. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Other compliances*. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) *Compliance with laws unique to Government contracts*. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) *Order of precedence*. Any inconsistencies in this contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause.

(3) The clause at 52.212-5.

(4) Addenda to this solicitation or contract, including any license agreements for computer software.

(5) Solicitation provisions if this is a solicitation.

(6) Other paragraphs of this clause.

(7) The Standard Form 1449.

(8) Other documents, exhibits, and attachments.

(9) The specification.

(t) System for Award Management (SAM).

(1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the SAM database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the SAM database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the SAM database to ensure it is current, accurate and complete. Updating information in the SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(2)

(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in Subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to:

(A) Change the name in the SAM database;

(B) Comply with the requirements of Subpart 42.12 of the FAR;

(C) Agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the SAM record to reflect an assignee for the purpose of assignment of claims (see FAR Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the SAM database. Information provided to the Contractor's SAM record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via SAM accessed through https://www.acquisition.gov.

(u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End Use License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) *Incorporation by reference*. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders – Commercial Items (Deviation 2013-O0019) (January 2017)

a) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (a) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(b)

(1) Notwithstanding the requirements of any other clause in this contract, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (b)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).

(ii) 52.219-8, Utilization of Small Business Concerns (Oct 2014) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $650,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(iii) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (1) of FAR clause 52.222-17.

(iv) 52.222-21, Prohibition of Segregated Facilities (Apr 2015). (v) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

(vi) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212).

(vii) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).

(viii) 52.222-62 Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(ix) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212).

(x) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xi) 52.222-41, Service Contract Labor Standards (May 2014), (41 U.S.C. chapter 67).

(xii) _____ (A) 52.222-50, Combating Trafficking in Persons (Mar 2015) (22 U.S.C. chapter 78 and E.O. 13627).

_____ (B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 E.O. 13627).

(xiii) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)

(xiv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)

(xv) 52.222-54, Employment Eligibility Verification (Oct 2015).

(xvi) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).

(xvii) 52.222-59, Compliance with Labor Laws (Executive Order 13673) (Oct 2016) (Applies at $50 million for solicitations and resultant contracts issued from October 25, 2016 through April 24, 2017; applies at $500,000 for solicitations and resultant contracts issued after April 24, 2017).

Note to paragraph (b)(1)(xvi): By a court order issued on October 24, 2016, 52.222-59 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the Federal Register advising the public of the termination of the injunction.

(xviii) 52.222-60, Paycheck Transparency (Executive Order 13673) (Oct 2016). (xix) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xx) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxi) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

PART III - ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

1. Security Plan
2. Technical Proposal
3. Invoice Instructions for Fixed Price Contracts
4. Sample Invoice Form
5. SF-LLL, Disclosure of Lobbying Activities
6. ACH Vendor/ Miscellaneous Payment Enrollment Form
7. Small Business Subcontracting Plan
8. Responses to Negotiation Questions

F. Security

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]

G. Quality Systems

Emergent has defined the Quality Management System (QMS) requirements for phase appropriate compliance from proof-of-concept and pre-clinical stages through commercial manufacturing.

Emergent's integrated QMS is regulated by our Quality Policy Manual. The SOP-supported manual describes QMS policies and activities performed at our Lansing facility. The Quality Policy Manual aligns with Emergent's strategic plan, corporate objectives, and cGMP regulations and expectations.

Each component of our QMS complies with applicable ICH and FDA regulatory standards and requirements applicable for each stage of the product lifecycle. Emergent's Quality Assurance Department will ensure internal compliance to these standards as well as compliance of subcontractors performing work on Emergent's behalf. Our QMS includes all of the following components:

- management responsibility and review
- personnel qualification and training
- document and data control
- validation
- equipment and facilities control
- supplier quality and materials management control
- production and in-process controls
- non-conformance handling
- change control
- corrective and preventive action

Management Responsibility
The senior leadership team at each site is ultimately responsible for ensuring an effective QMS is in place, demonstrating strong support of the QMS and continuous improvement efforts, and ensuring that roles, responsibilities and authorities are defined, communicated, and implemented at all levels in the organization.

Personnel Qualification and Training Policy
Emergent will ensure employees involved with vaccine operations have the necessary education, training, and experience appropriate to their positions. Current job descriptions and curricula vitae, or similar documentation, are established and maintained for all personnel responsible for conducting or overseeing activities.

Training records are maintained for employees, and periodic and systematic reviews of personnel training records are conducted to ensure that employees are receiving the training demanded by their job or function.

Management and Data Integrity Policy
Emergent will ensure established SOPs are in place to control all documents and processes required for phase appropriate compliance activities. The document management program prevents unapproved revisions to controlled documents that may in turn affect the safety, quality, identity, potency and purity of the Anthrax vaccine. Changes to documents are reviewed and approved by designated individuals and the changes are communicated through training on the revised procedure. Controlled documents are available to personnel conducting the work.

Data is fully traceable from the controlled record to the raw data and is maintained and stored in such a way as to remain legible, readily identifiable, and retrievable. Original records are archived in compliance with document control and records management procedures.

Supplier Quality and Materials Management Policy
Materials and services shall only be purchased from suppliers that have been appropriately qualified. A material qualification process is in place to ensure that materials are fit for their intended use.

Materials are controlled from the time of receipt to maintain complete identification and traceability at all times in accordance with established SOPs and compliance regulations.

Emergent will ensure product release does not proceed until all activities have been completed, documentation is available, and disposition has been authorized by QA. The materials management program will ensure proper segregation of materials that are under quarantine, release, and reject.

Offerer:
Emergent Biodefense Operations Lansing LLC
3500 N. Martin Luther King Jr. BLVD
Lansing, Ml 48906

DUNS: [**] CAGE CODE: 1HOB6

Administrative Business Contact:
[**]
Phone: [**]
E-Mail· [**]

/s/ [**]
[**]

This proposal is predicated upon all the terms and conditions contained in the above referenced solicitation.

Technical Contacts:
[**]
Phone: [**]
E-Mail· [**]

[**]
Phone: [**]
E-Mail· [**]

Prepared for:
[**], Contracting Officer
Phone: [**]
HHS/OS/ASPR/AMCG
330 Independence AV, SW, RM G-460 Washington, DC 20024
Email: [**]

Cognizant Audit Office:
The National Institutes of Health Office of Acquisition Mgmt. and Policy
Division of Financial Advisory Services
6100 Executive Blvd., Room 6805
Rockville, MD 20892

Solicitation Amendments:

- N/A

By submitting this proposal, the Offeror, if selected for discussions, grants the Contracting Officer or an authorized representative the right to examine, at any time before an award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
Unless disclosure is required by the Freedom of Information Act (5 U.S.C. 552, as amended) (the Act), and determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (the Department) according to the Act, any data contained in the portions of this proposal which have been specifically identified by page number, paragraph, sheet, etc. by the Offeror as containing restricted information shall not be used or disclosed except for evaluation purposes. The Offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) or deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The Offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act. If a contract is awarded to the Offeror as a result of, or in connection with, this proposal submission, the Government shall have the right to use or disclose the data to the extent provided in the awarded contract. Proposals not resulting in a contract remain subject to the Act. The Offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. Data subject to this restriction are contained in all marked proposal pages.

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PROPOSAL CROSS-REFERENCE TO SOLICITATION STATEMENT OF WORK & EVALUATION CRITERIA

C.1. VACCINE PRODUCTION AND CGMP COMPLIANCE

C.1.1 The Contractor shall manufacture BioThrax in accordance with current Good Manufacturing Practices (cGMP) guidelines — Sect IV.A

C.1.2 BioThrax® must be delivered on any business day, except Federal holidays, within the scheduled month in accordance with the targeted delivery schedule. The Contractor shall notify the Government promptly upon becoming aware of any deviations from the targeted delivery schedule. All changes to the targeted delivery schedule must be approved by the Contracting Officer and/or the Contracting Officer's Representative (COR). — Appendix B

C.1.3 Quantities for each scheduled delivery shall be of a specific quantity — Appendix B

C.1.4. The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the Food Drug Administration (FDA) approved Biologic License Application (BLA-License Number 1755, STN 103821, and any approved change). — Section IV.A

C.1.5. All BioThrax® delivered under this contract must be labeled with an expiration date consistent with its current product license at the time of manufacture. — Sections IV.A, V.E

C.1.6. The Contractor shall provide primary and secondary points of contact that shall be available 24 hours per day, seven days per week to be notified in case of a public health emergency. — Section VI.C

C.1.7. The Contractor shall report to the Government material correspondence from the FDA regarding the quality, safety, or efficacy of BioThrax®. — Section VI.A

C.1.8. The Contractor shall provide the Government with access to and/or provide copies of the following documents: (1) Form 483s form FDA inspections of Contractor's Lansing facility, (2) Establishment Inspection Reports (EIRs) from FDA inspections of Contractor's Lansing facility; (3) Warning Letters relating to BioThrax®; and Contractor's Annual Safety Report to FDA regarding BioThrax®. These documents will be provided to the Contracting Officer within 2 business days of receipt. — Section VI.A

C.1.9. The Contractor shall notify the Government of any issues with the safety and efficacy of BioThrax® and/or manufacturing or quality of the FDA-licensed production lines at the Contractor's Lansing facility within two business days of the determination of potential to be reported to FDA. — Section VI.A

C.1.10. The Government will have the option to conduct site inspections of the Contractor's Lansing facility during the period of performance of the contract. Such inspections will be performed by the COR or the COR's designee(s). — Section VI.A

C.1.11. If the contractor should obtain FDA approval for the manufacture and production of BioThrax® having [**] while under this contract, the Government will accept delivery of those doses with the [**] in addition to doses with a [**]. The Contractor may invoice only for those doses actually delivered under this contract in accordance with Section B. — Section IV.A

C.1.12. The product must be delivered in accordance with cGMP guidelines. — Section IV.B

C.1.13. The Contractor shall notify BARDA at least [**] days' prior of estimated shipment of product. At least [**] business days prior to the product being ready for shipment to DSNS, the Contractor shall obtain delivery address from the Contracting Officer and provide to the Contracting Officer and COR the following:

a. The date the product will be ready for loading on the truck(s) and the intended delivery date of product to the DSNS
b. Certificate(s) of Analysis d. FDA Lot Release(s)
c. Number of pallets, vials, and doses to be loaded and delivered to DSNS — Sections IV.B, VI.A

C.1.14. At least [**] hours before each scheduled delivery, the Contractor shall provide the following to the Contracting Officer and COR:

a. Packing Slip
b. Actual number of pallets, vials and doses to be loaded
c. Diagram of product shipment pallet (how many vials per box, per pallet) — Sections IV.B, VI.A

C.1.15. Within [**] hours after the product has been delivered to the DSNS, the Contractor shall provide to the Contracting Officer and COR:

a. The remaining ambient exposure time letter disclosing accumulated ambient temperature exposure until the point that BARDA (or DSNS-designated personnel) assumed responsibility for temperature control, per Section F, for each lot from the Contractor's Quality Department. The letter must indicate that the product was manufactured and released in accordance with cGMP and has met all acceptance criteria to allow for Government distribution. — Section VI.A

C.1.16. Funds provided shall be paid on a price per doses basis only on those products delivered and accepted to DSNS under contract. — See Business Vol. II

C.1.17. Under CLIN 0001 of this contract, the products shall have an [**] product. The Contractor shall target [**] of the [**] remaining when the Government takes delivery of the product. — Section IV.B

C.2. PROJECT MANAGEMENT & RISK MITIGATION OBJECTIVES

C.2.1	INTEGRATED MASTER PLAN AND EARNED VALUE MANAGEMENT	
C.2.1.1	The Offeror 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 [**] days of contract award with updates as requested by the COR).	Section VII
C.2.1.2	The Offeror shall submit an updated Integrated Master Schedule in an approved format.	Section VII
C.2.1.3	The Offeror shall submit a plan for a Performance measurement Baseline Review (PMBR).	Section VII
C.2.2	RISK MANAGEMENT OBJECTIVES	
C.2.2.1	The Offeror shall develop and maintain an acceptable risk management plan. If changes are needed to the risk management plan during the execution of the contract, the Offeror shall submit draft changes to risk management plan to USG for approval prior to implementation.	Sections VI.D,VII
C.2.2.2	The Offeror shall participate in regular meetings to coordinate and oversee the work performed.	Section VI.A
C.2.2.3	The Offeror 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.	Section VI.C
C.2.2.4	The Offeror shall provide a security plan, which is associated with all aspects of manufacture of product, process, storage, and inventory of the FDP including when procured for use under EUA and intended for delivery to the CDC/SNS.	Section VI.F
C.3.	MEETING/SITE VISITS/AUDITS	Section VI.A
C.4.	PRODUCT DELIVERIES	
C.4.1	TEMPERATURE CONTROL AND MONITORING, FOB Destination Deliveries	Section IV.B
C.4.2	DSNS QUALITY CONTROL UNIT (QCU) ACCEPTANCE PROCEDURE FOR BIOTHRAX (AVA)	Section IV.B
C.4.3	ACCEPTANCE PROCESS AND TIMEFRAME (FOB DESTINATION DELIVERY)	Section IV.B
C.4.4	BARDA RELEASE FOR BioThrax	Section IV.B
C.5.	REPORTING REQUIREMENTS	Section VI.A
M.1	FAR 52.212-2 EVALUATION – COMMERCIAL ITEMS (OCT 2014)	
M.1.(a)1.	The ability to manufacture BioThrax® vaccine in accordance with current Good Manufacturing Practices (cGMP) guidelines	Section IV.A
M.1.(a)2.	The ability to manufacture and deliver [**] doses of Final Drug Product (FDP) with an acceptable delivery schedule.	Section V.E
M.1.(a)3.	The ability to perform all requisite assays and release testing in accordance with the FDA approved Biologic License Application (BLA).	Section IV.A
M.1.(a)4.	The ability to package doses according to FDA approved labeling and packaging requirements and ship doses to SNS facilities for USG acceptance	Section V.D
M.1(a)5.	The product dose price shall be consistent with current dose prices under active USG procurement mechanisms	See Business Vol. II

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I. Executive Summary

Emergent Biodefense Operations Lansing LLC[1] is pleased to submit this proposal in response to Solicitation 17-100-SOL-00010 for procurement of [**] doses of anthrax vaccine for Biomedical Advanced Research and Development Agency (BARDA) to be delivered to the Strategic National Stockpile (SNS). Emergent is uniquely positioned as the manufacturer of the only FDA-licensed anthrax vaccine for human use, BioThrax® (Anthrax Vaccine Adsorbed). Emergent has:

- A state-of-the-art current Good Manufacturing Practices (cGMP) high capacity manufacturing facility at its Lansing, Michigan campus
- Available manufacturing capacity
- Sufficient inventory and supply lines for required raw materials
- Decades of experience and know-how in the manufacturing of BioThrax
- Significant experience managing large and small business subcontractors currently utilized for fill-finish and logistics functions

This proposal outlines Emergent's unique product and capabilities to fulfill this stated need.

