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 **June 30, 2020**

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 and zip code of Principal Executive Offices)

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

Securities registered pursuant to Section 12(b) of the Act

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock, Par Value $0.001 per share	EBS	New York Stock Exchange

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 every Interactive Data File required to be submitted 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 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	☐

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 July 24, 2020, the registrant had 52,924,889 shares of common stock outstanding.

Emergent BioSolutions Inc.
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PART I. FINANCIAL 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 and the expected impact of the COVID-19 pandemic, are forward-looking statements. We generally identify forward-looking statements by using words like "will," "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:

- the impact of global economic conditions and public health crises and epidemics, such as the novel strain of coronavirus (SARS-CoV-2) causing COVID-19 disease, on our markets, operations and employees as well as those of our customers and suppliers;
- the availability of U.S. government (USG) funding for procurement of our products;
- our ability to perform under our contracts with the USG including the timing of and specifications relating to deliveries;
- our ability to provide contract development and manufacturing services for the development and/or manufacture of product candidates of our customers at required levels;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the continued exercise of discretion by the Biomedical Advanced Research and Development Authority (BARDA) to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) prior to approval by the U.S. Food and Drug Administration (FDA);
- the exercise of all remaining options under our recently executed contract for the procurement of ACAM2000® (Smallpox (Vaccinia) Vaccine, Live);
- our ability to secure licensure of AV7909 from the FDA within the anticipated timeframe, if at all;
- our ability to secure follow-on procurement contracts for our public health threat (PHT) products that are under procurement contracts that have expired or will be expiring;
- our ability to successfully appeal the recent patent litigation decision related to NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray;
- our ability and the ability of our collaborators to enforce patents related to NARCAN Nasal Spray against potential generic entrants;
- our ability to develop safe and effective treatments for COVID-19 and obtain FDA approval or authorization for emergency or broader patient use of such treatments;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to comply with the operating and financial covenants required by our Senior Secured Credit Facilities;
- the procurement of products by USG entities under regulatory exemptions prior to approval by the FDA and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country;
- the impact on our revenues from declines in sales of our vaccine products that target travelers due to the reduction of international travel caused by the COVID-19 pandemic;
- 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 (SEC) when evaluating our forward-looking statements.

NOTE REGARDING COMPANY REFERENCES

References in this report to “Emergent,” the “Company,” “we,” “us,” and “our” refer to Emergent BioSolutions Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADENAMES

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), Anthrasil® (Anthrax Immune Globulin Intravenous (Human)), VIGIV (Vaccinia Immune Globulin Intravenous (Human)), Trobigard® (atropine sulfate, obidoxime chloride), ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), Vivotif® (Typhoid Vaccine Live Oral Ty21a), Vaxchora® (Cholera Vaccine, Live, Oral), NARCAN® (naloxone HCI) Nasal Spray and any and all Emergent brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

Emergent BioSolutions Inc.
Condensed Consolidated Balance Sheets
(unaudited, in millions, except per share amounts)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 268.8	$ 167.8
Restricted cash	0.2	0.2
Accounts receivable, net	258.6	270.7
Inventories	236.2	222.5
Prepaid expenses and other current assets	32.1	25.0
Total current assets	795.9	686.2
Property, plant and equipment, net	580.1	542.3
Intangible assets, net	693.2	712.9
In-process research and development	29.0	29.0
Goodwill	266.3	266.6
Other assets	101.6	90.3
Total assets	$ 2,466.1	$ 2,327.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 84.8	$ 94.8
Accrued expenses	33.8	39.5
Accrued compensation	59.0	62.4
Debt, current portion	29.1	12.9
Contract liabilities, current portion	32.7	3.3
Contingent consideration, current portion	22.3	3.2
Other current liabilities	32.0	0.2
Total current liabilities	293.7	216.3
Contingent consideration, net of current portion	6.9	26.0
Debt, net of current portion	758.1	798.4
Deferred tax liability	63.9	63.9
Contract liabilities, net of current portion	85.3	85.6
Other liabilities	59.4	48.6
Total liabilities	1,267.3	1,238.8
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.001 par value; 200.0 shares authorized, 54.1 and 53.0 shares issued; 52.9 and 51.7 shares outstanding, respectively	0.1	0.1
Treasury stock, at cost, 1.2 common shares	(39.6)	(39.6)
Additional paid-in capital	758.5	716.1
Accumulated other comprehensive loss, net	(22.2)	(9.9)
Retained earnings	502.0	421.8
Total stockholders' equity	1,198.8	1,088.5
Total liabilities and stockholders' equity	$ 2,466.1	$ 2,327.3

See accompanying notes.

Emergent BioSolutions Inc.
Condensed Consolidated Statements of Operations
(unaudited, in millions, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 298.5	$ 183.5	$ 446.7	$ 336.5
Contract development and manufacturing services	72.6	18.7	94.3	34.6
Contracts and grants	23.6	41.0	46.2	62.8
Total revenues	394.7	243.2	587.2	433.9
Operating expenses:				
Cost of product sales and contract development and manufacturing services	129.8	100.8	206.7	192.7
Research and development	47.9	63.9	90.6	110.0
Selling, general and administrative	76.0	70.8	145.7	136.4
Amortization of intangible assets	15.0	14.7	29.8	29.2
Total operating expenses	268.7	250.2	472.8	468.3
Income (loss) from operations	126.0	(7.0)	114.4	(34.4)
Other income (expense):				
Interest expense	(6.4)	(9.5)	(15.0)	(19.0)
Other, net	1.1	1.4	—	0.4
Total other income (expense), net	(5.3)	(8.1)	(15.0)	(18.6)
Income (loss) before provision for income taxes	120.7	(15.1)	99.4	(53.0)
Income tax provision (benefit)	28.0	(5.6)	19.2	(17.4)
Net income (loss)	$ 92.7	$ (9.5)	$ 80.2	$ (35.6)
Net income (loss) per common share				
Basic	$ 1.76	$ (0.18)	$ 1.53	$ (0.69)
Diluted	$ 1.73	$ (0.18)	$ 1.51	$ (0.69)
Shares used in computing income (loss) per share				
Basic	52.6	51.5	52.3	51.3
Diluted	53.5	51.5	53.2	51.3

See accompanying notes.

Emergent BioSolutions Inc.
Condensed Consolidated Statements of Comprehensive Income
(unaudited, in millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	$ 92.7	$ (9.5)	$ 80.2	$ (35.6)
Other comprehensive (loss) income, net of tax:				
Foreign currency translation	(0.3)	0.7	(0.4)	1.7
Unrealized losses on hedging activities	(0.7)	(1.2)	(11.9)	(1.2)
Total other comprehensive (loss) income	(1.0)	(0.5)	(12.3)	0.5
Comprehensive income (loss)	$ 91.7	$ (10.0)	$ 67.9	$ (35.1)

During the three and six months ended June 30, 2020 there were tax benefits related to unrealized losses on hedging activities of $0.8 and $3.6 million, respectively; the tax effects of foreign currency translations were de minimus. During the three and six months ended June 30, 2019 the tax effects of other comprehensive (loss) income were de minimus.

See accompanying notes.

Emergent BioSolutions Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited, in millions)

	Six Months Ended June 30,	
	2020	2019
Cash flows provided by operating activities:		
Net income (loss)	$ 80.2	$ (35.6)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	31.0	14.9
Depreciation and amortization	56.8	55.1
Amortization of deferred financing costs	1.5	1.5
Deferred income taxes	(3.7)	(1.3)
Change in fair value of contingent consideration, net	1.1	5.5
Other	1.1	2.9
Changes in operating assets and liabilities:		
Accounts receivable	12.1	44.6
Inventories	(13.7)	(26.1)
Prepaid expenses and other assets	(16.9)	(44.9)
Accounts payable	(14.5)	42.6
Accrued expenses	25.0	6.9
Accrued compensation	(3.4)	(13.5)
Contract liabilities	29.1	16.4
Net cash provided by operating activities:	185.7	69.0
Cash flows used in investing activities:		
Purchases of property, plant and equipment and other	(59.3)	(35.5)
Milestone payment from prior asset acquisition	(10.0)	(10.0)
Net cash used in investing activities:	(69.3)	(45.5)
Cash flows (used in) provided by financing activities:		
Proceeds from revolving credit facility	—	130.0
Principal payments on revolving credit facility	(20.0)	(80.0)
Principal payments on term loan facility	(5.6)	(5.6)
Proceeds from exercise of stock options	23.1	4.6
Taxes paid for share-based compensation activity	(11.7)	(6.3)
Contingent consideration payments	(1.1)	(1.0)
Net cash (used in) provided by financing activities:	(15.3)	41.7
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.1)	—
Net increase in cash, cash equivalents and restricted cash	101.0	65.2
Cash, cash equivalents and restricted cash at beginning of period	168.0	112.4
Cash, cash equivalents and restricted cash at end of period	$ 269.0	$ 177.6
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 11.6	$ 18.3
Cash paid during the period for income taxes	$ 12.2	$ 13.4
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 16.8	$ 11.4
Reconciliation of cash and cash equivalent and restricted cash at June 30, 2020 and December 31, 2019:		
Cash and cash equivalents	$ 268.8	$ 167.8
Restricted cash	$ 0.2	0.2
Total	$ 269.0	$ 168.0

See accompanying notes.

Emergent BioSolutions Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(unaudited, in millions)

	$0.001 Par Value Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balance at December 31, 2019	53.0	$ 0.1	$ 716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$ 1,088.5
Employee equity plans activity	1.1	—	42.4	—	—	—	—	42.4
Net income (loss)	—	—	—	—	—	—	80.2	80.2
Other comprehensive income	—	—	—	—	—	(12.3)	—	(12.3)
Balance at June 30, 2020	54.1	$ 0.1	$ 758.5	(1.2)	$ (39.6)	$ (22.2)	$ 502.0	$ 1,198.8
Balance at March 31, 2020	53.5	$ 0.1	$ 726.2	(1.2)	$ (39.6)	$ (21.2)	$ 409.3	$ 1,074.8
Employee equity plans activity	0.6	—	32.3	—	—	—	—	32.3
Net income (loss)	—	—	—	—	—	—	92.7	92.7
Other comprehensive income	—		—	—	—	(1.0)	—	(1.0)
Balance at June 30, 2020	54.1	$ 0.1	$ 758.5	(1.2)	$ (39.6)	$ (22.2)	$ 502.0	$ 1,198.8
Balance at December 31, 2018	52.4	$ 0.1	$ 688.6	(1.2)	$ (39.6)	$ (5.5)	$ 367.3	$ 1,010.9
Employee equity plans activity	0.3	—	13.2	—	(0.1)	—	—	13.1
Net income (loss)	—	—	—	—	—	—	(35.6)	(35.6)
Other comprehensive income	—	—	—	—	—	0.5	—	0.5
Balance at June 30, 2019	52.7	$ 0.1	$ 701.8	(1.2)	$ (39.7)	$ (5.0)	$ 331.7	$ 988.9
Balance at March 31, 2019	52.6	$ 0.1	$ 690.1	(1.2)	$ (39.6)	$ (4.5)	$ 341.2	$ 987.3
Employee equity plans activity	0.1	—	11.7	—	(0.1)	—	—	11.6
Net income (loss)	—	—	—	—	—	—	(9.5)	(9.5)
Other comprehensive income	—	—	—	—	—	(0.5)	—	(0.5)
Balance at June 30, 2019	52.7	$ 0.1	$ 701.8	(1.2)	$ (39.7)	$ (5.0)	$ 331.7	$ 988.9

See accompanying notes.

1. Business

Organization and business

Emergent BioSolutions Inc. (the "Company" or "Emergent") is a global life sciences company focused on providing civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs," each a “PHT”).

The Company is focused on the following five distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); emerging infectious diseases ("EID"); travel health; emerging health crises; acute/emergency care; and contract development and manufacturing ("CDMO"). The Company has a product portfolio of ten products (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. The Company has two product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the U.S. Food and Drug Administration ("FDA") or any health agency. The U.S. government (the "USG") is the Company's largest customer and provides the Company with substantial funding for the development of a number of its product candidates.

The Company's product and services portfolio includes:

Vaccines

- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only vaccine licensed by the FDA and the European Medicines Agency (EUA) for the prevention of cholera; and
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever.

Devices

- NARCAN® (naloxone HCl) Nasal Spray, the first needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression; and
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin.

Therapeutics

- raxibacumab (Anthrax Monoclonal), a fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil® (Anthrax Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism; and
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

Procured Product Candidates

- AV7909® (Anthrax Vaccine Absorbed with Adjuvant), is a procured product candidate being developed as a next generation anthrax vaccine for post-exposure prophylaxis of disease resulting from suspected or confirmed Bacillus anthracis exposure. The USG has started procuring AV7909 for the Strategic National Stockpile ("SNS") prior to its approval by the FDA and has been reducing its purchases of BioThrax as a result; and
- Trobigard® is a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but it is

procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Contract Development and Manufacturing Services

The Company's contract development and manufacturing service offerings cover development services, drug substance manufacturing and drug product manufacturing across the pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The Company's technology platforms include mammalian, microbial, viral, plasma and advanced therapies utilizing our core capabilities for manufacturing to third parties on a clinical and commercial (small and large) scale. Additional services include fill/finish formulation and analytical development services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, aseptic filling, lyophilization, final packaging and stability studies, as well as manufacturing of vial and pre-filled syringe formats multiple platforms.

The Company operates as one operating segment.

2. Basis of Presentation and Principles of Consolidation

Basis of presentation

The accompanying unaudited condensed consolidated financial statements include the accounts of Emergent and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The unaudited condensed consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the SEC. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed 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, 2019, as filed with the SEC.

All adjustments contained in the accompanying unaudited condensed consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of June 30, 2020. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Significant accounting policies

During the six months ended June 30, 2020, 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, 2019, as filed with the SEC. During the six months ended June 30, 2020, the Company entered into several multi-year CDMO arrangements and further defined our accounting policies around these arrangements in Note 10.

Fair value measurements

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. The Company has cash held in money market accounts (level 1), contingent purchase consideration (level 3) and interest rate swaps arrangements (level 2) that are measured at fair value on a recurring basis (Note 7 and Note 8). As of June 30, 2020 and December 31, 2019, the Company held cash in money market accounts of $178.7 million and $52.2 million, respectively. The Company also records the assets and liabilities of acquisitions at fair value.

On a non-recurring basis, the Company measures its long-lived assets, including IPR&D assets (level 3) using fair value measurements. Goodwill is allocated to the Company's reporting units, which are one level below its operating segment. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and earlier if an event or other circumstance indicates that we may not recover the carrying value of the asset. If the Company believes that as a result of its qualitative assessment it is more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, the quantitative impairment test is not required. If however it is determined that it is not more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, a quantitative test is required. Long-lived assets such as intangible assets and property, plant and equipment are not required to be tested for impairment annually. Instead, long-lived assets are tested for impairment whenever circumstances indicate that the carrying amount of the asset may not be recoverable, such as when there is an adverse change in the market relating to those related assets. The impairment test first requires a comparison of undiscounted future cash flows to the carrying value of the asset. Determining the need for a detailed impairment analysis requires the exercise of judgment about several business factors, including the timing of expected future cash flows and assumptions about the economic environment. During the three and six months ended June 30, 2020, the Company observed a decrease in sales related to its travel health vaccines and the increased risk of generic competition related to NARCAN® Nasal Spray. However, we do not believe that there is a long-term decrease in the expected cash flows of our reporting units that include goodwill or our long-lived asset groups such that our assets are not recoverable or that their carrying value is greater than their fair value as of June 30, 2020.

As of June 30, 2020 and December 31, 2019, the Company had no other significant assets or liabilities that were measured at fair value.

Recently issued accounting standards

Recently Adopted

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking “expected loss” model that is expected to generally result in the earlier recognition of allowances for losses. The guidance became effective for annual periods beginning after December 15, 2019, including interim periods within those years. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13")

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. The Company adopted the standard as of January 1, 2020 which has resulted in expanded disclosures around the Company's recurring level 3 fair value measurements. The disclosures are included in note 7 of the condensed consolidated financial statements.

ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15")

In August 2018, the FASB issued ASU 2018-15. ASU 2018-15 clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 is effective for all entities for fiscal years beginning after December 15, 2019. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2017-4, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-4")

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. The Company's measurement period is October 1. The Company adopted the standard as of January 1, 2020 and has evaluated the effects of this standard and determined that the adoption will not have a material impact on the Company's consolidation financial statements.

(unaudited, in millions, except share and per share amounts)

Not Yet Adopted

ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting

In March 2020, the FASB issued Topic 848. Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC 848 contains optional expedients and exceptions for applying US GAAP to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company continues to assess all potential impacts of the standard and will disclose the nature and reason for any elections that the Company makes.

ASU 2018-14, Compensation - Retirement Benefits - Defined Benefit Plans - General (Topic 715-20): Disclosure Framework - Changes to the Disclosure Requirements for Defined Benefit Plans ("ASU 2018-14")

In August 2018, the FASB issued ASU 2018-14. ASU 2018-14 modifies the disclosure requirements for defined benefit pension plans and other post-retirement plans. ASU 2018-14 is effective for all entities for fiscal years ending after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-14 on its consolidated financial statements.

ASU 2019-12, Simplifications to Accounting for Income Taxes ("ASU 2019-12")

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

3. Inventories

The components of inventory are as follows:

	June 30, 2020	December 31, 2019
Raw materials and supplies	$ 81.7	$ 70.5
Work-in-process	117.1	89.7
Finished goods	37.4	62.3
Total inventories	$ 236.2	$ 222.5

4. Property, plant and equipment

Property, plant and equipment consisted of the following:

	June 30, 2020	December 31, 2019
Land and improvements	$ 50.2	$ 46.5
Buildings, building improvements and leasehold improvements	253.0	234.8
Furniture and equipment	342.6	334.2
Software	56.0	55.7
Construction-in-progress	112.7	81.5
Property, plant and equipment, gross	814.5	752.7
Accumulated depreciation	(234.4)	(210.4)
Total property, plant and equipment, net	$ 580.1	$ 542.3

5. Leases

The Company has operating leases for corporate offices, research and development facilities and manufacturing facilities. We determine if an arrangement is a lease at inception. Operating leases are included in right-of-use ("ROU") assets and liabilities.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company uses an implicit rate when readily determinable. At the beginning of a lease, the operating lease ROU asset also includes any concentrated lease payments expected to be paid and excludes lease incentives. The Company's lease ROU asset may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise those options.

Lease expense for lease payments is recognized on a straight-line basis over the lease term. The Company has lease agreements with lease and non-lease components, which are accounted for separately. The Company's leases have remaining lease terms of 1 year to 15 years, some of which include options to extend the leases for up to 5 years, and some of which include options to terminate the leases within 1 year.

The components of lease expense were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost:				
Amortization of right-of-use assets	$ 1.0	$ 0.7	$ 2.1	$ 1.3
Interest on lease liabilities	0.3	0.2	0.6	0.3
Total operating lease cost	$ 1.3	$ 0.9	$ 2.7	$ 1.6

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	Balance Sheet location	June 30, 2020	December 31, 2019
Operating lease right-of-use assets	Other assets	$ 24.5	$ 24.7
Operating lease liabilities, current portion	Other current liabilities	4.5	3.6
Operating lease liabilities	Other liabilities	21.6	22.1
Total operating lease liabilities		$ 26.1	$ 25.7
Operating leases:			
Weighted average remaining lease term (years)		7.5	8.0
Weighted average discount rate		4.2%	4.2%

6. Intangible assets

The Company's intangible assets consist of products acquired via business combinations or asset acquisitions. The following tables summarize the Company's intangible assets for the periods ended June 30, 2020 and December 31, 2019:

		June 30, 2020			
(in millions)	Estimated Life	Cost	Additions	Accumulated Amortization	Net
Products	9-22 years	$ 788.0	$ 10.0	$ 109.8	$ 688.2
Customer relationships	8 years	28.6	—	24.7	3.9
Contract development and manufacturing	8 years	5.5	—	4.4	1.1
Total intangible assets		$ 822.1	$ 10.0	$ 138.9	$ 693.2

		December 31, 2019		
(in millions)	Estimated Life	Cost	Accumulated Amortization	Net
Products	9-22 years	$ 788.0	$ 82.2	$ 705.8
Customer relationships	8 years	28.6	23.0	$ 5.6
Contract development and manufacturing	8 years	5.5	4.0	$ 1.5
Total intangible assets		$ 822.1	$ 109.2	$ 712.9

During the six months ended June 30, 2020 and 2019, the Company achieved a sales milestone that resulted in a $10.0 million obligation related to the Company's asset acquisition of raxibacumab in October 2017. As of June 30, 2020 there are no remaining contractual obligations for sales milestones related to the raxibacumab acquisition.

During the six months ended June 30, 2020 and 2019, the Company recorded amortization expense for intangible assets of $29.8 million and $29.2 million, respectively. During the three months ended June 30, 2020 and 2019, the Company recorded amortization expense for intangible assets of $15.0 million and $14.7 million, respectively. As of June 30, 2020, the weighted average amortization period remaining for intangible assets was 13 years.

In-process research and development ("IPR&D") assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. There were no changes to the Company's IPR&D assets during the six months ended June 30, 2020.

Goodwill was $266.3 million and $266.6 million for the periods ended June 30, 2020 and December 31, 2019, respectively. The change in the balance during the period was due to foreign currency translation adjustments.

7. Contingent consideration

Contingent consideration liabilities associated with business combinations are measured at fair value. These liabilities represent an obligation of the Company to transfer additional assets to the selling shareholders and owners if future events occur or conditions are met. These liabilities associated with business combinations are measured at fair value at inception and at each subsequent reporting date. The changes in the fair value are primarily due to the expected amount and timing of future net sales, which are inputs that have no observable market (Level 3).

(unaudited, in millions, except share and per share amounts)

The following table is a reconciliation of the beginning and ending balance of contingent considerations and is based on level 3 significant unobservable inputs.

Balance at December 31, 2019	$ 29.2
Change in fair value	1.1
Settlements	(1.1)
Balance at June 30, 2020	$ 29.2

The recurring Level 3 fair value measurements for the Company's contingent consideration liability include the following significant unobservable inputs:

Contingent Consideration Liability	Fair Value as of June 30, 2020	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	$29.2 million	Discounted cash flow	Discount rate	2.5% - 8.6%	4.3%
			Probability of payment	10.0% - 40.0%	20.9%
			Projected year of payment	2020 - 2028	2022

8. Derivative instruments and hedging activities

Risk management objective of using derivatives

The Company is exposed to certain risk arising from both its business operations and economic conditions. The Company principally manages its exposures to a wide variety of business and operational risks through management of its core business activities. The Company manages economic risks, including interest rate, liquidity, and credit risk primarily by managing the amount, sources, and duration of its assets and liabilities and the use of derivative financial instruments. Specifically, the Company has entered into interest rate swaps to manage exposures that arise from the Company's senior secured credit agreement's payments of variable interest rate debt.

Accounting policy for derivative instruments and hedging activities

The Company entered into interest rate swaps in June 2019. The Company's interest rate swaps qualify for hedge accounting as cash flow hedges. All derivatives are recorded on the balance sheet at fair value. Hedge accounting provides for the matching of the timing of gain or loss recognition on these interest rate swaps with the recognition of the changes in interest expense on the Company's variable rate debt. For derivatives designated as cash flow hedges of interest rate risk, the gain or loss on the derivative is recorded in accumulated other comprehensive income and subsequently reclassified into interest expense in the same period during which the hedged transaction affects earnings. Amounts reported in accumulated other comprehensive income related to derivatives will be reclassified to interest expense as interest payments are made on the Company's variable-rate debt. The cash flows from the designated interest rate swaps are classified as a component of operating cash flows, similar to interest expense. If current fair values of designated interest rate swaps remained static over the next twelve months, the Company would reclassify $5.7 million of net deferred losses from accumulated other comprehensive loss to the statement of operations over the next twelve month period. All outstanding cash flow hedges mature in October 2023.

As of June 30, 2020, the Company had the following outstanding interest rate derivatives that were designated as cash flow hedges of interest rate risk:

	Number of Instruments	Notional
Interest rate swaps	7	$ 350.0

(unaudited, in millions, except share and per share amounts)

The table below presents the fair value of the Company's derivative financial instruments designated as hedges as well as their classification on the balance sheet.

	Asset Derivatives				Liability Derivatives			
	June 30, 2020		December 31, 2019		June 30, 2020		December 31, 2019	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Current Assets	$ —	Other Current Assets	$ —	Other Current Liabilities	$ 5.6	Other Current Liabilities	$ —
	Other Assets	$ —	Other Assets	$ —	Other Liabilities	$ 11.9	Other Liabilities	$ 2.0

The valuation of the interest rate swaps is determined using widely accepted valuation techniques, including discounted cash flow analysis on the expected cash flows of each interest rate swap. This analysis reflects the contractual terms of the interest rate swaps, including the period to maturity, and uses observable market-based inputs, including interest rate curves and implied volatilities. The fair values of interest rate swaps are determined using the market standard methodology of netting the discounted future fixed cash payments (or receipts) and the discounted expected variable cash receipts (or payments). The variable cash payments (or receipts) are based on an expectation of future interest rates (forward curves) derived from observable market interest rate curves. To comply with the provisions of ASC 820, Fair Value Measurement, we incorporate credit valuation adjustments in the fair value measurements to appropriately reflect both our own nonperformance risk and the respective counterparty's nonperformance risk. These credit valuation adjustments were concluded to not be significant inputs for the fair value calculations for the periods presented. In adjusting the fair value of our derivative contracts for the effect of nonperformance risk, we have considered the impact of netting and any applicable credit enhancements, such as the posting of collateral, thresholds, mutual puts and guarantees. The valuation of interest rate swaps fall into Level 2 in the fair value hierarchy.

The table below presents the effect of cash flow hedge accounting on accumulated other comprehensive income.

Hedging derivatives	Cumulative Amount of Gain/(Loss) Recognized in OCI on Derivative		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	
	June 30, 2020	December 31, 2019		Six Months Ended June 30, 2020	2019
Interest Rate Swaps	$ (17.5)	$ 2.0	Interest expense	$ (1.1)	$ —

9. Debt

The components of debt are as follows:

	June 30, 2020	December 31, 2019
Senior secured credit agreement - Term loan due 2023	$ 430.3	$ 435.9
Senior secured credit agreement - Revolver loan due 2023	353.0	373.0
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	796.9	822.5
Current portion of long-term debt, net of debt issuance costs	(29.1)	(12.9)
Unamortized debt issuance costs	(9.7)	(11.2)
Non-current portion of debt	$ 758.1	$ 798.4

Senior secured credit agreement

In October 2018, the Company entered into a senior secured credit agreement with multiple lending institutions (the "Credit Agreement"). The terms of the credit agreement include (i) a revolving credit facility (the "Revolving Credit Facility") of $600 million with a maturity date of October 13, 2023, and (ii) a term loan with a principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"). The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an "Incremental Loan") as long as requirements relating to net leverage ratio will be maintained on a pro forma basis.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50%, and a eurocurrency rate for an interest period of one month plus 1% plus a margin ranging from 0.25% to 1.00%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on the Company's consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. The Company is to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable. The Company has the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

The Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event the Company or its Subsidiaries (a) incur indebtedness not otherwise permitted under the Credit Agreement or (b) receive cash proceeds in excess of $100 million during the term of the Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights.

