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, 2021**

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 23, 2021 the registrant had 53,700,729 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 continued 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 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);
- our ability to negotiate follow-on procurement contracts for AV7909 and other follow-on procurement contracts for our PHT products that have expired or will be expiring;
- the impact on our revenues from the hold of certain COVID-19 vaccine bulk drug substance lots pending further review by the FDA;
- Our ability to meet our commitments to continued quality and manufacturing compliance at our Baltimore Bayview facility and the potential impact on our ability to continue production of bulk drug substance for Johnson & Johnson's COVID-19 vaccine at the facility;
- the availability of U.S. government (USG) funding for procurement of our products and certain product candidates;
- 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 (CDMO) services for the development and/or manufacture of product candidates of our customers at required levels and on required timelines;
- 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;
- changes to USG priorities for the strategic national stockpile (SNS) and the future exercise of all remaining options under our contract for the procurement of ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) and other government procurement contracts;
- the negotiation of further commitments or contracts related to the collaboration and deployment of capacity toward future commercial manufacturing under our CDMO contracts;
- the timing of our submission of an application for and our ability to secure licensure of AV7909 from the FDA within the anticipated timeframe, if at all;
- our ability to successfully appeal the patent litigation decision related to NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray, and the impact of competition from potential generic and branded naloxone entrants on NARCAN® Nasal Spray;
- the results of pending shareholder litigation and potential impact on our business;
- our ability to develop a safe and effective treatment for COVID-19 and obtain authorization for emergency use for or approval of such treatment from the FDA;

- 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 and our 3.875% Senior Unsecured Notes due 2028;
- 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 full impact of COVID-19 disease (COVID-19) on our markets, operations and employees as well as those of our customers and suppliers;
- the impact on our revenues from short-term 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 HCl) 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.

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 447.5	$ 621
Restricted cash	0.2	0
Accounts receivable, net	261.9	230
Inventories, net	386.4	307
Prepaid expenses and other current assets	66.1	36
Total current assets	1,162.1	1,195
Property, plant and equipment, net	743.5	644
Intangible assets, net	633.1	663
Goodwill	266.6	266
Other assets	109.9	113
Total assets	$ 2,915.2	$ 2,883
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 151.8	$ 136
Accrued expenses	33.8	46
Accrued compensation	63.2	84
Debt, current portion	28.8	33
Other current liabilities	100.2	83
Total current liabilities	377.8	384
Contingent consideration, net of current portion	5.0	34
Debt, net of current portion	825.2	841
Deferred tax liability	53.2	53
Contract liabilities, net of current portion	48.9	55
Other liabilities	61.4	67
Total liabilities	1,371.5	1,436
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, 54.9 and 54.3 shares issued; 53.7 and 53.1 shares outstanding, respectively	0.1	0
Additional paid-in capital	804.4	784
Treasury stock, at cost, 1.2 common shares	(39.6)	(39
Accumulated other comprehensive loss, net	(22.4)	(25
Retained earnings	801.2	726
Total stockholders' equity	1,543.7	1,447
Total liabilities and stockholders' equity	$ 2,915.2	$ 2,883

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,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 181.2	$ 298.5	$ 319.1	$ 446
Contract development and manufacturing services	190.9	72.6	374.7	94
Contracts and grants	25.4	23.6	46.7	46
Total revenues	397.5	394.7	740.5	587
Operating expenses:				
Cost of product sales and contract development and manufacturing services	227.8	129.8	327.1	206
Research and development	48.9	47.9	101.4	90
Selling, general and administrative	91.2	76.0	172.1	145
Amortization of intangible assets	15.1	15.0	30.0	29
Total operating expenses	383.0	268.7	630.6	472
Income from operations	14.5	126.0	109.9	114
Other income (expense):				
Interest expense	(8.6)	(6.4)	(17.1)	(15
Other, net	1.3	1.1	(0.4)	-
Total other income (expense), net	(7.3)	(5.3)	(17.5)	(15
Income before income taxes	7.2	120.7	92.4	99
Income taxes	(2.6)	(28.0)	(18.1)	(19
Net income	$ 4.6	$ 92.7	$ 74.3	$ 80
Net income per common share				
Basic	$ 0.09	$ 1.76	$ 1.40	$ 1.5
Diluted	$ 0.09	$ 1.73	$ 1.37	$ 1.5
Shares used in computing income per share				
Basic	53.6	52.6	53.5	52
Diluted	54.0	53.5	54.3	53

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,	
	2021	2020	2021	2020
Net income	$ 4.6	$ 92.7	$ 74.3	$ 80
Other comprehensive income (loss), net of tax:				
Foreign currency translation	0.5	(0.3)	(1.7)	(0
Unrealized gains (losses) on hedging activities	1.5	(0.7)	4.6	(11
Total other comprehensive income (loss)	2.0	(1.0)	2.9	(12
Comprehensive income	$ 6.6	$ 91.7	$ 77.2	$ 67

See accompanying notes.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows (used in) provided by operating activities:		
Net income	$ 74.3	$ 80.2
Adjustments to reconcile to net income to net cash (used in) provided by operating activities:		
Share-based compensation expense	21.9	31.0
Depreciation and amortization	61.9	56.8
Change in fair value of contingent consideration, net	1.7	1.1
Amortization of deferred financing costs	2.0	1.5
Deferred income taxes	(3.2)	(3.7)
Other	2.0	1.1
Changes in operating assets and liabilities:		
Accounts receivable	(34.7)	12.1
Inventories	(79.7)	(13.7)
Prepaid expenses and other assets	(2.4)	(16.9)
Accounts payable	8.0	(14.5)
Accrued expenses and other liabilities	(55.4)	25.0
Accrued compensation	(21.4)	(3.4)
Contract liabilities	0.4	29.1
Net cash (used in) provided by operating activities:	(24.6)	185.7
Cash flows used in investing activities:		
Purchases of property, plant and equipment	(123.1)	(59.3)
Milestone payment from prior asset acquisition	—	(10.0)
Net cash used in investing activities:	(123.1)	(69.3)
Cash flows used in financing activities:		
Principal payments on revolving credit facility	—	(20.0)
Principal payments on term loan facility	(11.3)	(5.6)
Principal payments on convertible senior notes	(10.6)	—
Proceeds from share-based compensation activity	10.0	23.1
Taxes paid for share-based compensation activity	(13.0)	(11.7)
Contingent consideration payments	(1.1)	(1.1)
Net cash used in financing activities:	(26.0)	(15.3)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.1)	(0.1)
Net change in cash, cash equivalents and restricted cash	(173.8)	101.0
Cash, cash equivalents and restricted cash at beginning of period	621.5	168.0
Cash, cash equivalents and restricted cash at end of period	$ 447.7	$ 269.0
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 15.5	$ 11.6
Cash paid during the period for income taxes	$ 50.3	$ 12.2
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 31.7	$ 16.8
Reconciliation of cash and cash equivalent and restricted cash at June 30, 2021 and December 31, 2020:		
Cash and cash equivalents	$ 447.5	$ 621.3
Restricted cash	0.2	0.2
Total	$ 447.7	$ 621.5

See accompanying notes.

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

	$0.001 Par Value Common Stock			Treasury Stock				
	Shares	Amount	Additional Paid-In Capital	Shares	Amount	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equi
Balance at December 31, 2020	54.3	$ 0.1	$ 784.9	(1.2)	$ (39.6)	$ (25.3)	$ 726.9	$ 1,447
Share-based compensation activity	0.6	—	19.5	—	—	—	—	19
Net income	—	—	—	—	—	—	74.3	74
Other comprehensive income (loss)	—	—	—	—	—	2.9	—	2
Balance at June 30, 2021	54.9	$ 0.1	$ 804.4	(1.2)	$ (39.6)	$ (22.4)	$ 801.2	$ 1,543
Balance at March 31, 2021	54.8	$ 0.1	$ 790.1	(1.2)	$ (39.6)	$ (24.4)	$ 796.6	$ 1,522
Share-based compensation activity	0.1	—	14.3	—	—	—	—	14
Net income	—	—	—	—	—	—	4.6	4
Other comprehensive income (loss)	—	—	—	—	—	2.0	—	2
Balance at June 30, 2021	54.9	$ 0.1	$ 804.4	(1.2)	$ (39.6)	$ (22.4)	$ 801.2	$ 1,543
Balance at December 31, 2019	53.0	$ 0.1	$ 716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$ 1,088
Share-based compensation activity	1.1	—	42.4	—	—	—	—	42
Net income	—	—	—	—	—	—	80.2	80
Other comprehensive income (loss)	—	—	—	—	—	(12.3)	—	(12
Balance at June 30, 2020	54.1	$ 0.1	$ 758.5	(1.2)	$ (39.6)	$ (22.2)	$ 502.0	$ 1,198
Balance at March 31, 2020	53.5	$ 0.1	$ 726.2	(1.2)	$ (39.6)	$ (21.2)	$ 409.3	$ 1,074
Share-based compensation activity	0.6	—	32.3	—	—	—	—	32
Net income	—	—	—	—	—	—	92.7	92
Other comprehensive income (loss)	—	—	—	—	—	(1.0)	—	(1
Balance at June 30, 2020	54.1	$ 0.1	$ 758.5	(1.2)	$ (39.6)	$ (22.2)	$ 502.0	$ 1,198

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 with 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"). 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 single-dose oral vaccine licensed by the FDA and the European Medicines Agency (EMA) 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 reduced 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, 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 on 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, 2020, 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, 2021. 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, 2021, 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, 2020, as filed with the SEC.

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) and time deposits (level 2), 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).

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

On a non-recurring basis, the Company measures its long-lived assets as part of impairment evaluations 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 the carrying value of the asset may not be recoverable. 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.

As of June 30, 2021 and December 31, 2020, the Company had no other significant assets or liabilities that were measured at fair value.

Recently issued accounting standards

Recently Adopted

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. As of January 1, 2021, the Company adopted the standard, which did not have a material impact on the Company's consolidated financial statements.

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, which was further amended in January 2021. Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC 848 contains optional expedients and exceptions 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.

3. Inventories, net

The components of inventory are as follows:

	June 30, 2021	December 31, 2020
Raw materials and supplies	$ 174.3	$ 160.6
Work-in-process	141.7	102.5
Finished goods	70.4	43.9
Total inventories, net	$ 386.4	$ 307.0

Inventories, net is stated at the lower of cost or net realizable value. During the three and six months ended June 30, 2021, the Company recorded inventory write-offs at its Bayview facility of $41.5 million. The inventory write-off was due to raw materials and in-process batches at the Bayview facility that the Company plans to discard as they were deemed unusable. The charge was reflected as a component of cost of product sales and contract development and manufacturing services.

4. Property, plant and equipment

Property, plant and equipment consisted of the following:

	June 30, 2021	December 31, 2020
Land and improvements	$ 51.7	$ 52.7
Buildings, building improvements and leasehold improvements	287.3	246.3
Furniture and equipment	437.0	362.1
Software	60.9	58.7
Construction-in-progress	194.3	183.4
Property, plant and equipment, gross	1,031.2	903.2
Accumulated depreciation	(287.7)	(259.1)
Total property, plant and equipment, net	$ 743.5	$ 644.1

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.

The components of lease expense were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating lease cost:				
Amortization of right-of-use assets	$ 1.5	$ 1.0	$ 2.8	$ 2.1
Interest on lease liabilities	0.3	0.3	0.7	0.6
Total operating lease cost	$ 1.8	$ 1.3	$ 3.5	$ 2.7

Operating lease costs are reflected as components of cost of product sales and contract development and manufacturing services, research and development expense and selling, general and administrative expense.

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	Balance Sheet location	June 30, 2021	December 31, 2020
Operating lease right-of-use assets	Other assets	$ 29.6	$ 31.0
Operating lease liabilities, current portion	Other current liabilities	5.7	5.4
Operating lease liabilities	Other liabilities	25.9	27.8
Total operating lease liabilities		$ 31.6	$ 33.2
Operating leases:			
Weighted average remaining lease term (years)		7.7	7.7
Weighted average discount rate		4.0 %	4.1 %

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

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, 2021 and December 31, 2020:

Asset Type	Estimated Life	June 30, 2021 Cost	June 30, 2021 Accumulated Amortization	June 30, 2021 Net	December 31, 2020 Cost	December 31, 2020 Accumulated Amortization	December 31, 2020 Net
Products	9-22 years	$ 798.0	$ 165.6	$ 632.4	$ 798.0	$ 137.8	$ 660.2
Customer relationships	8 years	28.6	28.3	0.3	28.6	26.5	2.1
CDMO	8 years	5.5	5.1	0.4	5.5	4.7	0.8
Total intangible assets		$ 832.1	$ 199.0	$ 633.1	$ 832.1	$ 169.0	$ 663.1

During the six months ended June 30, 2021 and 2020, the Company recorded amortization expense for intangible assets of $30.0 million and $29.8 million, respectively. During the three months ended June 30, 2021 and 2020, the Company recorded amortization expense for intangible assets of $15.1 million and $15.0 million, respectively. As of June 30, 2021, the weighted average amortization period remaining for intangible assets was 12.3 years.

The following table provides a roll forward of changes in our goodwill balance:

Goodwill, December 31, 2020	$ 266.7
Foreign currency translation	(0.1)
Goodwill, June 30, 2021	$ 266.6

7. Fair Value Measurements

The table below presents information about our assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques we utilized to determine fair value:

	June 30, 2021 Total	June 30, 2021 Level1	June 30, 2021 Level 2	June 30, 2021 Level 3	December 31, 2020 Total	December 31, 2020 Level1	December 31, 2020 Level 2	December 31, 2020 Level 3
Assets:								
Money market accounts	82.4	82.4	—	—	352.2	352.2	—	—
Time deposits	240.1	—	240.1	—	—	—	—	—
Total	322.5	82.4	240.1	—	352.2	352.2	—	—
Liabilities:								
Contingent consideration	38.1	—	—	38.1	58.1	—	—	58.1
Derivative instruments	11.4	—	11.4	—	15.0	—	15.0	—
Total	49.5	—	11.4	38.1	73.1	—	15.0	58.1

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. Any changes in fair value for the contingent consideration liabilities related to the Company's products are classified in the Company's statement of operations as cost of product sales and CDMO services. Any changes in fair value for the contingent consideration liabilities related to the Company's product candidates are recorded in research and development expense for regulatory and development milestones.

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

The following table is a reconciliation of the beginning and ending balance of contingent considerations.

Balance at December 31, 2020	$ 58.1
Change in fair value	1.7
Settlements	(21.7)
Balance at June 30, 2021	$ 38.1

As of June 30, 2021 and December 31, 2020, the current portion of the contingent consideration liability was $33.1 million and $23.9 million, respectively, and was included in other current liabilities on the condensed consolidated balance sheets.

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, 2021	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	$38.1 million	Discounted cash flow	Discount rate	—% - 7.3%	1.7%
			Probability of payment	25% - 100%	86%
			Projected year of payment	2021 - 2028	2022

Derivative Instruments

Refer to Note 8, Derivatives, to these condensed consolidated financial statements.

Non-Variable Rate Debt

As of June 30, 2021 and December 31, 2020, the fair value of the Company's 3.875% Senior Unsecured Notes is $443.3 million and $466.0 million. The fair value was determined through market sources, which are level 1 inputs, observable and corroborated. The carrying amounts of the Company's other long-term variable interest rate debt arrangements approximate their fair values. For additional information related to the Company's debt, please refer to Note 9, Debt, to these condensed consolidated financial statements.