[1] Emergent BioDefense Operations Lansing LLC is a subsidiary of Emergent BioSolutions Inc. (EBSI). Each EBSI company will be individually or collectively referred to as "Emergent" throughout this document.

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II. BioThrax Overview

A. Product Profile

BioThrax is the only FDA-licensed vaccine for the prevention of disease caused by Bacillus anthracis in persons 18 through 65 years of age. BioThrax is approved for pre-exposure prophylaxis of disease in persons at high risk of exposure and for post-exposure prophylaxis of disease following suspected or confirmed Bacillus anthracis exposure, when administered in conjunction with recommended antibacterial drugs. The efficacy of BioThrax for post- exposure prophylaxis is based solely on studies in animal models of inhalational anthrax. BioThrax is manufactured from a sterile culture filtrate, made from a non-virulent strain of Bacillus anthracis, and contains no dead or live bacteria. BioThrax contains aluminum hydroxide as an adjuvant in a suspension for intramuscular or subcutaneous injection, administered in 0.5 mL doses from a 5 mL multidose vial. For pre- exposure prophylaxis, a six-month three-dose primary series is followed by booster doses at 6 and 12 months and annually thereafter. For post-exposure prophylaxis, BioThrax is administered at 0, 2, and 4 weeks post-exposure in conjunction with appropriate antimicrobial therapy.

The BioThrax manufacturing process was first licensed in the United States in the 1970 and was originally designed to produce several thousand doses of vaccine annually. Demand for the vaccine remained relatively low, confined largely to veterinarians and mill workers involved in the processing of animal hair and hides. In the 1990s, the threat of the use of Bacillus anthracis as a bioterrorism weapon became a major concern to the military, leading the U.S. Department of Defense (DoD) to vaccinate select troops during the Gulf War and to establish the Anthrax Vaccine Immunization Program (AVIP) in 1998. Increased demand for the vaccine has driven capacity expansion at the Lansing facility, most recently with the approval of our large scale, large volume facility that has almost tripled our annual production capacity. While numerous modifications and expansions have occurred over time, the manufacturing process has remained similar since its original licensure.

B. Regulatory History and Status

United States

The U.S. National Institutes of Health (NIH) originally approved the manufacture and sale of BioThrax by the Michigan Department of Public Health in 1970. In 1972, responsibility for approving biological products transferred from the NIH to the U.S. Food and Drug Administration (FDA). The FDA set out to categorize the products according to evidence of safety and effectiveness and determine if the products should remain approved and on the market. In December 1985, the FDA issued a proposed rule containing a finding that BioThrax was safe and effective. However, the FDA did not finalize that proposed rule pursuant to applicable notice and comment requirements. In December 2005, based on a review of data from the study used to support the original marketing approval of BioThrax and other studies of the use of BioThrax in humans, including studies by the Centers for Disease Control (CDC) and the DoD, the FDA issued a final order regarding BioThrax. In the final order, the FDA affirmed its approval. In 2009, FDA approved intramuscular administration and reduced the primary pre-exposure vaccination series administrations from 6 doses to 5 doses over 18 months as well as 4-year expiry dating. In 2012, FDA approved a change to the pre-exposure primary series to a more manageable 3 doses over 6 months. Most recently, in 2015, FDA approved BioThrax for post-exposure prophylaxis with a 3-dose series of subcutaneous injections at 0, 2, and 4 weeks administered in conjunction with recommended antibacterial drugs. This marked the first FDA approval for a vaccine indication under the Animal Rule (21 CFR 601.90 through 601.95). Most recently, in 2016, FDA approved the 1,320 L scaled-up manufacture of BioThrax as an alternate for earlier manufacturing lines at the 110 L scale. This expands BioThrax manufacturing capacity up to approximately 25 million doses of BioThrax vaccine annually.

All of these regulatory milestones were pursued and achieved to fulfill U.S. Government needs for improving the efficacy and safety profiles of BioThrax, enhancing patient adherence with the vaccination regimen and reducing the number of doses required to protect each patient – while sustaining a manufacturing capacity commensurate with U.S. Government demand.

Ex-US Marketing Authorization

BioThrax is licensed for pre-exposure vaccination in the following countries:

- Singapore - Health Sciences Authority (HSA) approved 2011
- Germany – Paul-Ehrlich Institut (PEI) approved 2013

C. Important Safety Information

The most common (≥10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema, edema, and arm motion limitation. The most common (≥5%) systemic adverse reactions were muscle aches, headache, and fatigue. Acute allergic reactions, including anaphylaxis, have occurred with BioThrax.

Vaccination with BioThrax should be avoided by individuals with a history of anaphylactic or anaphylactic-like reaction following a previous dose of BioThrax or any component of the vaccine. If BioThrax is used during pregnancy, or if the patient becomes pregnant during the immunization series, the patient should be apprised of the potential hazard to the fetus. Pregnant women should not be vaccinated unless the potential benefits of vaccination have been determined to outweigh the potential risk to the fetus. It is not known whether BioThrax is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BioThrax is administered to a nursing woman.

The stopper of the vial contains natural rubber latex and may cause allergic reactions to patients with a possible history of latex sensitivity.

BioThrax may not protect all individuals vaccinated, particularly patients with impaired immune responses due to congenital or acquired immunodeficiency, or immunosuppressive therapy.

Individuals are not considered protected until they have completed the three-dose primary vaccination series.

The efficacy of BioThrax for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax.

III. Technical Approach for Manufacturing BioThrax Product

A. Manufacturing Practices

BioThrax is manufactured at Emergent's facility in Lansing, Michigan in accordance with cGMP. BioThrax to be provided in response to this RFP will be produced at Emergent's manufacturing line located on Emergent's Lansing, Michigan campus. All manufacturing processes have been validated and are approved by the FDA/CBER (BLA-License Number 1755, STN 103821). Emergent has extensive experience in all aspects of regulatory compliance with regard to vaccine manufacturing, and is compliant with Part 21 of the Code of Federal Regulations, which governs the manufacture of biological products. The FDA has repeatedly concluded that BioThrax is a safe and effective vaccine to protect against anthrax infection, including inhalation anthrax.

BioThrax is subject to the FDA's "lot release" program, which is used to verify that each lot of vaccine meets certain criteria, including sterility, potency and specified levels of certain ingredients (See FDA Final Order, 70 Fed. Reg. at 75,194). All lots of BioThrax released for administration to military personnel and other individuals meet these criteria. (*Id*.) In addition, FDA inspects all biological product license holders on a biennial basis and at additional times when FDA concludes that more regulatory oversight is warranted. (*Id*.) Emergent's most recent inspection by FDA for B12 was in April 2016. Emergent also hosted a pre-approval inspection (PAI) for Building 55 (B55) in June 2016. At the conclusion of this PAI, the company received a No Action Indicated decision and no Form 483 observations, followed by FDA approval in August 2016.

Emergent's FDA-approved testing program includes potency and stabilit y testing. BioThrax lot release testing is conducted on every vaccine lot prior to distribution and includes the following tests: [**]. Emergent's FDA-approved stability testing program is conducted on selected lots as described below and includes testing for [**].

The stability of BioThrax is continuously evaluated at ICH-defined intervals under long-term storage at [**]°C. Emergent places at least [**] into the stability program. BioThrax is currently approved for use up to [**] from the date of manufacture and all delivered product will be labeled with an expiration date in accordance with the current product license.

B. Delivering Doses to the Strategic National Stockpile

Communication
Emergent will coordinate deliveries of funded doses under this contract with the Contracting Officer and the Contracting Officer's Representative at least [**] days prior to delivery dates. SNS delivery destination will be provided by the Government at least [**] business days prior to the shipment date. All scheduled delivery dates will be on a business day, except Federal holidays. Any changes to the delivery schedule will require Government approval. Emergent will provide estimated number of doses and lots to be delivered at least [**] business days prior to the delivery date. The actual delivery date, dose totals, dose expiration dates, and FDA lot release letters will be prepared and supplied by Emergent at least [**] hours prior to each delivery date. Emergent will communicate with the Contracting Officer and Contracting Officer's Technical Representative (or their designees) regarding any potential changes from the delivery schedule.

Cold Chain Storage / Palletization
Emergent will maintain product temperature control in our validated [**]º C storage facilities. Emergent will prepare orders for BioThrax per its Standard Operating Procedures (SOP). The material will be packed in shipping packages, up to [**] vials per shipping package. Multiple packages can be palletized using a 40" x 48" plastic pallet and will be secured for transit to the pallet utilizing plastic shrink-wrap material. One lot or Batch of BioThrax is packaged on one pallet.

Shipment and Delivery Execution
Emergent will comply with Section C.4 of the Solicitation includes the parameters and requirements for each delivery and acceptance of goods delivered under this contract.

Section B. 2.2 requires delivered [**] product to have ≥[**] months remaining expiry dating upon date of delivery.

- The requirement of ≥[**] months remaining expiry dating upon date of delivery was modified in the Scope of Work according to ACMG's response to Emergent's Question 3, received February 1, 2017. As a consequence of this Emergent will deliver product with ≥[**] months remaining expiry dating upon date of delivery.

Emergent will utilize temperature-monitoring devices (e.g. TempTale) packaged with the product during loading and shipment to the designated SNS facility. In-transit temperature data will be evaluated for delivery acceptance in accordance with our current license.

Emergent will facilitate and manage the shipment and cGMP delivery per current approved SOPs. [**].

Emergent takes great lengths in ensuring security of the payload. [**].

Emergent can [**].

IV. Operations and Facilities

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of five pages were omitted. [**].

V. Other Supporting Technical Information

A. Meetings, Audits, Reports and Other Communications

Meetings

Emergent will meet regularly with the Contracting Officer and/or Contracting Officer's Representative, including, but not limited to the following:

- A Kickoff meeting
- Status update meetings/teleconferences as required ([**] frequency is preferred given the scope of work)
- Site visits and other meetings to discuss technical, regulatory and ethical aspects of performance of a contract awarded under this Solicitation

Audits

The Contracting Officer Representative and/or their designee(s) shall have the option to conduct site audits and inspections of Emergent's Lansing facility during the period of performance of this contract.

Reports

Regular performance reports will be provided according to the schedule in Solicitation section C. 5 unless otherwise specified by the Contracting Officer. Given the scope of this work, Emergent requests that:

- The Monthly progress report frequency be revised to Quarterly
- Submission of the Contract Final Report be tied to the last accepted delivery of goods under this contract, and formally mark the end of the period of performance under the contract
- Earned Value Management (EVM) requirements were removed from the Scope of Work according to ACMG's response to Emergent's Question 1, received February 1, 2017. As a consequence of this Emergent will not submit an EVM plan or associated reports per section C.5.E.a in the Solicitation.

Other Communications

All of the communication requirements in Section C.1 are agreed to, subject to the following exceptions that Emergent requests that the Government consider revising in order to align with identical communication and documentation requirements already agreed under our Current BioThrax supply contract with the CDC. Emergent proposes these revisions to insure consistency in communication with the SNS:

Solicitation Section C.1.7 requires Emergent to report to the Government material correspondence with the FDA related to quality, safety or efficacy of BioThrax.

- Emergent proposes sharing all such relevant material information as it does with all commercial customers related to FDA communications for BioThrax.

Solicitation Section C.1.8 requires specific regulatory documentation provided to/from FDA to be accessible and/or sent to the Government within [**] business days of sending or receipt.