The financial covenants under the Credit Agreement currently require the quarterly presentation of a minimum consolidated 12-month rolling debt service coverage ratio of 2.50 to 1.00, and a maximum consolidated net leverage ratio of 3.75 to 1.00 for the quarterly filing periods from October 1, 2019 through September 29, 2020 and 3.50 to 1.0, thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition. Negative covenants in the Credit Agreement, among other things, limit the ability of the Company to incur indebtedness and liens, dispose of assets, make investments, enter into certain merger or consolidation transactions and make restricted payments. As of the date of these financial statements, the Company is in compliance with all affirmative and negative covenants.

2.875% Convertible senior notes due 2021

On January 29, 2014, the Company issued 2.875% convertible senior notes due 2021 (the "Notes"). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021.

(unaudited, in millions, except share and per share amounts)

10. Revenue recognition

The Company operates as one operating segment. Therefore, results of its operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. The Company's revenues disaggregated by the major sources were as follows:

	Three Months Ended June 30, 2020			Three Months Ended June 30, 2019		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 224.2	$ 74.3	$ 298.5	$ 94.6	$ 88.9	$ 183.5
Contract development and manufacturing services	44.6	28.0	72.6	—	18.7	18.7
Contracts and grants	20.7	2.9	23.6	38.3	2.7	41.0
Total revenues	$ 289.5	$ 105.2	$ 394.7	$ 132.9	$ 110.3	$ 243.2

	Six Months Ended June 30, 2020			Six Months Ended June 30, 2019		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 288.1	$ 158.6	$ 446.7	$ 167.9	$ 168.6	$ 336.5
Contract development and manufacturing services	44.6	49.7	94.3	—	34.6	34.6
Contracts and grants	42.7	3.5	46.2	58.7	4.1	62.8
Total revenues	$ 375.4	$ 211.8	$ 587.2	$ 226.6	$ 207.3	$ 433.9

Contract liabilities

When performance obligations are not transferred to a customer at the end of a reporting period, cash received associated with amounts allocated to those performance obligations is reflected as contract liabilities on the consolidated balance sheets and is deferred until control of these performance obligations is transferred to the customer. The following table presents the rollforward of the contract liability balances:

December 31, 2019	$ 88.9
Deferral of revenue	56.3
Revenue recognized	(27.2)
June 30, 2020	$ 118.0

Transaction price allocated to remaining performance obligations

During the three and six months ended June 30, 2020, the Company entered into a number of multi-year contract development and manufacturing services arrangements for the production of developmental vaccines. The Company's performance obligations associated with these arrangements include multiple performance obligations such as technology transfer activities, stand-ready obligations and drug substance manufacturing. The Company has determined that the technology transfer and stand-ready performance obligations are satisfied over time, while the drug substance manufacturing performance obligations are satisfied at a point in time when the goods have been released, legal title has passed and the goods are in the customer's possession.

As of June 30, 2020, the Company expects future revenues of approximately $1.4 billion associated with all performance obligations that have not been satisfied, including the new arrangements referenced in the previous paragraph. The Company expects to recognize a majority of these revenues within the next 24 months. However, the amount and timing of revenue recognition for unsatisfied performance obligations can materially change due to timing of funding appropriations from the USG and the overall success of the Company's development activities associated with its PHT procured product candidates that are then receiving development funding support from the USG under development contracts. In addition, the amount of future revenues associated with unsatisfied performance obligations excludes the value associated with unexercised option periods in the Company's contracts.

(unaudited, in millions, except share and per share amounts)

Contract assets

The Company considers unbilled accounts receivables and deferred costs associated with revenue generating contracts, which are not included in inventory or property, plant and equipment, as contract assets. As of June 30, 2020 and December 31, 2019, the Company had contract assets associated with deferred costs of $40.6 million and $34.0 million, respectively, which is reflected as a component of other assets on the Company's consolidated balance sheets.

Accounts receivable

Accounts receivable, including unbilled accounts receivable contract assets, consist of the following:

	June 30, 2020	December 31, 2019
Billed, net	$ 202.2	$ 227.3
Unbilled	56.4	43.4
Total, net	$ 258.6	$ 270.7

As of June 30, 2020 and December 31, 2019, allowances for doubtful accounts were $0.5 million and de minimis, respectively.

11. Income taxes

On March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company has assessed the impact of the CARES Act and we do not expect there to be a material impact to our consolidated financial statements.

The estimated effective annual tax rate for the Company, which excludes discrete adjustments, was 26% and 27% for the six months ended June 30, 2020 and 2019. For the six months ended June 30, 2020 and 2019, the Company recorded a discrete tax benefit of $6.6 million and $3.2 million, respectively, primarily due to activity associated with equity awards. For the three months ended June 30, 2020 and 2019, the Company recorded a discrete tax benefit of $3.4 million and $1.4 million, respectively, primarily due to activity associated with equity awards. As of June 30, 2020 and December 31, 2019, the Company had deferred tax assets of $22.3 million and $13.4 million, respectively, which are included in other assets.

12. Net income (loss) per share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net income (loss)	$ 92.7	$ (9.5)	$ 80.2	$ (35.6)
Denominator:				
Weighted-average number of shares—basic	52.6	51.5	52.3	51.3
Dilutive securities—equity awards	0.9	—	0.9	—
Weighted-average number of shares—diluted	53.5	51.5	53.2	51.3
Net income (loss) per share - basic	$ 1.76	$ (0.18)	$ 1.53	$ (0.69)
Net income (loss) per share - diluted	$ 1.73	$ (0.18)	$ 1.51	$ (0.69)

Basic net income (loss) per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted income (loss) per share is computed using the treasury method by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period,

(unaudited, in millions, except share and per share amounts)

adjusted for the potential dilutive effect of other securities if such securities were converted or exercised and are not anti-dilutive.

The following table presents the share-based awards that are not considered in the diluted net income (loss) per share calculation because the exercise price of the awards was greater than the average per share closing price during the three and six months ended June 30, 2020 and 2019.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Anti-dilutive stock awards	0.4	3.0	0.6	3.0

13. Stock-based compensation

During the six months ended June 30, 2020, the Company granted stock options to purchase 0.4 million shares of common stock and 0.8 million restricted and performance stock units under the Emergent BioSolutions Inc. Stock Incentive Plan. Typically, the stock option and restricted stock unit grants vest over three equal annual installments beginning on the day prior to the anniversary of the grant date. The performance stock units settle in stock at the end of the three-year performance period based on the Company's results compared to the performance criteria. During the three months ended June 30, 2020, the Company issued a broad-based fully vested equity award of approximately 0.2 million shares to employees below the senior vice president level that was valued at $14.7 million and is recorded as share-based compensation expense for the period ended June 30, 2020.

Stock-based compensation expense was recorded in the following financial statement line items:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of product sales and contract development and manufacturing services	$ 8.1	$ 0.6	$ 8.8	$ 1.4
Research and development	5.4	1.0	6.3	2.1
Selling, general and administrative	10.9	6.5	15.9	11.4
Total stock-based compensation expense	$ 24.4	$ 8.1	$ 31.0	$ 14.9

14. Commitments and contingencies

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd. (collectively, "Adapt Pharma"), and Opiant Pharmaceuticals, Inc. ("Opiant"), received notice from Perrigo UK FINCO Limited Partnership ("Perrigo"), that Perrigo had filed an Abbreviated New Drug Application ("ANDA"), with the United States Food and Drug Administration seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the "'253 Patent"), 9,468,747 (the "'747 Patent"), 9,561,177, (the "'177 Patent"), 9,629,965, (the "'965 Patent") and 9,775,838 (the "'838 Patent"). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the "937 Patent"). Perrigo's notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant, (collectively, the "Plaintiffs"), filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt Pharma's patents to make, have made and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, (the "'644 Patent"), and U.S. Patent No. 9,707,226, (the "'226 Patent"). Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey. The case is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4 mg/spray case.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of U.S. Patent No. 9,211,253 (the "'253 Patent"). Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments took place on February 26, 2020.

In the complaints described in the paragraphs above, the Plaintiffs sought, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant in the consolidated case. Emergent has filed a Notice of Appeal (on July 23, 2020), after the U.S. District Court for New Jersey ruled June 5, 2020 in favor of Teva, and against Emergent and Opiant Pharmaceuticals Inc., Adapt Pharma's commercial partner, appealing the District Court decision to the Court of Appeals for the Federal Circuit. Emergent has filed suit in the Federal Court in Canada against Teva Pharmaceuticals (on July 23, 2020). The litigation in Canada is related to Teva Pharmaceuticals' recent filing of an abbreviated new drug submission (ANDS) in Canada seeking to manufacture and sell a generic form of NARCAN® Nasal Spray ahead of the expiry of the Canadian patent covering our product. Emergent, through its Adapt subsidiaries, has filed suit within the prescribed time period following notice from Teva of its ANDS filing in Canada.

Inter Partes Review ("IPR")

On or about February 19, 2019, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent with the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office. Nalox-1's petitions assert that each of the foregoing patents are invalid as obvious in view of prior art. Three of these petitions, IPR Nos. 2019-00685, 2019-00688, and 2019-00694, were instituted on August 27, 2019, September 9, 2019, and September 11, 2019, respectively. The oral hearing for the three instituted IPR proceedings was held before the PTAB on May 19, 2020. Adapt and Opiant remain committed to protect the intellectual property portfolio related to NARCAN®Nasal Spray.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and accompanying notes and other financial information included elsewhere in this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, includes information with respect to our plans and strategy for our business and financing, as well as 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.

Business Overview

We are a global life sciences company focused on providing to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring PHTs.

We are currently focused on the following five distinct PHT categories: CBRNE, EID, travel health, emerging health crises, acute/emergency care; and CDMO. We have a product portfolio of ten products (vaccines, therapeutics, and drug-device combination products) that contribute a substantial portion of our revenue. We also have two procured product candidates that are procured under special circumstances by certain government agencies, although they are not approved by the FDA or any other health agency. Additionally, we have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, therapeutics, devices and combination products). Finally, we have a fully-integrated portfolio of contract development and manufacturing services. Our CDMO service offerings cover development services, drug substance manufacturing and drug product manufacturing across pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The majority of our revenue comes from the following products and procured product candidates:

Vaccines

- Anthrax vaccines, including our AV7909 (Anthrax Vaccine Adsorbed with Adjuvant) procured product candidate being developed as a next-generation anthrax vaccine for post-exposure prophylaxis and BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever; and
- Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA and EUA licensed vaccine for the prevention of cholera.

Devices

- NARCAN® (naloxone HCl) Nasal Spray, the first needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard®, a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Therapeutics

- raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil® (Anthrax Immune Globulin Intravenous (Human)), the only polyclonal antibody

therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;

- BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), the only heptavalent antibody therapeutic licensed by the FDA, as well as the governing bodies in Canada, Singapore and Ukraine for the treatment of botulism; and
- VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

Contract Development and Manufacturing Services

Our CDMO business unit consists of a fully integrated molecule-to-market contract development and manufacturing services business, with offerings across development services, drug substance manufacturing and drug product manufacturing. These services include process development, formulation and analytical development, and packaging for supply. We compete for CDMO service business with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories. We also compete with in-house research, development and support service departments of other biopharmaceutical companies. Our customers for such services include pharmaceutical and biotechnology organizations as well as the USG and non-governmental organizations ranging from small to mid to large whose programs range from clinical stage to commercial stage.

Highlights and Business Accomplishments for 2020

- On January 13, 2020, received agreement from the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) on the company's proposed development plan to use Serum Neutralizing Antibodies (SNA) as surrogate endpoint to predict likely clinical benefit of CHIKV VLP, the company's chikungunya virus virus-like particle (VLP) vaccine candidate, in a Phase 3 safety and immunogenicity study anticipated in late 2020.
- On January 31, 2020, received positive opinion and subsequent approval from EMA of Vaxchora® (Cholera Vaccine, Live, Oral), the company's cholera vaccine, making it the only single-dose oral vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup 01 in adults and children from 6 years of age across all 27 member states of the European Union and the European Economic Area countries.
- On March 10, 2020, signed a development and manufacturing agreement with Novavax, Inc. for an experimental vaccine candidate for COVID-19.
- On March 11, 2020, initiated development of two investigational plasma-derived therapies. COVID-Human Immune Globulin (COVID-HIG) is being developed as a human plasma-derived therapy candidate for potential treatment of COVID-19 in severe hospitalized and high-risk patients, and COVID-Equine Immune Globulin (COVID-EIG) is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans.
- On March 18, 2020, signed a development and manufacturing agreement with Vaxart, Inc. to produce its experimental oral vaccine candidate for COVID-19.
- On March 31, 2020, signed an agreement with Novavax, Inc. to manufacture NanoFlu™, its seasonal influenza vaccine candidate.
- On April 2, 2020, announced HHS funding valued at $14.5 million to support the development of COVID-Human Immune Globulin (COVID-HIG) for treatment, which will be included in at least one of the studies of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, evaluating potential treatments for COVID-19.
- On April 23, 2020, announced an initial agreement, valued at $135 million, to be the U.S. manufacturing partner of Johnson & Johnson's lead COVID-19 vaccine candidate.
- On May 28, 2020, announced the exercise by the HHS of the first of nine annual contract options, valued at $176 million, to procure doses of ACAM2000® (Smallpox (Vaccine, Live) into the U.S. Strategic National Stockpile (SNS).
- On June 1, 2020, announced an agreement to join the USG's Warp Speed Program in public-private CDMO partnership for COVID-19 vaccine development and manufacturing. The agreement has a contract value of $628 million and includes manufacturing capacity valued at $542.7 million and $85.5 million for expansion of viral and non-viral CDMO drug product fill/finish capacity.

- On June 11, 2020, announced an agreement to be the U.S. manufacturing partner for AstraZeneca's COVID-19 vaccine candidate to provide large-scale manufacturing capacity through 2020. The agreement has a contract value of $87 million.
- On June 18, 2020, announced the $75 million acquisition and planned expansion of a property adjacent to our Canton, Massachusetts live viral drug substance development and manufacturing facility. The expansion will increase advanced therapy (viral vector and gene therapy) capability, which is expected to be available beginning in 2023.
- On July 2, 2020, the Company further announced signing a large scale drug substance manufacturing agreement for Johnson & Johnson's lead COVID-19 vaccine candidate for up to five years beginning in 2021. The first two years are valued at approximately $480 million, with the remaining three years providing flexible capacity.
- On July 6, 2020, announced the award of approximately $34.6 million by the U.S. Department of Defense Joint Program Executive Office and formed collaboration with Mount Sinai Health System and ImmunoTek Bio Centers to advance COVID-Human Immune Globulin (COVID-HIG) for potential post-exposure prophylaxis in populations at high risk of COVID-19.
- On July 14, 2020, announced the exercise by the Biomedical Advanced Research Development Authority (BARDA) of the contract option, valued at $258 million, to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) for delivery into the SNS over 12 months.
- On July 27, 2020, the Company further announced the signing of a large-scale drug substance manufacturing agreement for AstraZeneca's COVID-19 vaccine candidate, valued at approximately $174 million through 2021.

Financial Operations Overview

Revenues

We generate revenues from the sale of our marketed products and procured product candidates which include vaccines, therapeutics and devices which have been described above. The USG is the largest purchaser of our CBRNE products and primarily purchases our products for the SNS, a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The USG primarily purchases our products under long-term, firm fixed-price procurement contracts. Our opioid overdose reversal product, NARCAN® Nasal Spray and our travel health products, comprising Vivotif and Vaxchora, are sold commercially through wholesalers and distributors, physician-directed or standing order prescriptions at retail pharmacies, as well as to other state and local community healthcare agencies, practitioners and hospitals.

We also generate third-party revenue from our CDMO business unit, which is based on our established development and manufacturing infrastructure, technology platforms and expertise. Our services include a fully integrated molecule-to-market contract development and manufacturing services business offering across development services, drug substance and drug product for small to mid to large pharmaceutical and biotechnology industry and government agencies/non-governmental organizations.

We have received contracts and grants funding from the USG and other non-governmental organizations to perform research and development activities, particularly related to programs addressing certain CBRNE threats and EIDs.

Our revenue, operating results and profitability vary quarterly based on the timing of production and deliveries and the nature of our business to provide large scale bundles of products and services as needs arise. Our revenues from the sales of our vaccine products that target travelers have also declined recently due to the reduction of international travel caused by the COVID-19 pandemic. We expect continued variability in our quarterly financial statements.

Critical Accounting Policies and Estimates

During the six months ended June 30, 2020, 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, 2019, as filed with the SEC, (see Note 2 to the accompanying condensed consolidated financial statements).

(unaudited, amounts in millions, except share and per share amounts)

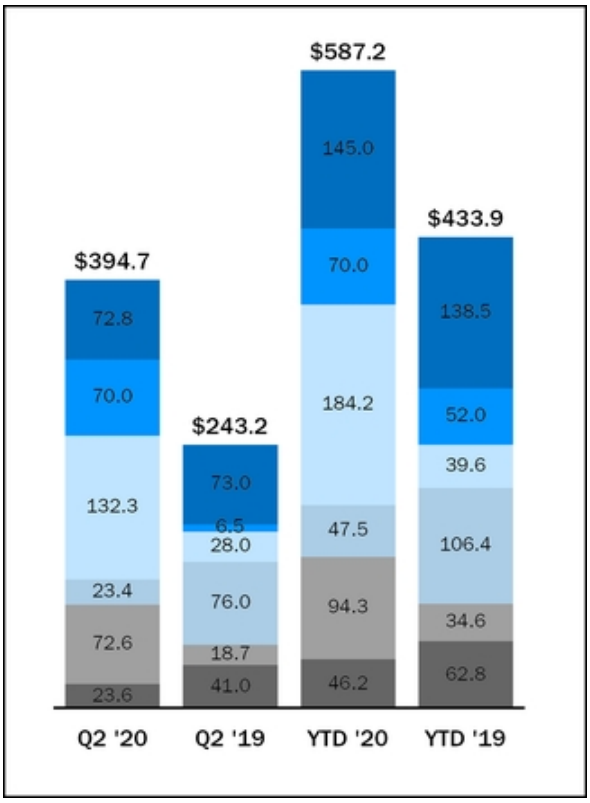
Results of Operations

	Three Months Ended June 30,				Six Months Ended June 30,			
	2020	2019	$ Change	% Change	2020	2019	$ Change	% Change
Product sales net:								
NARCAN Nasal Spray	$ 72.8	$ 73.0	$ (0.2)	—%	$ 145.0	$ 138.5	$ 6.5	5%
ACAM2000	70.0	6.5	63.5	NM	70.0	52.0	18.0	35%
Anthrax vaccines	132.3	28.0	104.3	NM	184.2	39.6	144.6	NM
Other product sales	23.4	76.0	(52.6)	(69)%	47.5	106.4	(58.9)	(55)%
Total product sales, net	298.5	183.5	115.0	63 %	446.7	336.5	110.2	33 %
Contract development and manufacturing services	72.6	18.7	53.9	NM	94.3	34.6	59.7	NM
Contracts and grants	23.6	41.0	(17.4)	(42)%	46.2	62.8	(16.6)	(26)%
Total revenues	394.7	243.2	151.5	62 %	587.2	433.9	153.3	35 %
Operating expenses:								
Cost of product sales and contract development and manufacturing services	129.8	100.8	29.0	29%	206.7	192.7	14.0	7%
Research and development	47.9	63.9	(16.0)	(25%)	90.6	110.0	(19.4)	(18%)
Selling, general and administrative	76.0	70.8	5.2	7%	145.7	136.4	9.3	7%
Amortization of intangible assets	15.0	14.7	0.3	2%	29.8	29.2	0.6	2%
Total operating expenses	268.7	250.2	18.5	7%	472.8	468.3	4.5	1%
Income (loss) from operations	126.0	(7.0)	133.0	NM	114.4	(34.4)	148.8	NM
Other income (expense):								
Interest expense	(6.4)	(9.5)	3.1	(33%)	(15.0)	(19.0)	4.0	(21%)
Other, net	1.1	1.4	(0.3)	(21%)	—	0.4	—	—%
Total other income (expense), net	(5.3)	(8.1)	2.8	(35%)	(15.0)	(18.6)	4.0	(22%)
Income (loss) before provision for income taxes	120.7	(15.1)	135.8	NM	99.4	(53.0)	152.4	NM
Income tax provision (benefit)	28.0	(5.6)	33.6	NM	19.2	(17.4)	36.6	NM
Net income (loss)	$ 92.7	$ (9.5)	$ 102.2	NM	$ 80.2	$ (35.6)	$ 115.8	NM

NM - Not meaningful

(unaudited, amounts in millions, except share and per share amounts)

Total Revenues



Legend			
	NARCAN nasal spray		Other product sales
	ACAM2000		Contracts development and manufacturing services
	Anthrax vaccines		Contracts and Grants

Product Sales, net

NARCAN Nasal Spray

The increase in NARCAN Nasal Spray sales for the six months ended June 30, 2020 was primarily due to an increase in sales to the U.S. public interest markets. Sales of NARCAN Nasal Spray for the three months ended June 30, 2020 were consistent with sales for the three months ended June 30, 2019.

ACAM2000

The increase in ACAM2000 sales for the three and six months ended June 30, 2020 was due to timing of deliveries to the SNS between the two periods. ACAM2000 product sales are made under a long-term procurement contract. The fluctuations in ACAM2000 revenue are dictated by the timing and delivery of orders to the USG.

Anthrax Vaccines

The increase in anthrax vaccine sales for the three and six months ended June 30, 2020 was primarily due to the transition of SNS deliveries from BioThrax to a more consistent cadence of deliveries of AV7909. There were limited sales of anthrax vaccines during the three and six months ended June 30, 2019 in anticipation of the USG's transition from BioThrax to AV7909. Deliveries of AV7909 began in September of 2019.

Other Product Sales

The decrease in the Company's other product sales during the three and six months ended June 30, 2020 was primarily due to a decline in sales of raxibacumab. Additionally sales of our travel health vaccines, Vaxchora and Vivotif, declined compared to same periods in the prior year due to a reduction in global travel.

Contract Development and Manufacturing Services

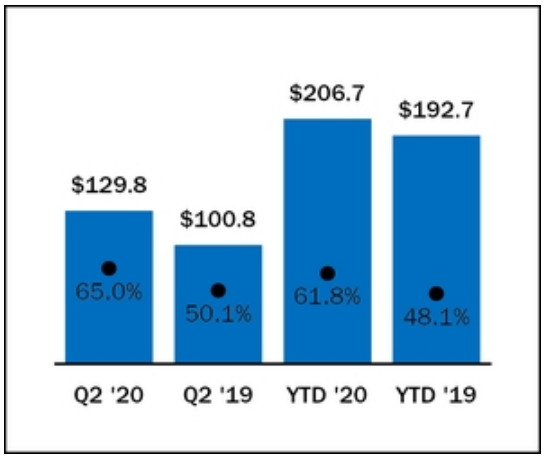
The increase in contract development and manufacturing services revenue for the three and six months ended June 30, 2020 is largely due to the expansion of our customer and project base, specifically the contribution of our recently announced arrangements with BARDA in support of the USG's Operation Warp Speed Program.

Contracts and Grants

The decrease in contracts and grants revenue for the three and six months ended June 30, 2020 is due to the completion of developmental activities associated with our AV7909 procured product candidate.

(unaudited, amounts in millions, except share and per share amounts)

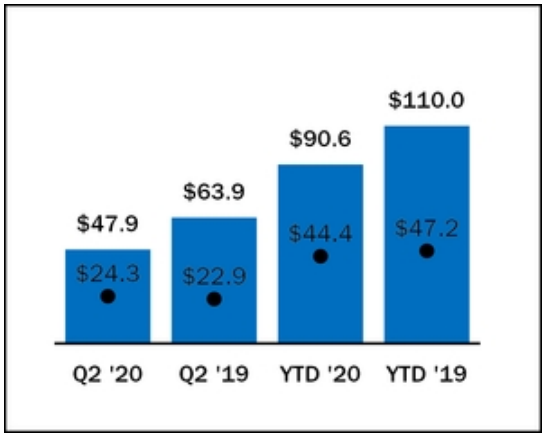
Cost of Product Sales and Contract Development and Manufacturing Services



	Cost of Product Sales and Contract Development and Manufacturing Services
l	Gross profit margin for product sales and contract development and manufacturing services

Cost of product sales and contract development and manufacturing services increased for the three and six months ended June 30, 2020 primarily due to the increase in product sales between periods and an increase in stock-based compensation expense due to a special broad-based, immediately vested equity award to employees below the senior vice president level. The gross profit margin increased for the three and six months ended June 30, 2020 due to changes in product and services mix.

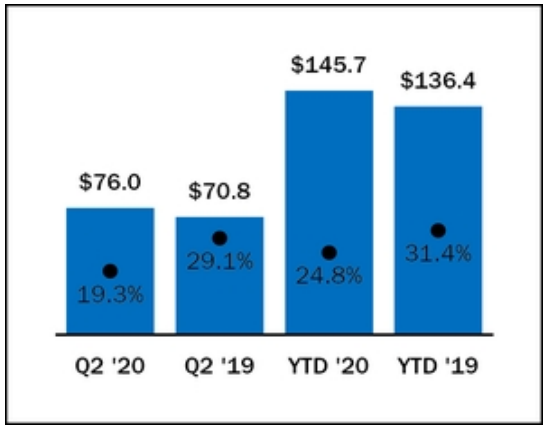
Research and Development Expenses (Gross and Net)



	Research and Development expense
l	Research and Development expense, net of contracts and grants revenue

The decrease in research and development expenses during the three and six months ended June 30, 2020 is consistent with the decline of contract and grant revenue following completion of development activities associated with our AV7909 procured product candidate offset by increased costs associated with our chikungunya product candidate.