8. Derivative instruments and hedging activities

Risk management objective of using derivatives

The Company is exposed to certain risks 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.

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, 2021, 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.

	Liability Derivatives					
	June 30, 2021			December 31, 2020		
	Balance Sheet Location		Fair Value	Balance Sheet Location		Fair Value
Interest Rate Swaps	Other Current Liabilities	$	5.7	Other Current Liabilities	$	5.7
	Other Liabilities	$	5.7	Other Liabilities	$	9.3

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. 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 not 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, 2021	December 31, 2020		Six Months Ended June 30, 2021	2020
Interest Rate Swaps	$ (11.4)	$ (15.0)	Interest expense	$ (3.0)	$ (1.1)

9. Debt

The components of debt are as follows:

	June 30, 2021	December 31, 2020
Senior secured credit agreement - Term loan due 2023	$ 410.6	$ 421.9
3.875% Senior Unsecured Notes due 2028	450.0	450.0
2.875% Convertible Senior Notes due 2021	—	10.6
Other	3.0	3.0
Total debt	863.6	885.5
Current portion of long-term debt, net of debt issuance costs	(28.8)	(33.8)
Unamortized debt issuance costs	(9.6)	(10.7)
Non-current portion of debt	$ 825.2	$ 841.0

As of June 30, 2021 and December 31, 2020, debt issuance costs associated with the revolver loan were classified as other current assets and other assets on the Company's consolidated balance sheets because there was no outstanding revolver balance at period end. As of June 30, 2021, the Company had $2.0 million and $2.6 million of debt issuance costs associated with the revolver loan classified as other current assets and other assets, respectively. As of December 31, 2020, the Company had approximately $2.0 million and $3.5 million of debt issuance costs associated with the revolver loan that were classified as other current assets and other assets, respectively.

3.875% Senior Unsecured Notes due 2028

On August 7, 2020, the Company completed its offering of $450 million aggregate principal amount of 3.875% Senior Unsecured Notes due 2028 (the “2028 Notes”) of which the majority of the net proceeds were used to pay down the Revolving Credit Facility (as defined below). Interest on the 2028 Notes is payable on February 15th and August 15th of each year until maturity, beginning on February 15, 2021. The 2028 Notes will mature on August 15, 2028.

On or after August 15, 2023, the Company may redeem the 2028 Notes, in whole or in part, at the redemption prices set forth in the related Indenture, plus accrued and unpaid interest. Prior to August 15, 2023 the Company may redeem all or a portion of the 2028 Notes at a redemption price equal to 100% of the principal amount of the 2028 Notes plus a “make-whole” premium and accrued and unpaid interest. Prior to August 15, 2023, the Company may redeem up to 40% of the aggregate principal amount of the 2028 Notes using the net cash proceeds of certain equity offerings at the redemption price set forth in the related Indenture. Upon the occurrence of a change of control, the Company must offer to repurchase the 2028 Notes at a purchase price of 101% of the principal amount of such 2028 Notes plus accrued and unpaid interest.

Negative covenants in the Indenture governing the 2028 Notes, 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.

Senior secured credit agreement

Also on August 7, 2020, the Company entered into a Second Amendment (the “Credit Agreement Amendment”) to its senior secured credit agreement, dated October 15, 2018, with multiple lending institutions relating to the Company’s senior secured credit facilities (the “Credit Agreement,” and as amended, the “Amended Credit Agreement”), consisting of a senior revolving credit facility (the “Revolving Credit Facility”) and senior term loan facility (the “Term Loan Facility,” and together with the Revolving Credit Facility, the “Senior Secured Credit Facilities”). The Credit Agreement Amendment amended, among other things, the definition of incremental facilities limit, the consolidated net leverage ratio financial covenant by increasing the maximum level, increased the permissible applicable margins based on the Company’s consolidated net leverage ratio and increased the commitment fee that the Company is required to pay in respect of the average daily unused commitments under the Revolving Credit Facility, depending on the Company’s consolidated net leverage ratio.

The Amended Credit Agreement includes (i) a Revolving Credit Facility of $600 million and (ii) a Term Loan Facility with a principal amount of $450 million. The Company may request incremental term loan facilities or increases in the Revolving Credit Facility (each an "Incremental Loan") as long as certain requirements involving our net leverage ratio will be maintained on a pro forma basis. Borrowings under the Revolving Credit Facility and the Term Loan Facility bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.25% 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 1.25%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments on the last business day of each calendar quarter under the Amended 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 0.35% per annum, depending on the Company's consolidated net leverage ratio, for 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 on the last business day of each calendar quarter 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 on October 13, 2023.

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

The Amended 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 Amended 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 Amended 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 4.50 to 1.00 (subject to an increase to 5.00 to 1.00 for an applicable four quarter period, at the election of the Company, in connection with a permitted acquisition having an aggregate consideration in excess of $75.0 million). Negative covenants in the Amended 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 bore 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 matured and were paid in full on January 15, 2021.

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, 2021			Three Months Ended June 30, 2020		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 66.3	$ 114.9	$ 181.2	$ 224.2	$ 74.3	$ 298.5
CDMO services	70.4	120.5	190.9	44.6	28.0	72.6
Contracts and grants	24.4	1.0	25.4	20.7	2.9	23.6
Total revenues	$ 161.1	$ 236.4	$ 397.5	$ 289.5	$ 105.2	$ 394.7

	Six Months Ended June 30, 2021			Six Months Ended June 30, 2020		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 122.7	$ 196.4	$ 319.1	$ 288.1	$ 158.6	$ 446.7
CDMO services	167.9	206.8	374.7	44.6	49.7	94.3
Contracts and grants	44.4	2.3	46.7	42.7	3.5	46.2
Total revenues	$ 335.0	$ 405.5	$ 740.5	$ 375.4	$ 211.8	$ 587.2

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

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 roll forward of the contract liability balances:

December 31, 2020	$ 100.1
Deferral of revenue	194.7
Revenue recognized	(191.4)
June 30, 2021	$ 103.4

As of June 30, 2021 and December 31, 2020, the current portion of contract liabilities was $54.5 million and $44.6 million, respectively, and was included in other current liabilities on the balance sheet.

Transaction price allocated to remaining performance obligations

The Company has certain performance obligations that are considered an operating lease as the customer obtains substantially all of the economic benefits of the identified asset and has the right to direct its use. The associated revenue is recognized on a straight-line basis over the term of the lease. The remaining term on the Company's operating lease performance obligations approximates 2.0 years. The Company utilizes a cost-plus model to determine the stand-alone selling price of the lease component to allocate contract consideration between the lease and non-lease components. During the three and six months ended June 30, 2021, the Company's lease revenues were $16.9 million and $35.6 million, respectively, which is included within contract development and manufacturing services in the condensed consolidated statement of operations. During the three and six months ended June 30, 2020 the Company's lease revenues were de minimis. The Company has allocated contracted operating lease revenues due under our long-term CDMO service arrangements as follows:

	Year ended December 31,
2021 (1)	$ 33.8
2022	67.7
2023	28.2
	$ 129.7

(1) As of June 30, 2021, amount represents the six months ending December 31, 2021.

As of June 30, 2021, the Company expects future revenues on unsatisfied performance obligations of approximately $1.4 billion associated with all arrangements entered into by the Company. 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 manufacturing activities, 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.

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, 2021 and December 31, 2020, the Company had contract assets associated with deferred costs of $39.7 million and $41.1 million, respectively, which is reflected as a component of other assets on the Company's consolidated balance sheets. During the three and six months ended June 30, 2021, the Company recorded amortization expense of contract assets of $1.6 million, which has been included as a component of research and development expense. The Company did not record amortization expense associated with its contract assets during 2020.

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

Accounts receivable

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

	June 30, 2021	December 31, 2020
Billed, net	$ 210.3	$ 172.7
Unbilled	51.6	58.2
Total, net	$ 261.9	$ 230.9

As of June 30, 2021 and December 31, 2020, the allowances for doubtful accounts was $3.4 million and $3.1 million, respectively.

11. Income taxes

The estimated effective annual tax rate for the years ended December 31, 2021 and 2020, excluding the impact of discrete adjustments, was 26%. For the six months ended June 30, 2021 and 2020, the Company recorded discrete tax benefits of $5.5 million and $6.6 million, respectively. For the three months ended June 30, 2021 and 2020, the Company recorded a discrete tax (expense) benefits of $(1.1) million and $3.4 million, respectively. The discrete tax benefits in 2021 and 2020 were primarily due to share-based compensation activity.

12. Net income per share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net income	$ 4.6	$ 92.7	$ 74.3	$ 80.2
Denominator:				
Weighted-average number of shares—basic	53.6	52.6	53.5	52.3
Dilutive securities—equity awards	0.4	0.9	0.8	0.9
Weighted-average number of shares—diluted	54.0	53.5	54.3	53.2
Net income per share - basic	$ 0.09	$ 1.76	$ 1.40	$ 1.53
Net income per share - diluted	$ 0.09	$ 1.73	$ 1.37	$ 1.51

Basic net income per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted income per share is computed using the treasury method by dividing net income by the weighted average number of shares of common stock outstanding during the period, 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 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, 2021 and 2020.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Anti-dilutive stock awards	1.4	0.4	0.5	0.6

13. Equity

Share-based compensation

During the six months ended June 30, 2021, the Company granted stock options to purchase 0.3 million shares of common stock and 0.5 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of product sales and contract development and manufacturing services	$ 2.0	$ 8.1	$ 3.7	$ 8.8
Research and development	1.7	5.4	3.1	6.3
Selling, general and administrative	7.7	10.9	15.1	15.9
Total share-based compensation expense	$ 11.4	$ 24.4	$ 21.9	$ 31.0

Accumulated other comprehensive income (loss)

The following table includes changes in accumulated other comprehensive (loss) income by component, net of tax:

(In Millions)	Defined Benefit Pension Plan	Derivative Instruments	Foreign Currency Translation Losses	Total
Balance, December 31, 2020	(7.7)	(11.0)	(6.6)	(25.3)
Other comprehensive (loss) income before reclassifications	—	1.6	(1.7)	(0.1)
Amounts reclassified from accumulated other comprehensive income	—	3.0	—	3.0
Balance, June 30, 2021	$ (7.7)	$ (6.4)	$ (8.3)	$ (22.4)
Balance, March 31, 2021	(7.7)	(7.9)	(8.8)	(24.4)
Other comprehensive (loss) income before reclassifications	—	(0.1)	0.5	0.4
Amounts reclassified from accumulated other comprehensive income	—	1.6	—	1.6
Balance, June 30, 2021	$ (7.7)	$ (6.4)	$ (8.3)	$ (22.4)
Balance, December 31, 2019	(3.4)	(1.6)	(4.9)	(9.9)
Other comprehensive (loss) income before reclassifications	—	(10.8)	(0.4)	(11.2)
Amounts reclassified from accumulated other comprehensive income	—	(1.1)	—	(1.1)
Balance, June 30, 2020	$ (3.4)	$ (13.5)	$ (5.3)	$ (22.2)
Balance, March 31, 2020	(3.4)	(12.8)	(5.0)	(21.2)
Other comprehensive (loss) income before reclassifications	—	0.4	(0.3)	0.1
Amounts reclassified from accumulated other comprehensive income	—	(1.1)	—	(1.1)
Balance, June 30, 2020	$ (3.4)	$ (13.5)	$ (5.3)	$ (22.2)

During the three and six months ended June 30, 2021, the tax impact related to unrealized gains (losses) on hedging activities was an expense of $0.3 million and $1.0 million, respectively; the tax effects of the defined benefit pension plan and foreign currency translation losses were de minimis. During the three and six ended June 30, 2020 there were tax benefits related to unrealized losses on hedging activities of $0.8 million and $3.6 million, respectively; the tax effects of the defined benefit pension plan and foreign currency translation losses were de minimis.

14. Commitments and contingencies

Securities Litigation

On April 20, 2021, May 14, 2021 and June 2, 2021 class action lawsuits were filed against the Company and certain of its current and former senior officers in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock, seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). These complaints were filed by Plaintiff Palm Tran, Inc. – Amalgamated Transit Union Local 1577 Pension Plan; Plaintiff Alan I. Roth; and Plaintiff Stephen M. Weiss, respectively. The complaints allege, among other things, that the defendants disseminated materially false and misleading information about its capabilities to manufacture COVID-19 vaccine bulk drug substance in violation of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The defendants believe that the allegations in the complaints are false and intend to defend the matters vigorously.

It is expected that all three of these cases will be consolidated into a single action. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot reasonably estimate the possible loss or range of loss, if any, that may result from these actions.

On June 29, 2021, Lincolnshire Police Pension Fund filed a stockholder derivative lawsuit in the United States District Court for the District of Maryland on behalf of the Company against certain of its current and former officers and directors for breach of fiduciary duties, waste of corporate assets, and unjust enrichment, each allegation related to the Company's capabilities to manufacture COVID-19 vaccine bulk drug substance. In addition to monetary damages, the complaint seeks the implementation of multiple corporate governance and internal policy changes. The defendants believe that the allegations in the complaint are false and intend to defend the matter vigorously.

In addition to the above actions, the Company has received preliminary inquiries and subpoenas to produce documents related to these matters from Representative Maloney and Representative Clyburn, members of the Oversight Committee and the Select Subcommittee on the Coronavirus Crisis, Senator Murray of the Committee on Health, Education, Labor and Pensions, the Financial Industry Regulatory Authority (FINRA), the Department of Justice, the Securities and Exchange Commission (SEC), the Maryland Attorney General's Office, and the New York Attorney General's Office. The Company is producing and has produced documents as required in response and will continue to cooperate with these government inquiries.

Intellectual Property

Emergent BioSolutions' Adapt Pharma subsidiaries ("Emergent") are as follows: Emergent Devices Inc. ("EBPA"), formerly known as Adapt Pharma Inc.; Emergent Operations Ireland Limited ("EIRE"), formerly known as Adapt Pharma Operations Limited; and Emergent BioSolutions Ireland Limited ("EIR2"), formerly known as Adapt Pharma Limited.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA and EIRE, and Opiant received a notice letter from Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA (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 4 mg/spray before the expiration of U.S. Patent No. 9,211,253, (the "'253 Patent"). Emergent and Opiant received additional notice letters from Teva relating to U.S. Patent Nos. 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") and 10,085,937 (the "'937 Patent"). Teva's notice letters asserted that the commercial manufacture, use or sale of its generic drug product described in its ANDA would 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 were invalid or

unenforceable. Emergent and Opiant filed a complaint for patent infringement against Teva in the U.S. District Court for the District of New Jersey with respect to the '253 Patent. Emergent and Opiant also filed complaints for patent infringement against Teva in the U.S. District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings were consolidated. On June 5, 2020, the U.S. District Court for the District of New Jersey ruled in favor of Teva. Emergent filed its Notice of Appeal on July 23, 2020 with the Court of Appeals for the Federal Circuit. Briefs in the appeal have been filed. The appeal hearing has been scheduled for August 2, 2021.