- Emergent proposes that this reporting requirement be covered by the modifications to Section C.1.7 above.

Solicitation Section C.1.9 requires Emergent to notify the Government of any issues with the safety and efficacy of BioThrax and/or manufacturing or quality of the FDA-licensed production lines within two business days of the determination of potential to be reported to FDA.

- Emergent proposes notifying the Government within [**] days after a Biologic Process Deviation Report (BPDR) is submitted and including these notifications in periodic reports.

Section C.1.13 requires that Certificates of Analysis and FDA Lot Releases be provided to the Government at least [**] business days before the Delivery Date.

- These communication requirements were modified in the Scope of Work according to ACMG's response to Emergent's Question 4, received February 1, 2017. As a consequence of this Emergent will provide Certificates of Analysis and FDA Lot Releases at least [**] prior to delivery.

Section C.5.D is related to FDA Regulatory correspondence, meeting summaries and submissions.

- These Regulatory communication requirements were modified in the Scope of Work according to ACMG's response to Emergent's Question 2, received February 1, 2017. As a consequence of this Emergent shall provide a copy of any regulatory communications (e.g. meeting minutes, submissions, etc.) that occur during the contract period of performance pertaining to the product being procured (i.e. BioThrax). Any pertinent regulatory communications or issues that may impact the product or ability of Emergent to complete delivery of the product on this particular contract shall be made known to BARDA/AMCG until delivery of all [**] doses are completed.

B. Recent Audit History

Table 5-1 outlines audits and site visits conducted by the USG from 2011 to the present.

Year	Agency	Purpose	Outcome/Classification
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

Table 5-1. Government Audits and Site 2011-Present

C. Organization and Personnel

Key Personnel / Points of Contact

Table 5-2 specifies Key Personnel and Emergent Points of Contact

The following key personnel will be available 24 hours a day, seven days a week to be notified in case of a public health emergency:

[**]

Their 24-hour contact information will be provided upon contract award

Name	Position
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

Table 5-2. Emergent Key Personnel

D. Risk Management

As a company, Emergent places great emphasis on identifying risks that potentially would impact our future success. *Figure 5-1* depicts an overview of our risk management strategy.

We use a defined process for the identification, assessment, control, and review of risks within the program. During risk assessment activities, we log risks identified by pre-defined program triggers into a risk matrix and identify each by its Work Breakdown Structure task designation. We assess each risk for its Probability of Occurrence and its Severity of Impact to the project. Once we assign the initial risk level of high/medium/ low, we direct project resources toward the most value-added activities, addressing project risks in their order of importance.

Our mitigation strategies include:

- Reduction: Reduction of risk wherever possible

- Transfer: Determination that the risk is outside control of the functional team and the PD identifies the team responsible for mitigation

- Retention: Determination that the risk to project cost, schedule, and performance can continue without action

- Avoidance: Decision to avoid the risk by not implementing the task involving the risk

We implement risk mitigation strategies associated with the identified risks.

Figure 5-1. Emergent's risk management strategy uses a defined process for the identification, assessment, control, and review of risks within the program.

E. Subcontract and Vendor Management

Our proposed subcontractors are experienced and have the requisite facilities necessary to perform their tasks under all applicable regulations and requirements. Subcontractors' quality systems and facilities are audited by Emergent prior to subcontract award and periodically thereafter to ensure compliance.

Subcontracts address the scope of work, schedule, price, risk, unique requirements such as the need for GMP/GCP/GLP/quality agreements/audits, technical and business assumptions, dispute resolution, etc. Subcontracts are managed in accordance with applicable Federal Acquisition Regulations.

Emergent's Contract Managers ensure that each subcontractor and Vendor is performing according to the requirements delineated in the subcontract. Contract Managers initiate and track subcontract modifications as required to adjust for changes in scope. We closely manage subcontractor performance, deliverables, and quality through regular communication, on site meetings, and schedule reviews. Noncompliance issues that cannot be resolved between Emergent and the subcontractor's management team are elevated to the subcontractor's senior management. Clauses are included in subcontracts to address noncompliance, contract termination, and dispute resolution.

F. Security

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**].

G. Quality Systems

Emergent has defined the Quality Management System (QMS) requirements for phase appropriate compliance from proof-of-concept and pre-clinical stages through commercial manufacturing.

Emergent's integrated QMS is regulated by our Quality Policy Manual. The SOP-supported manual describes QMS policies and activities performed at our Lansing facility. The Quality Policy Manual aligns with Emergent's strategic plan, corporate objectives, and cGMP regulations and expectations.

Each component of our QMS complies with applicable ICH and FDA regulatory standards and requirements applicable for each stage of the product lifecycle. Emergent's Quality Assurance Department will ensure internal compliance to these standards as well as compliance of subcontractors performing work on Emergent's behalf. Our QMS includes all of the following components:

- management responsibility and review

- personnel qualification and training

- document and data control

- validation

- equipment and facilities control
- supplier quality and materials management control
- production and in-process controls
- non-conformance handling
- change control
- corrective and preventive action

Management Responsibility
The senior leadership team at each site is ultimately responsible for ensuring an effective QMS is in place, demonstrating strong support of the QMS and continuous improvement efforts, and ensuring that roles, responsibilities and authorities are defined, communicated, and implemented at all levels in the organization.

Personnel Qualification and Training Policy
Emergent will ensure employees involved with vaccine operations have the necessary education, training, and experience appropriate to their positions. Current job descriptions and curricula vitae, or similar documentation, are established and maintained for all personnel responsible for conducting or overseeing activities.

Training records are maintained for employees, and periodic and systematic reviews of personnel training records are conducted to ensure that employees are receiving the training demanded by their job or function.

Management and Data Integrity Policy
Emergent will ensure established SOPs are in place to control all documents and processes required for phase appropriate compliance activities. The document management program prevents unapproved revisions to controlled documents that may in turn affect the safety, quality, identity, potency and purity of the Anthrax vaccine. Changes to documents are reviewed and approved by designated individuals and the changes are communicated through training on the revised procedure. Controlled documents are available to personnel conducting the work.

Data is fully traceable from the controlled record to the raw data and is maintained and stored in such a way as to remain legible, readily identifiable, and retrievable. Original records are archived in compliance with document control and records management procedures.

Supplier Quality and Materials Management Policy
Materials and services shall only be purchased from suppliers that have been appropriately qualified. A material qualification process is in place to ensure that materials are fit for their intended use.

Materials are controlled from the time of receipt to maintain complete identification and traceability at all times in accordance with established SOPs and compliance regulations.

Emergent will ensure product release does not proceed until all activities have been completed, documentation is available, and disposition has been authorized by QA. The materials management program will ensure proper segregation of materials that are under quarantine, release, and reject.

Quality Agreement Policy
The Emergent QMS extends to the oversight and review of all outsourced activities. Quality Agreements are implemented to delineate clear responsibilities between Emergent and the subcontractor to avoid conflicts. These agreements are reviewed and executed by both parties.

Emergent will maintain Quality Agreements with applicable material and service suppliers. The Quality Agreement shall define the respective responsibilities shared by Emergent and, suppliers, as they relate to the manufacturing, testing, storing, and shipping activities. Quality Agreements will be written to ensure that affected parties comply with phase appropriate compliance requirements.

Non-Conformance Policy
Emergent will ensure non-conforming events (e.g., deviations, Out of Specification, or Out of Trend results) are identified and investigated to correct the issue, protect end users from harm, and eliminate the root cause. Investigations are thorough in gathering all relevant facts, performing risk assessments, and determining a root cause whenever possible. The scope of the investigation is all inclusive of any product or processes that may have been impacted. Systemic problems are recognized and resolved.

Change Control
Emergent will ensure any changes are documented, controlled and approved to prevent undesired events that could adversely affect the Safety, Quality, Identity, Potency, or Purity (SQIPP) of BioThrax, and will collect information about the actual impact of the change. Risk assessment is incorporated into the change control process based on the scope and potential impact of the change.

Facilities and Equipment

Emergent will ensure facilities and equipment are adequately designed, qualified, and maintained. Emergent will ensure all buildings used in the manufacturing, testing, storing, or shipping of the cell banks, bulk drug substance, and final drug product are maintained in a good state of repair, cleanliness, and sanitary condition. The operational areas and equipment used in the manufacturing, testing, storing, or shipping of the cell banks, bulk drug substance, and final drug product must be of appropriate design, adequate size, and suitably located to facilitate operation for its intended use and for cleaning and maintenance. Equipment is constructed so that surfaces that contact components are not reactive, additive, or absorptive to make sure the SQIPP of BioThrax is not adversely affected.

Calibration and Preventative Maintenance Program Critical and non-critical equipment and utilities supporting manufacturing, testing, storing or shipping are included in the calibration and preventative maintenance programs. Instruments on equipment and utilities are calibrated and the systems themselves routinely maintained based on established schedules or history of performance. Out-of-tolerance conditions are documented, reviewed, and their impact on product and process are assessed. Appropriate corrective action is taken.

Laboratory Control Policy
Emergent will ensure analytical and/or microbial quality control testing is performed according to established specifications, sampling plans, test procedures, and laboratory control mechanisms required by the FDA regulations and guidance documents. Any deviations from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms are recorded and investigated.

All raw data generated in the course of testing raw materials, packaging materials, in process, and/or finished products shall be retained according to Emergent's corporate records retention schedule. Under no circumstance shall raw data be discarded, obliterated, or otherwise rendered unreadable or irretrievable during its established retention period.

Quality Assurance Oversight
Through oversight of the above listed requirements and process controls, Emergent QA will ensure that the cell banks, bulk drug substance, and final drug product is produced in compliance with Emergent's appropriate cGMP compliance requirements.

VI. Project Management & Risk Mitigation Objectives

Earned Value Management (EVM) requirements were removed from the Scope of Work according to ACMG's response to Emergent's Question 1, received February 1, 2017. As a consequence of this Emergent will not submit an EVM plan.

VII. Conclusion

Emergent is uniquely qualified to supply BioThrax to fulfill the specified requirement in this Solicitation. Not only do we offer BioThrax, the only FDA-licensed anthrax vaccine indicated for both pre-exposure and post-exposure prophylaxis, but we also have more than two decades of experience supplying BioThrax to multiple governments around the world for their anthrax medical countermeasure preparedness needs. Emergent has the manufacturing expertise, plus certified high-capacity cGMP manufacturing operations and all required support systems in place to confidently supply BioThrax as required under this Solicitation.

VIII. Appendices

The following Appendices are attached to this proposal:

A. Prescribing Information

B. Proposed Delivery Schedule

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SECTION B

A. Appendix A – Prescribing Information

(http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM074923.pdf)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BIOTHRAX safely and effectively. See full prescribing information for BIOTHRAX.
BIOTHRAX® (Anthrax Vaccine Adsorbed)
Suspension for Intramuscular or Subcutaneous Injection
Initial U.S. Approval: 1970

RECENT MAJOR CHANGES
INDICATIONS AND USAGE (1.1, 1.2) November/2015
DOSAGE AND ADMINISTRATION (2.1, 2.2) November/2015

INDICATIONS AND USAGE
BioThrax is a vaccine indicated for the active immunization for the prevention of disease caused by *Bacillus anthracis* in persons 18 through 65 years of age. BioThrax is approved for:

1. Pre-exposure prophylaxis of disease in persons at high risk of exposure.
2. Post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs.

The efficacy of BioThrax for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax. (1)

DOSAGE AND ADMINISTRATION
For intramuscular or subcutaneous injection only.
Each dose is 0.5 mL.
Pre-Exposure Prophylaxis (2.1):

Schedule	Route of Administration	Dosing Schedule
Primary Series	Intramuscular	0, 1, and 6 months
Booster Series	Intramuscular	6 and 12 months after completion of the primary series and at 12-month intervals thereafter

In persons who are at risk for hematoma formation following intramuscular injection, BioThrax may be administered by the subcutaneous route. The pre-exposure prophylaxis schedule for BioThrax administered subcutaneously is 0, 2, 4 weeks, and 6 months with booster doses 6 and 12 months after completion of the primary series, and at 12-month intervals thereafter.

Post-Exposure Prophylaxis (2.1):

Schedule	Route of Administration	Dosing Schedule
Primary Series	Subcutaneous	0, 2, and 4 weeks post-exposure combined with antimicrobial therapy

DOSAGE FORMS AND STRENGTHS
Suspension for injection (0.5 mL dose) in 5 mL multidose vials. (3, 11)

CONTRAINDICATIONS
Severe allergic reaction (e.g. anaphylaxis) after a previous dose of BioThrax or a component of the vaccine. (4)

WARNINGS AND PRECAUTIONS
- The stopper of the vial contains natural rubber latex and may cause allergic reactions in latex sensitive individuals. (5.2)
- Pregnancy: Avoid use in pregnancy unless the potential benefit outweighs the potential risk to the fetus (5.3, 8.1)

ADVERSE REACTIONS
The most common (>10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema, edema, and arm motion limitation. The most common (≥5%) systemic adverse reactions were muscle aches, fatigue, and headache. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Emergent BioSolutions at 1-877-246-8472 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

USE IN SPECIFIC POPULATIONS
- Pregnancy: Advise women of potential risk to the fetus. (5.3, 8.1) Pregnancy registry available, contact BioThrax (Anthrax) Vaccine in Pregnancy Registry (Phone: 1-619-553-9255). (8.1)
- Safety and effectiveness of BioThrax have not been established in pediatric or geriatric populations. (8.4, 8.5)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: November 2015

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BioThrax is a vaccine indicated for the active immunization for the prevention of disease caused by *Bacillus anthracis* in persons 18 through 65 years of age.