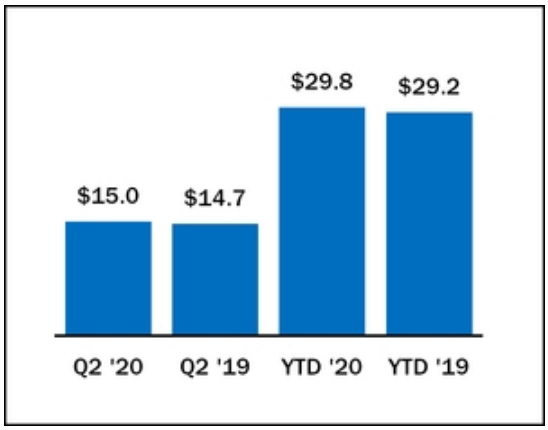
Selling, General and Administrative Expenses



	Selling, General and Administrative
l	SG&A as a percentage of total revenue

The increase in selling, general and administrative expenses for the three and six months ended June 30, 2020 is primarily due to an increase in stock-based compensation expense due to a special broad-based, immediately vested equity award to employees below the senior vice president levels and staffing costs to support the Company's growth.

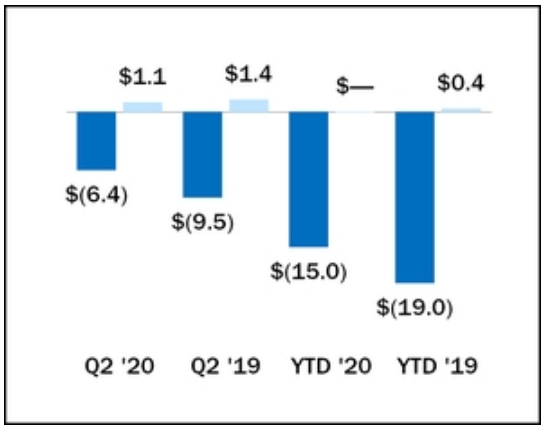
Amortization of Intangible Assets



Amortization of intangible assets for the three and six months ended June 30, 2020 was consistent with the three and six months ended June 30, 2019.

(unaudited, amounts in millions, except share and per share amounts)

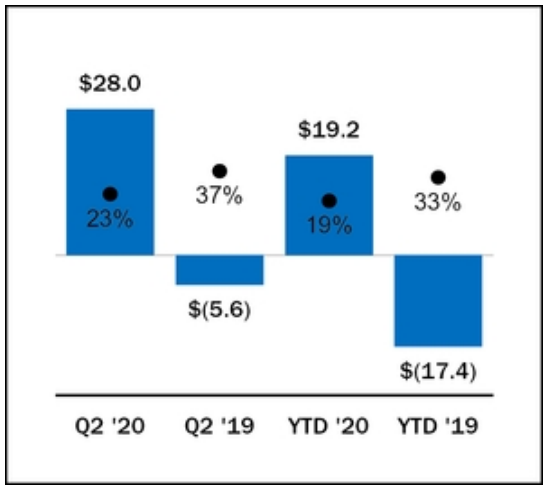
Other Income (Expense), Net



	Interest expense
	Other income (expense)

Total other income (expense), net decreased by $3.6 million for the three and six months ended June 30, 2020 due primarily to a decrease in interest expense due to a decline in the average balance of outstanding debt and interest rates period over period.

Income Tax Provision (Benefit)



	Income tax benefit
l	Effective tax rate

During the three and six months ended June 30, 2020 and 2019, the estimated effective tax rate was 26% and 27%, respectively. The actual effective tax rate includes the effects of discrete tax benefits of $6.6 million and $3.2 million during the six months ended June 30, 2020 and 2019.

(unaudited, amounts in millions, except share and per share amounts)

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and development funding. We also obtain financing from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years through the period ended December 31, 2019. As of June 30, 2020, we had unrestricted cash and cash equivalents of $268.8 million and capacity under our revolving credit facility of $244.3 million. As of June 30, 2020, we believe that we have sufficient liquidity to fund our operations over the next 12 months.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ 185.7	$ 69.0
Investing activities	(69.3)	(45.5)
Financing activities	(15.3)	41.7
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.1)	—
Net increase in cash, cash equivalents and restricted cash	$ 101.0	$ 65.2

Operating Activities

Net cash provided by operating activities of $185.7 million for the six months ended June 30, 2020 was due to net income excluding non-cash items of $168.0 million and working capital changes of $17.7 million, made up of increases in accrued expenses and accounts receivable offset by contract liabilities and various other items.

Net cash provided by operating activities of $69.0 million for the six months ended June 30, 2019 was due to net income excluding non-cash items of $43.0 million and working capital changes of $26.0 million.

The cash flows from operating activities increased $116.7 million during the six months ended June 30, 2020 largely due to an increase in net income of $115.8 million.

Investing Activities

Net cash used in investing activities largely relates to purchases of property, plant and equipment and was $69.3 million and $45.5 for the six months ended June 30, 2020 and 2019, respectively. We also made a milestone payment made from an asset acquisition of $10.0 million in each of the six months ended June 30, 2020 and 2019 relating to our acquisition of raxibacumab in October 2017. The cash used in investing activities increased during the six months ended June 30, 2020 due to the purchase of a building near our Canton, Massachusetts facility and an increase in infrastructure and equipment investments.

Financing Activities

Net cash used in financing activities of $15.3 million for the six months ended June 30, 2020 was primarily due to $25.6 million of principal payments on the term loan and credit facility, primarily offset by net cash provided by employee share-based compensation activity of $11.4 million.

Net cash used in financing activities of $41.7 million for the six months ended June 30, 2019 was primarily due to net $44.4 million of receipts on the term loan and credit facility, primarily offset by net cash used in employee share-based compensation activity of $1.7 million.

The cash flows used in financing activities increased $57.0 million during the six months ended June 30, 2020 due to a decrease in net receipts/payments on the term loan and revolving credit facility of $70.0 million and an increase in net cash provided by net employee share-based compensation activity of $13.1 million.

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;
- net proceeds from the sale of our products and contract development and manufacturing services;
- development contracts and grants funding; and
- our Senior Secured Credit Facilities 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):

- the level, timing and cost of product sales and contract development and manufacturing services;
- 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 adopt a share repurchase program and repurchase shares of our common stock 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.

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 Credit Facilities, 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 2.875% Convertible Senior Notes due 2021 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 Senior Secured Credit Facilities restrict our ability to incur additional indebtedness, including secured indebtedness.

Economic conditions, including market volatility and adverse impacts on financial markets as a result of the COVID-19 pandemic, may make it more difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Unused Credit Capacity

Available room under the revolving credit facility for the periods ended June 30, 2020 and December 31, 2019 was:

(in millions)			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness on Revolving Credit Facility	Unused Capacity
June 30, 2020			
$600.0	(2.7)	(353.0)	$244.3
December 31, 2019			
$600.0	(2.2)	(373.0)	$224.8

Share Repurchase Program

There were no repurchases of common stock that were made through open market transactions during the six months ended June 30, 2020. The Company previously had a share repurchase program, which expired as of December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of additional risks arising from our operations, see “Item 1A-Risk Factors” in this quarterly report.

Market Risk

We have interest rate and foreign currency market risk. 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.

Interest Rate Risk

We have debt with a mix of fixed and variable rates of interest. Floating rate debt carries interest based generally on the eurocurrency, as defined in our Amended Credit Agreement, plus an applicable margin. We manage our interest rate risk in part by entering into interest rate swap arrangements to convert a portion of our indebtedness from variable interest rates to a fixed rate. For debt that we have not hedged through our interest rate swap arrangements increases in interest rates could increase the associated interest payments that we are required to make on this debt.

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of June 30, 2020 would increase our interest expense by approximately $4.5 million annually.

Foreign Currency Exchange Rate Risk

We have exposure to foreign currency exchange rate fluctuations worldwide and primarily with respect to the Euro, Canadian dollar, Swiss franc and British pound. We manage our foreign currency exchange rate risk primarily by incurring operating expenses in the local currency in the countries in which we operate, to the extent practicable. We currently do not hedge our foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations.

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 June 30, 2020. The term "disclosure controls and

procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2020, the Company implemented a financial close and consolidation reporting system. We have updated our internal controls over financial reporting, as necessary, to accommodate the changes to our processes.

Other than the item listed above, there have been no other changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., (collectively, Adapt Pharma), and Opiant Pharmaceuticals, Inc. (Opiant), received notice from Perrigo UK FINCO Limited Partnership (Perrigo), that Perrigo had filed an Abbreviated New Drug Application, (ANDA), with the United States Food and Drug Administration, seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the '253 Patent), 9,468,747 (the '747 Patent), 9,561,177, (the '177 Patent), 9,629,965, (the '965 Patent) and 9,775,838 (the '838 Patent). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the 937 Patent). Perrigo's notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant (collectively, Plaintiffs) filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a non-exclusive license under Adapt Pharma's patents to make, have made, and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo's license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, Teva) that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, (the '644 Patent) and U.S. Patent No. 9,707,226, (the '226 Patent). Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey. The case is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4 mg/spray case.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments took place on February 26, 2020.

In the complaints described in the paragraphs above, the Plaintiffs sought, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant in the consolidated case. Emergent has filed a Notice of Appeal (on July 23, 2020), after the U.S. District Court for New Jersey ruled June 5, 2020 in favor of Teva, and against Emergent and Opiant Pharmaceuticals Inc., Adapt Pharma's commercial partner, appealing the District Court decision to the Court of Appeals for the Federal Circuit. Emergent has filed suit in the Federal Court in Canada against Teva Pharmaceuticals (on July 23, 2020). The litigation in Canada is related to Teva Pharmaceuticals' recent filing of an abbreviated new drug submission (ANDS) in Canada seeking to manufacture and sell a generic form of NARCAN® Nasal Spray ahead of the expiry of the Canadian patent covering our product. Emergent, through its Adapt subsidiaries, has filed suit within the prescribed time period following notice from Teva of its ANDS filing in Canada.

Inter Partes Review (IPR)

On or about February 19, 2019, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent with the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office. Nalox-1's petitions assert that each of the foregoing patents are invalid as obvious in view of prior art. Three of these petitions, IPR Nos. 2019-00685, 2019-00688, and 2019-00694, were instituted on August 27, 2019, September 9, 2019, and September 11, 2019, respectively. The oral hearing for the three instituted IPR proceedings was held before the PTAB on May 19, 2020. Adapt and Opiant remain committed to protect the intellectual property portfolio related to NARCAN®Nasal Spray.

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 flows. 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 flows. 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 flows. Discussion of these factors is incorporated by reference into and considered an integral part of Part I, Item 2, "Management's Discussion and Analysis of Financial Conditions and Results of Operations."

GLOBAL PANDEMIC RISK

The COVID-19 coronavirus pandemic could have a material adverse impact on our business, results of operations and financial performance.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced. Since then, the SARS-CoV-2 virus has been determined to cause the disease COVID-19. COVID-19 has spread worldwide, including in the United States, Canada and Europe. The World Health Organization declared the COVID-19 coronavirus outbreak as a global pandemic on March 11, 2020. The pandemic has caused various

governments, including in the United States at Federal and state levels, to impose restrictions on people and businesses, such as quarantines, closures, cancellations and travel restrictions. We may experience significant disruptions due to the COVID-19 pandemic, which has impacted and could severely impact our business and operations, including:

- diversion of government funding away from our primary procured products and product candidates resulting from changes in government priorities;
- limitation of company operations, including reduced productivity resulting from remote work and prolonged office closures as well as a potential adverse impact on our manufacturing operations if a significant number of our manufacturing employees contract the disease;
- potential delays or difficulties in receiving raw and other materials from third party suppliers to manufacture our products and product candidates as the pandemic has resulted in the extended shutdown of certain businesses which may in turn result in disruptions or delays to our supply chain;
- potential delays delivering products to our customers which may lead to decline in sales of our government or commercially procured products that may consequently negatively impact our revenues;
- further declines to our revenues from the sales of our vaccine products that target travelers due to the significant reduction to international travel caused by the COVID-19 pandemic;
- potential delays or disruptions in our key clinical trials; and
- limitations in employee resources that would otherwise be focused on our business.

The global pandemic caused by COVID-19 continues to rapidly evolve. The full extent to which the COVID-19 pandemic will impact our business, results of operations and our financial condition will depend on future developments, which are highly uncertain and cannot be predicted or reasonably estimated with confidence at this time, such as the duration of the pandemic, travel restrictions and social distancing policies and requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to mitigate and treat the disease.

Due to the widespread impact of the pandemic, it is possible that our consolidated financial results for future fiscal quarters and for 2020 may be negatively impacted, including as a result of increased government regulation and introduction of mitigation and prevention measures. The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. In addition, the COVID-19 pandemic has adversely affected, and is expected to continue to adversely affect the United States and the global economy, having resulted in an economic downturn and recession that could impact demand for our products. Such events that are generally outside of our control could have a material adverse impact on our business, operating results and financial conditions.

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of AV7909, BioThrax and ACAM2000. If the USG's demand for and/or funding for procurement of AV7909, BioThrax or ACAM2000 is substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from USG procurement of AV7909 and BioThrax. As AV7909 is a product development candidate, there is a higher level of risk that we may encounter challenges causing delays or an inability to deliver AV7909 than with BioThrax, which may have a material effect on our ability to generate and recognize revenue.

The success of our business and our future operating results are significantly dependent on anticipated funding for the procurement of our anthrax vaccines and the terms of our BioThrax and AV7909 sales to the USG, including the price per dose, the number of doses and the timing of deliveries. We have no certainty that funding will be made available for the procurement of our anthrax vaccines. If priorities for the SNS change generally or with respect to our anthrax vaccines, funding to procure future doses of BioThrax or AV7909 may be delayed, limited or not available, BARDA may never complete the anticipated full transition to stockpiling AV7909 in support of anthrax preparedness, and our future business, financial condition, operating results and cash flows could be materially harmed.

In addition, we currently derive a substantial portion of our revenues from sales of ACAM2000 to the USG. If priorities for the SNS change with respect to ACAM2000 or the USG decides not to exercise additional options under our ACAM2000 contract our

future business, financial condition, operating results and cash flows could be materially harmed.

Although a pre-EUA submission package related to AV7909 has been submitted to the FDA, we may not receive an EUA and eventual FDA licensure in a timely manner or at all. Delays in our ability to achieve a favorable outcome from the FDA could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of AV7909.

In collaboration with us, the CDC filed with the FDA a pre-EUA submission package related to AV7909, which enables FDA review of data in anticipation of a request for an EUA. This submission triggered BARDA to exercise its first contract option (valued at approximately $261 million) in July 2019 to procure 10 million doses of AV7909 and an another option in July 2020 to procure additional doses (valued at approximately $258 million) for inclusion into the SNS in support of anthrax preparedness.

Notwithstanding, the FDA may decide that our data are insufficient and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining an EUA and, ultimately, 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 flows. Furthermore, prior to FDA licensure, if we obtain an EUA, the EUA could be terminated if the emergency determination underlying the EUA terminates.

Our USG procurement and development contracts require ongoing funding decisions by the USG. Simultaneous reduction or discontinuation of funding of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially.

The USG is the principal customer for our PHT-focused MCMs and is the primary source of funds for the development of most of our product candidates in our development pipeline, most notably our AV7909 procured product candidate. We anticipate that the USG will also be a principal customer for those MCMs that we successfully develop within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG 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 are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations, changes in priorities due to global pandemics and stringent budgetary constraints.

Additionally, our government-funded development contracts typically give the USG 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 AV7909 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 AV7909 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 USG otherwise declines to exercise its options under our existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows.

There can be no assurance that we will be able to secure follow-on procurement contracts with the USG upon the expiration of any of our current product procurement contracts.

The majority of our revenue is substantially dependent upon product procurement contracts with the USG and foreign governments for our PHT products. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product for a similar product volume, period of performance, pricing or other terms, or at all. The inability to secure a similar or increased procurement contract could materially affect our revenues and our business, financial condition, operating results and cash flows could be harmed. For example, the BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as GSK), completed in November 2019. We intend to negotiate follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, including our procurement contract for raxibacumab, but there can be no assurance that we will be successful obtaining any follow-on contracts. Even if we are

successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our products could materially and adversely affect our revenues, and our business, financial condition, operating results and cash flows could be harmed.

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 many 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 USG 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 PHTs 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 and cash flows could be materially and adversely affected.

There are a number of laws and regulations that pertain to government contracts and compliance with those laws and regulations require significant time and cost, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

As a manufacturer and supplier of MCMs to the USG addressing PHTs, we must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. These laws and regulations govern how we transact business with our government clients and, in some instances, impose additional costs and related obligations on our business operations. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulation (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 (DFARs), and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of U.S. Department of Defense (DoD) government contracts;
- the Department of State Acquisition Regulation (DOSAR), which regulates the relationship between a Department of State organization and a contractor or potential contractor;
- 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;
- trade controls, including export and import control laws, International Traffic in Arms Regulations (ITAR), U.S. sanctions programs, and anti-boycott laws and 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.

We may be subject to government investigations of business practices and compliance with government acquisition regulations. USG agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. Even though we take significant precautions to identify, prevent and deter fraud, misconduct and non-compliance, we face the risk that our personnel or outside partners may engage in misconduct, fraud or improper activities. If we are audited or investigated and such audit or investigation were to uncover improper or illegal activities, we could be subject to civil and criminal fines and penalties, administrative sanctions, including suspension or debarment from government contracting, and suffer significant reputational harm. The loss of our status as an eligible government contractor or significant fines or penalties associated with contract non-compliance or resulting from investigations could have a material adverse effect on our business.

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.

Our current procurement contracts with HHS and the DoD are generally fixed price contracts. We expect that future procurement contracts we successfully secure with the USG 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 business, financial condition, operating results and cash flows.

Government contracts customarily contain provisions that give the USG substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the USG 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 USG's convenience. Under general principles of government contracting law, if the USG 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 USG 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 USG, are terminable at the USG's convenience with these potential consequences.

In addition, our USG contracts grant the USG 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 USG. Under our USG 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 USG.

REGULATORY AND COMPLIANCE RISKS

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

Our product candidates and the activities associated with them are subject to extensive FDA regulation and oversight, as well as oversight by other regulatory agencies in the United States and by comparable authorities in other countries. This includes, but is not limited to, laws and regulations governing product development, including testing, manufacturing, record keeping, storage and approval, as well as advertising and promotion. In limited circumstances, governments may procure products that have not obtained regulatory approval. In all other circumstances, failure to obtain regulatory approval for a product candidate will prevent us from selling and commercializing the product candidate.

In the United States, to obtain approval from the FDA to market any of our future drug, biologic, or vaccine products, we will be required to submit a new drug application (NDA) or biologics license application (BLA) to the FDA. Ordinarily, the FDA requires a company to support an NDA or BLA with substantial evidence of the product candidate’s effectiveness, safety, purity and potency in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase 3 trials conducted in patients with the disease or condition being targeted.

However, many of our MCM product candidates, for example, may take advantage of a different regulatory approval pathway under the FDA’s “Animal Rule.” The Animal Rule provides a regulatory pathway for drug and biologic products targeting indications for which human efficacy studies are not feasible or would be unethical. Instead, efficacy must be demonstrated, in part, by utilizing animal models rather than testing in humans. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, it can be a very long process, and 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 generally may cause delays in the approval or rejection of an application. There is a high rate of failure inherent in this process, and potential products that appear promising at early stages of development may fail for a number of reasons, and positive results from preclinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials.

There are many other difficulties and uncertainties inherent in pharmaceutical research and development that could significantly delay or otherwise materially delay our ability to develop future product candidates. These include, but are not limited to:

- Conditions imposed by regulators, ethics committees, or International Review Boards for preclinical testing and clinical trials relating to the scope or design of our clinical trials;
- Restrictions placed upon, or other difficulties with respect to, clinical trials and clinical trial sites, such as clinical holds or suspension or termination of clinical trials due to, among other things, potential safety or ethical concerns or noncompliance with regulatory requirements;
- Delayed or reduced enrollment in clinical trials, or high discontinuation rates;
- Failure by third-party contractors, contract research organizations (CROs), clinical investigators, clinical laboratories, or suppliers to comply with regulatory

requirements or meet their contractual obligations in a timely manner;

- Greater than anticipated cost of or time required to complete our clinical trials; and
- Insufficient product supply or inadequate product quality.

Failure to successfully develop future product candidates for any of these or other reasons may materially adversely affect our business, financial condition, operating results and cash flows.

Once an NDA or BLA is submitted, 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.

Unapproved and investigational products are also subject to FDA's laws and regulations governing advertising and promotion, which prohibit the promotion of both unapproved products and unapproved uses of approved products. There is some risk that the FDA could conclude that our communications relating to unapproved products or unapproved uses of approved products constitute the promotion of an unapproved product or product use in violation of FDA laws and regulations. There is also a risk that a regulatory authority in another country could take a similar position under that country's laws and regulations and conclude that we have violated the laws and regulations related to product development, approval, or promotion in that country. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations.

Even if we or our collaborators obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once approval has been granted, an approved product and its manufacturer and marketer remain subject to ongoing review and extensive regulation.

We and our collaborators must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to FDA-regulated products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our collaborators and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, were we to receive marketing approval for one or more of our product candidates, we would continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we and our collaborators are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we or our collaborators obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Any product candidate for which we or our collaborators 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 authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate 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 medicine, including the requirement to implement a risk evaluation and mitigation strategy.

Certain of our products are subject to postmarketing requirements (PMRs), which we are required to conduct, and postmarketing commitments (PMCs), which we have agreed to conduct. The FDA has the authority to take action against sponsors who fail to meet the obligations of a PMR, including civil monetary penalties and/or misbranding charges.

The FDA and other agencies, including the U.S. Department of Justice (DOJ) and the HHS Office of Inspector General (OIG), closely regulate and monitor the pre-approval and post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA, DOJ, and OIG impose stringent restrictions on manufacturers' communications regarding unapproved products and unapproved uses of approved products and if we market unapproved products or market our approved products for unapproved indications, we may be subject to enforcement action for marketing of unapproved products or unapproved uses of approved products. Violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturing partners or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturing partners or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU and other legal and regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non-compliance with similar requirements in other jurisdictions can also result in enforcement actions and significant penalties.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA), passed in 2010, contains the following provisions of potential importance to our business and our product candidates:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of health care fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board (IPAB), which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective on January 1, 2019. In addition, Congress will likely consider other legislation to replace elements of the ACA. It is possible that such initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business.

There have been executive actions to challenge or delay implementation of the ACA. Since January 2017, there have been two Executive Orders issued designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or

manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On May 16, 2019, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the rule changes allow Medicare Advantage plans to use preauthorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs. The first change took effect in January 2020, while the second change will take effect in January 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of legislative and executive branches have stated that they will address such costs through new legislative and administrative measures. While any proposed measures will require authorization through additional legislation to become effective, there may be new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

If we fail to comply with foreign, federal, state and local health care laws, including fraud and abuse and health information privacy and security laws, and antitrust laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

In the United States, certain of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, TriCare, and/or state pharmaceutical assistance programs. Many foreign countries have similar laws. Federal and state laws designed to prevent fraud and abuse under these programs prohibit pharmaceutical companies from offering valuable items or services to customers or potential customers to induce them to buy, prescribe, or recommend our product (the so-called “anti-kickback” laws). Exceptions are provided for discounts and certain other arrangements if specified requirements are met. Other federal and state laws, and similar foreign laws, not only prohibit us from submitting any false information to government reimbursement programs but also prohibit us, our employees, or any third party acting on our behalf from doing anything to cause, assist, or encourage our customers to submit false claims for payment to these programs. We are also subject to various federal, state and foreign antitrust and competition laws that prohibit certain activities that may have an impact against potential competitors. Violations of the various fraud and abuse and antitrust laws may result in severe penalties against the responsible employees and us, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Some of the laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded health care program, such as the Medicare or Medicaid program. The term “remuneration” has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with health care providers or other entities, among other activities;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $11,181 to $22,363 per false claim;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, health care benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to “business associates,” or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;

- the Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Centers for Medicare & Medicaid Services (CMS), certain payments and transfers of value made to U.S. physicians and teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to U.S. physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; state, local and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, obtain pharmaceutical agent licensure, and/or otherwise restrict payments that may be made to health care providers and entities; and state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to health care providers or entities, or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenges under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal health care fraud statutes, so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback

Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from funded health care programs and the curtailment or restructuring of our operations. Any such penalties could adversely affect our financial results. We continue to improve our corporate compliance program designed to ensure that our development, marketing, and sales of existing and future products and product candidates are in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded health care programs. If a third party fails to comply with applicable laws and regulations while acting on our behalf, we may also be subject to criminal, civil, and administrative penalties, including those listed above.

We are committed to conducting the development, sale and marketing of our applicable products and product candidates and all our activities in compliance with all applicable laws and regulations, but certain applicable laws and regulations may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee or third party acting on our behalf violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

The United States government, state governments and private payors regularly investigate the pricing and competitive practices of pharmaceutical companies and biotechnology companies, and many file actions alleging that inaccurate reporting of prices has improperly inflated reimbursement rates. We may also be subject to investigations related to our pricing practices. Regardless of merit or eventual outcome, these types of investigations and related litigation can result in:

- Diversion of management time and attention;
- Expenditure of large amounts of cash on legal fees, costs and payment of damages or penalties;
- Limitations on our ability to continue some of our operations;
- Decreased demand for our products; and
- Injury to our reputation.

Moreover, an adverse outcome, or the imposition of penalties or sanctions for failing to comply with the fraud and abuse and antitrust laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.

The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid rebate program will continue to increase our costs and the complexity of compliance and will be time-consuming. Changes to the definition of “average manufacturer price” (AMP), and the Medicaid rebate amount under the ACA and CMS and the issuance of final regulations implementing those changes has affected and could further affect our 340B “ceiling price” calculations. Because we participate in the Medicaid rebate program, we are required to report “average sales price” (ASP), information to CMS for certain categories of drugs that are paid for under Part B of the Medicare program. Future statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs, involve complex calculations and are often subject to interpretation by us,

governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and “best price” for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Price recalculations also may affect the “ceiling price” at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B/Public Health Service (PHS) drug pricing program.

In addition to retroactive rebate liability and the potential for 340B program refunds, if we are found to have made a misrepresentation in the reporting of ASP, we are subject to civil monetary penalties for each such price misrepresentation and for each day in which such price misrepresentation was applied. If we are found to have knowingly submitted false AMP or “best price” information to the government, we may be liable for civil monetary penalties per item of false information. Any refusal of a request for information or knowing provision of false information in connection with an AMP survey verification also would subject us to civil monetary penalties. In addition, our failure to submit monthly/quarterly AMP or “best price” information on a timely basis could result in a civil monetary penalty per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure that our submissions will not be found by CMS to be incomplete or incorrect.