Emergent has also 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.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries EBPA and EIRE, and Opiant received a notice letter 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 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 asserted that the commercial manufacture, use or sale of its generic drug product described in its ANDA would not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent were invalid or unenforceable. Emergent and Opiant filed a complaint for patent infringement against Teva in the U.S. District Court for the District of New Jersey. This case is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4 mg/spray case.

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, 2020. 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. 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 product 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. AV7909 has not been approved by the FDA, but is procured by certain authorized government buyers for their use;
- 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 single-dose oral vaccine approved by the FDA and EMA 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, 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 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.

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. 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. 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.

Financial Operations Overview

Revenues

We generate product 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, generally with annual options. 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 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. Since early 2020, our revenues from the sales of our vaccine products that target travelers have also declined due to the reduction of international travel caused by the COVID-19 pandemic. We expect continued variability in our quarterly financial statements.

Cost of Product Sales and CDMO Services

The primary expenses that we incur to deliver our products and to perform CDMO services consist of fixed and variable costs. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. Variable manufacturing costs primarily consist of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing operations, sales-based royalties, shipping and logistics. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity. For our commercial sales, other associated expenses include sales-based royalties (which include fair value adjustments associated with contingent consideration), shipping, and logistics.

We use the same manufacturing facilities and methods of production for our own products as well as for fulfillment of our CDMO service contracts. We operate nine manufacturing facilities, five of which perform manufacturing activities for CDMO services customers. As a result, management reviews expenses associated with manufacturing our own products as well CDMO service contracts on an aggregate basis when analyzing the financial performance of its manufacturing and development facilities. Our manufacturing process for our own products and our CDMO service business includes the production of bulk material and performing “fill finish” work for containment and distribution of biological products. For “fill finish” customers, we receive work in process inventory to be prepared for distribution. When producing bulk material, we generally procure raw materials, manufacture the product and retain the risk of loss through the manufacturing and review process until delivery.

Research and Development Expenses

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

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;

- costs of CDMO services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

In many cases, we plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing and development of our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies.

Selling, General and Administrative Expenses

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

Income Taxes

Uncertainty in income taxes is accounted for using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position.

Management believes that the assumptions and estimates related to the provision for income taxes are critical to the Company's results of operations.

New Accounting Standards

For a discussion of new accounting standards please read *Note 2. Basis of Presentation*, to our condensed consolidated financial statements included in this report.

Critical Accounting Policies and Estimates

The preparation of our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S., requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of revenues and expenses. Actual results may differ from these estimates. During the six months ended June 30, 2021, 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, 2020, 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)

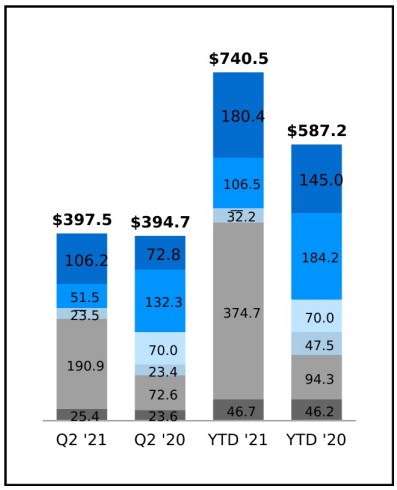
Results of Operations

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021	2020	$ Change	% Change	2021	2020	$ Change	% Change
Product sales net:								
NARCAN Nasal Spray	$ 106.2	$ 72.8	$ 33.4	46 %	$ 180.4	$ 145.0	$ 35.4	24 %
Anthrax vaccines	51.5	132.3	(80.8)	(61) %	106.5	184.2	(77.7)	(42) %
ACAM2000	—	70.0	(70.0)	(100) %	—	70.0	(70.0)	(100) %
Other product sales	23.5	23.4	0.1	— %	32.2	47.5	(15.3)	(32) %
Total product sales, net	181.2	298.5	(117.3)	(39) %	319.1	446.7	(127.6)	(29) %
Contract development and manufacturing services	190.9	72.6	118.3	NM	374.7	94.3	280.4	NM
Contracts and grants	25.4	23.6	1.8	8 %	46.7	46.2	0.5	1 %
Total revenues	397.5	394.7	2.8	1 %	740.5	587.2	153.3	26 %
Operating expenses:								
Cost of product sales and contract development and manufacturing services	227.8	129.8	98.0	76 %	327.1	206.7	120.4	58 %
Research and development	48.9	47.9	1.0	2 %	101.4	90.6	10.8	12 %
Selling, general and administrative	91.2	76.0	15.2	20 %	172.1	145.7	26.4	18 %
Amortization of intangible assets	15.1	15.0	0.1	1 %	30.0	29.8	0.2	1 %
Total operating expenses	383.0	268.7	114.3	43 %	630.6	472.8	157.8	33 %
Income from operations	14.5	126.0	(111.5)	(88 %)	109.9	114.4	(4.5)	(4 %)
Other income (expense):								
Interest expense	(8.6)	(6.4)	(2.2)	34 %	(17.1)	(15.0)	(2.1)	14 %
Other, net	1.3	1.1	0.2	18 %	(0.4)	—	(0.4)	NM
Total other income (expense), net	(7.3)	(5.3)	(2.0)	38 %	(17.5)	(15.0)	(2.5)	17 %
Income before income taxes	7.2	120.7	(113.5)	(94 %)	92.4	99.4	(7.0)	(7 %)
Income taxes	(2.6)	(28.0)	25.4	(91 %)	(18.1)	(19.2)	1.1	(6 %)
Net income	$ 4.6	$ 92.7	$ (88.1)	(95 %)	$ 74.3	$ 80.2	$ (5.9)	(7 %)

NM - Not meaningful

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

Total Revenues



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

Product Sales, net

NARCAN Nasal Spray

The increase in NARCAN Nasal Spray sales for the three and six months ended June 30, 2021 was largely driven by growth in sales to the U.S. public interest and commercial retail markets as well as an increase in sales to customer channels in Canada.

Anthrax Vaccines

The decrease in Anthrax vaccine sales for the three and six months ended June 30, 2021 was primarily due to the timing of deliveries to the U.S government. Anthrax vaccine product sales are made under procurement contracts with the USG and fluctuation in revenues are dictated by the timing of delivery of orders to the USG.

ACAM2000

The decrease in ACAM2000 sales for the three and six months ended June 30, 2021 was largely driven by timing of deliveries to the U.S. government. ACAM2000 product sales are made under procurement contracts with the USG and fluctuation in revenues are dictated by the timing of delivery of orders to the USG.

Other Product Sales

Other product sales for the three months ended June 30, 2021 remained consistent compared to the three months ended June 30, 2020. Other product sales for the six months ended June 30, 2021 decreased due to primarily due to a decrease in sales of BAT due to timing of deliveries to the SNS.

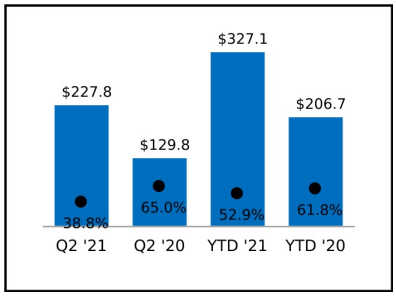
CDMO Services

The increase in contract development and manufacturing services revenue for the three and six months ended June 30, 2021 is due to the public-private partnership with BARDA and arrangements with innovators to address the COVID-19 pandemic. These arrangements were entered into during the second and third quarters of 2020.

Contracts and Grants

Contracts and grants revenue for the three and six months ended June 30, 2021 remained consistent compared to the three and six months ended June 30, 2020.

Cost of Product Sales and CDMO Services

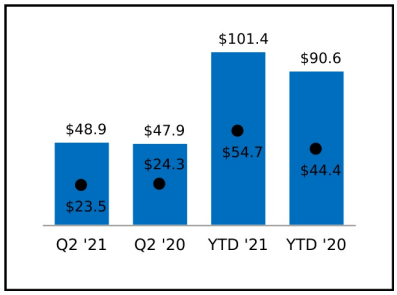


	Cost of product sales and contract development and manufacturing services
l	Gross profit margin for product sales and contract development and manufacturing services

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

Cost of product sales and contract development and manufacturing services increased for the three and six months ended June 30, 2021. The increase primarily consists of an increase in costs associated with our contract development and manufacturing services due to a higher volume of CDMO services, largely the Company's arrangements to address the COVID-19 pandemic. Additionally, the Company recorded inventory write-offs at its Bayview facility of $41.5 million during three and six months ended June 30, 2021. The inventory write-off was due to raw materials and in-process batches that the Company plans to discard as they were deemed unusable. These increases were partially offset by decreases in the cost of product sales due to less volume.

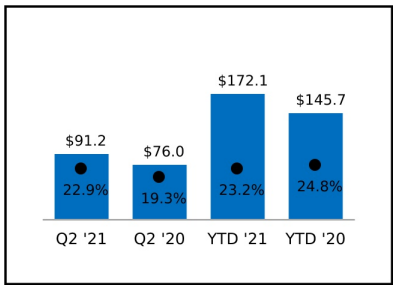
Research and Development Expenses (Gross and Net)



■	Research and development expense
I	Research and development expense, net of contracts and grants revenue

Research and development expense for the three months ended June 30, 2021 remained consistent compared to the three months ended June 30, 2020. Research and development expense for the six months ended June 30, 2021 increased due to due to costs associated with the development of the COVID-HIG therapeutic product candidate, offset by the decline in development costs associated with the AV7909 product candidate.

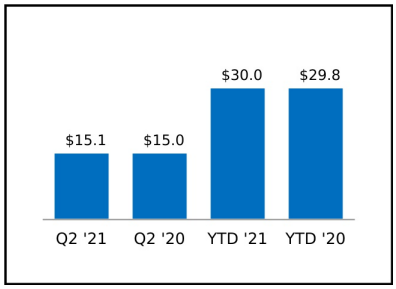
Selling, General and Administrative Expenses



■	Selling, general and administrative expenses
I	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, 2021 is due to an increase in costs related to defending and supporting the Company's corporate reputation.

Amortization of Intangible Assets

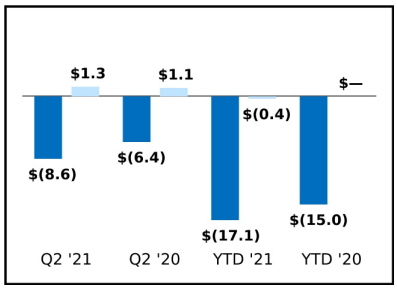


■	Amortization expense

Amortization of intangible assets and the composition of intangible assets amortized during the three and six months ended June 30, 2021 were consistent with the three and six months ended June 30, 2020.

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

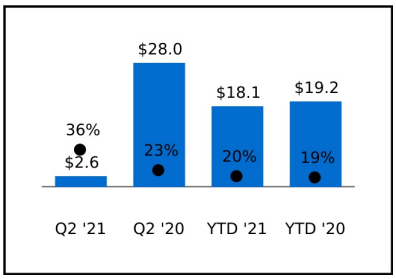
Other Income (Expense), Net



	Interest expense
	Other income (expense)

Total other income (expense), net decreased for the three and six months ended June 30, 2021 largely due to an increase in interest expense as a result of increases in total outstanding debt and interest rates during the periods.

Income Taxes



	Income taxes
l	Effective tax rate

During the three and six months ended June 30, 2021, and 2020, the estimated effective annual tax rates was 26%. The actual effective tax rates includes the impact of discrete tax benefits during the six months ended June 30, 2021 and 2020 of $5.5 million and $6.6 million, respectively. Income taxes decreased during the periods due to a decline in income before income taxes and the timing of the discrete tax benefits.

Financial Condition, Liquidity and Capital Resources

Our financial condition is summarized as follows:

(in millions, except percentages)	June 30, 2021	December 31, 2020	Change %
Financial assets:			
Cash and cash equivalents	$ 447.5	$ 621.3	(28)%
Borrowings:			
Debt, current portion	28.8	33.8	(15)%
Debt, net of current portion	825.2	841.0	(2)%
Total borrowings	854.0	874.8	(2)%
Working capital:			
Current assets	1,162.1	1,195.9	(3)%
Current liabilities	377.8	384.5	(2)%
Total working capital	784.3	$ 811.4	(3)%

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 annual fiscal years through the period ended December 31, 2020. As of June 30, 2021, we had unrestricted cash and cash equivalents of $447.5 million and capacity under our revolving credit facility of $597.2 million. As of June 30, 2021, 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, 2021 and 2020:

	Six Months Ended June 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (24.6)	$ 185.7
Investing activities	(123.1)	(69.3)
Financing activities	(26.0)	(15.3)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.1)	(0.1)
Net change in cash, cash equivalents and restricted cash	$ (173.8)	$ 101.0

Operating Activities

Net cash used in operating activities of $24.6 million for the six months ended June 30, 2021 was due to net income excluding non-cash items of $160.6 million offset by negative working capital changes of $185.2 million due to accumulation of inventory, reduced accrued expenses, other liabilities and accrued compensation, and increases in receivables.

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 positive working capital changes of $17.7 million due to increases in contract liabilities and accrued expenses and other liabilities and decreases in accounts receivable, offset by increases in inventory, prepaid expenses and other assets and decreases in accounts payable.

Investing Activities

Net cash used in investing activities relates to purchases of property, plant and equipment and was $123.1 million and $69.3 million for the six months ended June 30, 2021 and 2020, respectively. The cash used in investing activities increased during the six months ended June 30, 2021 largely due to infrastructure and equipment investments related to continued investments associated with increased

capacity and capabilities at our Rockville and Bayview facilities.

Financing Activities

Net cash used in financing activities of $26.0 million for the six months ended June 30, 2021 was primarily due to payments on debt of $21.9 million and net payments related to employee share-based compensation activity of $3.0 million.

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 cash provided by employee share-based compensation activity of $11.4 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, delivery of CDMO services 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 Unsecured Notes due 2028 and the 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.

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, 2021 and December 31, 2020 was:

(in millions)			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness on Revolving Credit Facility	Unused Capacity
June 30, 2021			
$600.0	2.8	—	$597.2
December 31, 2020			
$600.0	2.8	—	$597.2

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 rate, as defined in our Amended Credit Agreement, plus an applicable margin. We manage the impact of interest rate changes on our variable debt through derivative instruments such as interest rate swap arrangements. Increases in interest rates could result in an increase in interest payments for debt that we have not hedged through our interest rate swap arrangements. See Note 9, "Debt," to the Notes of our condensed consolidated financial statements included in this 2021 Quarterly Report under the caption Item 1, "Financial Statements.”

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, 2021 would increase our interest expense by approximately $0.6 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 either entering into foreign currency hedging transactions or incurring operating expenses in the local currency in the countries in which we operate, to the extent practicable. We currently do not hedge all of 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, 2021. 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, 2021, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the quarter ended June 30, 2021 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

See "Item 1 of Part I, “Financial Statements — Notes to condensed consolidated financial statements — Note 14 — Commitments and contingencies.”

ITEM 1A. RISK FACTORS

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The occurrence of any of the

following risks or of unknown risks and uncertainties may adversely affect our business, operating results and financial condition.

RISK FACTOR SUMMARY

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

In addition, there are a number of government contracting risks that could impact our business, financial condition, operating results and cash flows, including:

- Failure to receive FDA licensure of AV7909 in a timely manner or at all.
- Reduced demand for and/or funding for procurement of AV7909 and/or BioThrax or ACAM2000 and discontinuation of funding of our other USG procurement and development contracts.
- Failure to comply with laws and regulations pertaining to government contracts and resources required for responding to related government inquiries.