1.1 BioThrax is approved for pre-exposure prophylaxis of disease in persons whose occupation or other activities place them at high risk of exposure.

1.2 BioThrax is approved for post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs.

The efficacy of BioThrax for post-exposure prophylaxis is based solely on studies in animal models of inhalation anthrax.

2 DOSAGE AND ADMINISTRATION

For intramuscular or subcutaneous injection only.

2.1 Dose

Each dose is 0.5 mL.

Pre-Exposure Prophylaxis:

Schedule	Route of Administration	Dosing Schedule
Primary Series	Intramuscular	0, 1, and 6 months
Booster Series	Intramuscular	6 and 12 months after completion of the primary series and at 12-month intervals thereafter

In persons who are at risk for hematoma formation following intramuscular injection, BioThrax may be administered by the subcutaneous route. The pre-exposure prophylaxis schedule for BioThrax administered subcutaneously is 0, 2, 4 weeks, and 6 months with booster doses at 6 and 12 months after completion of the primary series and at 12-month intervals thereafter.

The optimal schedule for catch up of missed or delayed booster doses is unknown. [See *Clinical Studies* (14)]

Post-Exposure Prophylaxis:

Schedule	Route of Administration	Dosing Schedule
Primary Series	Subcutaneous	0, 2, and 4 weeks post-exposure combined with antimicrobial therapy

2.2 Administration

Shake the vial thoroughly to ensure that the suspension is homogeneous during withdrawal. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, do not administer the vaccine.

Administer pre-exposure prophylaxis vaccinations intramuscularly into the deltoid muscle. If pre-exposure prophylaxis requires subcutaneous administration, administer over the deltoid muscle. Administer post-exposure prophylaxis vaccinations subcutaneously over the deltoid muscle.

Do not mix with any other product in the syringe.

3 DOSAGE FORMS AND STRENGTHS

BioThrax is a suspension for injection (0.5 mL dose) in 5 mL multidose vials. See *Description* (11) for the complete listing of ingredients.

4 CONTRAINDICATIONS

Do not administer BioThrax to individuals with a history of anaphylactic or anaphylactic-like reaction following a previous dose of BioThrax or any component of the vaccine, including aluminum, benzethonium chloride, and formaldehyde. [See *Description* (11)]

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Acute allergic reactions, including anaphylaxis, have occurred with BioThrax. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine. [See *Contraindications* (4)]

5.2 Latex

The stopper of the vial contains natural rubber latex and may cause allergic reactions to patients with a possible history of latex sensitivity. [See *How Supplied/Storage and Handling* (16)]

5.3 Pregnancy

BioThrax can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. Weigh the potential benefits of vaccination against the potential risk to the fetus. [See *Use in Specific Populations* (8.1)]

Pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination have been determined to outweigh the potential risk to the fetus. Results of a large observational study that examined the rate of birth defects among 37,140 infants born to U.S. military service women who received anthrax vaccine in pregnancy between 1998 and 2004 showed that birth defects were slightly more common in first trimester-exposed infants (odds ratio = 1.18, 95% confidence interval: 0.997, 1.41) when compared with infants of women vaccinated outside of the first trimester and compared to unvaccinated women.[1] While the increased birth defect rates were not statistically significant when compared with infants born to women vaccinated outside of pregnancy, pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination have been determined to outweigh the potential risk to the fetus.

5.4 History of Anthrax Disease

History of anthrax disease may increase the potential for severe local adverse reactions.

5.5 Altered Immunocompetence

If BioThrax is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

5.6 Limitations of Vaccine Effectiveness

Vaccination with BioThrax may not protect all individuals.

6 ADVERSE REACTIONS

The most common (≥10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema, edema, and arm motion limitation. The most common (≥5%) systemic adverse reactions were muscle aches, headache, and fatigue.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a product cannot be directly compared to rates in the clinical trials of another product and may not reflect the rates observed in clinical practice.

Pre-Exposure Prophylaxis

In an open-label safety study of 15,907 doses of BioThrax administered by the subcutaneous route to approximately 7,000 textile employees, laboratory workers and other at risk individuals, local and systemic reactions were monitored. Over the course of the 5-year study the following local adverse reactions were reported: 24 (0.15% of doses administered) severe local adverse reactions (defined as edema or induration measuring greater than 120 mm in diameter or accompanied by marked limitation of arm motion or marked axillary node tenderness), 150 (0.94% of doses administered) moderate local adverse reactions (edema or induration greater than 30 mm but less than 120 mm in diameter), and 1,373 (8.63% of doses administered) mild local adverse reactions (erythema only or induration measuring less than 30 mm in diameter). Four cases of systemic adverse reactions were reported during the 5-year reporting period (<0.06% of doses administered). These reactions, which were reported to have been transient, included fever, chills, nausea, and general body aches.

In a randomized, double-blinded, placebo-controlled, and active-controlled multi-center clinical study, 1,564 healthy subjects were enrolled. The objective of this study was to evaluate the effect of (1) changing the route of vaccine administration from subcutaneous (SC) to intramuscular (IM), and (2) of reducing the number of doses on the safety and immunogenicity of BioThrax. The dosing schedules and routes studied are provided in Table 1. [See *Clinical Studies* (14)]

Group A (8SC) (N=259) received BioThrax via the SC route of administration at Weeks 0, 2, 4, and Months 6, 12, 18 followed by 2 annual boosters (original U S. licensed route/schedule). Group A served as the active control in this study.

Group B (8IM) (N=262) received BioThrax via the IM route of administration at Weeks 0, 2, 4, and Months 6, 12, 18 followed by 2 annual boosters.

Group C (COM) (N=782) received BioThrax via the IM route of administration at Weeks 0, 4 (no Week 2 dose), and Month 6 with various schedules thereafter. (Group C represents data from 3 randomized groups [Groups D, E, and F] combined for the analysis, through Month 7 because the schedules are identical through the Month 6 dose.)

Group D (7IM) (N=256) received BioThrax via the IM route of administration at Weeks 0, 4 (no Week 2 dose), and Months 6, 12, 18 followed by 2 annual boosters.

Group E (5IM) (N=258) received BioThrax via the IM route of administration at Weeks 0, 4 (no Week 2 dose), and Months 6, 18 followed by 1 booster dose at Month 42 (2 year interval).

Group F (4IM) (N=268) received BioThrax via the IM route of administration at Weeks 0, 4 (no Week 2 dose), and Month 6 followed by 1 booster dose at Month 42 (3 year interval).

Table 1: Vaccination Schedules and Routes Evaluated								
Group/Route	**Weeks**			**Months**				
	0	2	4	6	12	18	30	42
Group A (8SC)[a]	V	V	V	V	V	V	V	V
Group B (8IM)	V	V	V	V	V	V	V	V
Group D (7IM)	V	S	V	V	V	V	V	V
Group E (5IM)	V	S	V	V	S	V	S	V
Group F (4IM)	V	S	V	V	S	S	S	V
Placebo[b]	S	S	S	S	S	S	S	S

SC: subcutaneous; IM: intramuscular; V: vaccine; S: Saline

[a] Active Control

[b] Subjects randomized to the control group were then re-randomized (1:1) to receive saline by the IM or SC route. The IM and SC placebo groups are combined in analyses.

Subjects were instructed to complete a 14-day post-vaccination diary card after the first 2 doses and a 28 day diary card after the subsequent doses to capture solicited and unsolicited adverse reactions. Adverse reaction data were also collected from in-clinic exams, which were performed prior to, and 15 to 60 minutes after each injection, at 1 to 3 days after each injection for the first two injections, and at 28 days after injections 3 through 8. The mean age, gender ratio, and race distribution were not significantly different across treatment groups among the vaccinated cohort (N=1563). The mean age was 39 years (range 18 to 62 years). Fifty-one percent of participants were female and 49% were male. Seventy-four percent were white, 21% were black and 5% were categorized as "other".

Shown in Table 2 are the rates (percentage) of prospectively defined local and systemic solicited adverse reactions observed in the in-clinic exams for doses 1-4 as well as the rates (percentage) of local and systemic solicited adverse reactions observed in the in-clinic exams for doses 5-8.

Analysis of injection site (local) adverse reactions by study group was performed after each dose. It was observed that groups receiving BioThrax by the IM route had a statistically significant lower incidence ($p \leq 0.05$) of any (one or more) local adverse reactions compared to the BioThrax SC route, by dose in the in-clinic data set, in 23 out of 24 analyses. (This excludes doses where IM groups received a placebo.) Individual injection site adverse reactions occurring at statistically significantly lower frequencies ($p \leq 0.05$) in participants given BioThrax by the IM route included warmth (in all analyses), tenderness (in 19 out of 24 analyses), itching (in 22 out of 24 analyses), erythema (in all analyses), induration (in all analyses), edema (in 20 out of 24 analyses), and nodule (in all analyses). However, by dose, the incidences of arm motion limitation were comparable or higher in each BioThrax IM group compared to the 8SC group, with statistically significantly higher incidences ($p \leq 0.05$) observed in 10 out of 24 analyses. The incidence of any moderate or severe local adverse reactions was lower in BioThrax IM groups, compared to the 8SC group after each dose. Route of administration did not affect the occurrence of systemic adverse reactions, with the exception of muscle ache (increased incidence in the BioThrax IM groups after most doses). There was no pattern for differences in the incidence of any moderate or severe systemic adverse reactions for BioThrax IM groups compared to the 8SC group after each dose. The proportion of participants with severe local or systemic adverse reactions reported by adverse reaction category after each dose was very low (generally <1%).

Overall, women had a higher incidence of any local adverse reaction than did men, by dose, within BioThrax groups, regardless of the route of administration. Overall, women also had a higher incidence of any systemic adverse reaction than men, within BioThrax groups, regardless of the route of administration. A brief pain or burning sensation, felt immediately after vaccine injection, and distinct from injection site pain, was reported by 45 - 97% of all study participants receiving BioThrax. Reporting frequency and event intensity varied with route of administration and vaccine dose. Up to 11% of subjects rated the brief pain or burning they experienced immediately after vaccine injection as 8 out of 10 or greater. Female participants generally experienced a higher pain scale rating than male participants.

Eight serious adverse events (SAEs) were reported with 6 subjects and determined to be possibly related to the administration of BioThrax: (1) a case of generalized allergic reaction, (2) a case of ANA positive autoimmune disorder manifesting as a moderate bilateral arthralgia of the metacarpophalangeal (MCP) joints, (3) a right shoulder supraspinatus tendon tear, (4) a case of bilateral pseudotumor cerebri with bilateral disc edema, (5) a case of generalized seizure and hospitalization for evaluation of hydrocephalus and endoscopic fluid ventriculostomy, (6) a case of bilateral ductal carcinoma of the breast. No SAEs were determined by the investigator to be probably or definitely related to administration of BioThrax. The percent of serious adverse events was similar between the BioThrax combined groups (193/1303 or 15%) and the placebo group (38/260 or 15%).

Fifty-one pregnancies were reported in this study, 33 of which occurred in women who received BioThrax as their last dose prior to conception and 18 in women who received placebo as their last dose prior to conception. Pregnancy outcomes where BioThrax was given within 30 days prior to conception (n=5) were 3 full-term live births (including 1 healthy term infant with a mild right clubbed foot abnormality), 1 spontaneous abortion, and 1 first trimester intra-utero fetal death. Pregnancy outcomes in the placebo group (n=5) were 4 full-term live births (including one with bilateral congenital hip dysplasia) and 1 elective abortion.