In order for our products to be reimbursed by the primary federal governmental programs, we must report certain pricing data to the USG. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs (DVA), and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule (FSS), and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. The rules governing the calculation of certain reported prices are highly complex. Although we maintain and follow strict procedures to ensure the maximum possible integrity for our federal pricing calculations, the process for making the required calculations involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

To be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and certain federal grantees, we also must participate in the DVA FSS pricing program. To participate, we are required to enter into an FSS contract with the DVA, under which we must make our innovator “covered drugs” available to the “Big Four” federal agencies-the DVA, the DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard-at pricing that is capped pursuant to a statutory federal ceiling price (FCP), formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average wholesale price known as the Non-Federal Average Manufacturer Price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the DVA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject us to significant penalties for each item of false information. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to disclose the error and refund the difference to the government. The failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, can be expensive and time-consuming, and could have a

material adverse effect on our business, financial condition, results of operations and growth prospects.

Under certain circumstances, we might sell unapproved MCMs to government entities. While this is permissible in some cases, the extent to which we may be able to lawfully market and sell unapproved products in many jurisdictions may be unclear or ambiguous. Such sales could subject us to regulatory enforcement action, product liability and reputational risk.

Under certain circumstances, MCMs may be procured by government entities prior to approval by the FDA or other regulatory authorities, a practice which we follow in connection with AV7909 and Trobigard. In the United States, the Project BioShield Act of 2004 (Project BioShield) permits the Secretary of HHS to contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 also allow the FDA Commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. Absent an applicable exception, our MCM product candidates generally will have to be approved by the FDA or other regulatory authorities in the relevant country through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates are ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear. Nevertheless, government bodies, such as U.S. federal entities other than HHS, state and local governments within the United States, and foreign governments, may seek to procure our MCM product candidates that are not yet approved. If so, we would expect to assess the permissibility and liability implications of supplying our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country's government may take different positions regarding the permissibility of such sales than another country's government or even other agencies or branches of the same government. If we determine that we believe such activities are permissible, local enforcement authorities could disagree with our conclusion and take enforcement action against us.

In addition, the sale of unapproved products also could give rise to product liability claims for which we may not be able to obtain indemnification or insurance coverage. For example, liability protections applicable to claims arising under U.S. law and resulting from the use of certain unlicensed products, such as a declaration issued under the Public Readiness and Emergency Preparedness Act (the PREP Act) do not cover claims arising under non-U.S. law.

Regardless of the permissibility and liability risks, in the event a user of one or more of our products suffers an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory authority of another country, particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact, even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects.

There is also a risk that our communications with governments about our unapproved products, such as in the procurement context, could be considered promotion of an unapproved product or unapproved use of an approved product. Therefore, there is a risk that we could be subject to enforcement actions if found to be in violation of such laws or regulations.

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.

In addition to the requirements and uncertainties related to pre-approval activities discussed previously, 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, plasma donor testing, registration requirements, cGMP, requirements relating to potency and stability, 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.

Government regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign 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. Following several of these inspections, regulatory authorities have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, 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. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. 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. Regulatory approval may also 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, operating results and cash flows could be materially and adversely affected.

Additionally, companies may not promote unapproved products or unapproved uses of approved products (i.e. “off-label” uses or uses that are not described in the product’s approved labeling and that differ from the uses approved by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved product or unapproved use of an approved product may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the USG), as well as criminal sanctions. If our employees or agents engage in marketing of an unapproved product or the unapproved use of an approved product, we could be subject to civil or criminal investigations and monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our business, financial condition, operating results and cash flows, 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 currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products and have received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market our products in foreign jurisdictions under normal circumstances, we generally need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative “emergency use” or other exemptions from general approval and import requirements. Approval by the FDA in the United States or the mutual recognition procedure in the European member states does not ensure approval by all foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA or under the mutual recognition procedure. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval or promotion in that country. Therefore, there is a risk that we could be subject to a foreign enforcement action if found to be in violation of such laws and regulations. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products in desired jurisdictions internationally if no alternate procurement pathway is identified for authorized government customers in a particular

jurisdiction. 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 reliance on third parties can introduce additional uncertainty into the process.

On January 31, 2020, the United Kingdom formally withdrew from the European Union and entered into a transition period through December 31, 2020 pursuant to a Withdrawal Agreement. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our products or product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing product candidates in the United Kingdom and/or the European Union and could restrict our ability to generate revenue and achieve and sustain profitability. Therefore, there is a risk that we could be subject to an enforcement action if found to be in violation of such laws or regulations.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of, and must dedicate additional resources towards avoiding inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, and 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. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Many countries, including the United States, also have various lobbying laws and regulations governing the conduct of individuals and companies who interact with government officials. These laws and regulations typically include certain restrictions and disclosure obligations. If we, our employees, or third parties acting on our behalf do not comply with these laws and regulations, we may be subject to civil and criminal penalties.

Many countries, including the United States, restrict the export or import of products to or from certain countries through, for example, bans, sanction programs, and boycotts. Such restrictions may preclude us from supplying products in certain countries, which could limit our growth potential. Furthermore, if we, or third parties acting on our behalf, do not comply with these restrictions, we may be subject to civil and criminal penalties.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we continue to expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture AV7909, BioThrax, ACAM2000 or our other products, as well as deliver our contract development and manufacturing services, which would harm our business, financial condition, operating results and cash flows.

An interruption in our manufacturing operations could result in our inability to produce our products 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 flows. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- cyber-attacks;
- work stoppages or slowdowns;
- protests, including by animal rights activists;
- injunctions;
- damage to or destruction of the facility; and
- product contamination or tampering.

Providers of PHT countermeasures could be subject to an increased risk of terrorist activities. The USG has designated both our Lansing, Michigan and our Bayview 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 these 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 facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities in Camden; facilities in Canton, Massachusetts; Rockville, Maryland, Bern, Switzerland; and Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed 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, operating results and cash flows.

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

Despite our ongoing efforts to optimize the utilization of our manufacturing infrastructure (including bulk, fill/finish, support, aseptic filling, lyophilization, final packaging), we may not be able to realize full utilization, which could adversely affect our future revenues, financial condition, operating results and cash flows.

Problems may arise during the production of our marketed products and product candidates due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development could cause delays in revenues, which would harm our business, financial condition, operating results and cash flows.

Several of our products, including BioThrax and ACAM2000 and many of our current product candidates, including AV7909, 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 particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, 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-downs, 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.

Additionally, if changes are made to the manufacturing process, we may be required to provide the FDA with pre-clinical and clinical data showing the

comparable identity, strength, quality, purity or potency of any impacted products before and after the changes.

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 and adversely impact our revenues, which would harm our business, financial condition, operating results and cash flows.

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.

Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain potency and lot release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all.

Our products and product candidates procured by the USG and other customers require us to perform tests for and meet certain potency and lot release standards prescribed by the FDA and other agencies, which may not be met on a timely basis or at all. We are unable to sell any products and product candidates that fail to satisfy such testing specifications. For example, we must provide the FDA with the results of certain tests, including potency tests, before certain lots are released for sale. Potency testing of each applicable lot is performed against qualified control lots that we maintain. We continually monitor the status of such reference lots for FDA compliance and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are unable to satisfy USG requirements for the release of our products or product candidates, our ability to supply such products and product candidates to authorized buyers would be impaired until such time as we become able to meet such requirements, which could materially harm our future business, financial condition, operating results and cash flows.

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 Centers for Disease Control (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, financial condition, operating results and cash flows. 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.

RELIANCE ON THIRD PARTIES

The loss of any of our non-exclusive, sole-source or single source suppliers or an increase in the price of inventory supplied to us could have an adverse effect on our business, financial condition and results of operations.

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including key components for NARCAN® Nasal Spray. Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a

supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

Additionally, any failure by us to forecast demand for, or our suppliers to maintain an adequate supply of, the raw material and finished product for producing NARCAN® Nasal Spray could result in an interruption in the supply of NARCAN® Nasal Spray and a decline in sales of the product.

If we are unable to obtain supplies for the manufacture of our 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 products and product candidates could be impaired, which could materially harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise materially harm our business.

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of AV7909, BioThrax, ACAM2000, NARCAN Nasal Spray 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 AV7909. We also rely on single-source suppliers for the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. 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 materially harm our business, financial condition, operating results and cash flows.

We depend on third parties to conduct many of 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, financial condition, operating results and cash flows may suffer.

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, which may not be approved.

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.

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.

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 business, financial condition, operating results and cash flows.

Our failure to successfully integrate acquired businesses and/or 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, including our acquisitions of Adapt and PaxVax. 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 or products 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;
- successfully executing technology transfers and obtaining required regulatory approvals;
- consolidating sales and marketing operations;
- identifying and eliminating redundant and underperforming operations and assets;
- assumption of known and unknown liabilities;
- coordinating geographically dispersed organizations;
- managing tax costs or inefficiencies associated with integrating operations; and
- the strength of any intellectual property portfolio we may acquire.

If we are unable to successfully integrate pending and 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 condition, operating results and cash flows.

COMPETITIVE AND POLITICAL 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 and medical technology products is highly competitive and subject to rapid technological advances. We may face future competition from other companies and governments, universities and other non-profit research organizations in 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. 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 have greater resources to devote to marketing or selling 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 PHT preparedness that are competing with us for both USG procurement and development resources. Many of our competitors have greater financial, technical and marketing resources than we do. Our competitors may receive patent protection that dominates, blocks or adversely affects our products or product candidates.

Any reduction in demand for our products or reduction or loss of development funding for our products or product candidates in favor of a competing product could lead to a loss of market share for our products and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

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

Competition for BioThrax, ACAM2000, and our other biological products and product candidates, including AV7909, 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. The specific regulatory framework for this biosimilar approval path 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. 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, financial condition, operating results and cash flows.

Our NARCAN® Nasal Spray marketed product could face potential competition from other treatments.

Our marketed product NARCAN® Nasal Spray could potentially face substantial competition from other treatments, including injectable naloxone, auto-injectors, nasal sprays or improvised nasal spray kits. In addition, other entrants may seek approval to market generic versions of NARCAN® Nasal Spray before the expiration date of patents that cover the NARCAN® products.

In 2016, and in 2018, Teva and Perrigo each respectively filed an Abbreviated New Drug Application with the FDA (ANDA) seeking regulatory approval to market a generic version of NARCAN® Nasal Spray 4mg/spray. The Company, through its Adapt Pharma subsidiaries (collectively, Adapt), filed patent infringement lawsuits against both Teva and Perrigo related to their ANDA submissions. Adapt also filed a complaint related to Teva's ANDA seeking to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2mg/spray.

On February 12, 2020, Emergent entered into a settlement agreement with Perrigo. Under the terms of this settlement agreement, Perrigo is able to enter the market on January 5, 2033, except under certain circumstances related to the final outcome of the current litigation against Teva or litigation against future ANDA filers.

On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt in the consolidated case. The Company intends to appeal the decision to the U.S. Court of Appeals for the Federal Circuit. While the case is on appeal, it is possible that Teva could proceed with an at-risk launch of their generic NARCAN® Nasal Spray 4mg/spray. The 2mg/spray matter is still pending.

Sales of generic versions of NARCAN® Nasal Spray at prices lower than our branded product have the potential to erode our sales and could impact our product revenue related to NARCAN® Nasal Spray. Additionally, we are aware that other companies are developing other product candidates containing naloxone that, if successful, could compete with NARCAN Nasal Spray and potentially reduce market share. In January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigational naloxone nasal sprays and auto-injectors seeking approval from the FDA for over-the-counter naloxone products. Any reduction in demand for NARCAN® Nasal Spray in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could affect our business, financial condition, operating results and cash flows.

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 PHTs 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 products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows.

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 PHT countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition, operating results and cash flows.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION 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 USG'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.

The COVID-19 product candidates we are working on may not be safe or effective and, even if they are, we may not be able to manufacture sufficient quantities to meet demand.

We are developing two product candidates for the possible prophylaxis or treatment of COVID-19 and we are also providing contract development and manufacturing services for the development and/or manufacture of four vaccine product candidates for customers. There can be no assurance that any of these product candidates will be safe or effective. There can be no assurance that any of these product candidates will receive approval or be authorized for emergency use by the FDA or any other health regulatory authority. Even if these product candidates are safe and/or effective and receive approval or authorization by a health regulatory authority, the manufacturing processes for these programs are under development and will be complex. As a result, there can be no assurance that we will be able to produce any significant quantity of these products or a timely basis or at all, which could adversely affect our business, financial condition, operating results and cash flows.

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. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, which would adversely affect our business, financial condition, operating results and cash flows.

Before obtaining regulatory approval for the marketing of our product candidates, we and our collaborative partners, where applicable, must conduct 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.

Preclinical and clinical testing for certain of our product candidates addressing CBRNE threats may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. We therefore 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 Project BioShield, the Secretary of HHS can contract to purchase MCMs 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 EUA. 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 for distribution in the United States.

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

We continue to evaluate our product development 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. We may change or refocus our existing product development, commercialization and manufacturing activities based on government funding decisions. 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 or choose candidates for which government development funds are not available. 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 business 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, financial condition, operating results, and cash flows could be materially harmed.

Our success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into or covering our technology, products, and product candidates. Obtaining and maintaining protection of our intellectual property 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, and such happenings 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, narrow the scope of our patent protection, or result in costly defensive measures. In addition, some

countries do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our products or product candidates.

Changes to the U.S. patent system under the Leahy-Smith America Invents Act (the America Invents Act), affected the way patent applications are filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter parties review (IPR) post-grant review (PGR) and covered business methods review (CBM). These proceedings are conducted before the Patent Trial and Appeal Board (the PTAB) of the U.S. Patent and Trademark Office. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. The America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The cost of litigation to uphold the validity of patents to prevent or stop infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subjected to opposition proceedings or validity challenges. Some of our competitors may choose to or be better able to sustain the costs of complex patent litigation. Intellectual property lawsuits are expensive and unpredictable and consume management's time and attention and other resources, even if the outcome is successful. In addition, there is a risk that a court could decide that our patents are not valid, are unenforceable, or are not infringed by a competitor product. There is also a risk that, even if the validity of a patent is upheld, a court could 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 occur, our business, financial condition, operating results and cash flows 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 Opiant Pharmaceuticals, Inc. formulations of naloxone used in our NARCAN® Nasal Spray.

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, operating results, and cash flows could be materially and adversely affected.

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

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 for 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 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 is 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 a 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 are 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, these could materially harm our business, financial condition, operating results, and cash flows.

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 license and subject us to damages, which may be material.

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.

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for all of our current products, our only other intellectual property protection for 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 confidential information and 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, or if others independently develop our proprietary information or processes, competitors may be able to use this information to develop products that compete with our products, which could materially and adversely impact our business.

One or more of our products could be subject to early competition from generic drugs and biosimilars.

One or more of our products is approved as a drug product under the provisions of the U.S. Food, Drug and Cosmetic Act (FDCA), which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on pharmacists or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If the patent owner files suit within 45 days of receiving notice from an ANDA filer, the patent owner is entitled to receive a 30 month stay on the FDA's ability to give final approval for the generic product that is the subject of the ANDA.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the validity of patents listed in the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our enforcement or defense of our patent rights. Our existing patents could be invalidated, found unenforceable, or found not to cover a generic form of our product.

Further, the 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of

2009 (BPCIA). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 15, 2020, the FDA had approved thirty six biosimilar products for use in the United States. No interchangeable biosimilars, have been approved. The FDA has issued several guidance documents outlining approaches for review and approval of biosimilars.

Under the Act, a manufacturer may apply for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

FINANCIAL RISKS

We have incurred significant indebtedness in connection with our acquisitions and servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from our operations to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We may also 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, to the extent we are unable to offset the risk of such increases through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities, 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 Senior Secured Credit Facilities and other debt agreements could result in an event of default under those agreements. An event of default could result in the acceleration of amounts due under a particular debt agreement and a cross default and acceleration under other debt agreements, and we may not have sufficient funds to pay or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests in our assets securing our indebtedness.

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 connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated Senior Secured Credit Facilities that replaced our existing facility. The Senior Secured Credit Facilities include a $450 million Term Loan and

the ability to borrow up to $600 million with a revolving credit facility, of which we had outstanding borrowings of approximately $430 million and $353 million, respectively, as of June 30, 2020. We may also 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:

- the level, timing and cost of product sales and contract development and manufacturing services;
- 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 additional common stock under any future share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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 agreements 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 agreement and a cross default and acceleration under other debt agreements, 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 in our assets securing our indebtedness.

Our hedging program is subject to counterparty default risk.

We manage our interest rate risk in part by entering into interest rate swaps with a number of counterparties to swap a portion of our indebtedness that is based on variable interest rates to a fixed rate. As a result, we are subject to the risk that the counterparty to one or more of these contracts defaults on its performance under the contract. During an economic downturn, such as the current economic recession, the counterparty's financial condition may deteriorate rapidly and with little notice and we may be unable to take action to protect our exposure. In the event of a counterparty default, we could incur losses, which may harm our business and financial condition. In the event that one or more of our counterparties becomes insolvent or files for bankruptcy, our ability to eventually recover any losses suffered as a result of that counterparty's default may be limited by the liquidity of the counterparty.

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, and our results of operations and financial condition.

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 August 2018, 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 (which include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least $700 million of public float or issuing an aggregate amount of $1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 8, 2021, 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 do not file a new shelf registration statement prior to August 8, 2021, the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

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 Credit Facilities, 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 2.875% Convertible Senior Notes due 2021 (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 senior secured credit facilities restrict 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, operating results, financial condition and cash flows 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. Our profitability has been substantially dependent on 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 USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

The expansion of our international operations increases our risk of exposure to credit losses.

As we continue to expand our business activities with foreign governments in certain countries that have experienced deterioration in credit and economic conditions or otherwise, our exposure to uncollectible accounts will rise. Global economic conditions and liquidity issues in certain countries have resulted and may continue to result in delays in the collection of accounts receivable and may result in credit losses. Future governmental actions and customer specific actions may require us to re-evaluate the collectability of our accounts receivable and we may potentially incur credit losses that materially impact our operating results.

OTHER BUSINESS RISKS

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 PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection 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 liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT 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 or for cases brought in non-U.S. tribunals or under non-U.S. law. 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 (the 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 USG, or the USG does not honor its obligations to us under the PREP Act or SAFETY Act, or if the liability protections under the PREP Act and SAFETY Act are 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 we may incur. 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, raxibacumab, ACAM2000, Anthrasil, BAT 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. Additionally, potential product liability claims related to our commercial products, including NARCAN® Nasal Spray, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. A material weakness in our internal control over financial reporting 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, 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, or the internal controls of other companies we may acquire, 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 trading 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 materially and 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 June 30, 2020, Mr. El-Hibri was the beneficial owner of approximately 10% 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 (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 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 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 July 24, 2020, our common stock has traded as high as $107.16 per share and as low as $4.17 per share. Due to fears associated with COVID-19, the stock market has recently experienced extreme volatility and the market for biopharmaceutical companies has generally 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 USG affecting our anthrax vaccines and our other products and product candidates;
- CDMO contracts related to COVID-19 with collaboration partners;
- 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;
- 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 Facilities limit 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 June 30, 2020, have the right to require us to register these shares of common stock under specified circumstances.

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.

Exhibit Index

Exhibit Number	Description
10.1#†	Award/Contract, effective June 15, 2012 (BARDA ADM Contract), from the BioMedical Advance Research and Development Authority to Emergent Manufacturing Operations Baltimore LLC.
10.2#†	Modification No. 19, effective, May 25, 2020, to the BARDA ADM Contract.
10.3#†	Modification No. 20, effective, May 26, 2020, to the BARDA ADM Contract.
10.4#†	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated May 24, 2020, under the BARDA ADM Contract.
10.5#†	Modification No. 1, effective, May 28, 2020 to the Award/Contract, effective August 30, 2019 (ACAM2000 Contract), from the Assistant Secretary, U.S. Department of Health and Human Services (ASPR/OPM) to Emergent Product Development Gaithersburg Inc.
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 #	The following financial information related to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, (v) the Condensed Consolidated Statement of Changes in Stockholders' Equity; and (vi) the related Notes to the Condensed Consolidated Financial Statements.
104 #	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.

Filed herewith.

† Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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/ROBERT G. KRAMER
Robert G. Kramer
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: July 31, 2020

By: /s/RICHARD S. LINDAHL
Richard S. Lindahl
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Date: July 31, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.1

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 55
2. CONTRACT (*Proc. Inst. Indent.*) NO. HHSO100201200004I	3. EFFECTIVE DATE 06/15/2012	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. N/A	

5. ISSUED BY CODE	HHS/OS/ASPR/BARDA	6. ADMINISTERED BY *(if other than Item 5)*	CODE
HHS/OS/ASPR/AMOG 330 Independence Ave., SW, Room G-640 Washington, DC 20201			

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	8. DELIVERY FOB ORIGIN Other *(See below)*
Emergent Manufacturing Operations Baltimore LLC 5901 E. Lombard St. Baltimore, MD 21224	9. DISCOUNT FOR PROMPT PAYMENT
DUNS: [**] TIN: [**]	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM See Section G
CODE / FACILITY CODE	

11. SHIP TO/MARK FOR CODE		12. PAYMENT WILL BE MADE BY	CODE	PSC
HHS/OS/ASPR/BARDA		See Section G		
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 See Section G5		

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	See Schedule (for Pricing)				
15G. TOTAL AMOUNT OF CONTRACT					$ 99,941,719.80

16. TABLE OF CONTENTS

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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 _____, 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)* illegible	20A. NAME OF CONTRACTING OFFICER [**] Contracting Officer
19B. NAME OF CONTRACTOR BY /s/ illegible *(Signature of person authorized to sign)*	19C. DATE SIGNED
20B. UNITED STATES OF AMERICA BY /s/ [**] *(Signature of Contracting Officer)*	20C. DATE SIGNED 6/15/2012

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. Brief Description of Supplies or Services

The Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARD A) and the Office of Acquisitions Management, Contracts & Grants (AMCG) seek to establish Centers for Innovation in Advanced Development and Manufacturing (the 'Centers') as public-private partnerships that share facility construction costs, facilitate medical countermeasure (MCM) product development, ensure domestic vaccine manufacturing surge capacity, and provide workforce development training programs. These U.S.-based Centers are expected to provide, on a routine basis, core services including advanced development and manufacturing capabilities for chemical, biological, radiological and nuclear (CBRN) MCMs to address national preparedness and response priorities and needs. HHS/BARDA requires the services of Contractor(s) to provide core advanced development ("industrialization") and manufacturing services to other commercial partners under contract to the U.S. Government (USG) for development of biopharmaceuticals against CBRN threats. Additionally, HHS/BARDA requires Contractor(s) to provide new or renovated manufacturing facilities utilizing flexible manufacturing and modem platform technologies to produce pandemic influenza vaccine and MCMs for outbreaks of an emerging infectious pathogen or currently known or unknown threats. Further, HHS/BARDA requires Contractor(s) to provide a workforce development training program to enhance and maintain the U.S.-based ability to produce these MCMs.

The work performed at these Centers will be coordinated and integrated by HHS/BARDA with programs from other USG agencies to provide long-term solutions that address the medical consequences of known and unknown threats. The period of performance for the contract includes a multi-year base period and one-year option periods which in total shall not exceed 25 years.

B.2. Contract Line Item Numbers (CLINS)

Facility(s) design, construction, commissioning and validation; and availability to provide pandemic influenza vaccine in an emergency, shall take place during the base period of performance.

During the option periods, Service Task/Delivery Orders for requirements such as CBRN advanced development, Pandemic Influenza Vaccine Surge production (including warm-based), Biopharmaceutical Bulk Manufacturing, Formulation, Filling/finishing, Storage, and Shipping may be issued upon agreement by the parties. Option periods may be exercised by the Government by issuance of a unilateral contract modification. Each Service Task Order will specify its own period of performance which may differ from the option period of performance; however, the Service Task/Delivery Order period of performance shall in no event exceed the contract period of performance if all option years are exercised. Task orders for core advanced development and manufacturing services may be issued during the base period of the contract and all option years.

Once [**] is commissioned and validated, it is the Contractor's responsibility to maintain a cGMP manufacturing facility throughout the entire period of performance of the contract. Once the [**] Pilot Plant is commissioned and validated for its intended purpose, it is the Contractor's responsibility to maintain the intended state throughout the entire period of performance of the contract.

B.2.1. Base Period Bid Schedule

B.2.1.1. Lump Sum - Base Period for Pandemic Influenza Vaccine Candidate (CLIN 0001)

This contract includes CLIN 0001 and a description of the Contractor's technical approach toward securing a Pandemic Influenza Vaccine Candidate currently under development. The description shall include the Contractor's approach to obtaining access to all Intellectual Property (IP) necessary for the process development in accordance with the IP requirements specified under Federal Acquisition Regulations ("FAR") Part 27-Patents Data and Copyrights. The term IP as used in this section, as well as Section B.3.6 below, shall include any and all Inventions as defined under FAR Section 27.301, and any and all Data as defined under FAR Section 27.401.

All IP license rights necessary for the facility(s) process development and manufacturing of a Pandemic Influenza Vaccine Candidate will be under CLIN 0001. The Contractor will be prohibited from incurring any costs under other pre-defined CLINs that further the process development and the design/build of facility(s) in support of the pandemic influenza vaccine manufacturing surge capacity prior to receipt of the Contracting Officer's written authorization.

No later than [**] after award the Contractor must provide the Contracting Officer with a written description of the specific Pandemic Influenza Vaccine Candidate that it intends to utilize in order to meet the requirements under Pandemic Influenza Vaccine Surge Capacity (the "Vaccine Candidate"), as well as written description of all IP necessary to further the process development of the Influenza Vaccine Candidate. If required by the Contractor, HHS will identify to the Contractor a suitable Pandemic Influenza Vaccine Candidate currently under development with the USG that can be utilized by the Contractor as the specific Influenza Vaccine Candidate to be used in meeting the CLIN 0001 requirement. The Contractor has the option of using that Influenza Vaccine Candidate or proposing another Influenza Vaccine Candidate. The Contractor's acceptance of an Influenza Vaccine Candidate that is identified by HHS will not relieve the Contractor from complying with any of the IP requirements specified in this section or extend the time frames for complying with those provisions. The Contractor shall provide HHS with a written description of all IP necessary to complete process development leading to manufacturing surge capacity of the Pandemic Influenza Vaccine Candidate in the identified facility(s) ("Description"). The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in the process development of the Pandemic Influenza Vaccine Candidate. The Description shall also include written verification that the Contractor has secured all license rights that are necessary to utilize any and all IP for the process development of the Influenza Vaccine Candidate in accordance with the IP rights granted to HHS, the Contractor, and any and all and subcontractors and/or teaming partners whose IP will be utilized during the development process, as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract

and/or teaming agreement, FAR Clause 52.227-14, and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement. When requested by the Contracting Officer, the Contractor shall provide HHS with written copies of any and all applicable licenses that have been executed with any and all subcontractors and/or teaming partners who's IP will be utilized during the process development of the Pandemic Influenza Vaccine Candidate.