There are a number of product development and commercialization risks that could impact our business, financial condition, operating results and cash flows, including:

- The COVID-19 product candidates we are working on may not be safe or effective and we may be unable to manufacture sufficient quantities to meet demand.
- Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain.
- We may fail to capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

There are a number of regulatory and compliance risks that could impact our business, financial condition, operating results and cash flows, including:

- Conditions associated with approvals and ongoing regulation of products may limit how and to the extent we manufacture and market them.
- Failure to comply with various health care laws could result in substantial penalties.
- Failure to comply with obligations under U.S. governmental pricing programs may require reimbursement for underpayments and the payment of substantial penalties, sanctions and fines.
- The authority to sell unapproved MCMs to certain government entities can be ambiguous and subject us to regulatory enforcement actions.

There are a number of manufacturing risks that could impact our business, financial condition, operating results and cash flows, including:

- Disruption at, damage to or destruction of our development and/or manufacturing facilities may impede our ability to manufacture our products, as well as deliver our CDMO services.
- Our operations, including our use of hazardous materials, chemicals, bacteria and viruses expose us to significant potential liabilities.

There are a number of risks related to reliance on third parties that could impact our business, financial condition, operating results and cash flows, including:

- The loss of sole-source suppliers or an increase in the price of inventory.
- If third parties do not perform as contractually required or as expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

There are a number of risks related to our strategic acquisitions and collaborations that could impact our business financial condition, operating results and cash flows, including:

- Our strategy of generating growth through acquisitions may be unsuccessful.
- Our failure to successfully integrate acquired businesses and/or assets into our operations and our ability to realize the benefits of such acquisitions.

There are a number of competitive and political risks that could impact our business, financial condition, operating results and cash flows, including:

- Development and commercialization of pharmaceutical products are subject to evolving private and public sector competition.
- NARCAN® Nasal Spray may be subject to additional branded and new generic competition.
- Biologic Products may be affected by the approval and entry of follow-on biologics, or biosimilars in the United States and other jurisdictions.

There are a number of risks related to our intellectual property that could impact our business,

financial condition, operating results and cash flows, including:

- Challenges in defense or enforcement of our intellectual property rights, including against current or potential infringers.
- Potential discrepancies or challenges with respect to third party licenses.
- Potential loss of proprietary information and know-how, which carries the risk of reducing the value of our technology and products.
- Entry of competing generic drugs upon patent expiry or with patents no longer in force.

There are a number of financial risks that could impact our business, financial condition, operating results and cash flows, including:

- Our ability to maintain sufficient cash flow from our operations to pay our substantial debt, both now and in the future.
- Our ability to obtain additional funding and be able to raise capital when needed.

There are a number of legal and reputational risks that could impact our business, financial condition, operating results and cash flows, including:

- Pending litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact our business, financial condition and results of operations.
- Our work on public health threats has exposed us to criticism and may expose us to further criticism, from the media, government personnel, and others, which could further harm our reputation, negatively effect on our share price, operations, and our ability to attract and retain talent.
- The potential for cyber security incidents to harm our ability to operate our business effectively in light of our heightened risk profile.
- Inherent product liability exposure due to our unique business.

There are a number of risks associated with our common stock, including, but not limited to:

- Our business or our share price could be negatively affected as a result of the actions of shareholders.
- Due to his substantial ownership percentage, our Executive Chairman has the ability to exert significant influence over us with respect to the election of the members of our Board of Directors and to delay or prevent a change of control of us.
- The price of our common stock has been and remains subject to extreme volatility.

The risk factors below contain more detailed descriptions of the risks identified above, which may materially harm our business, financial condition or results of cash flows.

GLOBAL PANDEMIC RISK

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

Our business, operations and financial condition and results have been and may continue to be impacted by the COVID-19 pandemic to varying degrees. The pandemic has presented a number of risks and challenges for our business, including, among others, impacts due to travel limitations and government-mandated work-from-home or shelter-in-place orders; manufacturing disruptions and delays, including at our Baltimore Bayview facility, supply chain interruptions, including challenges related to reliance on third-party suppliers; disruptions to pipeline development and clinical trials and decreased product demand for our travel health vaccines due to the significant reduction in international travel. Additional travel restrictions and other governmental measures may result in further disruptions or continued delays in delivery of supplies by our third-party contractors and suppliers.

We continue to implement a work from home policy, with our administrative employees working outside of our offices, and on-site staff restricted to only those required to execute certain manufacturing, laboratory and related support activities. Working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. In addition, as a result of state or local restrictions, our on-site staff conducting research and development may not be able to access our laboratories, and these core activities may be significantly limited or curtailed, possibly for extended periods of time.

We also face uncertainties related to our efforts and those of our collaborative partners to develop a potential treatment or vaccine for COVID-19, including uncertainties related to pre-clinical or clinical trials, the risk that such development programs may not be successful, commercially viable, or that EUA or regulatory approval will not be received from regulatory authorities.

In addition, the trading price of our common stock, and that of other biopharmaceutical companies, has been highly volatile due to the COVID-19 pandemic, especially as a result of investor concerns and uncertainty related to the impact of the pandemic on the economies of countries worldwide. These broad market and industry fluctuations, as well as general economic, political and market conditions, may negatively impact the market price of shares of our common stock.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic further negatively impacts our business, supply chain, disrupts key clinical trials, diverts government funding away from our primary procured products and product candidates due to changes in government priorities and potential delays in the delivery of products to our customers will depend on future developments, which are highly uncertain. The ultimate geographic spread of the disease, the duration of the pandemic, further travel restrictions and social distancing 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 contain and treat the disease cannot be predicted with certainty.

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of AV7909 and ACAM2000 and have historically derived a substantial portion of our revenue from USG procurement of BioThrax. If the USG's demand for and/or funding for procurement of AV7909 and/or 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. 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 such 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 as a result of the conclusion of the USG's recently announced audit of the SNS, or with respect to the level of procurement of our anthrax vaccines, funding to procure future doses of AV7909 or BioThrax 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 or 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 in July 2019 to procure 10 million doses of AV7909 and another option in July 2020 to procure additional doses for inclusion into the SNS in support of anthrax preparedness.

We are also working on a BLA for filing with the FDA related to AV7909, with a current target submission date to the FDA of the end of this year. There can be no guarantee that we will meet our target date for submission. Moreover, even if we do, 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 and, more recently, from reservation of CDMO capacity by BARDA via our public-private CDMO partnership. 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 AV7909 to be supplied under our development and procurement contract with BARDA 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, the results of elections 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. 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. 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.

A significant portion 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 procurement aspect of our development and procurement contract for AV7909 expires this year. As another example, in November 2019, the BARDA procurement contract for raxibacumab that we acquired in our 2017 acquisition of the product from GlaxoSmithKline LLC was completed. We intend to negotiate a follow-on procurement contract for AV7909 and raxibacumab and other follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, 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 or procured product candidates 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;
- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals;
- 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 through 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. Our status as a USG contractor means that we are subject to various statutes and regulations, including:

- 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 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;
- export and import control laws and regulations, including but not limited to ITAR (International Traffic in Arms Regulations); and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

We may be subject to government investigations of 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 DoD are generally fixed price contracts. We expect that additional future procurement contracts we successfully secure with the USG would likely 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;
- unilaterally reduce or modify contracts or subcontracts;
- 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 certain 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 development and procurement contracts 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 may not be able to limit third parties, including our competitors, from accessing certain of these technology or data rights, including intellectual property, in providing products and services to the USG.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

An inability to maintain quality and manufacturing compliance at our Baltimore Bayview facility could hinder our ability to continue producing bulk drug substance for Johnson & Johnson's COVID-19 vaccine, which could adversely affect our business, financial condition, operating results and cash flows.

In April 2021, the FDA conducted an inspection of our Baltimore Bayview facility after an out-of-specification result was discovered involving the cross-contamination of a single drug substance lot intended for further drug product manufacturing and use in Johnson & Johnson's COVID-19 vaccine. The inspection revealed, among other things, the need for a more thorough investigation to explain cross-contamination issues identified in a viral vaccine drug substance batch intended for use in Johnson and Johnson's COVID-19 vaccine, and that improved building maintenance and sanitation practices were needed at the Bayview facility, which resulted in the issuance of a Form FDA 483. As a result, previously we agreed not to initiate the manufacturing of any new material at our Bayview facility pending completion of the remediation of the FDA's inspection concerns. We also agreed to quarantine existing material manufactured at the Bayview facility until further notice or review by the FDA and have been required to dispose of multiple batches of vaccine bulk drug substance. As a result, remediation activities were conducted in the second and third quarters. On July 29, 2021, in alignment with the FDA, we began a plan to resume production of bulk drug substance for Johnson & Johnson's COVID-19 vaccine. Our potential failure to maintain quality and manufacturing compliance could hinder our ability to continue manufacturing bulk drug substance for Johnson & Johnson's COVID-19 vaccine at the facility and we may also need to dispose of additional batches of bulk drug substance, all of which could adversely affect our business, financial condition, operating results and cash flows.

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 a product candidate for the possible treatment of COVID-19 in the outpatient setting and we are also providing CDMO services for the development and/or manufacture of multiple vaccine and therapeutic product candidates. There can be no assurance that any of these product candidates will be safe or effective. There can also be no assurance that any of these product candidates will be authorized for emergency use or approved by the FDA or any other health regulatory authority or that our facilities will receive authorization from the FDA to release additional batches of COVID-19 drug substance. Even if these product candidates are safe and/or effective and receive authorization or approval by a health regulatory authority or we receive authorization to produce drug substance at our facilities, the manufacturing processes for our CDMO COVID-19 programs are under development and are complex. There can be no assurance that we will be able to produce any significant quantity of these product candidates in a timely basis or at all, or negotiate further commitments under our existing CDMO contracts to manufacture vaccines against COVID-19, which could adversely affect our business, financial condition, operating results and cash flows.

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 efforts and financial resources in the development of our vaccines, therapeutics and medical device product candidates and the acquisition of additional product candidates. In addition to our product sales, our ability to generate revenue is dependent on a number of factors, including the success of our development programs, the 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;
- 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;
- successful registration and maintenance of relevant patent and/or other proprietary protection; and
- acceptance of the product by potential government and other customers.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products. 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 pre-clinical studies and clinical trials to establish proof of concept and demonstrate the safety and efficacy of our product candidates. Pre-clinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of such trials do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

Pre-clinical 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 for some of our CBRNE product candidates. 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. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans.

Prior to FDA approval of the countermeasure product candidates, the Secretary of HHS can contract to purchase MCMs for the SNS under Project BioShield under certain circumstances. Under PAHPRA, the USG may also, at its discretion, purchase critical biodefense products for the SNS prior to FDA approval after the filing of a pre-EUA application with the FDA. If our product candidates are not procured or funded under regulatory authority, they generally will have to be fully 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, pre-clinical 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 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.

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 an NDA or 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." Under the Animal Rule, 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 under the Animal Rule, product development can take a considerable amount of time, and the FDA may decide that our data are insufficient to support approval and require additional pre-clinical, 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. 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 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 pre-clinical 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, mostly related to clinical trials.

Failure to successfully develop future product candidates 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 and may refuse to accept any application or may decide that our data are insufficient to support approval and require additional pre-clinical, clinical or other studies.

Unapproved and investigational stage products are also subject to the 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 conditions 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 sell any products we develop for indications or uses for which they are not approved.

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.

Certain of our products are subject to post marketing requirements (PMRs), which we are required to conduct, and post marketing 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. Violations of the 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 result in various penalties and sanctions. For all FDA-regulated products, if the FDA finds that a manufacturer has failed to comply with applicable laws and regulations, or that a product is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, including but not limited to:

- restrictions on such products, manufacturers 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;
- refusal to approve pending applications or supplements to approved applications that are submitted;
- 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; and
- injunctions or the imposition of civil or criminal penalties.

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 foreign 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 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 substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to legal and political challenges, as well as efforts by the last Presidential administration to repeal or replace certain aspects of the ACA. More recently on January 28, 2021, however, the President issued an executive order to strengthen implementation of the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing penalties as of January 1, 2019 for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. Additionally, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA was unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Cuts & Jobs Act. That ruling was recently struck down by the U.S. Supreme Court on June 17, 2021 because, the Supreme Court found, the states and individuals that brought the action challenging the ACA's individual mandate did not have standing to sue. This Supreme Court decision effective affirmed that the ACA will remain the law.

Notwithstanding, other legislative changes have been proposed and adopted in the United States since the ACA was enacted that may negatively impact us. On August 2, 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. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 under the CARES Act.

Additionally, there has been recent heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and has been proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the last Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers.

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.

- 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. 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 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 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) to report 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 otherwise, 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 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 fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws, 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 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 of 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 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 on us.

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;
- Significant legal fees and payment of damages or penalties;
- Limitations on our ability to continue certain operations;
- Decreased product demand; 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 would 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, 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 would also 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 also be grounds for CMS to terminate our Medicaid drug rebate agreement, under 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. 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 is complex, 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 and purchased by certain federal agencies and 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 under 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. Under the VHCA, knowingly providing 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.

From time to time, we sell unapproved MCMs to government entities under certain circumstances. While this is permissible in some cases, the extent to which we may be able to lawfully offer to sell 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, 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 local enforcement authorities disagree with our conclusion that such activities are permissible, they may 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 or unauthorized products, such as a declaration issued under the PREP Act, may lead plaintiffs to assert that their claims are not barred under the PREP Act.

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 under a withdrawal agreement. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement to govern the United Kingdom’s departure from the European Union, known as Brexit. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the effects of the U.K.'s departure from the E.U. 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 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. We believe we are currently in compliance with such laws and regulations. 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 anthrax vaccines, ACAM2000 or our other products, as well as deliver our CDMO 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 and product candidates for delivery to satisfy the 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, particularly due to the impact of COVID-19;
- civil unrest and protests, including by animal rights activists;
- injunctions;
- damage to or destruction of one or more facilities;

- FDA facility inspection findings/recommendations; 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. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any damage to, or disruption or destruction of one or more of our 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 delays in the performance of our contractual obligations or delays in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

Problems may arise during the production of our marketed products and product candidates, as well as those we produce for our CDMO customers, due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development and our ability to ramp up production to meet the needs of our customers could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.

The majority of our products and product candidates are biologics. Manufacturing biologics, 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. 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, which has the potential to result in similar consequences. 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 the issuance of Forms FDA 483. warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business. For example in April 2021, we temporarily stopped manufacturing bulk drug substance material for Johnson & Johnson's COVID-19 vaccine at our Baltimore Bayview facility after issues were identified in a viral vaccine drug substance batch.

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.

In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. For example, we have not previously had to ramp our organization for a commercial launch of any product at the current pace required to address treatments related to COVID-19 and doing so in a pandemic environment with an urgent, critical global need creates unique manufacturing challenges, challenges related to distribution channels, and the need to establish teams of people with the relevant skills. Our inability to ramp up manufacturing to meet the demand or specifications of our customers or the inability to timely obtain regulatory authorization to produce the products or product candidates of our customers could also harm our business, financial condition, operating results and cash flows.

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 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 in this area 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.