Table 2: Adverse Reactions: In-Clinic Day 0 – 3, Solicited by Dose Number[a]

	STUDY GROUP																							
	Group D BioThrax 7IM (BioThrax Doses 1, 3-8) Weeks-0-4-26[b] Months 12-18-30-42								Placebo[c] Control SC/IM (Doses 1-8) Weeks-0-2-4-26 Months 12-18-30-42								Group A BioThrax 8SC (BioThrax Doses 1-8) Weeks-0-2-4-26 Months 12-18-30-42							
Number of Subjects (N)[d]	256								260								259							
	Dose								Dose								Dose							
	1	2[b]	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Local Adverse Reactions																								
Presence of any local adverse reaction	60	*23*	68	68	69	77	76	73	22	22	19	27	25	29	25	18	81	89	80	84	81	84	84	92
Warmth	4	*1*	8	10	11	13	14	19	1	0	0	0	0	0	1	1	29	41	32	39	34	40	51	49
Tenderness	46	*7*	51	47	41	44	44	48	6	8	7	10	6	7	7	4	64	72	48	65	53	57	61	63
Itching	1	*0*	2	4	7	7	7	10	0	0	0	0	1	0	0	0	3	16	23	20	17	22	25	26
Pain	16	*4*	20	15	16	13	16	15	4	2	3	4	4	2	3	2	16	22	12	19	16	14	18	20
Arm motion limitation	14	*1*	15	11	10	10	15	9	1	0	2	1	1	1	1	0	8	12	5	11	10	5	8	5
Erythema	15	*10*	20	30	35	48	40	37	11	12	7	13	14	17	14	11	53	64	57	65	64	64	68	71
Induration	7	*7*	12	16	21	23	15	17	1	3	2	3	4	4	3	3	26	35	28	40	38	36	38	35
Edema	5	*2*	11	20	15	23	30	25	3	4	4	4	4	7	8	5	17	33	31	33	31	35	37	46
Nodule	3	*0*	4	5	8	9	6	5	0	2	0	1	2	0	2	0	39	42	36	26	26	23	21	27
Bruise	5	*4*	5	3	2	4	3	2	4	5	1	4	3	5	5	4	6	7	6	6	3	6	5	6
Presence of any moderate/severe local adverse reactions[e]	5	*1*	8	7	4	5	6	4	0	0	0	0	0	0	0	0	7	16	8	13	10	7	12	14
Presence of any large local adverse reaction[f]	0	*0*	0	2	2	4	2	2	0	0	0	0	0	0	0	0	0	1	4	2	1	2	2	4
Systemic Adverse Reactions																								
Presence of any systemic adverse reaction	18	*12*	24	19	15	19	10	9	10	10	13	11	13	8	13	4	16	20	18	21	18	14	20	17
Fatigue	9	*4*	12	10	9	11	4	6	5	4	7	7	8	5	10	3	9	12	8	12	12	10	10	13
Muscle ache	8	*4*	13	6	5	5	3	5	2	2	3	4	5	3	1	1	5	8	4	5	4	3	9	5
Headache	6	*6*	9	7	8	8	5	4	4	6	5	4	7	4	6	1	7	9	8	11	7	5	9	2
Fever >100.4°F	0	*0*	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Tender/painful axillary adenopathy	0	*0*	0	1	1	1	0	0	0	0	0	0	0	0	0	1	0	1	2	1	1	0	1	0
Presence of any moderate/severe systemic adverse reactions[g]	2	*2*	6	3	3	5	4	3	1	2	2	1	3	1	2	1	2	5	4	3	3	2	3	2

[a] Per-dose, statistical assessment performed on Intent-to-Treat population data. Evaluations performed at 15-60 minutes and 1-3 days following each injection and prior to the next scheduled injection.
[b] Subjects received saline (instead of BioThrax) for the Week 2 dose. Placebo dose data for 7IM group is in italics.
[c] The two saline groups (SC and IM) were combined.
[d] N is the highest number per treatment arm (received at least one dose); denominator (N) varied with dose number due to attrition over time.

[e] Moderate = causes discomfort and interferes with normal daily activities; Severe = incapacitating and completely prevents performing normal daily activities. This is based on the local AE categories of warmth, tenderness, itching, pain, and arm motion limitation.
[f] Large = an occurrence of induration, erythema, edema, nodule, and bruise with a largest diameter greater than 120 mm.
[g] Moderate = causes discomfort and interferes with normal daily activities; Severe = incapacitating and completely prevents performing normal daily activities. This is based on the systemic AE categories of fatigue, muscle ache, headache, and fever.

Solicited and unsolicited adverse reactions observed from Day 0 through month 43 at a higher frequency (by at least 5%) in the BioThrax groups (IM and SC) as compared to the placebo (P) group were: headache (70.4% IM, 78.4% SC, 68.1% P); myalgia (72% IM, 76.1% SC, 50% P); and fatigue (70.1% IM, 76.8% SC, 60.8% P).

Post-Exposure Prophylaxis

A phase 3, open-label, uncontrolled, multi-center study evaluated the three-dose post-exposure prophylaxis BioThrax schedule (Week 0, 2 and 4) in 200 healthy adult subjects. The most common solicited adverse reactions reported 7 days after each vaccination comprised local reactions, including symptoms of lump, tenderness, and erythema. The most common solicited systemic reactions comprised fatigue, headache, and myalgia. Of the subjects that reported local and systemic solicited reactions, ≥ 98% required minimal or no treatment and resulted in little to no interference with subjects' daily activity. The most common (> 2.0%) unsolicited related adverse reactions reported following at least one dose up to 100 days after the third dose were: headache (4.0%), fatigue (3.5%), skin hyperpigmentation (3.5%), decreased joint range of motion (2.5%), myalgia (2.5%). No deaths were reported and neither of the two SAEs reported were considered to be related to vaccination. There were no pregnancies reported or subject withdrawals from the study due to adverse events.

6.2 Postmarketing Experience

The following adverse events have been reported spontaneously. Since these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The reports included below are listed due to one or more of the following factors: (1) seriousness of the event, (2) number of reports, or (3) strength of causal relationship to the drug.

- **Blood and lymphatic system disorders**

  Lymphadenopathy

- **Gastrointestinal Disorders**

  Nausea

- **Immune system disorders**

  Allergic reactions (including anaphylaxis, angioedema, rash, urticaria, pruritus, erythema multiforme, anaphylactoid reaction, and Stevens Johnson syndrome)

- **Nervous system disorders**

  Paresthesia syncope, dizziness, tremor, ulnar nerve neuropathy

- **Musculoskeletal, connective tissue, and bone disorders**

  Arthralgia, arthropathy, myalgia, rhabdomyolysis, alopecia

- **General disorders and administration site conditions**

  Malaise, pain, cellulitis, flu-like symptoms

- **Psychiatric disorders**

  Insomnia

- **Skin and Subcutaneous disorders**

  Pruritis, rash, urticaria

- **Vascular disorders**

  Flushing

Infrequent reports were also received of multisystem disorders defined as chronic symptoms involving at least two of the following three categories: fatigue, mood-cognition, and musculoskeletal system.

7 DRUG INTERACTIONS

7.1 Ciprofloxacin

Co-administration of 0.5 mL BioThrax SC with oral ciprofloxacin in human subjects did not alter the pharmacokinetics of ciprofloxacin or the immunogenicity of BioThrax as measured by the anthrax lethal toxin neutralization assay. [See *Clinical Studies* (14-3)]

7.2 Concomitant Administration with Other Vaccines

The safety and efficacy of concomitant administration of BioThrax with other licensed vaccines has not been evaluated.

BioThrax should not be mixed with any other vaccine in the same syringe or vial. If BioThrax is to be given at the same time as another injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

7.3 Immunosuppressive Therapies

Immunosuppressive therapies, including chemotherapy, corticosteroids (used in high-doses longer than 2 weeks), and radiation therapy may reduce the response of BioThrax.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category D. [See *Warnings and Precautions* (5.3)]

Healthcare practitioners are encouraged to register women who receive BioThrax during pregnancy in Emergent's vaccination pregnancy registry by calling 1-619-553-9255.

Male Fertility: A retrospective study was performed at an in-vitro fertilization clinic to evaluate whether BioThrax may impact reproductive function in men.. This study compared semen parameters, embryo quality, and pregnancy outcomes in 254 male clients who stated that they had received BioThrax, with those of 791 male clients who did not.[2] Prior receipt of BioThrax did not influence semen parameters (including concentration, motility, and morphology), fertilization rate, embryo quality or clinical pregnancy rates.

8.3 Nursing Mothers

It is not known whether BioThrax is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BioThrax is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established for BioThrax.

8.5 Geriatric Use

BioThrax has not been approved for use in patients greater than 65 years of age.

11 DESCRIPTION

BioThrax® (Anthrax Vaccine Adsorbed) is a sterile, milky-white suspension for intramuscular or subcutaneous injections made from cell-free filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of *Bacillus anthracis*. The production cultures are grown in a chemically defined protein-free medium consisting of a mixture of amino acids, vitamins, inorganic salts, and sugars. The final product, prepared from the sterile filtrate culture fluid contains proteins, including the 83kDa protective antigen (PA) protein, released during the growth period and contains no dead or live bacteria. The final product is formulated to contain 1.2 mg/mL aluminum, added as aluminum hydroxide in 0.85% sodium chloride. The final product is formulated to contain 25 mcg/mL benzethonium chloride and 100 mcg/mL formaldehyde, added as preservatives.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Anthrax is a zoonotic disease caused by the Gram-positive spore-forming bacterium *Bacillus anthracis*. BioThrax induces antibodies raised against PA that may contribute to protection by neutralizing the activities of the cytotoxic lethal toxin and edema toxin of *Bacillus anthracis*.[3] *Bacillus anthracis* proteins other than PA may be present in BioThrax, but their contribution to protection has not been determined.

13 NONCLINICAL TOXICOLOGY

The effect of BioThrax on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rabbits. One group of rabbits was administered BioThrax twice prior to gestation and during the period of organogenesis (gestation day 7). A second group of rabbits was administered BioThrax twice prior to gestation and on gestation day 17. BioThrax was administered at 0.5 ml/rabbit/occasion, by intramuscular injection. No adverse effects on mating, fertility, pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis noted in this study.

13.2 Animal Pharmacology

Since it is not feasible or ethical to conduct controlled clinical trials with anthrax, the efficacy of BioThrax in a post-exposure setting is based on studies in animals. Pre-exposure prophylaxis animal models were used to derive protective antibody thresholds to bridge animal efficacy and human immunogenicity data and predict efficacy in humans.

Pivotal efficacy animal studies were conducted in rabbits and nonhuman primates (NHPs). Animals received two IM vaccinations four weeks apart with serial dilutions of BioThrax and were subjected to lethal challenge on study day 70 with aerosolized *B. anthracis* spores at a target dose exceeding the 50% lethal dose by 200-fold. Serum samples were collected at various time points prior to challenge for immune response analysis via anthrax lethal toxin neutralizing antibody (TNA) assay. The relationship between pre-challenge serum TNA levels and survival was evaluated. Logistic regression analysis demonstrated that a 70% probability of survival was associated with a TNA NF_{50} (50% neutralization factor) level of 0.56 in rabbits and 0.29 in NHPs.

The ability of BioThrax to increase survival after the cessation of the post-exposure antimicrobial treatment, as compared with antimicrobial treatment alone, was investigated in two post-exposure animal model studies. In these studies, rabbits were challenged via inhalation with aerosolized *B. anthracis* spores and subsequently treated with levofloxacin administered via oral gavage once daily for 7 days starting at 6-12 hours post-exposure, with or without two intramuscular injections of BioThrax one week apart. Survival among animals that received both antimicrobial treatment and vaccination was between 70 – 100% and increased in a vaccine dose-dependent manner. In contrast, only 44% and 23% survival was observed among animals that received antimicrobial treatment only in the first and the second study, respectively ($p < 0.0006$ and $p < 0.004$, respectively). [See *Clinical Studies* (14.2)]

14 CLINICAL STUDIES

14.1 Pre-Exposure Prophylaxis

A controlled field study using an earlier version of a protective antigen-based anthrax vaccine developed in the 1950's and supplied by G. G. Wright and associates of the U.S. Army Chemical Corps, Fort Detrick, Frederick, MD, that consisted of an aluminum potassium sulfate-precipitated cell-free filtrate from an aerobic culture, was conducted from 1955-1959.[4] This study included 1,249 workers [379 received anthrax vaccine, 414 received placebo, 116 received incomplete inoculations (with either vaccine or placebo) and 340 were in the observational group (no treatment)] in four mills in the northeastern United States that processed imported animal hides. The anthrax vaccine was administered subcutaneously at 0, 2, 4 weeks, 6, 12, 18 months. Prior to vaccination, the yearly average number of human anthrax cases (both cutaneous and inhalational) was 1.2 cases per 100 employees in these mills. During the trial, 26 cases of anthrax were reported across the four mills – 5 inhalation and 21 cutaneous. Of the five inhalation cases (four of which were fatal), two received placebo and three were in the observational group. Of the 21 cutaneous cases, 15 received placebo, three were in the observational group, and three received anthrax vaccine. Of those three cases in the vaccine group, one case occurred just prior to administration of the scheduled third dose, one case occurred 13 months after an individual received the third of the scheduled 6 doses (but no subsequent doses), and one case occurred prior to receiving the scheduled fourth dose of vaccine. The calculated efficacy of the vaccine to prevent all types of anthrax disease, regardless of the route of exposure or clinical manifestations, was 92.5% (lower 95% Confidence Interval (CI) = 65%).

Between 1962 and 1974, the Centers for Disease Control and Prevention (CDC) collected surveillance data on the occurrence of anthrax disease in mill workers or those living near mills in the United States.[5, 6] In that time period, individuals received either BioThrax or the earlier protective antigen-based anthrax vaccine used in the field trial described above. Of the 27 reported cases of anthrax, 24 cases occurred in unvaccinated individuals. In vaccinated individuals one case occurred after the person had been given one dose of anthrax vaccine and two cases occurred after individuals had been given two doses of anthrax vaccine. No documented cases of anthrax were reported for individuals who had received at least three doses of the originally licensed six-dose series of anthrax vaccine.