FAR Clause 52.227-1, FAR Clause 52.227-3, FAR Clause 52.227-11, FAR Clause 52.227-14 and FAR Clause 52.227-16 are incorporated by reference into this Contract.

CLIN	Item Description	Qty	Unit of Issue	Cost	Total Cost
0001	Pandemic Influenza Vaccine Candidate (FFP)	1	Lump Sum	[**]	[**]
TOTAL Cost (CLIN 0001):					[**]

CLIN 0001 Pricing Schedule

Payment 1: $[**] Upon [**].

Payment 2: $[**] Upon [**].

Payment 3: $[**] Upon [**].

Payment 4: $[**] Upon [**].

Payment 5: $[**] Upon [**].

Payment 6: $[**] Upon [**].

B.2.1.2. Cost-Share - Base Period for Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity

The base period shall be cost-sharing (except for 0001). The base period provides for new facilities (design, construction, commissioning and validation) capable of providing core advanced development and flexible manufacturing services for CBRN medical countermeasures and, in an emergency, production of pandemic influenza vaccine.

Funding shall be provided for the total cost of performance as defined under CLIN 0002 from HHS and Emergent Manufacturing Operations Baltimore LLC. The percentages of cost-share are determined in the Pricing Schedule below. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation clause of this contract.

The Contractor shall have ownership/title or unencumbered access to designated property/land for the construction of new facility(s) and/or ownership/title or unencumbered access to designated structures for retrofitting.

The cost share percentages listed in the Pricing Schedule below shall not be exceeded.

BASE PERIOD - June 15, 2012 through June 14, 2020

CLIN	Item Description:		Not To Exceed Contractor Cost Share	Not To Exceed USG Cost Share	Not To Exceed Total Cost
0002	Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity	Cost-share	[**]	[**]	[**]

CLIN 0001 Pricing Schedule

Payment 1: $[**] Upon [**].

Payment 2: $[**] Upon [**].

Payment 3: $[**] Upon [**].

Payment 4: $[**] Upon [**].

Payment 5: $[**] Upon [**].

Payment 6: $[**] Upon [**].

B.2.1.2. Cost-Share - Base Period for Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity

The base period shall be cost-sharing (except for 0001). The base period provides for new facilities (design, construction, commissioning and validation) capable of providing core advanced development and flexible manufacturing services for CBRN medical countermeasures and, in an emergency, production of pandemic influenza vaccine.

Funding shall be provided for the total cost of performance as defined under CLIN 0002 from HHS and Emergent Manufacturing Operations Baltimore LLC. The percentages of cost-share are determined in the Pricing Schedule below. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation clause of this contract.

The Contractor shall have ownership/title or unencumbered access to designated property/land for the construction of new facility(s) and/or ownership/title or unencumbered access to designated structures for retrofitting.

The cost share percentages listed in the Pricing Schedule below shall not be exceeded.

BASE PERIOD - June 15, 2012 through June 14, 2020

CLIN	Item Description		Not To Exceed Contractor Cost Share	Not To Exceed USG Cost Share	Not To Exceed Total Cost‘
0002	Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity	Cost-share	[**]	[**]	[**]

Pricing Schedule (CLIN 0002)

Sub-CLIN	Item Description	Percent Gov/Ktr	Contractor Cost Share	USG Cost Share	Total Cost
0002.1	**[**] Pilot Plant —Facility Design, Construction and Commissioning**	[**]	**[**]**	**[**]**	**[**]**
0002.2	**[**] - Construction, Commissioning/Validation and Qualification**	[**]	**[**]**	**[**]**	**[**]**
0002.3	**Licensure of Pandemic Influenza Vaccine in Baltimore facility**	[**]	**[**]**	**[**]**	**[**]**
0002.4	**Project Management**	[**]	**[**]**	**[**]**	**[**]**
0002.5	**Security**	[**]	**[**]**	**[**]**	**[**]**
0002.6	**Workforce Development Program (Plan Development)**	[**]	**[**]**	**[**]**	**[**]**

B.2.2. Option Period(s) Bid Schedule

B.2.2.1. Option Period for ADM Core Services, Warm Base Influenza Vaccine Production, Pandemic Influenza Vaccine Production and Facility Readiness Reimbursement

The USG will provide one hundred percent (100%) of the allowable costs for core services for medical countermeasure Advanced Development and Manufacturing (ADM). HHS will not fund activities or supplies of the Contractor outside of the scope of this contract in these facilities under this contract. Activities or supplies of the Contractor in these facilities for other HHS contracts shall be funded under the applicable contract. Task orders shall be executed utilizing U.S.-based facilities.

Following contract award, actual Service Task/Delivery Orders may be issued to the Contractor as needed by HHS. Actual task order requirements will reflect the actual labor rates of the proposed staff in effect when the task order is issued. The terms and conditions set forth in this contract will always apply.

The USG will provide one hundred percent (100%) of the total funding for warm base influenza vaccine readiness activities and pandemic influenza vaccine production during an emergency. The USG will provide for up to [**] percent ([**]%) of the total annual maintenance and operating costs of [**] for Core Services Readiness.

Service Task/Delivery Orders maybe issued for requirements such as CBRN advanced development, Pandemic Influenza Vaccine Surge production(including warm-based), Biopharmaceutical Bulk Manufacturing, Formulation, Filling/finishing, Storage and Shipping.

Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program).

Option Period I - June 15, 2013 through June 14, 2014

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0003	Core Services Readiness	[**]	N/A
0004	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0005	Workforce Development	[**]	[**]
0006	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period II - June 15, 2014 through June 14, 2015

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0007	Core Services Readiness	[**]	N/A
0008	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0009	Workforce Development	[**]	[**]
0010	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period III - June 15, 2015 through June 14, 2016

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0011	Core Services Readiness	[**]	[**]
0012	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0013	Workforce Development	[**]	[**]
0014	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period IV - Jane 15, 2016 through June 14, 2017

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0015	Core Services Readiness	[**]	[**]
0016	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0017	Workforce Development	[**]	[**]
0018	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period V - June 15, 2017 through June 14, 2018

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0019	Core Services Readiness	[**]	[**]
0020	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0021	Workforce Development	[**]	[**]
0022	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VI - June 15, 2018 through June 14, 2019

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0023	Core Services Readiness	[**]	[**]
0024	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0025	Workforce Development	[**]	[**]
0026	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VII - June 15, 2019 through June 14, 2020

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0027	Core Services Readiness	[**]	[**]
0028	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0029	Workforce Development	[**]	[**]
0030	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VIII - June 15, 2020 through June 14, 2021

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0031	Core Services Readiness .	[**]	[**]
0032	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0033	Workforce Development	[**]	[**]
0034	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period IX - June 15, 2021 through June 14, 2022

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0035	Core Services Readiness	[**]	[**]
0036	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0037	Workforce Development	[**]	[**]
0038	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period X - June 15, 2022 through June 14, 2023

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0039	Core Services Readiness	[**]	[**]
0040	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0041	Workforce Development	[**]	[**]
0042	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XI - June 15, 2023 through June 14, 2024

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0043	Core Services Readiness	[**]	[**]
0044	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0045	Workforce Development	[**]	[**]
0046	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XII - June 15, 2024 through Jane 14, 2025

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0047	Core Services Readiness	[**]	[**]
0048	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0049 ‘	Workforce Development	[**]	[**]
0050	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XIII - June 15, 2025 through June 14, 2026

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0051	Core Services Readiness	[**]	[**]
0052	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0053	Workforce Development	[**]	[**]
0054	Service Task/Delivery Orders	Type of Contract’ TBN	[**]

Option Period XIII - June 15, 2026 through June 14, 2027

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0055	Core Services Readiness	[**]	[**]
0056	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0057	Workforce Development	[**]	[**]
0058	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XV - June 15, 2027 through June 14, 2028

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0059	Core Services Readiness	[**]	[**]
0060	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0061	Workforce Development	[**]	[**]
0062	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVI - June 15, 2028 through June 14, 2029

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0063	Core Services Readiness	[**]	[**]
0064	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0065	Workforce Development	[**]	[**]
0066	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVII - June 15, 2029 through June 14, 2030

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0067	Core Services Readiness	[**]	[**]
0068	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0069	Workforce Development	[**]	[**]
0070	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVIII - June 15, 2030 through June 14, 2031

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0071	Core Services Readiness	[**]	[**]
0072	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0073	Workforce Development	[**]	[**]
0074	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XIX - June 15, 2031 through June 14, 2032

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0075	Core Services Readiness	[**]	[**]
0076	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0077	Workforce Development	[**]	[**]
0078	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XX - June 15, 2032 through June 14, 2033

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0079	Core Services Readiness	[**]	[**]
0080	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0081	Workforce Development	[**]	[**]
0082	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXI - June 15, 2033 through June 14, 2034

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0083	Core Services Readiness	[**]	[**]
0084	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0085	Workforce Development	[**]	[**]
0086	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXII - June 15, 2034 through June 14, 2035

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0087	Core Services Readiness	[**]	[**]
0088	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0089	Workforce Development	[**]	[**]
0090	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXIII - June 15, 2035 through June 14, 2036

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0091	Core Services Readiness	[**]	[**]
0092	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0093	Workforce Development	[**]	[**]
0094	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXIV - June 15, 2036 through June 14, 2037

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0095	Core Services Readiness	[**]	[**]
0096	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0097	Workforce Development	[**]	[**]
0098	Service Task/Delivery Orders	Type of Contract TBN	[**]

B.2.3. Minimum and Maximum Ordering Limitations and Ceiling Limitations

B.2.3.1. There is no minimum guarantee under the base period. If an option period is exercised, then the Government may provide a reimbursement for readiness (e.g. Core Services Readiness CLIN) for no more than [**] of facility(s) capacity for that option period as per the Statement of Work, if:

(1) The Government fails to issue a task order (or task orders) that reasonably keep the facility(s) in use for a negotiated period that calculates to [**] of overall capacity; or,

(2) The facility(s) usage time per an issued task order (or task orders) is less than [**] of the overall capacity. In this case the Contractor shall be entitled to Core Services Readiness costs that are equivalent to the difference between the percentage of time that the facility(s) was in use per the issued task order(s) and the [**] threshold.

B.2.3.1.1. The minimum ordering limitation shall be $[**] for core services.

B.2.3.1.2. The maximum ordering limitation for a single item or combination of items shall be $[**] for ADM core services.

B.2.3.1.3. As referenced in FAR 52.216-19 , the Contractor is not obligated to honor-

(1) Any order for a single item in excess of $[**]
(2) Any order for a combination of items in excess of $[**] or
(3) A series of orders from the same ordering office within [**] that together calls for quantities exceeding the limitation in (1) or (2) of this section.

B.2.3.1.4. The above Ordering Limitations are not applicable to Pandemic Influenza Vaccine Surge requirement for delivery of [**] doses within [**].

B.2.3.2. The ceiling limitation for Cost Plus Fixed Fee (CPFF) portion of the contract is defined in the Option Period Bid Schedule.

B.2.4. Fair Opportunity Ordering (for Core Services, Warm Base Vaccine Production, and Pandemic Influenza Vaccine Production)

In accordance with FAR §16.505, Ordering, the following procedures will be used to issue orders under the contract:

All work under this contract will be ordered through tire issuance of written “Task Order(s)” and “Delivery Order(s)” on an Optional Form 347 executed by the Contracting Officer. The Contracting Officer is the only individual authorized to issue orders under this contract. The Contractor shall only commence work upon receipt of a properly awarded written order executed by the Contracting Officer.

For orders exceeding the micro-purchase threshold, see FAR § 2.101, at the time of the order placement, and subject to the exceptions to the fair opportunity process, see FAR § 16.505(b)(2), the Government will place an order with the Contractor that provides the greatest overall benefit to the Government upon consideration of factors pertinent to an individual order.

Orders over $[**]-FAR 16.505(b)(l)(iii) - For task or delivery orders in excess of $[**], the requirement to provide all awardees a fair opportunity to be considered for each order shall include, at a minimum— (A) A notice of the task or delivery order that includes a clear statement of the agency’s requirements; (B) A reasonable response period; (C) Disclosure of the significant factors and sub-factors, including cost or price, that the agency expects to consider in evaluating proposals, and their relative importance; (D) Where award is made on a best value basis, a written statement documenting the basis for award and the relative importance of quality and price or cost factors; and (E) An opportunity for a post-award debriefing in accordance with paragraph (b)(4) of this section.

Fair opportunity to be considered for each order will be accomplished by the Contracting Officer issuing a Task/DeliveryOrder Request (T/DOR) to establish an adequate basis for fair opportunity consideration of placement of that order. The Contracting Officer may issue a T/DOR to fewer than all contract-holders. However, this will only occur if the other contract-holders have not obtained the proper validation for their facility. A T/DOR will be issued either in a written format that either has been executed by the Contracting Officer or sent via electronic mail directly from the Contracting Officer. A review pursuant to this subparagraph will be deemed adequate for fair opportunity consideration.

A T/DOR may provide a Statement of Objective or Statement of Work, order-specific factors to be used in the selection decision, reporting requirements, deliverables and delivery schedule, and any special instructions or terms applicable to the order. Selection factors for award will be specific for each individual order.

A T/DOR will request a written proposal to be prepared and submitted by the contract-holder to the Contracting Officer. The Contracting Officer will use the T/DOR proposal as one basis, or the sole basis, for the order placement decision. The T/DOR will set forth the specific requirements or objectives for the proposal, information that may be requested includes, but is not limited to, an approach to perform the work, technical and managerial resources, and schedule for performance identifying major milestones, conflict-of-interest certification, and price/cost itemized by price/cost elements. Unless otherwise specified in a T/DOR, a contract holder shall prepare and deliver a proposal within the timeframe stipulated in the T/DOR in order to receive consideration.

Orders placed hereunder will be executed on an OF 347 and will, at a minimum, contain the following information:

Date of order
Contract number and order number
Description of services, contract item number(s) and description, quantity, and price
Delivery or performance schedule
Place of delivery or performance (including consignee)
Any packaging, packing, and shipping instructions
Accounting and appropriation data
Delegation of a Task/Delivery Order COR, if applicable

Ombudsman: The name, address, telephone number, facsimile number and e-mail address of the agency task and delivery order ombudsman is available upon request to the Contracting Officer.

B.3. ADVANCED UNDERSTANDINGS

B.3.1. Priority Rating

HHS may assign a priority rating to any contract awarded under this solicitation. The Contracting Officer may unilaterally modify the task order(s) to add FAR Clause 52.211-15, Defense Priority and Allocation Requirements (Sep 1990) and assign a Health and Human Services priority rating under Defense Priorities and Systems Regulation (15 CFR 700).

B.3.2. Facility Ownership

The Contractor and the USG will share ownership of the portions of the facility to be retrofitted or newly constructed under this Contract, commensurate with the cost share arrangement. The USG ownership of facilities/materials/equipment procured under the terms of this contract and specified as required to prepare a facility(s) for occupancy shall be turned over to the Contractor upon receipt of the Occupancy Permit(s). Local laws and ordinances will govern when a newly constructed and/or retrofitted facility is suitable to occupy. USG ownership of process equipment/materials procured under the terms of this contract shall be turned over to the Contractor upon successful installation and commissioning/qualification of the equipment at the US-based facility specified in the Technical Proposal. During the execution of Option Periods, equipment/materials procured under an executed Task/Delivery Order would be considered Contractor Acquired USG property throughout the Period of Performance. Upon successful completion of a given Task Order, the Contracting Officer will direct the Contractor of the disposition of Contractor Acquired USG property, if applicable.

B.3.3. Failure to Meet Requirements - CLIN 0001

Failure to meet the licensing requirements within the [**] deadline specified under Section B. 2.1.1 shall constitute grounds for termination of any Contract awarded in response to this Solicitation. The termination shall be at the sole discretion of the Contacting Officer. In the

event that the Contractor fails to meet the [**] deadline specified under Section B. 2.1.1, and, as a result, the Contractor incurs additional performance costs necessary to meet any objective in the Contract, the Contractor will be responsible for those additional costs, and those incurred costs may not be charged to any CLIN in any Contract awarded in response to this Solicitation.

B.3.4. Costs

The Contractor shall insure the Contracting Officer receives all necessary cost elements, which will require the prior written approval of the Contracting Officer before the incurrence of cost (e.g., foreign travel, consultant fees, subcontracts). The Contracting Officer will determine all necessary cost elements and thresholds at the kick-off meeting and during the administration of the contract.

B.3.5. FDA Interactions

Offerors are encouraged to interact with the FDA prior to and during the process to review their proposed methodology related to facility construction and validation plans against current FDA guidelines in the development of CBRN medical countermeasures and influenza vaccines.

B.3.6. Intellectual Property for Development of Other CBRN Medical Countermeasures

Execution of an MCM Task Order will require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the “MCM IP Holder”), and the firm providing the Core Services under the Task/Delivery Order (the “Core Services Contractor”). The relationship must reflect the Parties’ rights to all IP developed and/or IP used in performance of the Task/Delivery Order, and be consistent with HHS’s IP rights per the Federal Acquisition Regulations (FAR) clauses described herein. Prior to execution of any MCM Task Order, the MCM IP Holder and/ or the Core Services Contractor shall provide Contracting Officer with a written description of all IP necessary to develop the MCM (the “Description”). The Description must identify the basis for offering HHS less than unlimited rights to any preexisting IP identified in the Description that will be utilized in performance of the MCM Task/Delivery Order. The Description shall also include written verification that the IP Holder will provide HHS with rights to any and all IP utilized or developed during performance of the MCM Task/Delivery Order as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of the MCM Task/Delivery Order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the “FAR Clauses”). The MCM IP Holder and the Core Services Contractor will remain free to negotiate any agreement for their own regarding their use of any of the IP utilized or developed during performance of an MCM Task/Delivery Order, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under the MCM Task/Delivery Order. When requested by the Contracting Officer, the agreement shall be furnished to the Contracting Officer within [**] after the agreement is finalized. All MCM Task/Delivery Orders will specifically incorporate the FAR Clauses and also FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

B.3.7. Good Faith Commitment

The Contractor acknowledges that performance under this contract is subject to negotiated partnering arrangements (e.g. intellectual property rights) and industry development/regulatory risks. The Contractor agrees to work in good faith with all partners, subcontractors, and other relevant parties to address issues relating to the development and regulatory process for any biopharmaceutical or biopharmaceutical manufacturing facility as they arise to reach agreement on a path forward, which shall include allowing the Contractor a reasonable period of time to address particular issues. Such issues include, but are not limited to, successful partnering arrangements, the determination of appropriate dosing levels, ongoing process developments and improvements, insuring adequate production capacity, and other aspects of the FDA regulatory approval process. Further, the FDA's failure to grant licensure, in and of itself, shall not be considered a default of the Contractor's obligations hereunder, so long as the Contractor performs in accordance with the Statement of Work and the Contractor's Technical Proposal incorporated by reference into the contract.

After completing the base period, or before if contractually capable, the Contractor shall propose on all T/DORs that are issued by the Government. Proposals exceeding $[**] shall include non-certified cost or pricing data unless a determination is made by the Contracting Officer that the exceptions in FAR 15.403-1 do not apply; in that case certified cost or pricing data is required as outlined in FAR 15.403-4 and 15.406-2. Failure to submit a proposal in accordance with the technologies and capabilities highlighted in a Contractor's statement of work, and/or a failure to provide a reasonable cost proposal based upon the cost or pricing data submitted, may result in a termination of the contract as prescribed in FAR 49.403. If this type of termination is determined by the Contracting Officer, the Government may seek other damages as prescribed in FAR 49.402-7, these damages may include but are not limited to construction costs and facility readiness reimbursement costs.

B.3.8. DETERMINATION OF READINESS

B.3.8.1. Readiness for Core Services

The Contractor shall be considered eligible for a core services readiness reimbursement when they have successfully demonstrated to the Contracting Officer that all of the core services included in the technical proposal are operational, qualified to the extent required, and available for use by the USG. Operational readiness will be verified by an onsite audit by the Contracting Officer and/or Contracting Officer's Representative (COR). The Contracting Officer will make a written determination as to readiness. The contactor must maintain the accepted conditions of operational readiness to be eligible for continued core services readiness reimbursement.

B.3.8.2. Pandemic Influenza Vaccine Surge Readiness

The contractor shall be considered eligible for a Pandemic Influenza Vaccine Surge readiness reimbursement when they have successfully demonstrated to the Contracting Officer that the facilities, utilities, equipment, quality systems and all associated operations that support Pandemic Influenza Vaccine surge capability are operational, qualified to the extent required and

available for use by the USG. Moreover, the data package from the Clinical Phase III and/or bridging study for the Pandemic Influenza Vaccine candidate must have been submitted to the FDA. Operational readiness will be verified by an onsite audit by the Contracting Officer and/or Contracting Officer's Representative (COR). The Contracting Officer will make a written determination as to Pandemic Influenza Vaccine Surge readiness. The contactor must maintain the accepted conditions of operational readiness to be eligible for continued Pandemic Influenza Vaccine Surge readiness reimbursement.

B.3.9. WORKFORCE DEVELOPMENT

The Contractor shall be considered eligible for workforce development task orders when they have successfully demonstrated to the Contracting Officer that they have established their workforce development program as stated in the Statement of Work (SOW). The workforce development program shall be verified and approved in writing by the Contracting Officer.

SECTION C - DESCRIPTIONS/SPECIFICATIONS/WORK OBJECTIVES

C.1. BACKGROUND

In the last ten years, the U.S. has experienced the destructive effects of both acts of terrorism and infectious disease outbreaks. While limited in scope, the anthrax attacks that followed were highly disruptive and suggested the impact that large-scale acts of bioterrorism would have if carried out successfully. Similarly, concerns have escalated that terrorist groups might obtain and use chemical, radiological, and nuclear weapons against civilian populations. Events of the last decade – the SARS epidemic of 2003, the global spread of H5N1 avian influenza, and the 2009-H1N1 pandemic – have also highlighted the persistent threats of pandemic influenza and emerging infectious diseases.

The U.S. Government (USG) has mobilized in many ways to meet such threats. Among the most prominent of these have been the efforts to develop safe and effective medical countermeasures (MCMs) against chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases. The need for MCMs to diagnose, prevent, mitigate, or treat the illness caused by such agents is clear, but their development has been hindered by the lack of viable markets for such products. The USG has addressed these market barriers by providing substantial support for the research, development, and procurement of MCMs. Many of the firms that have been attracted to bio-defense lack experience in the late stages of product development and have encountered significant challenges with the advanced development and manufacturing of their products.

Moreover, the U.S. biopharmaceutical industry as a whole has been in a state of flux, with many manufacturers and biotechnology firms shifting their production capabilities overseas. The decline of domestic manufacturing capacity jeopardizes a critical national infrastructure and raises concerns about where the workforce of the future will acquire the requisite skills and experience to support biopharmaceutical manufacturing and process development. The 2009 H1N1 influenza pandemic, in which the U.S. was dependent upon offshore manufacturers for a

significant portion of its vaccine supply, illustrated the vulnerability that such dependency entails.

These events and trends prompted the President and the Secretary of Health and Human Services to call for a critical review of the civilian Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This review, led by the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR), resulted in the August 2010 publication of a report, *The Public Health Emergency Medical Countermeasures Review: Transforming the Enterprise to Meet Long-Range National Needs*, that articulated as a strategic imperative that "***Our nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease.***"

To meet this imperative, the PHEMCE Review laid out a forward-looking strategy with the following critical elements:

- MCM investments that address current, future, and unknown threats
- A focus on nimble, multi-use technology platforms and products, when appropriate, to increase the likelihood of developing and procuring products in a cost-efficient and timely way and transform our response capacity
- Greater investment in regulatory innovation and regulatory science
- New, more collaborative approaches to public-private partnerships
- An emphasis on providing core advanced development and manufacturing services

To address these requirements, and to enhance domestic manufacturing capacity to rapidly produce and package an influenza vaccine for the American public in the face of a pandemic, the PHEMCE Review called for HHS and the Department of Defense (DoD) to establish Centers for Innovation in Advanced Development and Manufacturing (the "Centers") that could provide advanced development and manufacturing capabilities as core services for CBRN MCMs to address national security and to augment public health needs on a cost-effective, reliable and sustainable basis.

As presently envisioned, the Centers will connect our industrial partners with needed technical and regulatory expertise during the most challenging stages of product development and industrialization. HHS/BARDA will coordinate the activities of the Centers and will provide guidance and oversight in terms of specific product objectives and contract management in collaboration with National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Department of Defense (DoD). Additional core services (e.g., clinical trials, animal challenge studies) that are provided already by the USG for product development will be coordinated and integrated with services offered by the Centers. These Centers will work to improve the application of flexible manufacturing and any other emerging technologies to support MCM product development.

Establishing the Centers with different capabilities and manufacturing platforms will allow for maximum flexibility and adaptability to respond to changes in technology and/or disease threats. As an element of critical national infrastructure, the Centers will augment existing U.S.-based

manufacturing capacity to produce vaccines and other biologics against emerging infectious diseases and currently known or unknown threats, including pandemic influenza, during public health emergencies. The Centers will provide an ideal setting for needed workforce training and development. As a nexus of public, private and academic partnership, the Centers will reinvigorate the workforce and promote the development of the next generation of biopharmaceutical scientists and engineers.

Previous HHS investments into cost-sharing public-private partnerships have included the establishment of a domestic cell-based influenza vaccine manufacturing facility in 2009 and the retrofitting of domestic facilities to produce egg-based influenza vaccine in 2007 that were utilized for production of 2009 H1N1 pandemic influenza vaccine. A major objective of HHS/BARDA is to further expand U.S.-based biopharmaceutical manufacturing surge capacity through the awarding of multiple cost sharing contracts to private sector partners in order to retrofit or construct new facilities for commercial-scale manufacturing using innovative platform technologies. These initiatives will be coordinated with concomitant DoD efforts to ensure availability of needed MCMs for the U.S. war-fighter.