RISKS RELATED TO RELIANCE ON THIRD PARTIES

The loss of any of our non-exclusive, sole-source or single source suppliers, a shortage of related supplies 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. We depend on certain single-source suppliers for key materials and services necessary to manufacture the majority of our products and certain 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 AV7909 and BioThrax and the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. We also rely on single-source suppliers for the materials necessary to produce NARCAN®Nasal Spray, such as the naloxone active pharmaceutical ingredient and other excipients, along with the vial, stopper and device.

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 impact of COVID-19 on such supplier, the acquisition of 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 product candidates, a reduction in quality or an increase in the price of those materials or components could adversely affect us. 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. 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
- risks associated with intellectual property rights related to an acquisition or collaboration.

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

Development and commercialization of pharmaceutical products, including for PHT preparedness, are routinely subject to evolving private and public sector competition.

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. The market for current products can be subject to development of safer, more effective, more convenient or less costly products. The market for current products can also depend on what resources can be devoted to marketing or selling products, or how companies are positioned to adapt more quickly to new technologies, respond to scientific advances or patient preferences and needs, initiate or withstand substantial price competition and/or procure 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. Factors to consider include competitors' financial, technical and marketing resources as well as potential leverage that their intellectual property estates may offer.

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.

Biological products and product candidates, otherwise referred to as our “Biologic Products,” can be affected by the approval and entry of “biosimilars” in the United States and other jurisdictions. Biologic Products in our current pipeline include AV7909, BioThrax, and ACAM2000. 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.

NARCAN® Nasal Spray may be subject to potential competition.

Although NARCAN® Nasal Spray is the first FDA-approved needle-free naloxone nasal spray for the emergency reversal of opioid overdoses and has advantages over certain other treatments, we expect the treatment to face additional competition. For example, on April 30, 2021, the FDA approved Kloxxado, a branded product developed by Hikma Pharmaceuticals, Inc. which delivers a higher dose naloxone nasal spray. In addition, Orexo AB and Harm

Reduction Therapeutics both have development programs for novel naloxone nasal spray formulations intended for use in opioid overdose reversal.

NARCAN® Nasal Spray faces additional branded competition from other injectable naloxone, auto-injectors and improvised nasal kits including Amphastar Pharmaceuticals, Inc.'s naloxone injection product and Kaléo's EVZIO™ (naloxone HCl injection) Auto-Injector. NARCAN® Nasal Spray may face additional branded competition in the future.

With respect to potential generic competition, ANDAs seeking regulatory approval to market a generic version of NARCAN® Nasal Spray were filed with the FDA by Teva (in 2016), and by Perrigo UK FINCO Limited Partnership ("Perrigo") (in 2018). ANDA litigation involving Teva is pending (via Emergent BioSolutions Ireland Limited and Emergent Operations Ireland Ltd. (our prior Adapt subsidiaries) having appealed the June 5, 2020 decision of the U.S. District Court for the District of New Jersey to the Court of Appeals for the Federal Circuit. The appeal hearing is currently scheduled for August 2, 2021. An at-risk launch by Teva remains possible. Settlement with Perrigo regarding their ANDA filing was entered on February 12, 2020 providing for a license effective January 5, 2033, or earlier under certain circumstances, including those related to the outcome of the current Teva litigation or future ANDA filers.

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. In addition, 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.

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 and the level of emphasis placed on such risks by the USG 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.

INTELLECTUAL PROPERTY RISKS

Protection of our intellectual property rights is an important tool for sustaining our business and the failure to do so could impact our financial condition, operating results, and cash flows.

We actively seek to protect intellectual property rights related to our Company's assets, including patent rights, trademark rights, trade secrets and proprietary confidential information, through defense and enforcement of existing rights and pursuit of protection on new and arising innovations.

Obtaining, maintaining and defending our intellectual property rights in the United States and other countries remains a critical component of the development and commercialization of our Company's assets.

Some of the risks associated with procurement, maintenance and enforcement of intellectual property rights include changes in patent laws or administrative patent office rules, evolving criteria and eligibility of obtaining patent protection on particular subject matter, the validity and enforceability of our intellectual property rights, the potential scope of coverage of our intellectual property rights, and/or the availability or strength of legal remedies in a particular country to defend and enforce intellectual property rights.

Other risks include associated costs, such as costs of patent prosecution and maintenance, costs associated with post-grant challenges including, for example, *inter partes review* (IPR) proceedings in the United States and oppositions in Europe, as well as costs associated with litigating and enforcing patent and trademark rights.

Additional risks include limitations on our extent or ability to procure, maintain or defend intellectual property rights associated with in-licensed or acquired intellectual property, where, for example, third parties may have the first right to maintain or defend intellectual property rights in which we have an interest, or may pursue strategies that are divergent to the interest of our Company.

Third party challenges for patent infringement could impact our business, financial condition, operating results, and cash flows.

Challenges by third parties for alleged patent infringement could delay or affect the development and commercialization of our products. Such challenges, while ongoing, could be costly, requiring and utilizing company resources. Such challenges, if successful, may impact marketing or launch of products, or require ongoing license and/or royalty fees associated with potential settlement agreements. These may have the potential to materially harm our business, financial condition, operating results, and cash flows.

Intellectual property licenses with third parties carry risks of challenges, which may be costly and time consuming and could impact the commercialization of our products.

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. Such license agreements or collaboration arrangements can be subject to challenges if interests or expectations under such license agreements diverge. Such challenges may be costly, risk time and resources, and could delay or impact development, commercialization or launch of our products.

Potential loss of proprietary information and know-how generally carries the risk of reducing the value of our technology and products.

We also rely upon unpatented proprietary technology, processes, and know-how, particularly as to our proprietary manufacturing processes. 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 always be successful in protecting our trade secrets and confidential information.

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 FDCA, which may render it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Other of our products may be susceptible to challenges by entry of biosimilars through the route established under the Biologics Price Competition and Innovation Action of 2009.

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.

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 further 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 can have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of cash flows from operations to payment on our debt, which would reduce available funds for 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 such risk through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities and the indenture governing the 3.875% Senior Unsecured Notes due 2028 (Senior Unsecured Notes), to restrictive covenants that 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, including the maintenance of a specified consolidated net leverage ratio and debt service coverage ratio under our Senior Secured Credit Facilities, 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 restricts and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

The Senior Secured Credit Facilities include a $450 million Term Loan Facility and the ability to borrow up to $600 million under our Revolving Credit Facility, of which we had outstanding borrowings of approximately $410.6 million and no outstanding balance, respectively, as of June 30, 2021. On August 7, 2020, we completed an offering of $450 million aggregate principal amount of Senior Unsecured Notes, of which $353 million of the net proceeds were used to pay down our Revolving Credit Facility. We may also seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing can have significant adverse consequences for our business, including:

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

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 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. Debt financing, if available, may involve agreements that include covenants, like those contained in our Senior Secured Credit Facilities and the indenture governing the Senior Unsecured Notes, 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. Our Senior Secured Credit Facilities as well as the indenture governing the Senior Unsecured Notes restrict our ability to incur additional 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 on an annual basis since becoming a public company, 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.

A substantial portion of our indebtedness bears interest at variable interest rates based on LIBOR and certain of our financial contracts are also indexed to LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate (LIBOR) announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR.

On November 30, 2020, the International Exchange (ICE) Benchmark Association, which administrates LIBOR, announced that it intends to begin a phase out of LIBOR at the end of 2021, by ceasing (i) entering into new contracts that use LIBOR as a reference rate by December 31, 2021 and (ii) publication of two LIBOR rates (one-week and two-month) after December 31, 2021, while the remaining LIBOR rates (overnight, one-month, three-month, six-month and 12-month) will be retired on June 30, 2023. It is unclear if LIBOR will cease to exist at that time or if new methods of calculating LIBOR will be established such that it continues to exist after 2023. We have certain financial contracts, including the amended credit agreement related to our Senior Secured Credit Facilities and our interest rate swaps, that are indexed to LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. The transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

LEGAL AND REPUTATIONAL RISKS

Pending *litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact our business, financial condition and results of operations.*

We are currently involved in numerous lawsuits, including stockholder derivative and putative class action lawsuits and anticipate that we will continue to be a target of such lawsuits in the future due to the volatility of our stock price. Certain of these actions include, and future actual or threatened legal actions may include, claims for substantial and indeterminate amounts of damages, or may result in other actions adverse to us.

For example, multiple purported class action lawsuits have been filed against us and certain of our current and former senior officers in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of

persons who purchased or otherwise acquired shares of our common stock during various date ranges. The complaints, allege, among other things, that we made materially false and misleading statements regarding our procedures and quality controls relating to vaccine production, in violation of federal securities laws. As another example, a purported stockholder derivative lawsuit was recently filed in the United States District Court for the District of Maryland on behalf of the Company against certain of our current and former officers and directors for breach of fiduciary duties, waste of corporate assets, and unjust enrichment. In addition to monetary damages, the complaint seeks the implementation of multiple corporate governance and internal policy changes.

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

We *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. We also have contracted with the USG and pharmaceutical companies, such as Johnson & Johnson and AstraZeneca, for the development and manufacture of a significant quantity of COVID-19 vaccines, and separately we are working on a proprietary COVID-19 therapeutic with support from the USG and other private sector entities, which has raised our security profile, and heightened potential risks that malicious actors may seek to disrupt our systems or misappropriate our information. 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. Our systems are also potentially vulnerable to data security breaches through employee error, phishing scams and malfeasance, which may expose sensitive data to unauthorized persons. No system of protection is adequate to protect against all such threats, even if they are deemed to be industry standard, and there can be no assurance that we will be able to repel any such attacks. Data security breaches could lead to the loss of trade secrets or other intellectual property or the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers and others. Responding to any such threats may also be expensive and time-consuming.

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

Our *work on public health threats has exposed us to criticism and may expose us to further criticism, from the media, government personnel, and others, that can negatively effect on our share price, reputation, operations, and our ability to attract and retain talent.*

Our work on public health threats, including recent manufacturing issues at our Baltimore Bayview facility, has exposed us to recent criticism and may expose us to additional potential criticism, from the media, government personnel, and others. In addition, our work on public health threats has exposed us to governmental inquiries and investigations, including by Congress and other government agencies. For example, a joint panel of the U.S. House of Representatives recently launched an investigation into, among other things, the cause of the previously mentioned cross-contamination issues identified in a viral vaccine drug substance batch at the Baltimore Bayview facility. Such criticism can be particularly acute during a public health emergency like the COVID-19 pandemic. The unfavorable media coverage and increased government scrutiny, including the recent Congressional inquiry, could further harm our reputation, distract management's attention from our operations, and impact our ability to attract and retain talent and result in further declines to our share price. We have already incurred significant legal costs to respond to government inquiries and are likely to incur additional costs. Any adverse actions by government authorities may result in significant civil or criminal fines or penalties, all of which could adversely impact our financial condition, operating results and cash flows.

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 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.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Our business or our share price could be negatively affected as a result of the actions of shareholders.

In recent years, some shareholders have placed increasing pressure on publicly traded companies in our industry and others to effect changes to corporate governance practices, executive compensation practices, social and environmental practices and to undertake certain corporate actions. This may be true even if they only hold a minority of shares. In addition, some institutional investors are increasingly focused on environmental, social and governance (ESG) factors. These investors may be seeking enhanced ESG disclosures or implement policies adverse to our business. There can be no assurances that shareholders will not publicly advocate for us to make corporate governance changes or engage in certain corporate actions. Responding to challenges from shareholders, such as proxy contests, media campaigns or other public or private means, could be costly and time consuming and could have an adverse effect on our reputation and divert the attention and resources of management and our board, which could have an adverse effect on our business and operational results. Any such shareholder actions or requests, or the mere public presence of shareholders with a reputation for taking such actions among our shareholder base, could also cause the market price of our common stock to experience periods of significant volatility.

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, 2021, Mr. El-Hibri was the beneficial owner of approximately 9% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over 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 23, 2021, our common stock has traded as high as $137.61 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 and the indenture governing our Senior Unsecured Notes 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 based on current expectations.

Future issuances of our common stock or securities convertible into common stock could result in dilution of our stockholders and could cause our share price to decline.

We expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. To the extent we raise additional capital by issuing equity securities or securities convertible or exchangeable into common stock, our stockholders may experience substantial dilution. We may sell common stock, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such common stock, convertible or exchangeable securities or other equity securities in subsequent transactions, existing stockholders may be materially diluted.

GENERAL RISKS

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.

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 (including quality and manufacturing 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.

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#†	Modification No. 7, effective December 2, 2020, to the Award/Contract, effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (the BARDA AV7909 Contract).
10.2#†	Modification No. 8, effective March 22, 2021, to the BARDA AV7909 Contract.
10.3#†	Modification No. 9, effective April 21, 2021, to the BARDA AV7909 Contract.
10.4#†	Modification No. 10, effective June 10, 2021 to the BARDA AV7909 Contract.
10.5#†	Modification No. 3, effective, April 1, 2021, to the Award/Contract, effective August 30, 2019 (ACAM2000 Contract), from the Assistant Secretary, U.S. Department of Health and Human Services to Emergent Product Development Gaithersburg Inc.
10.6#†	Modification No. 27, effective May 6, 2021, to the Award/Contract, effective June 15, 2012 (the BARDA ADM Contract), from the BioMedical Advance Research and Development Authority to Emergent Manufacturing Operations Baltimore LLC.
10.7#†	Modification No. 28, effective May 27, 2021, to the BARDA ADM Contract.
10.8#†	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated April 2, 2020, under the BARDA ADM Contract (Task Order 75A50120F33006).
10.9#†	Modification No. 1, effective April 12, 2021, to Task Order 75A50120F33006.
10.10#†	Modification No. 7, effective May 24, 2021, to Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated May 24, 2020 (Task Order 75A50120F33007), the BARDA ADM Contract.
10.11#†	Change Order No. 1 to Work Order #5997-01, effective July 31, 2020, to Manufacturing Services Agreement, dated June 10, 2020, between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP (AZ MSA1) (included under Manufacturing Services Agreement, dated July 24, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP (AZ MSA2).
10.12#†	Change Order No. 2 to Work Order #5997-01, effective August 04, 2020, to AZ MSA1 (included under AZ MSA2).
10.13#†	Change Order No. 4 to Work Order #5997-01, effective November 17, 2020, to AZ MSA1 (included under AZ MSA2).
10.14#†	Change Order No. 5 to Work Order #5997-01, effective September 16, 2020, to AZ MSA1 (included under AZ MSA 2).
10.15#†	Change Order No. 6 to Work Order #5997-01, effective October 13, 2020, to AZ MSA1 (included under AZ MSA2).
10.16#†	Change Order No. 10 to Work Order #5997-01, effective March 10, 2021, to AZ MSA1 (included under AZ MSA2).
10.17#†	Change Order No. 13 to Work Order #5997-01, effective April 23, 2021, to AZ MSA1 (included under AZ MSA 2).
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, 2021, 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 portions of this exhibit have been omitted because they are not material and they are the type of information that the registrant treats as private or confidential.

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 29, 2021

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

Date: July 29, 2021

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential.

Exhibit 10.1

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE 1	OF PAGES 2
2. AMENDMENT/MODIFICATION NO. P00007	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. (If applicable)	
6. ISSUED BY CODE ASPR-BARDA ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		7. ADMINISTERED BY (If other than Item 6) CODE ASPR-BARDA ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201		

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

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or 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 date, etc) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 43.103(a) Mutual Agreement of the Parties

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

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

Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to modify ARTICLE G.3 KEY PERSONNEL.