Between 2002 and 2007, a prospective double-blinded, randomized, placebo-controlled and active-controlled study was conducted to evaluate the impact on safety and immunogenicity on changing the administration route from SC to IM, and reducing the number of doses. This study enrolled 1,564 healthy civilian men and women between the ages of 18 and 61. A total of 1,563 subjects received at least one dose (one subject withdrew consent prior to the first injection). Subjects were randomized to one of six groups. See Table 1.

Using an Enzyme-Linked Immunosorbent Assay (ELISA), Immunoglobulin G (IgG) antibodies directed against anthrax protective antigen (PA) were measured at the Week 8 and Months 7, 13, 19, 31, and 43 time points. The three primary immunogenicity endpoints were: (1) Geometric Mean Concentration (GMC) (mcg/mL), (2) Geometric Mean Titer (GMT) and (3) percentage with 4-fold rise in anti-PA antibody titer from baseline.

The criteria for non-inferiority of comparisons based on ratios of GMCs and GMTs and differences in the rates of 4-fold rise in antibody titer were defined as follows:

Mean antibody concentration ratio: non-inferiority was achieved when the upper bound of the 95% confidence limit was < 1.5

Mean antibody titer ratio: non-inferiority was achieved when the upper bound of the 95% confidence limit was < 1.5

4-fold rise in antibody titer: non-inferiority was achieved when the upper bound of the 95% confidence limit was < 0.10

To compare the originally licensed 6-dose SC schedule (0, 2, 4 weeks and 6, 12, and 18 months) versus a 3-dose IM primary series (at 0, 1, and 6 months) non-inferiority analyses were performed for all three primary immunogenicity endpoints. This evaluation compared the immune response at Month 7 for

Group C (COM, where COM is Combined, as described in 6.1) to Month 19 for Group A (TRT-8SC, where TRT is Treatment) and Group B (TRT-8IM). Non-inferiority was demonstrated for all analyses (See Table 3). These results support a 3 dose primary series of BioThrax administered IM at 0, 1 and 6 months, followed by booster doses at 12 and 18 months and at 1-year intervals thereafter to maintain protective immunity.

The Month 7 antibody levels of Group A (TRT-8SC) were non-inferior to Month 13 and 19 antibody levels after a 0, 2, 4 week and 6 month primary SC series followed by SC booster injections at 12 and 18 months (see Table 3). These results support a 4 dose SC primary series of BioThrax administered at weeks 0, 2, 4, and at 6 months followed by booster doses at 12 and 18 months after initiation of the series, and at 1-year intervals thereafter to maintain protective immunity.

Catch-Up Administration for Delayed or Missed Doses

In subjects who did not receive booster doses at 12, 18, and 30 months, PA antibody levels decline over time following the third dose of BioThrax administered intramuscularly at 6 months. (Group F; 4IM; 0, 1, 6, and 42 months). In the absence of booster doses it is not known whether these individuals are adequately protected between 12 months and receipt of a booster dose at 42 months. One month following a dose of BioThrax at 42 months the immune response for Group F met the criteria for non-inferiority relative to Group A (8SC) for all three primary immunogenicity endpoints (see Table 3). The optimal schedule for further intramuscular booster doses among persons administered a single booster dose at 42 months following completion of a three-dose primary series at 0, 1, and 6 months is not known.

Table 3: Primary Immunogenicity Endpoints (According to Protocol[a])

	Week 4	Week 8	Month 7	Month 13	Month 19	Month 31	Month 43
Anti-PA Specific IgG GMC, mcg/mL							
	n GMC 95%CI	n GMC 95%CI	n GMC 95%CI	n GMC 95%CI	n GMC 95%CI	n GMC 95%CI	n GMC 95%CI
TRT-8SC Group A	242 49.72 (43.32, 57.06)	235 94.29 (82.08, 108.31)	219 201.14 (174.71, 231.56)	203 201.67 (174.77, 232.71)	190 193.45 (167.29, 223.69)	167 250.07 (215.38, 290.34)	144 216.83 (185.80, 253.05)
TRT-7IM[b] Group D	723 2.63 (2.39, 2.89)	698 46.39 (42.18, 51.01)	636 206.09 (187.14, 226.96)	203 229.86 (203.20, 260.02)	192 204.95 (180.82, 232.29)	169 263.13 (231.09, 299.61)	139 254.80 (222.03, 292.40)
TRT-5IM[b] Group E				399 28.64 (25.79, 31.81)	174 293.60 (258.30, 333.73)	153 33.68 (29.48, 38.48)	141 310.02 (270.49, 355.33)
TRT-4IM[b] Group F					193 13.71 (12.11, 15.53)	179 7.80 (6.87, 8.86)	157 433.20 (379.58, 494.40)
Anti-PA Specific IgG GMT							
	n GMT 95% CI	n GMT 95% CI	n GMT 95% CI	n GMT 95% CI	n GMT 95% CI	n GMT 95% CI	n GMT 95% CI
TRT-8SC Group A	242 565.16 (492.57, 648.45)	235 1048.50 (913.05, 1204.05)	219 2211.94 (1921.78, 2545.90)	203 2184.59 (1893.62, 2520.26)	190 2080.89 (1799.87, 2405.79)	167 2677.97 (2306.82, 3108.83)	144 2282.36 (1955.79, 2663.45)
TRT-7IM[b] Group D	723 36.61 (33.32, 40.23)	698 514.57 (468.08, 565.68)	636 2257.09 (2050.12, 2484.94)	203 2546.81 (2251.11, 2881.35)	192 2254.56 (1988.85, 2555.75)	169 2867.88 (2518.14, 3266.19)	139 2760.35 (2404.66, 3168.64)
TRT-5IM[b] Group E				399 296.08 (266.67, 328.74)	174 3167.26 (2785.88, 3600.85)	153 348.89 (305.33, 398.66)	141 3286.41 (2866.50, 3767.83)
TRT-4IM[b] Group F					193 135.30 (119.44, 153.26)	179 79.63 (70.10, 90.44)	157 4683.79 (4102.99, 5346.80)
4-fold response							
	n 4-fold response 95% CI	n 4-fold response 95% CI	n 4-fold response 95% CI	n 4-fold response 95% CI	n 4-fold response 95% CI	n 4-fold response 95% CI	n 4-fold response 95% CI
TRT-8SC Group A	242 80.99 (75.47, 85.73)	235 94.89 (91.25, 97.33)	219 98.63 (96.05, 99.72)	203 99.51 (97.29, 99.99)	190 98.95 (96.25, 99.87)	167 100.00 (97.82, 100.00)	144 100.00 (97.47, 100.00)
TRT-7IM[b] Group D	723 4.15 (2.82, 5.87)	698 78.80 (75.57, 81.77)	636 97.80 (96.33, 98.79)	203 100.00 (98.20, 100.00)	192 98.96 (96.29, 99.87)	169 100.00 (97.84, 100.00)	139 100.00 (97.38, 100.00)
TRT-5IM[b] Group E				399 60.40 (55.41, 65.23)	174 99.43 (96.84, 99.99)	153 63.40 (55.24, 71.03)	141 99.29 (96.11, 99.98)

Table 3: Primary Immunogenicity Endpoints (According to Protocol[a])

	Week 4	Week 8	Month 7	Month 13	Month 19	Month 31	Month 43
TRT-4IM[b] Group F					193 37.82 (30.96, 45.07)	179 22.35 (16.47, 29.16)	157 99.36 (96.50, 99.98)

CI: Confidence Interval;

[a] According to Protocol (ATP): [NCT00119067] To be included in the ATP population at a particular timepoint, a participant must have: (a) received all injections up through that timepoint, (b) received these injections within the windows defined by protocol, (c) received the correct agent administered by the correct route according to subject's assigned study arm, (d) received the correct injection volume. A shot of 0.3 mL or greater is considered valid.

[b] Groups TRT-7IM, -5IM, and -4IM combined as group TRT-COM (combined) through Month 7 of the study, GMC: geometric mean concentration. GMT: geometric mean titer. IM: Intramuscular; SC: Subcutaneous, TRT: treatment.

14.2 Post-Exposure Prophylaxis

Based on the rabbit model-derived TNA threshold [See *Nonclinical Toxicology* (13.2)], a pivotal clinical study was conducted to evaluate the immunogenicity and safety of a post-exposure SC administration schedule of BioThrax in healthy adults following 3 doses at 0, 2, and 4 weeks. Two hundred subjects were enrolled and followed for 128 days. The primary objective was to assess immunogenicity using TNA following the completion of three SC doses of BioThrax. The primary immunogenicity endpoint was the proportion of subjects achieving a threshold TNA NF_{50} value ≥0.56 at Day 63, 5 weeks after the third vaccination. Success was concluded if the lower bound of the 2-sided 95% CI of the proportion of human subjects achieving the TNA NF_{50} threshold was ≥ 40%.

Overall, 71.2% of subjects achieved an NF_{50} value ≥0.56 on Day 63 in the pivotal study. The lower bound of the 95% CI was 94.1%. (See Table 4.)

In a separate analysis of the pivotal clinical study using the threshold associated with a 70% probability of survival in NHPs, 93.5% of subjects achieved an NF_{50} value ≥0.29 on Day 63 (Table 4). The lower bound of the 95% CI was 88.9% (Table 4). The bridging of human immunogenicity data to the NHP study was supportive of the primary analysis comparing human threshold data with rabbit survival. [See *Nonclinical Toxicology* (13.2)]

Table 4: Proportion of Subjects Achieving TNA NF_{50} Threshold[a] in the Pivotal Clinical Study (PP Population[b])

Animal Model	Time Point Human/Animal	n	Human GMT TNA NF_{50} (SD)	Animal TNA NF_{50} Threshold	Number of Subjects Meeting Threshold	Proportion of Subjects Meeting Threshold (%)[d]		
						Point Est. (%)	95% CI (%)	
							Lower Bound	Upper Bound
Rabbit[e]	Day 63/Day 69	184	0.86 (2.09)	0.56	131	71.2	64.1	77.6
Non-human Primate[f]	Day 63/Day 70	184	0.86 (2.09)	0.29	172	93.5	88.9	96.6

CI = confidence interval; NF_{50} = 50% neutralization factor; PP = per protocol; SD = standard deviation; TNA = toxin neutralizing antibody.
Note: sample size (N) and denominators used for percentages are based on the number of subjects meeting the PP criteria at specified day(s).
[a] TNA NF_{50} threshold is defined as the TNA NF_{50} value associated with 70% survival in the animal challenge studies.
[b] Human data are from the pivotal clinical study (NCT01491607).
[c] A logistic regression model with log10-transformed TNA NF_{50} values as the predictor and survival as the response is used to derive the TNA NF_{50} threshold associated with 70% probability of survival in rabbis and non-human primates, respectively.
[d] 95% CI is calculated with the exact (Clopper-Pearson) method.
[e] The proportion of subjects achieving a TNA NF_{50} response at Day 63 that met or exceeded the TNA NF_{50} threshold in the rabbit model at Day 69 comprised the primary immunogenicity endpoint.
[f] Comparison of the human TNA NF_{50} response at Day 63 with the NHP TNA NF_{50} threshold at Day 70 was defined as an immunogenicity endpoint and was supportive of the bridging of human immunogenicity data to rabbit survival.

14.3 Non-Interference of Post-Exposure Prophylaxis Vaccination and Antimicrobials When Used Concurrently

An open-label study was conducted to evaluate the potential impact 0.5mL BioThrax administered SC at 0, 2 and 4 weeks had on the pharmacokinetics of ciprofloxacin in healthy adult male and female subjects (N=154). It also evaluated the potential impact of ciprofloxacin on immunogenicity of BioThrax two weeks following the last BioThrax dose.

Co-administration of 0.5 mL BioThrax SC with oral ciprofloxacin in human subjects did not alter the pharmacokinetics of ciprofloxacin or the immunogenicity of BioThrax as measured by the anthrax lethal toxin neutralization assay.

15 REFERENCES

1. Ryan MA, Smith TC, Sevick CJ, Honner WK, Loach RA, Moore CA, Erickson JD. 2008. Birth defects among infants born to women who received anthrax vaccine in pregnancy. Am J Epidemiol, 168:434-442.
2. Catherino WH, Levi A, Kao TC, Leondires MP, McKeeby J, Segars JH. 2005. The anthrax vaccine does not affect semen parameters, embryo quality, or pregnancy outcome in couples with a vaccinated male military service member. Fertility and Sterility, 83:480-483
3. Brachman P, Friedlander A, Grabenstein J. 2008. Anthrax Vaccine. In: Vaccines, Fifth Edition, Plotkin, S.A.: Orenstein W.A. and Offit P.A. (eds.), 111-126
4. Brachman, PS, Gold H, Plotkin SA, Fekety FR, Werrin M, Ingraham NR. 1962. Field evaluation of a human anthrax vaccine. Amer. J. Public Health, 52:632-645.
5. Food and Drug Administration, 2005, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order. FDA Federal Register 2005; 70(242): 75180-75198.
6. Food and Drug Administration. Biological Products; Bacterial vaccines and toxoids; Implementation of efficacy review. Federal Register (December 13, 1985), 50(240):51002-51117.

16 HOW SUPPLIED/STORAGE AND HANDLING

BioThrax is supplied in 5 mL multidose vials containing ten 0.5 mL doses.