The envisioned result is an integrated, domestic infrastructure based on strategic partnerships with industry and/or academia with multi-purpose capabilities to develop and manufacture new biopharmaceutical MCMs in a timely manner to protect the U.S. civilian population. The Centers for Innovation in Advanced Development and Manufacturing would develop the next generation of the MCM production workforce through training opportunities, including graduate level training programs, for current and future industry and government scientists engaged in advanced development and manufacturing of MCMs. The Centers would also be used to explore emerging technologies that could be applied to current or future MCM development efforts to reduce risk, increase yield and ultimately to reduce total life-cycle costs. This could be achieved through flexible manufacturing, consolidating other costly product development expenditures, or any other economy-of-scale opportunities.

C.2. STATEMENT OF WORK (SOW)

Independently and not as an agent of the Government, the Contractor (Emergent) shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work.

C.2.1. Overview/Scope

Emergent’s Center for Innovation in Advanced Development and Manufacture (CIADM) shall expand domestic biopharmaceutical (vaccines and other CBRN biologic MCMs) production capacity for advanced development at pilot and commercial scale to augment existing manufacturing infrastructure. The CIADM shall provide a capability to incorporate emerging and innovative technologies that could be applied to current or future USG MCM development efforts to reduce risk, increase yield, and/or reduce total life cycle costs.

The SOW for this contract includes addition of a [**] facility, provision of advanced development and manufacturing core services, provision of surge capacity for pandemic influenza vaccine manufacturing, and workforce development.

C.2.2. Retrofit Existing Pharmaceutical Facility(s) to Augment Current U.S.-based Capacity (Base Period):

Emergent shall execute the following tasks to establish the CIADM infrastructure:

- [**]

The following high level timeline/chart will be revised upon review and acceptance of the Integrated Master Project Plan component of the Overall Project Plan deliverable

[**]

C.2.2.1. [**] Facility Retrofit/Construction

Emergent shall perform architectural/engineering design, construction, material/equipment procurement, commissioning, qualification and validation necessary to expand ([**] foot print) the existing capacity at the [**] facility as outlined below and in accordance with the Technical Proposal.

The engineering firm that performed the detailed design of the [**] manufacturing areas associated with the current [**] facility retrofit also performed a preliminary site plan to provide a conceptual layout of an expansion to incorporate necessary features [**].

The expansion shall be connected to the existing [**] facility and provide expanded capacity of the existing utility systems. The manufacturing area shall have the same design features, segregation controls, and production capacities as the [**] existing manufacturing areas at the [**] facility. The warehouse portion shall be connected to the existing smaller warehouse space. The Preliminary Site Plan allows for the following:

[**]

C.2.2.1. [**] Pilot Plant Facility Retrofit

Emergent shall perform architectural/engineering design, construction, material/equipment procurement, commissioning, qualification and validation necessary to retrofit the pilot plant at its [**] facility ([**]) as outlined below and in accordance with the Technical Proposal. The pilot plant shall be the primarily location for core advanced development and manufacturing services and allow for eventual transfer of CBRN MCM candidates to the commercial-scale manufacturing facility in [**].

Emergent’s [**] facility accommodates much of the company’s project management, contract management, and product development activities. This [**] story building of approximately [**] is configured for both laboratory and office support. [**] level is dedicated to [**] with an

approximately [**] footprint. These laboratories include [**] laboratories. The [**] facility. Emergent's [**] facility is capable of [**]. Under this contract, the retrofitted Pilot Plant shall allow Emergent to scale-up and produce biologies and vaccines for clinical testing. The benefits include:

- Decrease in product timeline as there is no need to tech transfer for clinical production (e.g. the same personnel will be employed for both non-GMP process development and cGMP clinical production);
- Similar equipment as our commercial manufacturing which allows for ease of scale-up and production.

The space used for our pilot plant shall target:

[**]

The pilot plant shall be capable of [**].

The pilot plant shall contain [**] facility.

C.2.3. Provide Biopharmaceutical Production Surge Capacity:

Emergent's CIADM shall provide biopharmaceutical manufacturing surge capacity for emerging infectious diseases, pandemic influenza and other threats during public health emergencies utilizing flexible technologies that will augment the existing manufacturing infrastructure. The CIADM shall use cell, recombinant and molecular-based expression systems for the manufacture of pandemic influenza vaccine.

Emergent shall provide a surge capacity able to manufacture and deliver [**] finished doses of pandemic influenza vaccine within [**] of receipt of the virus reference strain, with the 1st doses available to the USG within [**] of receipt of the virus reference strain by using [**].

Emergent shall seek and follow FDA guidance for the FDA approval of the [**] facility as a manufacturing site for pandemic influenza vaccine surge manufacturing capacity by the end of the base period of the contract.

Emergent shall perform the following tasks aligned with established intellectual property (IP) milestone payment plan and the 'GO/NO GO DECISION POINTS FOR CONTINUING WITH THE [**] PANDEMIC INFLUENZA VACCINE' matrix contained within the Technical Proposal Appendix 16:

- Pandemic Influenza - Demonstration of feasibility of manufacture in disposable bioreactor
- Pandemic Influenza - Freedom to Operate (FTO) Analysis
- Pandemic Influenza - Paper Technical Transfer
- Pandemic Influenza - Assay Technical Transfer and Re-qualification
- Pandemic Influenza - Transfer of Small Scale
- Pandemic Influenza - Scale-up Confirmation

- Pandemic Influenza - BDS Engineering Lot 1
- Pandemic Influenza - BDS Engineering Lot 2
- Pandemic Influenza - BDS Engineering Lots Stability
- Pandemic Influenza - FDP Engineering Lot 2
- Pandemic Influenza - FDP Engineering Lot2 Stability
- Pandemic Influenza - BDS Consistency Lot 1
- Pandemic Influenza - BDS Consistency Lot 2
- Pandemic Influenza - BDS Consistency Lot 3
- Pandemic Influenza - BDS Consistency Lots Stability .
- Pandemic Influenza - FDP Consistency Lot 1
- Pandemic Influenza - FDP Consistency Lot 2
- Pandemic Influenza - FDP Consistency Lot 3
- Pandemic Influenza - FDP Consistency Lots Stability
- Pandemic Influenza - Rabbit Repeat-Dose Tox Study
- Pandemic Influenza - Clinical Bridging Study
- Pandemic Influenza - Type B Meeting
- Pandemic Influenza - Type C Meeting
- Pandemic Influenza - BLA Supplement

The following high level timeline/chart will be revised upon review and acceptance of the Integrated Master Project Plan component of the Overall Project Plan deliverable.

[**]

C.2.4. Pandemic Influenza Vaccine Readiness (Option)

After the Pandemic Influenza Vaccine is eligible for Emergency Use Authorization (EUA), Emergent shall conduct the activities necessary to maintain eligibility for an EUA. Once the facility has been FDA licensed for production of the Pandemic Influenza Vaccine, Emergent shall then conduct the activities necessary to maintain the license for the pandemic influenza vaccine manufacturing capability. The activities for maintaining the license will be determined as required by the FDA.

C.2.5 Implement Workforce Development (Base & Option):

Emergent shall supply biopharmaceutical oriented workforce development that is aligned with current regulatory guidelines via training programs with U.S.-based, accredited academic institutions or other industry recognized U.S.-based organizations that specialize in this area.

Emergent shall develop a plan for implementing their Workforce Development program during the first year of the base period of this contract. Full implementation of the Workforce Development program shall be offered as one (1) year renewable options.

Emergent’s proposed Workforce Development Program shall build on an established internship program to promote the development of the next generation of biopharmaceutical scientists and engineers. The current internship program was implemented [**] ago to 1) to identify talent

early on in their educational/career development and 2) to provide a much valued network of future employees in order to attract top talent. The program in place is administered by our Human Resources Department and encompasses all aspects of Medical Counter Measure (MCM) development and production including process development, engineering, manufacturing, non-clinical, clinical, regulatory, quality, business, finance, human resources and security. The current internship program is not integrated into a university curriculum. The internship program complements the curricula of the universities from which we hire interns. The internship program provides students with industry relevant skills and experience in an industry work environment as well as industry references to facilitate entry into the biotechnology workforce. It is a paid internship program with a pay structure for high school, undergraduate, graduate, and post-graduate positions. Emergent has an active outreach program with a number of universities to identify interns.

Emergent shall expand this program to increase the number of interns in scientific and engineering positions and to implement the program at Emergent Manufacturing Operations Baltimore LLC in parallel with commissioning and validation of the facility and licensure of the pandemic influenza vaccine candidate.

C.2.6. Management Approach:

Emergent shall provide the personnel and functions necessary to oversee, integrate, and coordinate all aspects of the SOW.

C.2.6.1. Integrated Master Project Plan: Emergent shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support the use of the product in the event of an EUA, and product approval. Attention shall be placed on the amount of time that will be needed by the USG (i.e. BARDA, FDA, CDC) for review of critical documentation. The Integrated Master Project Plan will be incorporated into the contract, and will be used to monitor performance of the contract.

C.2.6.1.1. Critical Path Milestones: The Integrated Master Project Plan shall outline key, critical path milestones, with “GO/NO GO” decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing and necessary regulatory submissions.

C.2.6.1.2. Contract Work Breakdown Structure: Emergent shall further delineate the CWBS to [**] as part of their Integrated Master Project Plan. The CWBS shall be discernable and consistent. BARDA may require Emergent to furnish CWBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

C.2.6.1.3. Risk Management Plan: Emergent shall develop a risk management plan highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and the appropriate plans to mitigate these risks. This plan should reference relevant WBS elements where appropriate.

C.2.6.1.4. Earned Value Management System Plan: Emergent shall use an Earned Value Management System (EVMS) in the management of this contract that is consistent with ANSI/EIA-STD-748 guidelines. EVMS shall be part of the Integrated Master Project Plan. Emergent shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements to include the following topics:

- Integrated Baseline Review
- Integrated Master Schedule
- Earned Value Contract Performance Report (EV-CPR)

C.2.6.2. Subcontractor Management Plan: Emergent shall provide to the USG a subcontractor management plan that describes how, and by whom, all major subcontractors will be managed by the prime contractor (Emergent). A list of all subcontractors utilized in the performance of the proposed work shall be maintained by Emergent.

SECTION D - PACKAGING AND MARKING

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, delivery of the items to be furnished to the Government under this contract (including invoices) shall be made by commercial carrier, first class mail, overnight carrier, or e-mail.

D.2. PACKAGING AND SHIPPING

D.2.1. Packaging

As required, packaging of biopharmaceuticals and samples shall be consistent with the FDA-approved labeling and packaging at the time of manufacturing. Appropriate packaging and labeling changes may be required for product delivered under the Investigational New Drug (IND) and following product FDA marketing approval.

D.2.2. Shipping

Shipment of deliverables will be at the direction of the Contracting Officer.

D.3. REPORT DELIVERABLES

Unless otherwise specified by the Contracting Officer delivery of reports to be furnished to the Government under the resultant contract (including invoices), shall be addressed as follows:

[**]
Contracting Officer (CO)
HHS/OS/ASPR/AMCG
330 Independence Ave., SW
Rm [**]
Washington, DC 20201

[**]
Contracting Officer’s Representative (COR)
HHS/OS/ASPR/BARDA
330 Independence Ave, SW
Rm [**]
Washington, DC 20201

SECTION E - INSPECTION AND ACCEPTANCE

E.1. FAR CLAUSES

FAR Clause 52.252-2

Clauses Incorporated by Reference (FEB 1998)

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

FAR Clause	Title and Date
52.246-1	Contractor Inspection Requirements (Apr 1984)
52.246-2	Inspection of Supplies - Fixed Price (Aug 1996)
52.246-16	Responsibility of Supplies (Apr 1984)
52.246-12	Inspection of Construction (applies to Base Period) (Aug 1996)
52.246-15	Certificate of Conformance (applies to Base Period) (Apr 1984)

E.2. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

E.2.1. Inspection and Acceptance

The Contracting Officer or the duly authorized representative (who for purposes of this contract will be the Contracting Officer's Representative) will inspect and accept materials and services to be delivered under the contract.

E.2.2. People in Plant

USG may place, for duration of its choosing, person(s) in the Contractor's facility with a [**] advance notice to the Contractor. The Person(s) in Plant will observe, verify, inspect and survey the Contractor's performance, environment and adherence to the Statement of Work and applicable regulations under this contract.

E.2.3. Audits

The Contractor shall allow for and provide requested information to support security, quality, regulatory, and cGMP audits conducted by USG on an ad hoc basis. The estimated frequency of audits under this paragraph is [**], unless an audit for cause is determined necessary at the discretion of the Contracting Officer. If the USG finds non-compliances or deficiencies during its audit(s) on firm fixed price line items, the Contractor, at its sole expense, shall take all necessary corrective action within a timely manner. In addition, the Contractor shall provide all

information requested by the USG, including the FDA, to facilitate a cGMP inspection at the time of production of vaccine lots.

SECTION F - DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The total period of performance (base and all option periods, if exercised) shall not exceed 25 years under this contract,

F.1.1. Base Period

The base period of performance is from the June 15, 2012 through June 14, 2020.

F.1.2. Option Periods

Each option period, if exercised, will extend the contract period of performance for an additional 12 month period. Each option will be exercised in accordance with FAR clause 52.217-09, entitled “Option to Extend the Term of the Contract (Mar 2000)”. Upon the Government’s failure to exercise an annual option period, all of the Contractor’s future performance obligations which would have otherwise arisen under this contract shall cease and/or be void and of no effect. Multiple option periods may be exercised at one time. However, no options shall be exercised before the Contractor has submitted a Description to the Contracting Officer as described in CLIN 0001 and secured the IP rights necessary to develop, manufacture, and sell the Pandemic Influenza Vaccine.

Depending when the Contractor is ready (and verified/approved by the Contracting Officer) to accept service task/delivery orders, option periods may be exercised during the base period. Under no circumstances shall the total period of performance (base period and all option periods) under this contract exceed twenty-five (25) years.

F.1.3. Period of Performance for Task Orders

Task orders related to ADM core services and warm-based influenza vaccine production will state their own deliverables and period of performance. The period of performance for task order issued pursuant to this contract are anticipated to run from one (1) to five (5) years.

F.2. TECHNICAL REPORT DELIVERABLES

The following is the Technical Report delivery schedule that shall be commensurate with the pricing schedule in Section B.

Deliverable	Quantity	Due Date
Monthly Technical Progress Report (12 of each per year - Base and Option Periods) (all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	The initial Technical Progress Report due on/before [**]; thereafter, due on/before the [**] of the month or milestone following each reporting period. NOTE: A Technical Progress Report is not due when the Pinal Technical Closeout Report is due.
Executive Summary (12 of each per year - Base and Option Periods) (all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	The initial Executive Summary due on/before [**]; thereafter, due on/before the [**] of the month or milestone following each reporting period. NOTE: An Executive Summary is not due when the Final Technical Closeout Report is due.
Facility(s) Construction/ Retrofit - Overall Project Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Regulatory and Clinical Bridging Study Plan (CLIN 0002.3)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Facility Operation Feasibility Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Detailed Manufacturing Facility Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Final Security Plan (CLIN 0002.5)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Commissioning and Validation Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Operating Plan and Facility Cost Model (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of the base period of the contract.
Final Technical Closeout Report (CLIN 0002.3)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of last acceptable consistency/validation lot in the new and/or retrofitted facility(s).
Development/ Manufacturing Summary Report (Task Order #/Delivery Order#____)(all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of a specific Task Order/Delivery Order, a written report summarizing the campaign, cost of goods, and release documents must be submitted.

F.3. MEETINGS

F.3.1. Monthly Teleconferences

The Contractor shall participate in monthly teleconferences with USG to discuss the performance of the contract. At the discretion of the Contracting Officer, additional [**] teleconferences may

be scheduled. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each teleconference, or as otherwise authorized by the Contracting Officer.

F.3.2. Periodic Site Visits

The Contractor shall accommodate for periodic site visits by USG on an ad hoc basis. The estimated frequency of visits under this paragraph is [**]. The Contractor shall keep minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the Contracting Officer.

F.3.3. Quarterly Site Visits

The Contractor shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the Contractor's site on a quarterly basis. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the Contracting Officer.

F.4. PLACE AND METHOD OF DELIVERY

F.4.1. Delivery of contract deliverables specified under Section F.2 and Section F.3 shall be F.O.B. destination, within consignee's premises.

F.4.2. Unless otherwise specified, deliveries shall be Monday through Friday (excluding Federal Holidays) between the hours of 8:30 AM and 5:00 PM EST only. Contract deliverables scheduled for delivery on a Federal holiday shall be made the following business day.

F.4.3. Deliveries shall be made to the address specified in Section D.3.

F.5. CONTRACT CLAUSES

FAR Clause 52.252-2

CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

www.acquisition.gov
http://www.hhs.gov/oamp/policies/

FAR CLAUSES	TITLE	DATE
52.211-10	Commencement, Prosecution and Completion of Work	APR 1984
52.242-15	Stop Work Order - Alternate I (AUG 1984)	AUG 1989
52.247-35	F.O.B. Destination, Within Consignee's Premises	APR 1984
52.211-17	Delivery of Excess Quantities	SEP 1989
52.242-17	Government Delay of Work	APR 1984

SECTION G-CONTRACT ADMINISTRATION DATA

G.1. CONTRACT ADMINISTRATION

G.1.1. Contracting Officer

The Contracting Officer is the only individual who can legally commit 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.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) 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.1.2. Contracting Officer's Representative (COR)

The Contracting Officer's Representative (COR), to be named prior to contract award, will assist the contracting officer is resolving technical issues that arise during performance. The Government Contracting Officer's Representative is not authorized to change any of the terms and conditions of the contract. Changes shall be made only by the Contracting Officer by proper written modification(s) to the contract. Any changes in Contracting Officer's Representative delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

G.2. PAYMENTS AND INVOICING

G.2.1. Payment By Electronic Funds Transfer - Central Contractor Registration (OCT 2003)

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34 (May 1999), Payment by Electronic Funds Transfer in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

The Contractor shall make the designation by submitting the form titled “ACH Vendor/Miscellaneous Payment Enrollment Form” to the address indicated below. In cases where the Contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and has been enrolled in the program, the form may not be required unless the designation has changed.

The completed form shall be submitted prior to contract award, but no later than [**] before an invoice is submitted, to the Contracting Officer at the address in Section G.2.2.1.

G.2.2. Invoice Submission

G.2.2.1. The Contractor shall submit an original and two hard copies as well as one electronic copy (address to be provided at a later date) of contract invoices to the address shown below:

HHS/OS/ASPR/AMCG
Attn.: Contracting Officer
330 Independence Ave., S.W.
Room G640
Washington, D.C. 20201

G.2.2.2. 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 and delivery/task order (if applicable)
(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 (c)(1).
(12) Any additional backup information required to justify the invoice.

G.2.2.3. See Section J for additional invoicing instructions.

G.3. MISCELLANEOUS CONTRACT ADMINISTRATION

G.3.1. Evaluation Of Contractor Performance (Service) (JAN 2000)

(a) *Purpose:* In accordance with FAR 42.1502 - Policy, 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 an approved Contractor Performance Evaluation Report which will be discussed and agreed to at the kick-off meeting.

(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 [**] 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 [**] after completion of contract performance for the purpose of providing source selection information for future contract awards.

G.3.2. Contract Communications/Correspondence

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number (and delivery/task order if applicable) from Page 1 of the contract.

G.3.3. Notice Prior To Publication

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written advanced notice to the Contracting Officer, provided that no such notice 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.

G.3.4. 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

G.4. INDIRECT COST RATES

Pending the establishment of final indirect cost rates which shall be negotiated based on audit of actual costs as provided in Subpart 42.7 of the Federal Acquisition Regulation, the Contractor shall be reimbursed for allowable indirect costs hereunder at the billing rate listed below.

This INDIRECT COST provision does not operate to waive the LIMITATION OF FUNDS Clause. Tire Contractor's audited final indirect costs are allowable only insofar as they do not cause the Contractor to exceed the total estimated costs for performance of the contract.

BILLING RATES

Fringe benefits at [**]%, applied to a base sum of total direct labor, development overhead at [**]%, applied at a base sum of total direct labor plus fringe benefits and G&A at [**]% applied to a modified base that excludes subcontracts, materials and equipment.

The provisional labor and indirect rates negotiated under this contract for billing purposes shall remain in effect until revised rates have been approved in writing by the Contracting Officer. The Contractor shall request new provisional billing rates in writing. Such request shall delineate the current and proposed rates to be used.

G.5. ACCOUNTING AND APPROPRIATION DATA

BASE PERIOD:

CLIN 0001: $ [**] (NOT TO EXCEED)
CLIN 0002: $[**] (NOT TO EXCEED)

Accounting and Appropriation Data: 2012 1994020 32201

OPTION PERIODS:

All option periods are Subject to the Availability of Funds (FAR 52.232.18)

Accounting & Appropriation data will be listed on task/delivery orders issued pursuant to this contract

SECTION H - Special Contract Requirements

H.1. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES (JUL 1999)

The Contractor is hereby notified of the restrictions on the use of HHS funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 - Limitations on the Payment of Funds to Influence Federal Transactions and FAR Clause 52.203-12 (Sep 2007).

In addition, the current HHS Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes; for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress; or any State or Local legislative body itself. The current HHS Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.2. REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The Representations, Certifications and Other Statements of Offerors submitted by the Contractor dated July 6, 2011 through July 12, 2012 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

H.3. LABORATORY LICENSE REQUIREMENTS

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

H.4. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer, 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.5. ACCESS AND DISPOSITION OF DATA

The government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, and all Contractor commitments and responses. Contractor shall provide the government with an electronic copy of all correspondence with the FDA within [**] of receipt. The Government shall have unlimited rights to all animal and human data funded under this RFP. The contractor shall keep copies of all data required by the FDA relevant to this contract for the time specified by the FDA.

H.6. INCORPORATION OF TECHNICAL PROPOSAL

The Contractor's Technical Proposal included in its Proposal dated April 13, 2012 or as revised by the Final Proposal Revision dated April 30, 2012, submitted in response to RFP-11-SOL-00011 is hereby incorporated into the contract by reference. 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. Within [**] after contract award, the Contractor is required to deliver to the Contracting Officer a consolidated copy of their full Technical Proposal. In the event of a conflict between Section C, SOW, and the Contractor's Technical Proposal, Section C will take precedence.

H.7. PROTECTION OF HUMAN SUBJECTS

No contract involving human subjects research shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee(s) as described in 45 CFR Part 46. Contracts involving human subjects will not be awarded to an individual unless 1) the individual is affiliated with or sponsored by an institution that has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and 2) the individual will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. The Contractor further agree to provide certification at least [**] that the Institutional Review Board has reviewed and approved the procedures that involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects such 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 the OHRP, terminate the contract in whole or in part, and the name of the Contractor may be removed from the list of those contractors with approved HHS Human Subject Assurances.

H.8. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

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

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH), http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. PHS.

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

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates

programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as its primary evaluation tool. It also uses the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. It is published by the Federated of Animal Science Societies http://www.fass.org.

H.9. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

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

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

H.10. CARE OF LIVE VERTEBRATE ANIMALS

Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.

The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the USDA (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OLAW, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances.

The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector 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: Animal Care Staff USDA/APHIS 4700 River Road, Unit 84 Riverdale, MD 20737 (301) 734-4980. Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the NIH at (301) 594-2289.

H.11. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within [**] of the date of this award and approved by the Office

of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet.

H.12. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

H.13. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice (cGMP) regulations (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product. If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, and purity of the product (a material failure) as identified by the FDA, then the Contractor shall have [**] from the time such material failure is identified to institute a comprehensive plan and obtain approval by the Contracting Officer to cure such material failure. If the Contractor fails to take such an action within the [**] period, then the contract may be terminated.

H.14. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 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.15. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer at least [**] in advance and shall submit justification (including proposed substitutions possessing the same or greater qualifications/experience as the individual being substituted) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written

consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete key personnel as appropriate.

Contractor Key Personnel:

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

H.16. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with BARDA, or APHIS, as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will he administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries

of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS Select Agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

H.17. SECURITY

The work to be performed under this contract will involve access to sensitive Biomedical Advanced Research and Development Authority (BARDA) program information. Upon contract award, the Program Protection Officer (PPO) will review the Draft Security Plan (submitted as part of the Contractor's Technical Proposal) in detail and submit comments within [**] to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and if changes are required, submit a Final Security Plan to the U.S. Government within [**] after receipt of the Program Protection Officer's (PPO) comments. The Final Security Plan shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan. The execution of the work under this contract shall be in accordance with the approved Final Security Plan. As outlined above, the content of the Final Security Plan shall be a continuation of the Draft Security Plan submitted as part of the Contractor's Technical Proposal. The Security Plan should address facilities providing core ADM services for CBRN medical countermeasures and influenza vaccine manufacturing. Therefore, at a minimum, the Final Security Plan shall address the following items:

Personnel Security Policies and Procedures including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/adjudication policy; Access determination; Rules of behavior/conduct; Termination procedures; Non-disclosure agreements.

Physical Security Policies and Procedures including but not limited to: Internal/external access control; Identification/badge requirements; Facility visitor access; Parking areas and access; Barriers/perimeter fencing; Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.

Information Security Policies and Procedures including but not limited to: Identification of sensitive information; Access control/determination; Secured storage infrastructure; Document control; Retention/destruction requirements.

Information Technology Security Policies and Procedures including but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/

media; Passwords; Removable media; Laptop policy; Media access control/determination; Secure storage; System document control; System backup; System disaster recovery.

The following instruction/intent shall be incorporated:

> Security Reporting Requirement - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. Contracting Officer will determine if the severity of the violation requires further U.S. Government (USG) intervention.

H.18. FAR 52.234-4 - EARNED VALUE MANAGEMENT SYSTEM (JULY 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and
(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted within [**] after contract award.

(d) The Contracting Officer may require an IBR at—

(1) Exercise of significant options; or
(2) Incorporation of major modifications.

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

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government

surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause:

_____
_____
_____
_____

(End of clause)

H.19. INTERACTIONS WITH REGULATORY AGENCIES

The obligations set forth in this paragraph shall apply to the contractor and any subcontract at any tier thereunder as applicable under this Contract and any Task Orders issued hereunder.

(a) The Contractor shall prepare and submit initial draft minutes and final accepted minutes of all formal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(b) The Contractor shall prepare and submit initial draft minutes and the final accepted minutes of all informal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(c) The Contractor shall forward the dates and times of all scheduled meetings with U.S. regulatory agencies, to include FDA, to BARDA and make arrangements for appropriate BARDA staff to attend such U.S. regulatory agencies meetings.

(d) The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to U.S. regulatory agencies. The contractor shall provide BARDA with [**], or such shorter period as may be practicable in time-sensitive situations, to review and provide comments to the Contractor prior to its submittal to U.S. regulatory agencies.