Funds Obligated Prior to this Modification: $722,692,203
Funds Obligated with Mod #6: $ 0
Total Funds Obligated to Date: $722,692,203

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

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)
	SABRINA J. MCINTYRE

Kelly Warfield	VP, VaxBU R&D		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Kelly Warfield Reason: I approve this document Date: Nov 19, 2020 11:48 EST (Signature of person authorized to sign)	Nov 19, 2020	Sabrina J. Mcintyre -S Digitally signed by Sabrina J. Mcintyre -S Date: 2020.12.02 10:09:43 -05'00' (Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

ARTICLE G.3. KEY PERSONNEL is hereby modified as follows:

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder.

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

*Bold indicated changes in this modification

All other terms and conditions of this contract remain unchanged.

End of Modification #7

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.2

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE NO.	5. PROJECT NO. (If applicable)
P00008	See Block 16C		

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

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

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or 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 date, etc) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 43.103 (a) Mutual Agreement of the Parties

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 modify ARTICLE C.1 STATEMENT OF WORK and SECTION J LIST OF ATTACHMENTS.

Funds Obligated Prior to this Modification:	$722,692,203
Funds Obligated with Mod #8:	$ 0
Total Funds Obligated to Date:	$722,692,203

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

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)
Kelly Warfield VP, Vaccines R&D	SABRINA J. MCINTYRE

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Kelly Warfield Reason: I approve this document Date: Mar 18, 2021 09:10 EDT (Signature of person authorized to sign)	Mar 18, 2021	Digitally signed by Sabrina J. Mcintyre -S Date: 2021.03.22 17:57:58-04'00' Sabrina J. Mcintyre -S (Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary service, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work set forth in SECTION J – List of Attachments, attached hereto and made a part of the contract.

SECTION J – LIST OF ATTACHMENTS is hereby modified as follows:

1. Statement of Work, dated March 11, 2021, 10 pages

All other terms and conditions of this contract remain unchanged.

End of Modification #8

ATTACHMENT 1: STATEMENT OF WORK

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

1.0 Contractual Statement of Work

Preamable to the Statement of Work

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to RFP 16-100-SOL-00015.

1.1 Scope

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

1.2 Objective

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

- CLIN 0001 – Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)
- CLIN 0001A – Conduct of a Phase 2 clinical [**] study or other studies required by the FDA [**] (Option)
- CLIN 0012 – Include [**] the Phase 2 clinical [**] study and qualify a redundant contract filler (Base)
- CLIN 0002 – Initial purchase, storage, and delivery of product (Base)
- CLIN 0003 – Phase 4 post marketing requirements (Option)
- CLIN 0004 – Surge Capacity-Additional procurement of product (Option)
- CLIN 0006 – Surge Capacity- Additional procurement of product (Option)

1.3 CLIN 0001 - Approval of Emergency Use Authorization (EUA), licensure, approval, and clearance of product through the FDA (Base)

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

[**] Program Management

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

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

[**] Non-Clinical Toxicology

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

- [**]

[**] Non-Clinical Efficacy

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

- [**]

[**] Clinical Evaluation

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

- [**]

[**] Regulatory Activities

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

- [**]

[**] – Chemistry and Manufacturing Controls (CMC)

Emergent shall complete the manufacturing activities necessary to support BLA submission. The activities shall include but are not limited to:

  - [**]

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

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

[**] Program Management

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

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

[**] Clinical Evaluation

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

- [**] – AVA.214 Phase 2 [**] Study

[**] – Chemistry and Manufacturing Controls (CMC)

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

- [**]

1.5 CLIN 0012 – Include [**] the Phase 2 clinical [**] study and [**] contract filler (Base)

This section identifies representative activities of CLIN 0012 associated with CLIN000l subtask [**] – AVA.210 Phase 2 [**] and [**] Chemistry and Manufacturing Controls:

- [**]

1.6 CLIN 0002 – Initial purchase, storage. and delivery of product (Base)

Under the Base Period funding Emergent shall manufacture, fill, and deliver 3,000,000 doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). Emergent is approved to use management reserve funding for shipping costs associated with these deliveries.

1.7 CLIN 0003 – Phase 4 post marketing requirements (Option)

[**].

Program Management

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

- Identification of and management to, distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Integrated Product Development Plan.
- Establishment of and tracking of milestones and timelines for the initiation conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- Ongoing evaluation of qualitative and quantitative criteria and accompanying data used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.
- Maintaining and managing staff (in-house and contracted) to assure the necessary expertise and dedicated effort to perform the work.
- Directing and overseeing subcontractors and consultants to assure successful performance of planned activities within the cost and schedule constraints of the contract.

- Conducting performance measurement that shall include establishing an initial plan; defining measurable parameters; defining how these parameters relate to cost and schedule impacts; their approach in providing a detailed schedule that generates a critical path for the project; and a description of the cost-accounting system used or intended to be used based on budget estimates to monitor all costs related to the contract award for both Emergent and subcontractors on a real time basis.
- Manage contract activities in accordance with Earned Value Management. In this regard, Emergent shall:
    - Provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support product approval. The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria and a contract Work Breakdown Structure (due within 90 days of contract award with updates as requested by the Contracting Officer's Representative(COR).
    - Submit an updated Integrated Master Schedule in an approved format.
    - Use principles of Earned Value Management System (EVMS) in the management of this contract.
    - Submit a plan for a Performance Measurement Baseline Review (PMBR) electronically via email to the Contracting Officer (CO) and COR for a PBMR to occur within 90 days of contract award.
- Develop and maintain a risk management plan.
- Participate in regular meetings to coordinate and oversee the contracting effort.

[**]

1.8 CLIN 0004 through 11 – Surge Capacity – Additional procurement of product (Option)

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

Under CLIN 0004, Emergent shall manufacture, fill, and deliver 10,263,000 doses procured in fiscal year 2019 as an initial procurement to the Strategic National Stockpile (SNS). [**].

Under CLIN 0006 Emergent shall manufacture, fill, and deliver 10,000,000 doses procured from August 1, 2020 through July 31, 2021, as an additional procurement to the SNS. [**].

For CLINs 0004 and 0006, BARDA may accept [**] shall be calculated as [**]% of the number of delivered [**].

For delivery to the SNS, Emergent shall comply with the relevant associated activities and deliverables as outlined in the Quality Agreement (attached) as signed by Emergent, BARDA, and the SNS. Emergent shall provide appropriate documentation to BARDA for quality assurance of the final drug product delivered to the SNS and invoice appropriately.

1.9 Reporting Requirements and Deliverables Reports

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

Monthly Technical Progress Reports

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

Annual Progress Reports

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

Draft Final Report and Final Report

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

FDA Regulatory Agency Correspondence. Meeting Summaries, and Submissions

With regard to interactions with the FDA, Emergent shall:

- Forward the initial draft minutes to BARDA within five business days of any formal meeting with the FDA or other regulatory agency, and forward the final minutes when available.

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

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

Key Deliverables

A summary of Key Deliverables for this contract follow

No.	Deliverable	Description	Due Date
01	Monthly Progress Report	Shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.	Due on or before the 15th day of each month following the end of each reporting period. Monthly progress reports are not required in the same month Annual Progress reports or a Final Report are due.
02	Annual Progress Report	Shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.	Due on or before the 30th calendar day following the end of each reporting period.
03	Draft Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due 45 Calendar days prior to the expiration date of the contract.
04	Final Progress Report	To include a summation of the work performed and results obtained for execution of various studies or technical work packages during entire contract period of performance. Shall be in sufficient detail to describe comprehensively the results achieved.	Due on/before the expiration date of the contract.
05	FDA/Regulatory Agency Correspondence and Meeting Minutes	The Contractor shall forward initial draft minutes and final draft minutes of any formal or informal meeting with the FDA or other regulatory agency. The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall forward SOPs upon request from the COR. The contractor shall notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency, and provide copies of any associated reports, documentation, or communication.	Due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR or Co-COR.
06	Integrated Master Project Plan (Critical Path Milestones, Work	The contractor shall provide an Integrated Master Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables (key,	Due within 90 days of contract award. Updates are due as requested by the COR or Co-COR.

No.	Deliverable	Description	Due Date
	Breakdown Structure, Risk Mitigation Plan/ Matrix)	critical path milestones, with "Go/No Go" decision criteria) and Work Breakdown Structure (WBS) elements that shall be discernable and consistent. The contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans.	
07	Technology Packages	Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA COR.	Due upon request from the COR or Co-COR.
08	Experimental Protocols	The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Co-COR when required.	Due upon request from the COR or Co-COR.
09	Annual/Final Invention Report	All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the CO.	Annual Invention Report Due on or before the 30th calendar day after the completion of each reporting period. Final Invention Report due on or before the expiration of the contract.
10	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission.	Due within 30 calendar days for manuscripts prior to publication and 15 calendar days for abstracts.
11	Press Releases	The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the CO has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.	Reports/Notices due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
12	Security Report	The contractor shall report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products	Due within 24 hours after occurrence of an activity or incident.
13	Earned Value Management System Requirements	Subject to the requirements under FAR 52.234-4 Earned Value Management System, the Contract shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Contractor shall also submit a Performance Measurement Baseline Review	As detailed in Section F.3.2 Subpart F.

No.	Deliverable	Description	Due Date
		plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award, and an Integrated Master Schedule electronically via email as outlined in a format agreed upon by BARDA to the COR and CO. The Offeror shall deliver an Earned Value Contract Performance Report on a monthly basis.	

	Milestone #	WBS #	Milestone	Deliverables Summary (Details as specified in the Deliverables)	Quantity	Estimated Completion Date
CLIN 0001 & CLIN 0012	1	[**]	[**]	[**]	1 Electronic Copy to Contract Officer Representative (COR); 1 Electronic Copy to Contracting Officer (CO)	[**]
	2	[**]	[**]	[**]	See Above	[**]
	3	[**]	[**]	[**]	See Above	[**]
	4	[**]	[**]	[**]	See Above	[**]
	5	[**]	[**]	[**]	See Above	[**]
	8	[**]	[**]	[**]	See Above	[**]
	9	[**]	[**]	[**]	See Above	[**]
	10	[**]	[**]	[**]	See Above	[**]
	11	[**]	[**]	[**]	See Above	[**]
	12	[**]	[**]	[**]	See Above	[**]
CLIN 0002	16	-	Completion of delivery of 3 million doses of AV7909	Delivery of 3 million doses of AV7909	See Above	[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.3

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

2. AMENDMENT/MODIFICATION NO. P0009	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)

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., S.W. 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 PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR# 100 GAITHERSBURG MD 208793419		9B. DATED (SEE ITEM 11)
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHS0100201600030C
		10B. DATED (SEE ITEM 13) 09/30/2016
CODE 1365869 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or 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).
☐	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
☐	D. OTHER (Specify type of modification and authority) FAR 43.103(a) Mutual Agreement of the Parties

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to modify ARTICLES F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

Funds Obligated Prior to this Modification: $722,692,203
Funds Obligated with Mod #9: $ 0
Total Funds Obligated to Date: $277,692,203

Expiration Date: September 29, 2021 (unchanged)
Period of Performance: 09/03/2016 to 09/29/2021

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

15A. NAME AND TITLE OF SIGNER (Type or print).		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) SABRINA J. MCINTYRE	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA Sabrina J. Mcintyre -S Digitally signed by Sabrina J Mcintyre -S Date 2021.04.21 18:25:20'4'00 _____ (Signature of Contracting Officer)	16C. DATE SIGNED

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STANDARD FORM 30 (Rev. 11/2016)

ActiveUS 189106461v.1

The purpose of this modification is to modify ARTICLES F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

ARTICLE F.3. DELIVERIES IS hereby modified as follows:

Email Addresses: CO – [**]
COR – [**]

ARTICLE G.1. CONTRACTING OFFICER is hereby modified as follows:

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

[**]
HHS/OS/ASPR/BARDA
200 C St. SW
O'Neil House Office building
Washington, DC 20515
[**]

ARTICLE G.4. INVOICE SUBMISSION is hereby modified as follows:

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

ARTICLE G.1.CONTRACTING OFFICER is hereby modified as follows:

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

[**]
HHS/OS/ASPR/BARDA
200 C St. SW
O'Neill House Office Building
Washington, DC 20515
[**]

ARTICLE G.4. INVOICE SUBMISSION is hereby modified as follows:

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

Sabrina McIntyre Contracting Officer HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	Adam Clark Contracting Officer Representative HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	Email invoices to: PSC Invoices@psc.hhs.gov e-Room

All other terms and conditions of this contract remain unchanged.

End of Modification #9

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.4

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 | 3

2. AMENDMENT/MODIFICATION NO. P00010	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)

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., S.W. 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 PRODUCT DEVELOPMENT GAITHERSBURG INC. EMERGENT PRODUCT DEVELOPMENT GAITHE 300 PROFESSIONAL DR# 100 GAITHERSBURG MD 208793419		9B. DATED (SEE ITEM 11)
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHS0100201600030C
		10B. DATED (SEE ITEM 13) 09/30/2016
CODE 1365869 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or 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).
☐	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
☒	D. OTHER (Specify type of modification and authority) FAR 43.103(a) Mutual Agreement of the Parties

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

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

Tax ID Number: [**]
DUNS Number: [**]
The purpose of this modification is to modify ARTICLES B.2 BASE PERIOD, B.3 OPTION PRICES, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

Funds Obligated Prior to this Modification:	$722,692,203
Funds Obligated with Mod #10:	$ 0
Total Funds Obligated to Date:	$277,692,203

Expiration Date: May 31, 2025 (Changed)
FOB: Destination
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).		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Kelly Warfield VP, Vaccines R&D		SABRINA J. MCINTYRE	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Kelly Warfield Reason: I approve this document Date: June 10, 2021 09:09 EDT' /s/ Kelly Warfield (Signature of person authorized to sign)	Jun 10, 2021	Sabrina J. Mcintyre -S Digitally signed by Sabrina J. Mcintyre-S Date: 2021.06.10 10:50:28-04'00' (Signature of Contracting Officer)	

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

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

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 09/30/2012 to 05/31/2025 Change Item 1 to read as follows (amount shown is the obligated amount):				
1	CLIN 0001 and CLIN 0002 for Licensure, Approval, and Clearance or Product through the FDA/Initial Purchase, Storage, and Delivery of Product Accounting Info: 2016.1990007.26201 Appr. Yr.: 2016 CAN: 1990007 Object Class: 26201 Funded: $0.00 Change Item 5 to read as follows(amount shown is the obligated amount):				0.00
5	CLIN 0012 [**] Accounting Info: 2018.199TWNP.25106 Appr. Yr.: 2018 CAN: 199TWNP Object Class: 25106 Funded: $0.00				0.00

The purpose of this modification is to modify ARTICLES B.2 BASE PERIOD, B.3 OPTION PRICES, F.3 DELIVERIES, G.1 CONTRACTING OFFICER, and G.4. INVOICE SUBMISSION.