NDC 64678-211-05 (vial), 64678-211-01 (carton)

Store at 2 °C to 8 °C (36 °F to 46 °F). Do not freeze. Do not use BioThrax after the expiration date printed on the label.

The stopper of the vial contains natural rubber latex and may cause allergic reactions in latex sensitive individuals.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information).

Advise women of the potential risk to the fetus. Encourage women who are exposed to BioThrax during pregnancy to inform their healthcare provider and enroll in the BioThrax (Anthrax) Vaccine in Pregnancy Registry (Phone: 1-619-553-9255). [See *Warnings and Precautions* (5.3) and *Use in Specific Populations* (8.1)]

Inform patients of the benefits and risks of immunization with BioThrax.

Instruct patients to report any serious adverse reaction to their health care provider.

Manufactured by:

Emergent BioDefense Operations Lansing LLC

Lansing, MI 48906

US License No. 1755

BioThrax® is a registered trademark of Emergent BioDefense Operations Lansing LLC

Information for Patients
BioThrax® (Anthrax Vaccine Adsorbed)

Please read this Patient Information summary carefully before you get this shot. This summary does not take the place of talking with your healthcare provider about BioThrax. If you have questions or would like more information, please talk with your healthcare provider.

What is BioThrax?

- BioThrax is a vaccine licensed by the FDA to protect against anthrax disease in persons 18 through 65 years of age:
  - It can be used before exposure to anthrax to protect people at high risk of getting the disease.
  - It can be used after exposure to anthrax, along with antibiotics, to protect people from getting the disease.
- BioThrax may not protect all people who get the vaccine.
- How well BioThrax works when given after exposure to anthrax has been studied only in animals. It has not been studied in humans because there are not enough people who get the disease naturally, and it is not ethical to expose people to anthrax on purpose to find out how well BioThrax works.
- The safety of BioThrax was studied in healthy adults.

What is BioThrax?
You should not get BioThrax if you have a history of severe allergic reaction to any ingredient of the vaccine, including aluminum hydroxide, benzethonium chloride, and formaldehyde or had a serious reaction after getting BioThrax previously.

What should I tell my healthcare provider before getting BioThrax?

- If you may be pregnant, plan to get pregnant soon, or are nursing a baby.
- About medicines that you take, including over-the-counter medicines and supplements.
- About immune problems you have, including steroid treatments and cancer treatments.
- About blood clotting problems or if you have "blood thinners."
- If you are allergic to latex.

What if I discover I was pregnant at the time I got BioThrax?

- Inform your healthcare provider
- You can enroll in the BioThrax (Anthrax) Vaccine in Pregnancy Registry (Phone: 1-619-553-9255), if eligible

How is BioThrax given?
BioThrax is given as a shot in your arm.

After getting the first shot, you should come back for the next shots on the schedule given to you by your health care provider. It is important that you get all your shots to get the best protection.

If you get BioThrax because you may have been exposed to anthrax, it is important that you also take antibiotics for 60 days.

What are the possible or reasonably likely side effects of BioThrax?
The most common side effects of BioThrax are:

- Pain, tenderness, redness, bruising, or problems moving the arm in which you got the shot
- Muscle aches
- Headaches
- Fatigue
- Fainting

Tell your healthcare provider about any side effects that concern you. Your healthcare provider can give you a complete list of side effects available to healthcare professionals.

You may report side effects to FDA by calling 1-800-822-7967 or to the website www.vaers.hhs.gov. You may also report side effects directly to Emergent BioSolutions at 1-877-246-8472 or at productsafety@ebsi.com.

What are the ingredients in BioThrax?
BioThrax does not contain live bacteria. BioThrax contains non-infectious proteins, aluminum hydroxide, benzothonium chloride and formaldehyde (as preservatives).

The vial stopper contains natural rubber latex.

Manufactured by Emergent BioDefense Operations Lansing LLC
Lansing, MI 48906, US
License No. 1755

B. Appendix B – Proposed Delivery Schedule

Lot	CLIN	Delivery #	Shipment Date	Delivery Date	Expiry Date*	Remaining Expiry (Months)*	Expected Doses	Cum Expected Doses
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
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[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]

Notes:

- **Delivery Date is dependent upon delivery destination provided by Government at least [**] business days prior to Shipment Date**
- **For planning purposes, typical transit time between Shipment Date and Delivery Date is [**] days**
- **Actual delivery dates and quantities subject to available FDA-released lots of BioThrax on hand for shipment**

ATTACHMENT #3
INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General The Offeror 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 Offeror'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 Offeror, or a different payee has been designated, then insert the name and address of the payee instead of the Offeror.
(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 Offeror. 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

Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer 330 Independence Avenue., S.W. Room G640 Washington, D.C. 20201 **Contractor's Address and Contact Information:** POC: Name of accountant or COO or signatory authority for invoice Title: Phone: E-Mail: **TIN:** **DUNS #:**	**Invoice/Finance Number:** **Date Invoice Prepared:** **Contract No.** **Effective Date:** **Total Estimated Cost of Order:** **Office of Acquisitions:** Contracting Officer (insert name here) Office of Acquisitions Management, Contracts, and Grants (AMCG) **Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

Expenditure Category	Amount Billed 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

_____

D. Attachment D- Disclosure of Lobbying Activities

DISCLOSURE OF LOBBYING ACTIVITIES

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

Approved by OMB
4040-0013

1. * Type of Federal Action:
- [ ] a. contract
- [x] b. grant
- [ ] c. cooperative agreement
- [ ] d. loan
- [ ] e. loan guarantee
- [ ] f. loan insurance

2. * Status of Federal Action:
- [ ] a. bid/offer/application
- [x] b. initial award
- [ ] c. post-award

3. * Report Type:
- [x] a. initial filing
- [ ] b. material change

4. Name and Address of Reporting Entity:

[x] Prime [ ] SubAwardee

*Name: Emergent BioSolutions

*Street 1: 1455 Pennsylvania Ave NW Street 2: Suite 1225

*City: Washington State: DC: District of Columbia Zip: 20004

Congressional District, if known:

5. If Reporting Entity in No.4 is Subawardee, Enter Name and Address of Prime:

6. * Federal Department/Agency:

CDC and BARDA

7. * Federal Program Name/Description:

Strategic National Stockpile, preparedness and response initiatives

CFDA Number, if applicable:

8. Federal Action Number, *if known:*

9. Award Amount, *if known:*

$

10. a. Name and Address of Lobbying Registrant:

Prefix: Mr. *First Name: Chris Middle Name:

*Last Name: Frech Suffix:

*Street 1: 1455 Pennsylvania Ave NW Street 2: Suite 1225

*City: Washington State: DC: District of Columbia Zip: 20004

b. Individual Performing Services (including address if different from No. 10a)

Prefix: *First Name: Middle Name:

*Last Name: Suffix:

*Street 1: Street 2:

*City: State: Zip:

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 the transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and 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: [signature]

*Name: Prefix: Mr. *First Name: Chris Middle Name:

*Last Name: Frech Suffix:

Title: SVP Government Affairs Telephone No.: Date: 1-26-17

Federal Use Only

Authorized for Local Reproduction
Standard Form - LLL (Rev. 7-97)

G. Attachment G – ACH Vendor / Miscellaneous Payment Enrollment Form

ACH VENDOR / MISCELLANEOUS PAYMENT ENROLLMENT FORM

Payment Information Form

The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 USC 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System

Check one of the following:

	Federal Employee:	X	Contractor:		Vendor:

Name: Emergent BioSolutions, Inc.

Business Address: 400 Professional Drive, Suite 400

Gaithersburg, MD 20879

Remit To Address:
(If same as above, leave blank. Must match address on invoice for internal control purposes.)

Taxpayer Identification # (TIN): 14-1902018

(If you are an individual, this may be your Social Security number)

1. Payee's Telephone Number: (240) 631-3200

The following information must be completed by your financial institution representative:

2. Name of Financial Institution:

[**]

3. Address of Financial Institution:

[**]

4. Financial Institution's 9-digit ABA Routing Number for Transfer of Funds: [**]

5. Depositor Account Title: Emergent BioSolutions, Inc.

6. Depositor Account Number:	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]				

7. Type of Account	X	Checking	Savings

8. Signature and Title of Authorized Official of Financial Institution:
Please refer to attached letter from our bank.

Telephone Number: (____) _____ Date: _____

**************The following must be signed by the payee**************

I have verified the information on this form.

Signature Date

E. Attachment E – Small Business Subcontracting Plan

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION
SMALL BUSINESS SUBCONTRACTING PLAN

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerors use the following format to submit proposed Individual Subcontracting Plans, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive. A subcontracting Plan is required if the estimated cost of the contract may exceed $650,000 ($1,500,000 for construction) Small businesses are excluded. Questions should be forwarded to the Contracting Officer or Operating Division (OPDIV) Small Business Specialist.

Operating Division (OPDIV):

SOLICITATION OR CONTRACT NUMBER: 17-100-SOL-00010

DATE OF PLAN: February 1, 2017

CONTRACTOR: Emergent Biodefense Operations Lansing LLC

ADDRESS: 3500 N. Martin Luther King Jr. Blvd

STATE/ZIP CODE Lansing, Michigan 48906

DUNN & BRADSTREET NUMBER: [**]

ITEM/SERVICE (Description): Manufacturing and Delivery of BioThrax® to SNS

NEW/INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE: 04/01/2017 – 03/31/2019

Base (plus options) $99,941,720 Performance Period: 04/01/17 – 03/31/19

$99,941,720 Total Contract Cost

CONTRACT MODIFICATION (if applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY – MM/DD/YYYY): _____N/A_____

Original/Base $_____N/A_____ Performance Period/Quantity _____

Modification $_____N/A_____ Performance Period/Quantity _____

Task Order $_____N/A_____ Performance Period/Quantity _____

$_____N/A_____ Modified Total Contract Cost

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/about/smallbusiness/osdbustaff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is 33.0% for Small Business (hereafter referred to as SB), 5.00% for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), 5.00% for Women-Owned Small Business and Economically Disadvantaged Women-Owned Small Business (hereafter referred to as WOSB), 3.00% HubZone business (hereafter referred to as HUBZone), 3.00% Veteran Owned Small Business (hereafter referred to as VOSB) and 3.00% Service Disabled Veteran-Owned Small Business (hereafter referred to as SDVOSB) concerns for Fiscal Year (FY) 2017. For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages. These percentages shall be expressed as percentages of the total estimated subcontracting dollars.

1. Type of Plan (check one)

__X__ *Individual plan* (all elements developed specifically for this contract and applicable for the full term of this contract).

Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

Commercial products/service plan (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non- government purposes. The plan is effective during the offeror's fiscal year (attach a copy). *The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies*.

2. Goals

Below indicate the dollar and percentage goals for Small Business (SB), Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Women-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Veteran Owned Small Business (VOSB), Service-Disabled Veteran-Owned (SDVOSB) Small Businesses and "Other than Small Business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach additional sheets which illustrate dollar amounts and percentages. PLEASE NOTE: Zero dollars is not an acceptable goal for the SB, SDB, WOSB, HUBZone, VOSB or SDVOSB categories since this does not demonstrate a good faith effort throughout the period of performance of the contract. Formula for below: 2.b. + 2.h. = 2.a.

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is $[**] (Base Period – plus options).