(e) The Contractor shall furnish all findings of U.S. regulatory agencies inspections, including FDA Form 482 and 483 inspection notice and observations and Establishment Inspection Reports (EIR) pertinent to the contract, to BARDA within [**] of receipt.

(f) The Contractor shall notify the USG of all site visits/audits by U.S. regulatory agencies, to include FDA, within [**] of agency personnel’s arrival.

(g) The Contractor shall include the USG in all scheduled meetings and teleconferences with U.S. regulatory agencies.

H.20. SUBCONTRACTING PROVISIONS

(a) Small Business Subcontracting Plan

1. The Small, Small Disadvantaged and Women Owned Small Business Subcontracting Plan, dated April 13, 2012 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 (Attachment 5) 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

As of October 28, 2005 the Electronic Subcontract Reporting System (eSRS) is available for use by all civilian agencies and their contractors at www.esrs.gov. The eSRS will eliminate both standard forms Subcontracting Reports for Individual Contracts (formerly SF 294) and Summary Subcontract Reports (formerly SF 295) paper submissions, and contractors will now submit all their reports electronically to a single, government wide system. The eSRS is the latest system under the umbrella of the Integrated Acquisition Environment (IAE).

All civilian agency contractors must now submit their Summary Subcontract Reports into the eSRS.

No contractors of any agency will be required to submit the Subcontracting Reports for Individual Contracts into the eSRS for fiscal year 2004.

No contractors of any agency will be required to submit mid-year reports for fiscal year 2005 (normally due April 30 for the period ended March 31st) into the eSRS. This exemption applies to both the Subcontracting Reports for Individual Contracts and the Summary Subcontract Reports.

Frequently Asked Questions and other information are available on the eSRS website at www.esrs.gov. If you have any further questions or comments, you may contact the SBA at eSRS@sba.gov or the IAE at integrated.acquistion@gsa.gov.

H.21. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant. This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with

the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.22. RESERVED

H.23. LIABILITY PROTECTION

The Secretary's Declaration for Public Readiness and Emergency Preparedness Act (PREP Act), Section 319F-3 of the Public Health Service Act, 42 U.S.C. 247d-6d, Coverage for Vaccines Against Pandemic Influenza A Viruses and Influenza A Viruses With Pandemic Potential effective February 29, 2012 (as amended) applies to this contract, subject to the terms and conditions of such Declaration and any amendments thereto.

In the event the Contractor delivers vaccine under this contract which is not covered by the aforementioned declaration because of the expiration of the aforementioned declaration and any renewals or amendments thereof, the Government agrees that the medical countermeasure delivered by the Contractor under this contract will not be administered for use in humans, unless the Secretary executes a new declaration in accordance with section 319F-3(b) of the Public Health Service Act, 42 U.S.C. 247d-6d, or renews or amends the an existing declaration, to provide that such medical countermeasures delivered under this contract are covered countermeasures to which section 319F-3(a) applies subject to the terms and conditions of the Declaration and any amendments thereto, and the new or renewed or amended declaration provides the Contractor at least the same coverage as the aforementioned declaration.

H.24. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Privacy Act (JAN 2006): Data obtained from human subjects.

H.25. NATIONAL ENVIRONMENTAL POLICY ACT OF 1969 (NEPA)

HHS is required to follow the National Environmental Policy Act of 1969 (NEPA), implementing regulations, and executive orders; for any project that utilizes federal funds or federal property. The Offeror/Awardee must submit, as required by the Contracting Officer, an assessment of the impact of the construction and/or renovation of facilities in the proposed project on the human environment pursuant to section 102(2)(c) of NEPA and its implementing regulations, as well as a report showing the results of tests for environmental hazards present in the facility, ground water, and soil. HHS will provide advice and assistance to the Offeror/Awardee, as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

H.26. FACILITY

In consideration for the agreements and mutual benefits herein provided, upon receipt of the Occupancy Permit(s) (as defined under paragraph B.3.2.) or termination for convenience of this contract by the Government, whichever occurs earlier, all rights and title to the facility shall pass

to the Contractor, and the Government shall retain no right of ownership in the facility and related equipment to be funded under this contract. Notwithstanding the foregoing, in the event this contract is terminated for the default of the Contractor, all rights and title to tire facility shall similarly pass to the Contractor; provided, however that the Contractor shall thereupon be obligated to pay to the Government, as liquidated damages for such transfer of rights and title and not as a penalty, an amount in proportion to the cost share agreement between the Contractor and the Government. That is, up to [**] percent ([**]%) for a new facility, and up to [**] percent ([**]%) of a retrofitted facility (See Pricing Schedule under CLIN 0002). Appraisal of the facility for purposes of determining the compensation due the Government under this Subsection shall be performed in accordance with the then most current version of the Uniform Appraisal Standards for Federal Land Acquisitions. Notwithstanding any term or provision contained in this contract to the contrary, the obligations of the parties under this Subsection shall survive the termination of this contract, including, but not limited to any termination for default.

SECTION I - CONTRACT CLAUSES

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

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. Also, the full text of a clause may be accessed electronically at this/these address(es):

www.acquisition.gov
http ://farsite.hill.af.mil/vffar1.htm

I.1.1. Clauses Applicable all of the Contract (Base Period and Options)

FAR CLAUSE	*TITLE*	*DATE*
52.202-1	Definitions	JAN 2012
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	JAN 1997
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	APR 2010
52.203-14	Display of Hotline Poster(s) [handwritten note: applicable to subs if ---- executed]	DEC 2007
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-7	Central Contractor Registration	FEB 2012
52.204-8	Annual Representations and Certifications	FEB 2012
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	FEB 2012
52.209-6	Protecting the Government’s Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.215-2	Audit and Records - Negotiation	OCT 2010
52.215-8	Order of Precedence - Uniform Contract Format	OCT 1997

FAR CLAUSE	***TITLE***	***DATE***
52.215-10	Price Reduction for Defective Certified Cost or Pricing Data	AUG 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data - Modifications	AUG 2011
52.215-12	Subcontractor Cost or Pricing Data	OCT 2010
52.215-13	Subcontractor Cost or Pricing Data - Modifications	OCT 2010
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications	OCT 2010
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost and Payment	JUN 2011
52.216-18	Ordering	OCT 1995
52.216-19	Order Limitations (See Section B.2.3.1.3)	OCT 1995
52.215-22	Indefinite Quantity	OCT 1995
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-9	Small Business Subcontracting Plan - Alternate II (OCT 2001)	JAN 2011
52.219-16	Liquidated Damages - Subcontracting Plan	JAN 1999
52.219-25	Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting	DEC 2010
52.222-1	Notice to the Government of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-29	Notification of Visa Denial	JUN 2003
52.222-35	Equal Opportunity for Veterans	SEP2010
52.222-36	Affirmative Action for Workers with Disabilities	OCT 2010
52.222-37	Employment Reports Veterans	SEP 2010
52.222-50	Combating Trafficking in Persons	FEB 2009
52.223-1	Biobased Product Certification	DEC 2007
52.223-2	Affirmative Procurement of Biobased Products under Service and Constructions Contracts	DEC 2007
52.223-4	Recovered Material Certification	MAY 2008
52.223-6	Drug-Free Workplace	MAY 2001
52.223-9	Estimate of Percentage of Recovered Material Content for EPA-Designated Items	MAY 2008
52.223-15	Energy Efficiency and Energy Consuming Products	DEC 2007
52.225-1	Buy American Act - Supplies	FEB 2009

FAR CLAUSE	***TITLE***	***DATE***
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.226-1	Utilization of Indian Organizations and Indian-Owned Economic Enterprises	JUN 2000
52.227-1	Authorization and Consent - Alternate I (APR 1984)	DEC 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	DEC 2007
52.227-3	Patent Indemnity	APR 1984
52.227-14	Rights in Data - General	DEC 2007
52.227-16	Additional Data Requirements	JUN 1987
52.230-2	Cost Accounting Standards	OCT 2010
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-9	Limitation on Withholding of Payments	APR 1984
52.232-17	Interest	OCT 2010
52.232-23	Assignment of Claims	JAN 1986
52.232-25	Prompt payment - Alternate I (FEB 2002)	OCT 2008
52.232-33	Payment by Electronic Funds Transfer - Central Contractor Registration	OCT 2003
52.233-1	Disputes - Alternate I (DEC 1991)	JUL 2002
52.233-3	Protest after Award - Alternate I (JUN 1985)	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.243-6	Change Order Accounting	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition in Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	APR 2012
52.245-9	Use and Charges	APR 2012
52.246-23	Limitation of Liability	FEB 1997
52.248-1	Value Engineering	OCT 2010
52.249-2	Termination for Convenience of the Government (Fixed-Price) (Applicable to only the FFP items under the contract)	APR 2012
52.253-1	Computer Generated Forms	JAN 1991

I.1.2. Clauses Applicable to Design and Construction (Base Period)

FAR CLAUSE	***TITLE***	***DATE***

FAR CLAUSE	***TITLE***	***DATE***
42.211-5	Material Requirements	AUG 2000
52.216-12	Cost-Sharing Contract - No Fee [handwritten note – N/A to subs]	APR1984
52.222-6	Davis-Bacon Act	JUL 2005
52.222-7	Withholding of Funds	FEB 1988
52.222-8	Payrolls and Basic Records	JUN 2010
52.222-9	Apprentices and Trainees	JUL 2005
52.222-10	Compliance with Copeland Act Requirements	FEB 1988
52.222-11	Subcontracts (Labor Standards)	JUL 2005
52.222-12	Contract Termination - Debarment	FEB 1988
52.222-13	Compliance with Davis-Bacon and Related Act Regulations	FEB 1988
52.222-15	Certification of Eligibility	FEB 1988
52.222-16	Approval of Wage Rates	FEB 1988
52.222-19	Child Labor - Cooperation with Authorities and Remedies	APR 2012
52.222-27	Affirmative Action Compliance Requirements for Construction	FEB 1999
52.223-17	Affirmative Procurement of EPA-designated Items in Services and Construction Contracts	MAY 2008
52.225-11	Buy American Act--Construction Materials Under Trade Agreements	APR 2012
52.225-12	Notice of Buy American Act Requirements - Construction Materials under Trade Agreements	APR 2012
52.227-4	Patent Indemnity - Construction Contracts	DEC 2007
52.228-2	Additional Bond Security	OCT 1997
52.228-14	Irrevocable Letter of Credit	DEC 1999
52.228-15	Performance and Payment Bonds - Construction *(Total value of performance and Payment Bonds shall he for the total Government's share of construction costs.)*	OCT 2010
52.229-3	Federal, State, and Local Taxes	APR 2003
52.232-16	Progress Payments	APR 2012
52.232-27	Prompt Payment for Construction Contracts	OCT 2008
52.236-2	Differing Site Conditions	APR 1984
52.236-3	Site Investigation and Conditions Affecting the Work	APR 1984
52.236-5	Material and Workmanship	APR 1984
52.236-6	Superintendence by the Contractor	APR 1984
52.236-7	Permits and Responsibilities	NOV 1991
52.236-12	Cleaning Up	APR 1984
52.236-13	Accident Prevention	NOV 1991
52.236-15	Schedules for Construction Contracts	APR 1984
52.236-18	Work Oversight in Cost-Reimbursement Construction Contracts	APR 1984

FAR CLAUSE	***TITLE***	***DATE***
52.236-19	Organization and Direction of the Work	APR 1984
52.236-21	Specifications and Drawings for Construction - Alternate I (APR 1984)	FEB 1997
52.236-23	Responsibility of the Architect-Engineer Contractor	APR 1984
52.236-24	Work Oversight in Architect-Engineer Contracts	APR 1984
52.236-25	Requirements for Registration of Designers	JUN 2003
52.236-26	Preconstruction Conference	FEB 1995
52.243-4	Changes	JUN 2007
52.248-2	Value Engineering - Architect-Engineering	MAR 1990
52.248-3	Value Engineering - Construction	OCT 2010
52.249-6	Termination (Cost-Reimbursement) (Applicable to the cost-share.) [handwritten note – N/A to subs]	MAY 2004
52.249-14	Excusable Delays	APR 1984

NOTE: There is no fee in a cost-share contract

I.1.3. Clauses Applicable to Option Periods (FFP and CPFF)

FAR CLAUSE	***TITLE***	***DATE***
52.215-14	Integrity of Unit Prices	OCT 2010
52.216-8	Fixed Fee	JUN 2011
52.222-4	Contract Work Hours and Safety Standards Act - Overtime Compensation (Applicable to Readiness CLIN)	JUL 2005
52.222-41	Service Contract Act of 1965 (Applicable to Readiness CLIN)	NOV 2007
52.227-14	Rights in Data—General -- Alternate I (DEC 2007)	DEC 2007
52.232-20	Limitation of Cost	APR 1984
52.232-22	Limitation of Funds	APR 1984
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.243-2	Changes - Cost-Reimbursement - Alternate I (APR 1984)	AUG 1987
52.249-6	Termination (Cost-Reimbursement) (Applicable to the CPFF portion of the contract)	MAY 2004
52.249-14	Excusable Delays-	APR 1984

DOL Wage Determinations under the Service Contract Act and Davis-Bacon Act are included as an attachment to this contract

I.1.3. Clauses Incorporated in Full Text

I.1.3.1. Clauses Applicable to the Entire Contract

FAR 52.209-9

Updates of Publicly Available Information Regarding Responsibility Matters (Feb 2012)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a [**] basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database via https://www.acquisition.gov.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments —

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by—

(i) Government personnel and authorized users performing business on behalf of the Government; or
(ii) The Contractor, when viewing data on itself; and

(2) The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for—

(i) Past performance reviews required by subpart 42.15;
(ii) Information that was entered prior to April 15, 2011; or
(iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within [**], to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within [**] remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within [**] of the posting to FAPIIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of [**]. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

FAR Clause 52.217-8

Option to Extend Services (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed [**]. The Contracting Officer may exercise the option by written notice to the Contractor within [**].

FAR Clause 52.217-9

Option to Extend the Term of the Contract (MAR 2000)

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

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 25 years.

I.1.3.2. Clauses Applicable to the Base Period of the Contract

FAR Clause 52.222-2

Payment for Overtime Premiums (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium - does not exceed $0 or the overtime premium is paid for work -

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;
(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;
(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or
(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall -

(1) Identify the work unit; *e.g.*, department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;
(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance reasons schedule;
(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and
(4) Provide why the required work cannot be performed by using multishift operations or by employing additional personnel.

FAR 52.223-19

Compliance with Environmental Management Systems (MAY 2011)

The Contractor’s work under this contract shall conform with all operational controls identified in the applicable agency or facility Environmental Management Systems and provide monitoring and measurement information necessary for the Government to address environmental performance relative to the goals of the Environmental Management Systems.

(End of clause)

FAR Clause 52.236-22

Design Within Funding Limitations. (APR 1984)

(a) The Contractor shall accomplish the design services required under this contract so as to permit the award of a contract, using standard Federal Acquisition Regulation procedures for the construction of the facilities designed at a price that does not exceed the estimated construction contract price as set forth in paragraph (c) below. When bids or proposals for the construction contract are received that exceed the estimated price, the contractor shall perform such redesign and other services as are necessary to permit contract award within the funding limitation. These

additional services shall be performed at no increase in the price of this contract. However, the Contractor shall not be required to perform such additional services at no cost to the Government if the unfavorable bids or proposals are the result of conditions beyond its reasonable control.

(b) The Contractor will promptly advise the Contracting Officer if it finds that the project being designed will exceed or is likely to exceed the funding limitations and it is unable to design a usable facility within these limitations. Upon receipt of such information, the Contracting Officer will review the Contractor's revised estimate of construction cost. The Government may, if it determines that the estimated construction contract price set forth in this contract is so low that award of a construction contract not in excess of such estimate is improbable, authorize a change in scope or materials as required to reduce the estimated construction cost to an amount within the estimated construction contract price set forth in paragraph (c) below, or the Government may adjust such estimated construction contract price. When bids or proposals are not solicited or are unreasonably delayed, the Government shall prepare an estimate of constructing the design submitted and such estimate shall be used in lieu of bids or proposals to determine compliance with the funding limitation.

(c) The estimated construction contract price for the project described in this contract is $[**] (final negotiated construction price minus contractors cost share).

I.1.3.3. Clauses Applicable to all Option Periods (FFP and CPFF)

FAR Clause 52.227-11

Patent Rights -- Ownership by the Contractor (DEC 2007)

(a) As used in this clause--

"Invention" means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

"Made" means—

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or
(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

"Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

"Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system

and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject invention” means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor’s rights.

(1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License.

(i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor’s license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor’s business to which the invention pertains.

(ii) The Contractor’s license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor’s obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within [**] after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within [**] of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than [**] prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within [**] after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within [**] of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either [**] of the first filed patent application (whether provisional or nonprovisional) or [**] from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within [**] after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipts of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than [**] before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention."

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than [**] on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured

substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor’s licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary’s review discloses that the Contractor could take reasonable

steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. Shall be addressed to the Contracting Officer.

(k) Subcontracts.

(1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

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

HHSAR CLAUSE	***TITLE***	***DATE***
352.201-70	Paperwork Reduction Act	JAN 2006
352.202-1	Definitions	JAN 2006
352.203-70	Anti-Lobbying	MAR 2012
352.216-70	Additional Cost Principles	JAN 2006
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	JAN 2010
352.223-70	Safety and Health	JAN 2006
352.224-70	Privacy Act	JAN 2006
352.227-70	Publications and Publicity	JAN 2006
352.228-7	Insurance - Liability to Third Persons	DEC 1991
352.231-70	Salary Rate Limitation	MAR 2012
352.231-71	Pricing of Adjustments -	JAN 2001
352.233-71	Litigation and Claims	JAN 2006
352.242-70	Key Personnel MJ/v >	JAN 2006
352.242-73	Withholding of Contract Payments	JAN 2006
352.242-74	Final Decisions on Audit Findings	APR 1984

SECTION J - LIST OF ATTACHMENTS

Attachment #	Title	Pages
1	Definitions	1
2	Core Services Matrix	1
3	Disclosure of Lobbying Activities	2
4	Points of Contact	1
5	Small Business Subcontracting Plan, dated April 13, 2012	18
6	Invoice/Financing Request Instructions	2
7	Protection of Human Subjects OF310	1
8	Wage Determinations (Service Contract Act & Davis- Bacon Act)	10
9	Contractor’s Technical Proposal, dated April 13,	836

ATTACHMENT #1 (REVISED 6-6-11)
DEFINITIONS

COMMERCIAL ACTIVITY: For the purpose of this contract, commercial activity is defined as all efforts performed by the Contractor that are not specifically supporting the Statement of Work in this contract, including a resulting Task Order or Delivery Order.

FLEXIBLE MANUFACTURING: Flexible manufacturing is the capability to modify equipment, facilities and processes to meet changing requirements. It could include disposables, modular skids, etc.

NEW FACILITY: A new facility (new construction) would be a greenfield site or a new building constructed on an existing campus.

RETROFITTED FACILITY: A retrofitted facility (renovated) would involve an existing pharmaceutical structure requiring modifications to architecture, equipment, piping, HVAC, etc. to meet the stated requirements.

US-BASED: US-based is defined as within the United States of America and its territories and possessions.

SUCCESSFUL INITIATION OF PHASE I TRIAL: A successful initiation of a Phase I trial would be at the point where the first patient has been placed on the study.

BIOPHARMACEUTICALS: Biopharmaceutical is defined as vaccines and other therapeutic biologies manufactured by biotechnology methods involving live organisms/bio-processing [e.g. vaccines, monoclonal antibodies, rDNA proteins] that would be regulated by the FDA.

AVAILABLE TO THE USG: Doses of pandemic influenza vaccine will be considered “available to the USG” after completion of internal quality release by the manufacturer and completion of final packaging and movement into the distribution system under manufacturers control, so that the doses are ready to ship upon CBER release.

PRINCIPAL INVESTIGATOR (PI): For the purpose of this solicitation and resulting contract awards, the PI shall be an officer, director, owner, partner, or a person having primary management or supervisory responsibilities that is duly and legally authorized to represent and speak on behalf of the prime contractor and has overarching leadership to direct personnel in executing all aspects of the statement of work in an efficient and effective manner. The PI will be the main contact with HHS regarding all scientific, process and technology related issues.

PROJECT MANAGER (PM): For the purpose of this solicitation and resulting contract awards, the PM shall be a person having primary management or supervisory responsibilities that is duly and legally authorized to represent and speak on behalf of the prime contractor. The PM will be the main contact with HHS regarding all scheduling, deliverables and other business-related aspects of the contract.

UNENCUMBERED ACCESS: Unencumbered Access is defined as a means of entering, visiting, using, and exiting without being obstructed.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.2

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00019	See Block 16C		

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA 330 Independence Ave, SW, Rm G640 Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445	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 electronic communication 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 letter or electronic communication, provided each letter or electronic communication 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 data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: MUTUAL AGREEMENT OF THE PARTIES.
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return ____1____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to: (1) include language on contract minimum and maximum; (2) include language on order limitations during Presidential declared national emergencies; and (3) include “Additional CIADM Requirements.”

See attached.

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*.		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) [**]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
sean m kirk *(Signature of person authorized to sign)*	05/25/2020	[**] -S *(Signature of Contracting Officer)*	05/25/2020

Previous edition unusable STANDARD FORM 30 (Rev. 11/2016)

Prescribed by GSA FAR (48 CFR) 53.243

On the effective date of this modification, Contract Number HHSO100201200004I is modified as follows:

SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS is modified to include the following:

B.4. This is a Multiple Award Indefinite Quantity contract as contemplated by FAR 16.504. The total minimum quantity of services the Government will acquire under the contract has been satisfied. The total maximum quantity of services the Government may acquire under the contract is $1,733,653,347.02.

Paragraph **B.2.3 Minimum and Maximum Ordering Limitations and Ceiling Limitations** is modified to include the following:

B.2.3.1.5. The above Ordering Limitations are not applicable to requirements issued in response to a Presidential declared national emergency under the National Emergencies Act (50 U.S.C. 1601 et seq.).

SECTION H—Special Contract Requirements is modified to include the following:

H.27. Additional CIADM Requirements

As provided in Section C.2.1, the purpose of the CIADM is to expand domestic biopharmaceutical (vaccines and other CBRN biologic MCMs) production capacity for advanced development at pilot and commercial scale to augment existing manufacturing infrastructure. This purpose includes the capability to incorporate emerging and innovative technologies that could be applied to current or future USG MCM development efforts to reduce risk, increase yield, and/or reduce total life cycle costs.

Contractor and Government acknowledge that additional biopharmaceutical manufacturing capabilities, including additional manufacturing facilities, may be required to effectuate the purpose of this contract. When such needs arise, Contractor and Government shall negotiate and agree upon a defined scope of work and estimated costs. As a result, this contract may be bilaterally modified from time to time and task orders may be issued as may be required to incorporate such changes.

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.3

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00020	05/02/2020		

6. ISSUED BY CODE	ASPR-BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR-BARDA02
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		ASPR-BARDA 330 Independence Ave, SW, Rm G640 Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824			9B. DATED *(SEE ITEM 11)*
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I
			10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445	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 electronic communication 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 letter or electronic communication, provided each letter or electronic communication 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 data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: MUTUAL AGREEMENT OF THE PARTIES.
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return ____1____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to align the language of Section B.2.4 section of the contract with the requirements of FAF 16.505.

See attached.

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*.		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
Sean M. Kirk EVP, Manufacturing and Tech Ops		[**]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ sean m kirk *(Signature of person authorized to sign)*	5/26/20	[**] -S *(Signature of Contracting Officer)*	

Previous edition unusable STANDARD FORM 30 (Rev. 11/2016)

Prescribed by GSA FAR (48 CFR) 53.243

On the effective date of this modification, Contract Number HHSO100201200004I is modified as follows:

Paragraph **B.2.4 Fair Opportunity Ordering (for Core Services, Warm Base Vaccine Production, and Pandemic Influenza Vaccine Production)** is superseded by the following:

B.2.4 Fair Opportunity Ordering (for Core Services, Warm Base Vaccine Production, and Pandemic Influenza Vaccine Production)

In accordance with FAR 16.505, Ordering, the following procedures will be used to issue orders under the contract:

All work under this contract will be ordered through the issuance of written "Task Order(s)" and "Delivery Order(s)" on an Optional Form 347 executed by the Contracting Officer. The Contracting Officer is the only individual authorized to issue orders under this contract. The Contractor shall only commence work upon receipt of a properly awarded written order executed by the Contracting Officer.

For orders exceeding $3,500 (see FAR 16.505(b)(1)(i)), the Government will provide each awardee a fair opportunity to be considered for task order award unless an exception exists (see FAR 16.505(b)(2)) and is justified in writing and approved (see FAR 16.505(b)(2)(ii)).

Unless an exception to the fair opportunity process exists (see FAR 16.505(b)(i)) and the exception is justified in writing and approved (see FAR 16.505)(b)(2)(ii)), for orders exceeding the simplified acquisition threshold (see FAR 16.505(b)(1)(iii)), the Government will (A) provide a fair notice of the intent to make a purchase, including a clear description of the supplies to be delivered or the services to be performed and the basis upon which the selection will be made to all contractors offering the required supplies or services under the multiple-award contract; and (B) Afford all contractors responding to the notice a fair opportunity to submit an offeror and have that offer fairly considered.

Unless an exception to the fair opportunity process exists (see FAR 16.505(b)(i)) and the exception is justified in writing and approved (see FAR 16.505)(b)(2)(ii)), for orders over $5.5 million (see FAR 16.505(b)(1)(iii)), the requirement to provide all awardees a fair opportunity to be considered for each order shall include, at a minimum— (A) A notice of the task or delivery order that includes a clear statement of the agency's requirements; (B) A reasonable response period; (D) Disclosure of the significant factors and sub-factors, including cost or price, that the agency expects to consider in evaluating proposals, and their relative importance; (D) Where award is made on a best value basis, a written statement documenting the basis for award and the relative importance of quality and price or cost factors; and (E) An opportunity for a post-award debriefing in accordance with paragraph (b)(4) of this section.

Fair opportunity to be considered for each order will be accomplished by the Contracting Officer issuing a Task/Delivery Order Request (T/DOR) to establish an adequate basis for fair opportunity consideration of placement of that order. The Contracting Officer may issue T/DOR to fewer than all contract-holders. However, this will only occur if the other contract-holders have not obtained the proper validation for their facility. AT/DOR will be issued either in a written format that either has been executed by the Contacting Officer or set via electronic mail directly from the Contracting Officer. A review pursuant to this subparagraph will be deemed adequate for fair opportunity consideration.