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

CLIN	Period of Performance	Supplies/Services	Total Est. Cost	Fixed Fee 7%	Total Cost Plus Fixed Fee
COST REIMBURSEMENT					
0001 (Funded)	09/30/2016 - 05/31/2025	Licensure, approval, and clearance of product through the FDA	[**]	[**]	[**]

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

CLIN	Period of Performance	Supplies/Services	Total Est. Cost	Fixed Fee 7%	Total Cost Plus Fixed Fee
COST REIMBURSEMENT					
0012 (Funded)	09/29/2018 – 05/31/2025	[**]	[**]	[**]	[**]

ARTICLE F.3. DELIVERIES is hereby modified as follows:

Email Addresses: CO – [**]
COR – [**]

ARTICLE G.1. CONTRACTING OFFICER is hereby modified as follows:

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

[**]
HHS/OS/ASPR/BARDA
200 C St. SW
O'Neill House Office Building
Washington, DC 20515
[**]

ARTICLE G.4. INVOICE SUBMISSION is hereby modified as follows:

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

Jill Johnson Contracting Officer HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	Adam Clark Contracting Officer Representative HHS/ASPR/BARDA 200 C Street, S.W. Washington, DC 20024 Email: [**]	Email invoices to: PSC Invoices@psc.hhs.gov e-Room

All other terms and conditions of this contract remain unchanged.

End of Modification #10

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. 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. P00003	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS273903	5. PROJECT NO. (If applicable)

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: $[**]
2021.199SN21.25102

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).
☒	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.

Tax ID number: [**]
DUNS Number: [**]
ACAM2000, Smallpox (Vaccinia) Vaccine, Live (ACAM)

The purpose of this modification is to exercise and fund Option Year 2, CLIN 2004, Task 4 - Relabeling of ACAM 2000; 1 JOB @ $[**] = $[**]. The Period of Performance is 10/01/20 - 09/30/21.

This modification also corrects verbiage as stated on Modification P00001 as follows:
Option 1001 - Task 4 is hereby corrected to read Option 1004 - Task 4; all other information is correct.
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). Chris Sinclair VP, Federal Public Health		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) NATASHA Y. ROWLAND	
15B. CONTRACTOR/OFFEROR /s/ Chris Sinclair (Signature of person authorized to sign)	15C. DATE SIGNED Apr 1, 2021	16B. UNITED STATES OF AMERICA /s/ Natasha Rowland (Signature of Contracting Officer)	16C. DATE SIGNED 04/01/2021

STANDARD FORM 30 (Rev. 11/2016)

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50119C00071/P00003	PAGE OF 2	2

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)
	No further changes. Appr. Yr.: 2021 CAN: 199SN21 Object Class: 25102 Period of Performance: 10/01/20 – 09/30/21 Add Item 4 as follows: ACAM2000 Relabeling Obligated Amount: $[**]				
4					[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.6

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES
		1 of 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00027	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)	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT BIODEFENSE 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).
☒	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a)(3)Bilateral mutual agreement of both parties
☐	D. OTHER (Specify type of modification and authority)

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

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

A. Revise Contractor's Key Personnel.
B. Change Contracting Officer from [**] to [**].
C. See attached following pages for details.
All other terms and conditions remain in full force and effect.
Period of Performance: 06/15/2012 to 06/30/2021

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

15A. NAME AND TITLE OF SIGNER (Type or print).		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Mark Alley Vice President		MONICA WATSON	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Mark Alley Reason: I approve this document Date: May 6, 2021 12:13 EDT /s/ Mark Alley	May 6, 2021	Digitally signed by Monica Watson -S Date: 2021.05.05 09:40:53 -04'00' /s/ MONICA WATSON	

(Signature of person authorized to sign)		(Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (Rev. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

A. This is Modification No.0027 to contract No.HHS01002012000041 for Innovation in Advanced Development and Manufacturing (CIADM)
B. The purpose of this modification is to update the Contractor's Key Personnel. Accordingly, the following changes are made to the contract:
[**]
C. Delete the current "Contractor Key Personnel" under Section H.15 KEY PERSONNEL in its entirety, and replace with the following Contractor Key Personnel table:

Contractor Key Personnel Table

Current		Status	Revision required	
[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	
[**]	[**]	[**]		
[**]	[**]	[**]		

D. Remove [**] as Contracting Officer under section D.3. REPORT DELIVERABLES and replace with [**] as Contracting Officer.

E. All other terms and conditions remain in full force and effect.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.7

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

2. AMENDMENT/MODIFICATION NO. P00028	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)

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. HHS0100201200004I
		10B. DATED (SEE ITEM 13) 06/15/2012
CODE 330303 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).
☒	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR. 52.217- 8, Option to extend service – and FAR 52.217- 9 option to extend the term of the contract
☐	D. OTHER (Specify type of modification and authority)

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

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

I) TO exercise Option Period IX associated with CLINS 0035, 0036, 0037 and 0038.
a) The period of performance for Option Period IX is from June 15, 2021 through June 14, 2022

2) Extend the Base Period of Performance(POP).
a) The Base period is hereby extended from June 15, 2012 to September 30, 2021.

All other terms and conditions remain the same and in full force and effect.
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).	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Patrick D. Saam VP, Government Contracting and Accounting	JEFFREY R. SCHMIDT

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by: Patrick D. Saam Reason: I approve this document Date: May 26, 2021 15:41 EDT		Jeffrey R. Schmidt-S Digitally signed by Jeffrey R. Schmidt-S Date: 2021.05.27 11:47:15 -04'00'	

/s/ Patrick D. Saam (Signature of person authorized to sign)	May 26, 2021	(Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (Rev. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED HHS01002012000041/P00028	PAGE OF 2	2

NAME OF OFFEROR OR CONTRACTOR
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC 1410445

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 06/15/2012 to 09/30/2021				

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.8

ORDER FOR SUPPLIES OR SERVICES						PAGE OF PAGES	
IMPORTANT: Mark all packages and papers with contract and/or order numbers.						1	17
1. DATE OF ORDER	2. CONTRACT NO. (if any)		6. SHIP TO				
04/02/2020	HHS01002012000041		a. NAME OF CONSIGNEE Multiple Destinations				
3. ORDER NO. 75A50120F33006	4. REQUISITION/REFERENCE NO. 0S256855						
5. ISSUING OFFICE (Address correspondence to) ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201			b. STREET ADDRESS c. CITY		d. STATE	e. ZIP CODE	
7. TO:			f. SHIP VIA				
a. NAME OF CONTRACTOR EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC			8. TYPE OF ORDER				
b. COMPANY NAME			☐ a. PURCHASE REFERENCE YOUR:		☒ 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.		
c. STREET ADDRESS EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST			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.				
d. CITY BALTIMORE	e. STATE MD	f. ZIP CODE 212246824					
9. ACCOUNTING AND APPROPRIATION DATA 2020.199C0V2.25103			10. REQUISITIONING OFFICE BARDA				
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) ☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone ☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB					12. F.O.B. POINT		
13. PLACE OF a. INSPECTION Destination	13. PLACE OF b. ACCEPTANCE Destination	14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 10/02/2021		16. DISCOUNT TERMS		

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: [**] A detailed breakdown of CLIN costs is reflected in Section B of this task order. Appr. Yr.: 2020 CAN: 199C0V2 Object Class: 25103 Continued . . .					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:				
	a. NAME PSC/FMS			$[**]	
	b. STREET ADDRESS (or P.O.Box) PSC_invoices@psc.hhs.gov				17(i) GRAND TOTAL
	c. CITY	d. STATE	e. ZIP CODE	$[**]	

22. UNITED STATES OF AMERICA BY (Signature)	Crystal R. Reed-tweedy-S Digitally signed by Crystal R. Reed-tweedy-S Date: 2020.04.02 13:38:13 -04'00'	23. NAME (Typed) CRYSTAL R. REED-TWEEDY TITLE: CONTRACTING/ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
04/02/2020	HHS0100201200004I	75A50120F33006

ITEM No. (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Period of Performance: 04/02/2020 to 10/02/2021					
1	ASPR- 2 0- 01770 -- Award of a Task Order to Emergent Product Development under Emergent's current CIADM IDIQ contract (HHS0100201200004I) to support Development of a COVID-19 Therapeutic Medical Countermeasure (COVID-HIG) Delivery Location Code : HHS /OS/ ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US Amount : $[**]				[**]	
2	OPTIONAL- Support of additional clinical trial, including the supply of at least [**] doses, plus storage and shipping as required Amount: $[**] (Option Line Item) Delivery Location Code: HHS HHS 200 Independence Avenue, SW Washington DC 20201 US Amount: $[**] The total amount of award: $[**]. The obligation for this award is shown in box 17(i).				0.00	
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))			▷	$[**]	

B. COST / PRICE SCHEDULE

Cost-Plus-Fixed Fee CLINS

Base CLIN Table				
CLIN	ITEM DESCRIPTION	Cost	Fee ([**]%)	Cost Plus Fixed Fee
0001	• Collection of human plasma containing antibodies to SARS-CoV-2 sufficient to supply at least [**] doses of drug product. • cGMP manufacture of at least [**] doses of drug product for use in a controlled clinical trial; manufacturing approach must be amenable to commercial-scale production within potential EUA timeframe estimated to be [**]; stability testing as needed to support clinical use. • Development and validation/qualification of assays as required for screening, stability testing, and manufacturing. • Supportive nonclinical studies as required for development of drug product. • Regulatory filings to FDA, including formal interactions (e.g., Pre-IND) as necessary, IND submission, and EUA submission within targeted [**] of task order award. • Support of clinical trial through drug supply, including storage and shipping as required. • Program management and reporting as required.	[**]	[**]	[**]

Option CLIN Table				
CLIN	ITEM DESCRIPTION	Cost	Fee ([**]%)	Cost Plus Fixed Fee
0002	• Support of additional clinical trial, including the supply of at least [**] doses, plus storage and shipping as required. • Program management and reporting as required.	[**]	[**]	[**]

Total Not to Exceed Amount	$[**]

C. STATEMENT OF OBJECTIVES

C.1 Background

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 CO VID-19. As a result of the virus' global spread, HHS declared a public health emergency for the U.S. on January 31, 2020 to aid the nation's healthcare community in responding to COVID-19. On March 13, 2020, the President proclaimed that the COVID-19 outbreak in the U.S. constitutes a national emergency.

Currently, there are no FDA-approved therapeutics for the treatment of COVID-19. There is great interest in evaluating the use of convalescent plasma and plasma-derived products as therapeutics for COVID-19, given their historical use as treatments in other outbreaks. Notably, the FDA recently published guidance on the investigational use of COVID-19 convalescent plasma under emergency INDs.

As part of the HHS' response to COVID-19, BARDA is seeking solutions for the manufacture and development of plasma-derived polyclonal antibody-based COVID-19 therapeutics for clinical evaluation, with potential for commercial-scale manufacture under EUA.

C.2 Scope of Work (SOW)/Objectives

Independently and not as an agent of the US Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described below.

The Contractor shall:

- Collect human plasma containing antibodies to SARS-CoV-2 sufficient to supply at least [**] doses of drug product.
- Manufacture at least [**] doses of cGMP drug product for use in a controlled clinical trial using an approach amenable to commercial-scale production within potential EUA timeframe of [**], plus stability testing as required for clinical use. The clinical trial is anticipated to start within [**] of contract award.
- Develop and validate/qualify assays required for screening, manufacturing, and stability testing as necessary.
- Conduct supportive nonclinical studies as required for development of drug product.
- Prepare and submit regulatory filings to FDA, including IND submission, and conduct formal meetings (e.g., Pre-IND) with FDA as necessary. EUA submission is targeted within [**] of task order award.
- Support clinical trial(s) through the delivery of cGMP drug product (includes storage and shipping) and all supporting information as required.
- Provide program management and reporting as required.

C.3 (SOW) Tasks

TASKS

The Contractor shall perform the following Tasks:

CLIN 0001: Manufacture and Development of Human Immune Globulin Drug Product from Human Plasma for Clinical Evaluation

A. Collection of Human Plasma Containing Antibodies to SARS-CoV-2

The Contractor shall collect human plasma containing antibodies to SARS-CoV-2 which will include utilizing FDA-approved plasma collection centers in the U.S. Collection may rely on a [**]. The volume of plasma collected shall be sufficient to supply at least [**] doses of final human immune globulin drug product.

B. Manufacture of at Least [**] doses of Human Immune Globulin Drug Product

The Contractor shall use the collected plasma to manufacture at least [**] doses of fill-finished human immune globulin final drug product under cGMP conditions. The manufacturing approach used should be scalable based on the availability and timing of plasma collections, with potential to scale-up to commercial manufacturing within a potential EUA timeframe of [**] from task order award. A manufacturing process used previously for FDA-approved human immune globulin products is preferred as a means

of reducing technical and regulatory risk. The process should include purification and viral inactivation/removal as necessary. BARDA anticipates that the purified product will be formulated as a liquid formulation.

The [**] doses of fill-finished drug product must be made available for clinical evaluation; the clinical trial is expected to start within [**] of task order award. The Contractor must oversee storage and shipping of plasma, intermediates, and drug product between facilities as required. The Contractor must also conduct stability testing as required to support clinical use of the product.

C. Development and Validation/Qualification of Assays to Support Screening and Manufacturing

The Contractor shall develop assays as needed to support cGMP manufacturing, including (but not limited to) in-process, release, and stability assays. Potency assays specific to SARS-CoV-2 will need to be developed based on either wildtype SARS-CoV-2 (will require [**]) or pseudotype virus (will require [**]). The assays must be qualified and/or validated as appropriate using available reference standards or positive controls. This shall include the production of all analytical documentation, training and facility readiness required to support on-going testing. In the event that assays are to be subcontracted, the Contractor shall provide copies of the Supply and Quality Agreements between the Prime Contractor and Subcontractor for review prior to approval.

D. Conduct Supportive Nonclinical Studies as Required for Development of Drug Product

The Contractor shall conduct nonclinical studies to support the development of the human immune drug product, including any as specified by FDA. Supportive efficacy studies in animal models (e.g., mice or ferrets) may also be warranted (for example, for the submission of an EUA to FDA). In the event that studies are to be subcontracted, the Contractor shall provide copies of the Subcontractor Agreements between the Prime Contractor and Subcontractor for review prior to approval.

E. Prepare and Submit Regulatory Filings to FDA (including IND Submission and EUA Submission)

The Contractor shall prepare and submit regulatory filings to the FDA as required for the development and clinical use of the human immune globulin drug product, including the submission of an IND. Preliminary discussions, including (but not limited to) Pre-IND meetings, may be necessary to ensure FDA concurrence with regulatory strategy. Following the conduct of a clinical trial(s) using the drug product, the Contractor should also be prepared to support an expedited EUA submission within [**] of task order award.

F. Support clinical trial through the delivery of cGMP drug product and all supporting information as required.

The Contractor shall support the conduct of a clinical trial evaluating the safety and efficacy of the human immune globulin drug product. BARDA anticipates that the clinical trial will be conducted in partnership with another entity (e.g., The National Institutes of Health), who will oversee the clinical operations of the trial; the Contractor is not expected to manage the clinical operations of the trial. The Contractor is expected to support the clinical trials through the supply of clinical trial material as necessary (includes storage and shipping as necessary), while also providing all documentation and information as required by the study sponsor.

G. Provide program management and reporting as required

This task shall reimburse the cost for managing the contract in connection with the deliverables described in section F2. Schedule of Deliverable below. The following are examples of those typically required: project plans, tech transfer plans, protocols, validation reports, [**] and final reports. Additionally, regular update meetings, ad hoc meetings, periodic site visits and [**] site visits shall be included.