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBZone, VOSB and SDVOSB): (% of "a") $[**] and [**]% (Base Period – plus options)

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $[**] and [**]% (Base Period – plus options)

d. Total estimated dollar value and percent of planned subcontracting with WOMEN-OWNED SMALL BUSINESSES: (% of "a") $[**] and [**]% (Base Period – plus options)

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES:
(% of "a") $[**] and [**]% (Base Period – plus options)

f. Total estimated dollar and percent of planned subcontracting with VETERAN-OWNED SMALL BUSINESSES: (% of "a") $[**] and [**]% (Base Period – plus options)

g. Total estimated dollar and percent of planned subcontracting with SERVICE- DISABLED VETERAN-OWNED SMALL BUSINESSES: (% of "a")
$[**] and [**]% (Base Period – plus options)

h. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES" (*As defined by the Small Business Administration as "any entity that is not classified as a small business. This includes large businesses, state and local governments, non-profit organizations, public utilities, educational institutions and foreign-owned firms.*) (% of "a")$[**] and [**]% (Base Period – plus options)

i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply):

Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	VOSB	SDVOSB
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, WOSB, HUBZone, VOSB and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

Emergent Biodefense Operations Lansing LLC (Emergent) solicited proposals from sources with the qualifications required to perform commercial item manufacturing and delivery services, which are the same as those required under this contract. Those contractors that best meet the business specifications, capability, performance expectations, cost competitiveness and other relevant criteria have been considered for this effort. Emergent plans to utilize small business concerns to the maximum extent practical and regularly surveys the healthcare community to identify small businesses with the skills and experience to provide either validated cGMP manufacturing services or to provide validated controlled-temperature shipping services to destinations in the continental United States. BioThrax anthrax vaccine is a FDA-licensed product and manufacturing and shipment must conform to FDA regulations. Subcontractors such as our fill finish facilities must also be FDA-licensed to manufacture BioThrax. When we initially licensed our fill finish subcontractors, they were small businesses. However, subsequently they were purchased by large businesses. The process to identify, qualify and then, when required, FDA-license a new subcontractor is comparatively long and expensive. In addition, delivery under this contract requires a niche skill set and due to the complexity and very specialized nature of the program, there is a very small pool of qualified small businesses from which to make a selection and switching from our currently established subcontractors may introduce significant delivery risk. With these caveats, Emergent will use small businesses to perform work under this contract whenever practicable.

k. Indirect costs have _____ have not _X_ been included in the dollar and percentage subcontracting goals above (check one).

l. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns:

3. Program Administrator:

NAME: _**[**]**

TITLE: _**[**]**

ADDRESS: **400 Professional Drive, Suite 500**

Gaithersburg, Maryland 20879

TELEPHONE: _**[**]**

E-MAIL: _**[**]**

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; X yes __ no

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns from all possible sources; X yes __ no

c. Ensuring periodic rotation of potential subcontractors on bidder's lists; X yes __ no

d. Assuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. X yes __ no

e. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns. X yes __ no

f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone, VOSB and SDVOSB small business participation. X yes __ no

g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns to include the Central Contractor Registration (http://www.ccr.gov/), local small business and minority associations, local chambers of commerce and Federal Agencies' Small Business Offices; X yes __ no

h. Establishing and maintaining contract and subcontract award records; X yes __ no

i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc.; X yes __ no

j. Ensuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; X yes __ no

k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; X yes __ no

l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; X yes __ no

m. Preparing and submitting timely, required subcontract reports; X yes __ no

n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; X yes __ no

o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and X yes __ no

p. Other duties:

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone, VOSB and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (http://www.ccr.gov/); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides, and other data for soliciting

subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

Additional efforts:

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $650,000 ($1,500,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

6. Reporting and Cooperation

The contractor gives assurance of 1) cooperation in any studies or surveys that may be required; 2) submission of periodic reports which illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors' submission of ISRs and SSRs. ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.symplicity.com/index?_tab=signin&cck=1

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (***Note***: Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.gov/about/smallbusiness/osdbustaff.html).

Note: *The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contractor may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information, contact Courtney Carter, Agency Coordinator-eSRS (Courtney.Carter@hhs.gov).*

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB and SDVOSB sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, VOSB and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This is not required on a contract–by–contract basis for commercial plans.)

g. Other records to support your compliance with the subcontracting plan: (Please describe)

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with SB concerns, SOB, WOSB, HUBZone, VOSB and SDVOSB concerns.

Your company has established and used such procedures: X yes __ no

9. Description of Good Faith Effort

Maximum practicable utilization of SB, SOB, WOSB, HUBZone, VOSB and SDVOSB concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor. In order to demonstrate your compliance with a good faith effort to achieve the SB, SOB, WOSB, HUBZone, VOSB and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

Implement a supplier diversity program, 2) upgrade current vendor system software to allow for enhanced measurement of Small/Minority Business activities, 3) attend Small Business seminars to identify qualified candidates, 4) review all contract forms to ensure terms support Small Business subcontracting goals.

SIGNATURE PAGE

Signatures Required

This subcontracting plan was submitted by:

Signature: **[**]**

Typed/Print Name: **[**]**

Title: **[**]**

Date: **February 1, 2017**

This plan was reviewed by:

Signature:

Typed/Print Name:

Title: **Contracting OfficerDate:**

This plan was reviewed by:

Signature:

Typed/Print Name:

Title: **HHS Small Business SpecialistDate:**

This plan was reviewed by:

Signature:

Typed/Print Name:

Title: **Small Business Administration Procurement Center Representative**

Date:

This plan was approved by:

Signature:

Typed/Print Name:

Title: **Contracting OfficerDate:**

HHS SUBCONTRACTING PLAN REVIEW FORM

OSDBU Control No.: **Multiple Awards?Yes:No:(If yes, attach a copy of each subcontracting plan)**

PROJECT INFORMATION			
Solicitation/Contract No.: RFP-17-100-SOL-00010		MOD No. (If applicable):	
Title of Acquisition: ANTHRAX VACCINE FOR THE STRATEGIC NATIONAL STOCKPILE (SNS)			
Contractor's Name: Emergent BioSolutions			
Period of Performance: 04/01/17-03/31/19		Total Contract Amount (including options): $ 99,941,720	
Total Modification Amount: (if applicable) $		Base Period (if there are options): $	
Option 1 (if applicable): $		Option 2 (if applicable): $	
Option 3 (if applicable): $		Option 4 (if applicable): $	
Contracting Officer/Specialist Name: [**]		Tei&Fax: [**]	
OPDIV/Division/Branch (including location): HHS/ASPR/AMCG O'Neil 11B16		Email: [**]	

SUBCONTRACT PLAN REQUIREMENTS

1. Type of Plan (check one): **Individual X** **MasterCommercial**

(A=Acceptable; U=Unacceptable)	C.O.		SBS		SBA/PCR	
2. Subcontracting Goal Data	A	U	A	U	A	U
a. Total Subcontracting Dollars [(**2b+2h=2a**), except when subcontract baseline equals contract value]: $[**]	X		X			
b. Total Subcontracting Dollars & Percentage with Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB)- [Percentage of 2a.]: $ [**] and[**] %	X		X			
c. Total Subcontracting Dollars & Percentage with Small Disadvantaged Businesses - [Percentage of 2.a.) $ [**] and[**] %	X		X			
d. Total Subcontracting Dollars & Percentage with Woman-owned Small Businesses - [Percentage of 2.a.] $[**] and[**] %	X		X			
e. Total Subcontracting Dollars & Percentage with HUBZone Small Businesses - [Percentage of 2.a.] $[**] and[**] %	X		X			
f. Total Subcontracting Dollars & Percentage with'Veteran Owned Small Businesses - [Percentage of 2.a.) $[**] and[**] %	X		X			
g. Total Subcontracting Dollars & Percentage with Service-Disabled Veteran Small Businesses - [Percentage of 2.a.] $[**] and[**] %	X		X			
h. Total Subcontracting Dollars & Percentage with "Other" than Small Businesses (i.e., large companies, non profits, etc.) [Percentage of 2.a.] $[**] and [**] %	X		X			
i. Subcontracting Opportunities (description of all principal products/services to be subcontracted to all types of concerns) • Raw Materials/Supplies: other, SB, WOSB • Fill/Finish: other • Shipping: other, SB	X		X			
j.k.l. Methodology used to develop goals & identify potential sources (e.g. historical trends, information on technical and competitive bidding, formula for calculating goals, etc.)	X					

HHS SUBCONTRACTING PLAN REVIEW FORM – Page 2

SUBCONTRACT PLAN REQUIREMENTS (con't)	C.O.		SBS		SBA/PCR	
(A=Acceptable; U=Unacceptable)	A	U	A	U	A	U
3. Subcontracting Plan Administrator's Name (Contractor): [**]	X		X			
4. Description of efforts to ensure the Small Businesses (incl. SDB, WOSB, HUBZone, SDVOSB) entities have equitable opportunity to compete for subcontracts.	X		X			
5. Required flow-down clause(s) to be included in prime contractor's subcontracts (i.e., FAR Clause 52.219-8, 52-219-9, 52.212-5(e)):	X		X			
6. Reporting and Cooperation:						
a. Agreement to submit required reports	X		X			
b. Agreement to cooperate in studies and surveys	X		X			
7. Record keeping	X		X			
8. Timely Payment to Subcontractos	X		X			
9. Description of Good Faith Effort	X		X			

CONTRACTING OFFICER DETERMINATION, OSDBU SMALL BUSINESS SPECIALIST AND SBA PCR RECOMMENDATION	C.O.		SBS		SBA/PCR	
	Yes	No	Yes	No	Yes	No
1. The proposed plan meets the requirements of FAR 19.704.	X		X		X	
2. In accordance with 19.705-4, past performance has been considered when determining acceptability of this plan.	X		X			
3. The proposed plan requires an additional pre-award review.		X		X		X

HHS OPDIV Contracting Officer Signature

Contracting Officer: /s/ [**] Date: 2/21/17

Additional Comments:
Though the contractor did not meet most of HHS's SB subcontracting goals, per the justification from the contractor as to the reason why, the proposed SB plan is deemed acceptable.

HHS OSDBU SBS Signature

Small Business Specialist: Date: 2/23/17

COMMENTS: If any elements are determined to be unacceptable, summarize below:

SBA PCR Signature

SBA PCR: Barbara Weaver Date: 2/23/2017

COMMENTS: If any elements are determined to be unacceptable, summarize below:
Justification accepted for goals below agency-established minimums.

HHS SUBCONTRACTING PLAN REVIEW FORM INSTRUCTIONS

OSDBU Control No.: Insert the control number from the HHS 653 which was assigned by the SBS
Multiple Awards: indicate as appropriate. If yes, attach a copy of each subcontracting plan

PROJECT INFORMATION:

· Solicitation/Contract No.: Enter the assigned RFP or Contract Number

· Modification: Identify the modification number for the contract if applicable.

· Title of Acquisition: Enter the item/service description or project title

· Contractor's Name: Enter Successful Offeror/Contractor's name

· Period of Performance: Enter the estimated performance period, including all options, in the following format (mm/dd/yy - mm/dd/yy)

· Total Contract Amount: Enter the total estimated dollar value of the contract, including all options & modifications.

· Total Modification Amount: (if applicable)

· Base Period & Options 1 through Option 4: Complete these boxes if options are part of the contract.

· CO/CS Contact Information: Enter Contracting Officer/Specialist's Name, OPDIV, Building, Room, Telephone, and Fax and e-mail.

SUBCONTRACTING PLAN REQUIREMENTS (ITEMS 1 - 9)

1. Enter type of plan: individual, master or commercial
2. For each of the sub-items 2.a. through 2.1., the C.O. must review the plan & determine if the requirement is acceptable or unacceptable. For each of the sub-items 2.b. through 2.h., the C.O. shall include the subcontracting dollars & percentage for the category. In calculating percentage, use the subcontracting dollars for the sub-item as the numerator & the total subcontracting dollars for the contract as the denominator. (i.e. 2.b. divided by 2.a. =%for 2.b.)

3. through 9: the C.O. must review the plan & determine if the requirements are acceptable or unacceptable.

CONTRACTING OFFICER DETERMINATION, OSDBU SMALL BUSINESS SPECIALIST & SBA PCR RECOMMENDATION (ITEMS 1- 3)

1. The CO must review the plan to determine if it meets the requirements in FAR 19.7.
2. Indicate whether past performance had been considered when determining acceptability of plan
3. Indicate whether plan requires further pre-award review.

SIGNATURES

· The CO who has the authority to bind the government will make a determination, sign and date.

· The HHS SBS will sign and date the review form and the subcontracting plan signature page if acceptable. During the plan review, the SBS may require additional input from the CO and/or contractor. The SBS may also include comments regarding the plan as necessary

· The SBA PCR shall sign and date the review form & the subcontracting plan signature page if acceptable. Concurrence or non-concurrence of the acquisition method determined by the CO The SBA PCR may also include comments regarding the plan as necessary.

NOTE: In order for the HHS Small Business Specialist to conduct a comprehensive review of each plan, at a minimum, the documentation forwarded by the CO should include:

1. A completed HHS Subcontracting Plan Review Form signed by the Contracting Official
2. A completed Subcontracting Plan, using the HHS Subcontracting Plan template, signed by the offeror and the CO.
3. The Summary of Proposed Costs from the offeror's Final Proposal Revision.
4. Any narrative, attachment or supplemental documentation to the offeror's plan describing efforts to locate small business subcontractors, rationale for using other than small businesses as subcontractors, etc.

February 1, 2017

Attn: [**]

Emergent Bio Solutions
400 Professional Drive, Suite 400
Gaithersburg, MD 20879

Subject: Solicitation # 17-100-SOL-00010 Responses to Questions

Dear [**],

We received several questions regarding solicitation # 17-100-SOL-00010 and would like to provide responses to those questions.

Please let us know if you have any further questions.

Thanks,

[**]

[**]
Contracting Officer, Section Chief
Office of Acquisitions Management, Contracts & Grants (AMCG)
Assistant Secretary for Preparedness & Response (ASPR)
U.S. Department of Health & Human Services

Encl.

Solicitation # 17-100-SOL-00010: USG's Responses to
Emergent's January 27, 2016 Questions

Question 1 Response:

Earned Value Management (EVM) deliverables will not be required for this procurement and will be removed from Section C.

Question 2 Response:

Section C.5.D. will be altered to state that the Offeror shall provide a copy of any regulatory communications (e.g. meeting minutes, submissions, etc.) that occur during the contract period of performance pertaining to the product being procured (i.e. BioThrax). Any pertinent regulatory communications or issues that may impact the product or ability of the Offeror to complete delivery of the product on this particular contract shall be made known to BARDA/AMCG until delivery of all [**] doses are completed.

Question 3 Response:

Yes, the lower limit will be aligned with the new CDC [**] contract at [**] months.

Question 4 Response:

Yes, the items (Certificate(s) of Analysis and FDA Lot Release(s)) can be provided at least [**] before each scheduled shipment.