Fair opportunity is not required if an exception to the fair opportunity process exists (see FAR 16.505(b)(2)(i)) and the exception is justified in writing and approved (see FAR 16.505(b)(2)(ii)).

A T/DOR may provide a Statement of Objectives or Statement of Work, order-specific factors to be used in the selection decision, reporting requirements, deliverables and delivery schedule, and any special instructions or terms applicable to the order. Selection factors for award will be specific for each individual order.

A T/DOR will request a written proposal to be prepared and submitted by the contract-holder to the Contracting Officer. The Contracting Officer will use the T/DOR proposal as one basis, or the sole basis, for the order placement decision. The T/DOR will set forth the specific requirements or objectives for the proposal. Information that may be requested includes, but is not limited to, an approach to perform the work, technical and managerial resources, and schedule for performance identifying major milestones, conflict-of-interest certification, and price/cost itemized by price/cost elements. Unless otherwise specified in a T/DOR, a contract holder shall prepare and deliver a proposal within the timeframe stipulated in the T/DOR in order to receive consideration.

Orders placed hereunder will be executed on an OF347 and will, at a minimum, contain the following information:

Date of order
Contract number and order number
Description of services, contract item number(s) and description, quantity, and price
Delivery or performance schedule
Place of delivery or performance (including consignee)

Any packaging, packing, and shipping instructions
Accounting and appropriation data
Delegation of a Task/Delivery Order COR, if applicable

Ombudsman: the name, address, telephone number, facsimile number, an e-mail address of the agency task and delivery order ombudsman is available upon request to the Contracting Officer.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.4

ORDER FOR SUPPLIES OR SERVICES | PAGE OF PAGES 1 | 18

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER	2. CONTRACT NO. *(if any)*
05/24/2020	HHSO1002012000004I

3. ORDER NO.	4. REQUISITION/REFERENCE NO.
75A50120F33007	OS258575

5. ISSUING OFFICE *(Address correspondence to)*

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. SHIP TO

a. NAME OF CONSIGNEE

HHS/OS/ASPR

b. STREET ADDRESS

200 C St SW
Washington DC 20201

c. CITY	d. STATE	e. ZIP CODE
WASHINGTON	DC	20201

7. TO:

a. NAME OF CONTRACTOR

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC

b. COMPANY NAME

c. STREET ADDRESS

EMERGENT MANUFACTURING OPERATIONS B
5901 E LOMBARD ST

d. CITY	e. STATE	f. ZIP CODE
BALTIMORE	MD	212246824

f. SHIP VIA

8. TYPE OF ORDER

☐ a. PURCHASE
REFERENCE YOUR:

x b. DELIVERY

Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

9. ACCOUNTING AND APPROPRIATION DATA	10. REQUISITIONING OFFICE
2020.199C001.25103	BARDA

11. BUSINESS CLASSIFICATION *(Check appropriate box(es))*

☐ a. SMALL x b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ☐ h. EDWOSB
VETERAN-OWNED ELIGIBLE UNDER THE WOSB PROGRAM

12. F.O.B. POINT

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION	b. ACCEPTANCE		Multiple	
Destination	Destination			

17. SCHEDULE *(See reverse for Rejections)*

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: [**] DUNS Number: [**] Task Order Title: “Emergent CIADM Manufacturing Capacity Reservation and Expansion” Continued . . .					

18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.		17(h) TOTAL *(Cont. pages)*
			$628,250,000.00	

21. MAIL INVOICE TO:

a. NAME
PSC/FMS

SEE BILLING INSTRUCTIONS ON REVERSE

b. STREET ADDRESS PSC_invoices@psc.hhs.gov
(or P.O.Box)

c. CITY	d. STATE	e. ZIP CODE		17(i) GRAND TOTAL
			$628,250,000.00	

22. UNITED STATES OF AMERICA BY *(Signature)*	23. NAME *(Typed)*
[**] -S	[**] TITLE: CONTRACTING/ORDERING OFFICER

AUTHORIZED FOR LOCAL REPRODUCTION **OPTIONAL FORM 347** (Rev.. 2/2012)
PREVIOUS EDITION NOT USABLE Prescribed by GSA/FAR 48 CFR 53.213(f)

ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION	PAGE NO 2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
05/24/2020	HHSO100201200004I	75A50120F33007

ITEM No. (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	See attached Appr. Yr.: 2020 CAN: 199C001 Object Class: 25103 Period of Performance: 05/13/2020 to 12/31/2021					
1	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (1 of 3) Delivery: 12/31/2021				[**]	
2	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (2 of 3) Delivery: 12/31/2021				[**]	
3	ASPR-20-02178 -- Emergent CIADM Manufacturing Capacity Reservation and Expansion (3 of 3) Delivery 12/31/2021 The total amount of award: $628,250,000.00. The obligation for this award is shown in box 17(i) Contractor to sign below:				[**]	
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))			w	$628,250,000.00	

B. COST / PRICE SCHEDULE

B.1 Prices

B.1.1 The total fixed price of this task order (sum of Task 1 and Task 2) is $628,250,000.

B.1.2 The total fixed price of Task 1: Capacity Reservation is $542,750,000.

B.1.3 The total fixed price of Task 2: Pharmaceutical Manufacturing Capacity Expansion is $85,500,000.

B.2 Task 1 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.1 Task 1: Capacity Reservation** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

Item Description	Reporting Period	Due Date	Unit Price
Monthly Report #1	05/13/2020 – 05/31/2020	06/15/2020	$27,137,500
Monthly Report #2	06/01/2020 – 06/30/2020	07/15/2020	$27,137,500
Monthly Report #3	07/01/2020 – 07/31/2020	08/15/2020	$27,137,500
Monthly Report #4	08/01/2020 – 08/31/2020	09/15/2020	$27,137,500
Monthly Report #5	09/01/2020 – 09/30/2020	10/15/2020	$27,137,500
Monthly Report #6	10/01/2020 – 10/31/2020	11/15/2020	$27,137,500
Monthly Report #7	11/01/2020 – 11/30/2020	12/15/2020	$27,137,500
Monthly Report #8	12/01/2020 – 12/31/2020	01/15/2021	$27,137,500
Monthly Report #9	01/01/2021 – 01/31/2021	02/15/2021	$27,137,500
Monthly Report #10	02/01/2021 – 02/28/2021	03/15/2021	$27,137,500
Monthly Report #11	03/01/2021 – 03/31/2021	04/15/2021	$27,137,500
Monthly Report #12	04/01/2021 – 04/30/2021	05/15/2021	$27,137,500
Monthly Report #13	05/01/2021 – 05/31/2021	06/15/2021	$27,137,500
Monthly Report #14	06/01/2021 – 06/30/2021	07/15/2021	$27,137,500
Monthly Report #15	07/01/2021 – 07/31/2021	08/15/2021	$27,137,500
Monthly Report #16	08/01/2021 – 08/31/2021	09/15/2021	$27,137,500
Monthly Report #17	09/01/2021 – 09/30/2021	10/15/2021	$27,137,500
Monthly Report #18	10/01/2021 – 10/31/2021	11/15/2021	$27,137,500
Monthly Report #19	11/01/2021 – 11/30/2021	12/15/2021	$27,137,500
Monthly Report #20	12/01/2021 – 12/31/2021	12/31/2021	$27,137,500
		Total =	$542,750,000

B.3 Task 2 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

Item Description	Due Date	Unit Price
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
	Total =	$85,500,000

C. SCOPE OF WORK

C.1 Project Background

BARDA established a Center for Innovation in Advanced Development and Manufacturing (CIADM) with a subsidiary of Emergent BioSolutions Inc. (including all of its subsidiaries, "Emergent"), as a public-private partnership to ensure domestic vaccine manufacturing surge capacity to address national preparedness and response priorities. HHS/BARDA requires the services of Emergent to provide core advanced development ("industrialization") and manufacturing services to other commercial partners under contract to the U.S. Government (USG) for development of biopharmaceuticals against public health threats. Additionally, HHS/BARDA requires Emergent to provide manufacturing facilities utilizing flexible manufacturing and modem platform technologies to produce vaccines for outbreaks of an emerging infectious pathogens.

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("the virus") was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the President's Operation Warp Speed Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of

COVID-19 vaccine candidates to maximize probability of having one or more safe and effective vaccines as fast as possible for mass distribution. As such, it is a national security concern to quickly make available safe and effective COVID-19 vaccines. To this end, BARDA must reserve existing manufacturing capacity and expand manufacturing capacity in order to ensure adequate domestic capabilities are established and ready.

C.2 Objectives

The objective of this task order is to expand the public-private partnership with Emergent to reserve and expand the capacities and capabilities at Contractor's CIADM facility, and its affiliated Camden, MD and Rockville, MD facilities.

C.3 Tasks

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the tasks described below and in Attachment 1 – Contractor Capacity and Pricing.

C.3.1 Task 1: Capacity Reservation

The Contractor shall reserve drug substance and drug product manufacturing capacity at the contractor's Bayview CIADM, Camden, MD, and Rockville, MD facilities for the exclusive use of the USG for the duration of the period of performance. The Contractor's facilities shall have the capability of producing the number of batches specified as follows in each applicable calendar month. In the event the Contractor is not tasked with producing batches in a given month, the capacity shall lapse and the unused batch production capacity cannot be allocated to a future period. Specifically, the areas to be reserved and number of batches over the period of performance associated with each area under the reservation, shall be as follows (number of batches is based upon a generic manufacturing process):

Area Description	Estimated Monthly Number of Batches	Total Number of Vials for Full Period of Performance
Bayview CIADM Area [**] Drug Substance	[**]	[**]
Bayview CIADM Area [**] Drug Substance	[**]	[**]
Camden, MD Fill/Finish Line [**]	[**]	[**]
Camden, MD Fill/Finish Line [**]	[**]	[**]
Camden, MD Fill/Finish Line New	[**]	[**]
Rockville, MD Fill/Finish Line Existing	[**]	[**]
Rockville, MD Fill/Finish Line New	[**]	[**]

Bayview CIADM, Baltimore, MD Facility

The reservation fee per batch for drug substance at Bayview shall include the space and manufacturing activities from batch record preparation through manufacturing execution, including batch readiness activities, labor, and available equipment to produce one batch. Reservation fee does not include tech transfer, process and analytical development, process development, raw materials and lot release testing of a batch; these costs will be paid for under separate product development task orders/contracts/agreements. When the reserved capacity is utilized for manufacturing drug substance on behalf of the government, the contractor will credit the reservation fee according to the table in Section B to the manufacturing of the batch in the specific area. The government will be responsible for any cost difference between the applied reservation fee and the actual cost of performing the manufacturing of the batch.

Camden, MD and Rockville, MD Facilities

The reservation fee per batch of drug product at Camden and Rockville, MD facilities shall include the space and manufacturing activities from batch record preparation through manufacturing execution, including batch readiness activities, labor, and available equipment to produce one batch. Reservation fee does not include tech transfer, process and analytical development, process development, raw materials and lot release testing of a batch; these costs will be paid for under separate product development task orders/contracts/agreements. When the reserved capacity is utilized for manufacturing drug product on behalf of the government, the contractor will credit the reservation fee according to the table in Section B to the manufacturing of the batch in the specific area. The government will be responsible for any cost difference between the

applied reservation fee and the actual cost of performing the manufacturing of the batch.

The contractor shall maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities, approved by the USG, under separate task orders/contracts/agreements for the entirety of the period of performance. If no manufacturing occurs in reserved capacities, the fees paid to contractor will cover reservation activities for that specific reserved capacity.

On a monthly basis, the contractor shall provide a monthly report that includes capacity availability and utilization or non-utilization, as well as any issues that impact the operational availability of the reserved capacity.

C.3.2 Task 2: Pharmaceutical Manufacturing Capacity Expansion

The contractor shall expand its existing capacities and capabilities in drug product manufacturing on an accelerated timeline. Specifically, the contractor shall establish a fill/finish manufacturing line at the contractor's Camden, MD facility that is capable of filling approximately [**] vials per batch based on vial specifications. The contractor will use it reasonable best efforts to ensure the expanded capacity at the Camden facility will be operational for at-risk manufacturing no later than [**]. The contractor shall also establish a fill/finish manufacturing line at the contractor's Rockville, MD facility capable of filling approximately [**] vials per batch based on vial specifications. The contractor will use its reasonable best efforts to ensure the expanded capacity at the Rockville facility will be operational for at-risk manufacturing no later than [**]. Both of the new capacities must be designed to be in compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211) or agreed upon at-risk manufacturing state. The Rockville facility must be able to manufacture drug product from viral drug substance. The contractor shall be responsible for management of all activities, subcontractors, etc. to meet the goals of the Task Order, including holding routine meetings with BARDA, and completion of meeting minutes. BARDA will assist in facilitating appropriate discussions with the FDA.

As a firm-fixed price arrangement, it is expected that all property acquired under this task order will be owned by contractor. To the extent any Contractor Acquired Property is deemed to be owned by the Government, such property shall transfer to the contractor upon completion of the applicable CLIN. In consideration for the government's funding for this capacity expansion, the contractor agrees to provide the government priority access to the new fill/finish lines for the period of performance. The contractor also agrees to fund any/all sustainment costs associated with maintaining the equipment/infrastructure paid for by the government.

This maintenance includes compliance with FDA current good manufacturing practices (cGMP) regulations (21 CFR parts 210 and 211).

On a monthly basis, the contractor shall provide a monthly report that includes progress in establishing the expanded drug product capacities at the Camden and Rockville facilities, including updates to the IMS.

D. PACKAGING AND MARKING

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

E. INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the CIADM's facility or approved subcontractor facility, by the Contracting Officer or the duly authorized representative of the Government.

The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this task order.

F. PERFORMANCE / DELIVERABLES

F.1 Period of Performance

The period of performance of this task order shall be from May 13, 2020 through December 31, 2021.

F.2 Deliverable Requirements

F.2.1 Manufacturing Schedule with Allocated Capacity through Period of Performance

A Manufacturing Schedule shall be provided quarterly that includes the utilization and non-utilization of the reserved manufacturing capacities (Bayview Areas [**]; Camden fill/finish lines [**] and the new line; and Rockville existing and new fill/finish lines). The schedule shall include:

- Length of time for manufacturing in each area

•Name of the teaming partner (i.e. [**], etc)

•Vaccine/product technical information (i.e. cell line expression system, live viral, subunit, etc.)

•Batch Size or Scale

•Number of batches

F.2.2 Integrated Master Schedule (IMS) for Camden and Rockville New Fill/Finish Lines

The Fill/Finish IMS shall include the time-phased activities to completely execute the Fill/Finish CWBS. Microsoft Project compatible file required and will result in a Gantt Chart for project tracking. The IMS will document the delivery date for each deliverable, critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships, and will be directly traceable to the SOW and the WBS to a minimum of a level [**].

F.2.3 Work Breakdown Structure (WBS) for Camden and Rockville New Fill/Finish Lines

The WBS shall extend to elements to completely define the entire effort proposed to establish the fill/finish capability as described in the SOW. The WBS shall be to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of a level [**].

F.2.4 Validation Master Plan (VMP)

The VMP shall include a list of the Standard Operating Procedures that will be used in the commissioning, qualification and validation (CQV) of the Camden and Rockville new fill/finish areas. The VMP shall also include a list of the equipment and facilities' systems and extent of their CQV (i.e. Commissioning, Facility Acceptance Testing, Site Acceptance Testing, Installation Qualification, Operational Qualification, Performance Qualification, etc.).

F.2.5 Monthly Report

Each monthly report must include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. Specific to Task 1, each monthly report must include a summary of capacity availability and utilization / non-utilization, as well as any issues that impact the operational availability of the reserved capacity. Specific to Task 2, each monthly report must include a summary of the progress in establishing the expanded drug product capacities at the Camden and Rockville facilities, including updates to IMS.

F.3 Schedule of Deliverables

Satisfactory performance of the task order shall be deemed to occur upon performance of the work described in **SECTION C** of this task order and upon delivery and acceptance of the following items.

Item	Task	Deliverable	Delivery Method	Due Date
1	1	Manufacturing Schedule with Allocated Capacity through Period of Performance	Electronically to CO and COR	[**] after TO award; every [**] thereafter
2	2	Integrated Master Schedule	Electronically to CO and COR	[**]
3	2	Work Breakdown Structure	Electronically to CO and COR	[**]
4	2	Validation Master Plan	Electronically to CO and COR	[**]
5	1 & 2	Monthly Report	Electronically to CO and COR	[**] day of every month throughout the task order period of performance

F.4 Meeting Requirements

F.4.1 Routine Update Teleconferences

The Contractor shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the Contractor and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held [**]. The Contractor is responsible for securing a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within [**] after each teleconference, or as otherwise authorized by the Contracting Officer.

F.4.2 Person-in-Plant

Contractor shall accommodate up to [**] BARDA personnel at an agreed upon time throughout the performance of this task order. On-site BARDA personnel will provide support of the work and technical consultation in alignment with Contractor and per guidance from the BARDA program office in Washington, D.C.

F.4.3 Periodic Site Visits

The Contractor shall accommodate for periodic site visits by BARDA on an ad hoc basis or as agreed upon, with at least [**] prior written notice. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the CO.

F.4.4 Quarterly Site Visits

The Contractor shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the Contractor's site on a quarterly basis. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within [**] after each site visit, or as otherwise authorized by the CO.

F.4.5 Kick-Off Meeting

The Contractor shall participate in a kick-off meeting, within [**] of task order award; content, format, and location to be determined by the USG and the Contractor. The Contractor is responsible for securing a physical location or a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after the meeting is held, or as otherwise authorized by the Contracting Officer.

G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The following CO will represent the Government for the purpose of this Contract:

[**]

The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, or other stipulations of this Contract.

The CO is the only person with the authority to act as agent of the Government under this contract. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this Contract; and (5) 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 CO, which may be received from any person employed by the Government, or otherwise, shall be considered grounds for deviation from any stipulation of this Contract.

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2 Contracting Officer's Representative

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

[**]

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

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

G.3 Key Personnel

Key personnel specified in this task order are considered to be essential to work performance. At least [**] prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement, and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than [**] notice, the Contractor shall provide the

maximum notice practicable under the circumstances. The Contractor shall not divert, replace or announce any such change to key personnel without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The task order will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel.

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

G.4 Invoicing Instructions

Invoices for payment shall be submitted electronically and shall include an SF-1034 and all supporting documentation.

G.5 Evaluation of Contractor Performance

Purpose: In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

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

Performance Evaluation Factors: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

Contractor Review: A copy of the evaluation will be electronically sent 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 [**] after receipt of the evaluation.

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.

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.

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.

Retention Period: The agency will retain past performance information for a maximum period of [**] after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL REQUIREMENTS

H.1 Advance Understandings

H.1.1 The Government recognizes that Contractor's operations are essential as a matter of national security and, as such, Contractor is directed to maintain operations to the extent practicable regardless of state or local restrictions to the contrary. In addition, all Contractor employees, independent contractors, and subcontractors are considered essential personnel supporting critical infrastructure as set forth in DHS CISA Memorandum dated March 19, 2020.

H.1.2 Government confirms that all activities conducted by Contractor, any independent contractors and subcontractors under the task order as well as all general operations necessary to ensure execution of activities under the task order are subject to that certain declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) issued by the Secretary of Health and Human Services on March 10, 2020.

H.1.3 Government reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System. Emergent BioSolutions agrees that the Government's right to exercise priorities and allocations authority with respect to this order, to include the use of directives in accordance with 45

CFR Part 101, Subpart A—Health Resources Priorities and Allocations System, constitutes a no-cost change to this order.

H.1.4 Contractor will act as the Contract Development Manufacturing Organization (CDMO) for priority targets as determined by the Government and the scope will encompass Drug Substance and Drug Product within above network.

H.1.5 Upon approval of a direct relationship between Contractor and priority target, the Government will release the associated capacity to Contractor to deploy and contract with identified by the Government.

H.1.6 Contractor will negotiate pricing with the identified party for full scope of activities including manufacturing and raw materials.

H.1.7 Contractor may retain a reasonable quantity of vaccine manufactured at is facilities, not to exceed [**] courses of therapy, to vaccinate Contractor's employees and critical subcontractors, and their respective immediate families. Any such retained product will be at the Contractor's cost.

H.2 Intellectual Property

Execution of a subsequent task order for utilization of capacity reserved under this task order may require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the "MCM IP Holder"), and the firm providing the Core Services under the task order (the "CIADM"). The relationship must reflect the Parties' rights to all IP developed and/or IP used in performance of the task order, and be consistent with HHS' IP rights per the Federal Acquisition Regulations (FAR) clauses described in the base contract. Prior to any performance of work, the MCM IP Holder and/or the CIADM shall provide the Contracting Officer with a written description of all IP necessary to develop (the "Description"). The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in performance of the task order. The Description shall also include written verification of the rights provided to HHS to any and all IP utilized or developed during performance of the task order as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of the task order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the "FAR Clauses").

The MCM IP Holder and the CIADM will remain free to negotiate any agreement of their own regarding their use of any of the IP utilized or developed during performance of an task order, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under the

task order. The agreement shall be furnished to the Contracting Officer within [**] after the agreement is finalized. In addition, this task order incorporates FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

H.3 Consultants and Sub-Contractors

As a commercial-item, firm fixed price arrangement, BARDA acknowledges that Contracting Officer authorization is not required for use of subcontractors or consultants.

H.4 Non-Personal Services and Inherently Governmental Functions

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

I. CONTRACT CLAUSES

Only the clauses incorporated in the base contract that are applicable to fixed price contracts and task orders (i.e., 52.212-4 – Contract Terms & Conditions – Commercial Items) are in full effect at the task order level. This section or other parts of this TO may incorporate 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. In addition, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/.

J. ATTACHMENTS

Attachment 1 – Contractor Capacity and Pricing

Attachment 1 – Contractor Capacity and Pricing

Emergent CIADM Manufacturing Capacity Reservation and Expansion

The Government secures the below capacity at the specified pricing:

1. Drug Substance – Baltimore, MD (Bayview – CIADM)
    a. [**]
        i. Estimated timeframe: [**] in total, [**] through [**]
        ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches
        iii. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
    b. [**]
        i. Estimated timeframe: [**] in total, [**] through [**]
        ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches
        iii. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
    c. Total for Drug Substance: $[**] (excluding raw materials)

2. Drug Product – Baltimore, MD (Camden)
    a. Existing Line [**] vials / batch)
        i. Estimated timeframe: [**] in total, [**] through [**]
        ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches, [**] units
        iii. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s)

selected, but these would be passed through to the Government at Contractor's cost.

b. Existing Line [**] vials / batch)
    i. Estimated timeframe: [**] in total, [**] through [**]
    ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches, [**] units
    iii. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
c. New Line ([**] vials / batch)
    i. Estimated timeframe: [**] in total, [**] through [**]
    ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches, [**] units
    iii. Estimated CAPEX Acceleration Fee: $[**] (best estimate, actual numbers may vary)
    iv. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
d. Total for Drug Product: $[**] (excluding raw materials) + Capex Acceleration of approximately $[**]

3. Drug Product – Rockville, MD
    a. Existing Line ([**] vials / batch)
        i. Estimated timeframe: [**] in total, [**] through [**]
        ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches, [**] units
        iii. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

b. New Line ([**] vials / batch)
    i. Estimated timeframe: [**] in total, [**] through [**]
    ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc): up to [**] batches, [**] units
    iii. Estimated CAPEX Installation / Acceleration Fee: $[**] (best estimate, actual numbers may vary)
    iv. Estimated pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
c. Total for Drug Product: $[**] (excluding raw materials) + Capex Installation / Acceleration of approximately $[**]

4. Total Value for Drug Substance and Drug Product Capacity Commitment & Manufacturing: $542.75 million, excluding raw materials

5. Total Value for Capex: approximately $85.5M (best estimate, actual numbers may vary)

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.5

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	See Block 16C	OS259039	

6. ISSUED BY CODE	ASPR/SNS	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR/SNS
ASPR/SNS ASPR/SNS 2945 FLOWERS ROAD ATLANTA, GA 30341		US DEPT OF HEALTH & HUMAN SERVICES ASPR/SNS 2945 FlOWERS ROAD ATLANTA, GA 30341	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. Attn: STEVE RAMBO EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR GAITHERSBURG MD 208793419			9B. DATED *(SEE ITEM 11)*
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50119C00071
			10B. DATED *(SEE ITEM 13)* 08/30/2019
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 electronic communication 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 letter or electronic communication, provided each letter or electronic communication 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)* Net Increase: $176,293,094.00
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 data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR Clause 52.217-9 Option to Extend the Term of the Contract (Mar 2000)
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not, is required to sign this document and return ____1____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*
Tax ID Number: [**]
DUNS Number: [**]
ACAM2000, Smallpox (Vaccinia) Vaccine, Live (ACAM)
Period of Performance: 10/01/19 – 12/31/20

Add Item 2 as follows:

2 Option 1001 – Task 1 [**]
Warm based manufacturing delivery for ACAM2000
Vaccine
Continued …

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)*. Adam R. Havey		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) [**]	
15B. CONTRACTOR/OFFEROR /s/ Adam R. Havey *(Signature of person authorized to sign)*	15C. DATE SIGNED May 28, 2020	16B. UNITED STATES OF AMERICA [**] -S *(Signature of Contracting Officer)*	16C. DATE SIGNED May 28, 2020

Previous edition unusable STANDARD FORM 30 (Rev. 11/2016)

Prescribed by GSA FAR (48 CFR) 53.243

CONTINUATION	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE OF

NAME OF OFFEROR OR CONTRACTOR

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC. 1365869

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	[**] Doses @ $[**] dose =$[**] Obligated Amount: $[**] Accounting Info: 2020.199SN20.26088 Appr. Yr.: 2020 CAN: 199SN20 Object Class: 26088 Funded: $[**]				
3	Add Item 3 as follows: Option 1001 – Task 4 Relabeling of ACAM2000 1 JOB @ $[**] = $[**] Obligated Amount: $[**] Accounting Info: 2020.199SN20.25235 Appr. Yr.: 2020 CAN: 199SN20 Object Class: 25235 Funded: $[**] <u>Delivery Location</u>: [**]				[**]

EXHIBIT 31.1

CERTIFICATION

I, Robert G. Kramer, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: July 31, 2020

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

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl, 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: July 31, 2020

/s/RICHARD S. LINDAHL
Richard S. Lindahl
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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert G. Kramer, 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: July 31, 2020

/s/ROBERT G. KRAMER
Robert G. Kramer
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 June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, 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: July 31, 2020

/s/RICHARD S. LINDAHL
Richard S. Lindahl
Chief Financial Officer