OPTIONAL TASKS

CLIN 0002 (Option): Support for Additional Clinical Trial

A. Support clinical trial through the delivery of cGMP drug product and all supporting information as required.

The Contractor shall support the conduct of an additional a clinical trial evaluating the safety and efficacy of the human immune globulin drug product. The Contractor is expected to support the clinical trials through the supply of clinical trial material (at least [**] doses) as necessary (includes storage and shipping as necessary), while also providing all documentation and information as required by the study sponsor

B. Provide program management and reporting as required

This task shall reimburse the cost for managing the contract in connection with the deliverables described in section F2. Schedule of Deliverable below. The following are examples of those typically required: project plans, tech transfer plans, protocols, validation reports, [**] and final reports. Additionally, regular update meetings, ad hoc meetings, periodic site visits and [**] site visits shall be included.

D. PACKAGING AND MARKING (if applicable)

All deliverables shall be preserved, packaged, and packed in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that, which is necessary, to prevent deterioration and damages due to the hazard of shipping, handling, and storing.

E. INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the Contractor'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 for all optional tasks, if exercised, will fall within the Task Order award date through eighteen (18) months.

Therefore, the entire period of performance for this task order will be eighteen (18) months from task order issuance. Period of performance for CLINs with stability testing beyond this date will be adjusted as needed to accommodate completion.

The location of performance should be at the CIADM Contractor's U.S.-based facility, unless otherwise authorized by the Contracting Officer. Subcontractors may be offered for specific tasks (alternate facilities); however, the CIADM Contractor's capability and capacity, as outlined in the CIADM base contract, is the USG's preferred location for executing the majority of this work

F.2 Schedule of Deliverables

Task	Deliverable Title	Format	Deliverable Due Dates
CLIN0001/CLIN0002			
CLIN0001/CLIN0002	Regular update teleconferences	BARDA and Contractor to determine format	First meeting will be [**] post kick off meeting, subsequent meetings will be at a frequency (as short as every [**]) to be agreed by the Contractor and BARDA
CLIN0001/CLIN0002	Meeting agenda and minutes for teleconferences	Contractor-determined format	Agenda – draft [**] before teleconference; Minutes – draft within [**] of teleconference
CLIN0001/CLIN0002	[**] Status Report	BARDA-provided template	[**], on [**] following period
CLIN0001/CLIN0002	Integrated Master Schedule	Contractor-determined format	Within [**] of contract award, updated [**]
CLIN0001/CLIN0002	Incident Report	Contractor-determined format	Notification of incident within [**]. Draft report within [**] of incident, final

Task	Deliverable Title	Format	Deliverable Due Dates
			report within [**] of resolution
CLIN0001/CLIN0002	Quality Assurance Plan	Contractor-determined format	Draft – [**] Final – [**] post contract award
CLIN0001/CLIN0002	Risk Management Plan / Risk Register	Contractor-determined format	Within [**] of contract award; Risk Register updated [**]
CLIN0001/CLIN0002	Detailed data regarding locations where work will be performed	Contractor-determined format	Within [**] of contract award, updated [**]
CLIN0001/CLIN0002	Detailed spreadsheet on critical project materials that are sourced from a location other than the United States,	Contractor-determined format	Within [**] of contract award, updated [**]
CLIN0001/CLIN0002	Final Task Order Report and Assessment	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001/CLIN0002	Continuity of Operations Plan (to continue operations in the event of a declared pandemic emergency)	Contractor-determined format	Draft – [**] Final – [**] \post award of contract
CLIN0001			
CLIN0001	Plasma Collection Plan (including list of sources)	Contractor-determined format	Draft – [**] Final – [**] post award of CLIN0001
CLIN0001	Reports for Plasma Collection	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001	Final Manufacturing Report	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001	Analytical Verification Protocols	Contractor-determined format	Draft – [**] prior to planned execution Final – [**] after protocol execution
CLIN0001	Analytical Reports	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001	Validation Protocols	Contractor-determined format	Draft – [**] prior to planned execution Final – [**] after protocol execution
CLIN0001	Validation Reports	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001	Fill / Finish Strategy Report	Contractor-determined format	Draft – [**] Final – [**] post award of CLIN0001
CLIN0001	Nonclinical Protocols (BARDA approval needed prior to study execution)	Contractor-determined format	Draft – [**] prior to planned execution Final – [**] after study execution

Task	Deliverable Title	Format	Deliverable Due Dates
CLIN0001	Nonclinical Reports	Contractor-determined format	Draft – [**] Final – [**] post completion of task
CLIN0001	Regulatory Submissions to FDA (e.g., Meeting Requests, Briefing Books, etc.)	Contractor-determined format	Draft – [**] prior to submission to FDA (or as agreed-to by the COR) Final – [**] post submission to FDA
CLIN0001	Investigation New Drug (IND) Application	Contractor-determined format	Draft – [**] prior to submission to FDA (or as agreed to by the COR), within [**] post award of CLIN0001 Final – [**] post submission to FDA
CLIN0001	Information supporting Emergency Use Authorization (EUA) Request	BARDA-determined format	Within [**] of BARDA's request
CLIN0001	Documentation of drug product as requested by Sponsor of Clinical Trial	Determined by Sponsor of clinical trial	Final – [**] post submission to trial sponsor
CLIN0001	Documentation of delivery of batch of fill-finished drug product for clinical trials	Determined by Sponsor of clinical trial	Final – [**] post submission to trial sponsor
CLIN0001	Confirmation of cumulative availability of at least [**] doses of fill-finished drug product	Contractor-determined format	Final – [**] post completion of task
CLIN0002 (Option)			
CLIN0002 (Option)	Regulatory Submissions to FDA (e.g., Meeting Requests, Briefing Books, etc.)	Contractor-determined format	Draft – [**] prior to submission to FDA Final – [**] post submission to FDA
CLIN0002 (Option)	Documentation of drug product as requested by Sponsor of Clinical Trial	Determined by Sponsor of clinical trial	Final – [**] post submission to trial sponsor
CLIN0002 (Option)	Documentation of delivery of batch of fill-finished drug product for clinical trials	Determined by Sponsor of clinical trial	Final – [**] post submission to trial sponsor
CLIN0002 (Option)	Confirmation of cumulative availability of at least [**] (additional) doses of fill-finished drug product	Contractor-determined format	Final – [**] post completion of task

Meetings

Routine Update Teleconferences
The CIADM shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the CIADM and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held [**] or [**]. The CIADM shall keep meeting minutes and forward a finalized copy to the Contracting Officer (CO) and Contracting Officer's Representative (COR) for approval within [**] after each teleconference, or as otherwise authorized by the Contracting Officer.

Person-in-Plant
CIADM shall accommodate up to [**] BARDA personnel at any given time throughout the performance of this task order. On-site BARDA personnel will provide oversight of the work and real-time technical direction per guidance from the BARDA program office in Washington, D.C.

Periodic Site Visits
The CIADM shall accommodate for periodic site visits by USG on an ad hoc basis. The CIADM 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.

[**] Site Visits
The CIADM shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the CIADM's site on a [**] basis. The CIADM 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.

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 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 Government Personnel

(a) Contracting Officer
[**]
ASPR/BARDA/CMA
O'Neill House Office Building
Washington, DC 20015
Email: [**]
Phone: [**]

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 Task Order.

The Contracting Officer is also the only individual with authority to act as agent of the Government under this Task Order, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Task Order and/or (5) otherwise change any terms and conditions of this Task Order.

(b) Contracting Officer's Representative
[**]
ASPR/BARDA
24H26, O'Neill House Office Building
Washington, DC 20515
Email: [**]
Phone: [**]

[**]
ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
Email: [**]
Phone: [**]

G.2 Invoicing Instructions

Invoices for payment shall be submitted as two (2) hard copies and one (1) electronic copy to the following address, and shall include SF-1034. In addition, for Cost Plus Fixed Fee (CPFF) CLINs, the CIADM shall provide supporting documentation with the invoice to support all claimed costs. This includes an itemized breakdown of all associated costs such as labor classification, labor hours, labor rate, indirect costs, timecards, etc. This shall be provided for the CIADM (prime contractor) and all subcontractors. Further invoicing details are included in Section G of the base CIADM contract.

[**]
ASPR/BARDA/CMA
O'Neill House Office Building
Washington, DC 20515
Email: [**]
Phone: [**]

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices.

G.3 Evaluation of Contractor Performance

(a) Purpose: In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least [**] and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

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

(c) 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).

(d) 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.

(e) 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.

(f) 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.

(g) 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.

(h) 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 Intellectual Property

Execution of a 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.2 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. 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. The offeror may list other individual(s) it deems would fall under the Key Personnel category, for USG evaluation.

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

H.3 Personnel Qualifications

The offeror shall provide curriculum vitae (CV) for each individual specified in its proposal as key personnel. The CV shall clearly describe the individual's knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual's involvement in similar work.

H.4 Consultants and Sub-Contractors

If the Contractor determines that the use of Subcontractors or Consultants is needed, the Contractor is directed to submit a Contracting Officer's Authorization request.

H.5 No Personal Services or Inherently Governmental Function

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor 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, hi 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 this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall 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 this 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.

H.6 ADDITIONAL TERMS AND CONDITIONS

The terms and conditions applicable to this Task Order Award are as follows:
References:

- Base Contract Number: HHSO 1002012000041
- Task Order (TO) Award Number: 75A50120F33006

- HHS reserves the right to exercise priorities and allocations authority with respect to this task order, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

Documents Incorporated By Reference:

1. Proposal dated March 20, 2020
2. Revised price proposal dated March 31, 2020

I. FAR/HHSAR CONTRACT CLAUSES

I.1 52.232-2 Clauses Incorporated by Reference

All clauses incorporated in the base contract are in full effect at the task order level. This section or other parts of this TOR 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/

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.9

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

2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS273315	5. PROJECT NO. (If applicable)

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 75A50120F33006
		10B. DATED (SEE ITEM 13) 04/02/2020
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) Net Increase: $[**]
2020.199COV2.25103

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).
☒	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR. 52.232-20, (i) Limitation of cost of funds.
☐	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: [**]
This is Modification No. P00001 to Contract No. 75A50120F33006.
The purpose of this modification is to add funds to cover plasma acquisition costs for the manufacture of anti-SARS-CoV-2 hyperimmune globulin.
Accordingly, the following changes are made to the contract:
A. Add Supplemental Funds to CLIN 0001 in the amount $[**] in supporting manufacturing of hyperimmune globulin for NIH-sponsored clinical trials.
B. The value if CLIN 0001 was $[**], increased by $[**], as a result of this modification, new total for CLIN 0001 is now $[**].
C. Replace Contract Officer (CO) under section (G) Contract Administration, G.1.(a) government
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).		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Syed T Husain SVP and CDMO BU Head		MONICA WATSON	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by Syed T Husain Reason: I approve this document Date: April 7, 2021 00:00 EDT /s/ Syed T Husain (Signature of person authorized to sign)	Apr 7, 2021	/s/ Monica Watson Digitally signed by Monica Watson -S Date: 2021.04.12 15:44:23 -04'00' (Signature of Contracting Officer)	

STANDARD FORM 30 (Rev. 11/2016)

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED HHS01002012000041/75A50120F33006/P00001	PAGE OF 2	2

NAME OF OFFEROR OR CONTRACTOR

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC 1410445

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	personnel. Contract Officer [**] is being replaced by [**] D: All other terms and conditions remain the same. Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103 Period of Performance: 04/02/2020 to 10/02/2021 Change Item 1 to read as follows (amount shown is the obligated amount) :				
1	ASPR-20-01770 – Award of a Task Order to Emergent Product Development under Emergent's current CIADM IDIQ contract (HHSO100201200004I) to support Development of a COVID-19 Therapeutic Medical Countermeasure (COVID-HIG)				[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.10

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

2. AMENDMENT/MODIFICATION NO. P00007	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS251972	5. PROJECT NO. (If applicable)

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	AS PR-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 75A50120F33007
		10B. DATED (SEE ITEM 13) 05/24/2020
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).
☒	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103 (a) (3) 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:

A. Incorporate language under H.1.13 to reflect Third Party batch production and the associated credit to BARDA.

B. Update Contractor's Key Personnel.

See attached page for full details.

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).		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Catherine Hanley VP, Interim Head of CDMO Business Unit		JEFFREY R. SCHMIDT	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Electronically signed by Catherine Hanley Reason: I approve this document Date: May 24, 2021 09:00 EDT /s/ Catherine Hanley (Signature of person authorized to sign)	May 24, 2021	/s/ Jeffrey R, Schmidt Digitally signed by Jeffrey R, Schmidt Date: 2021.05.24 14:25:18 -04'00' (Signature of Contracting Officer)	

Previous edition unusable

STANDARD FORM 30 (Rev. 11/2016)
Prescribed by GSA
FAR (48 CFR) 53.243

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE OF	
	HHS01002012000041/75A50120F33007/P00007	2	3

NAME OF OFFEROR OR CONTRACTOR

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC 1410445

ITEM No. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	All other terms and conditions remain in full force and effect. Period of Performance: 05/13/2020 to 12/31/2021				

Contract Number HHSO100201200004I, Task Order 75A50120F33007, P00007

On the effective date of this modification, the following changes are made to, Contract Number HHSO100201200004I, Task Order 75A50120F33007.

A. The purpose of this modification is to incorporate language under H.1.13. Accordingly, the following language is being added to the contract.

1. "H.1.13 The Contractor, after entering into a separate agreement with a third-party [**] agrees to reduce the total payments in Paragraph B.2. Task 1 Payment Schedule by $[**] per batch, up to [**] batches a month and estimated not-to-exceed [**] batches, or $[**], as a credit for reallocating a portion of the current monthly reserve capacity from BARDA to the third-party.

The Contractor will reduce the monthly Unit Price billings accordingly upon completion of all third-party batch production, release, and receipt of payment by Emergent from the third party or as otherwise agreed upon by the Government and Contractor in good faith, for the Reporting Periods in which the third-party batches occur. For avoidance of doubt, the third-party batch production and associated Unit Price reductions are limited to the calendar month in which such production actually occurs and credit for batches in excess of [**] for any calendar month do not carryover to future Reporting Periods.

Any reduction to the monthly Unit Price will result in a corresponding reduction to the total fixed price of Task 1: Capacity Reservation listed in Paragraph B.1.2 and the total fixed price of this task order listed in Paragraph B.1.1.

B. Update Contractor's Key Personnel in Section G.3 as follows:
1. Replace [**] as Principal Investigator with [**] as Principal Investigator.

C. Current		Status	Revision required	
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	

All other terms and conditions remain in full force and effect.

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.11

CHANGE ORDER NO. 1 TO WORK ORDER #5997-01 – [**] STUDY AND [**]

This Change Order No. 1 entitled – [**] STUDY AND [**] ("Change Order") effective as of July 31, 2020 ("Change Order Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order is to add to the Services set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01, Service Provider will render to Astrazeneca the following Services:

1.1 Stage 1 Development Study. The goal is to evaluate [**] storage solutions for [**] of the [**] used for [**] of the Product bulk drug substance, and determine a [**] for [**]. The study will utilize [**]. The detailed study design will be approved in writing by both Service Provider and AstraZeneca. The experiment will be documented in the lab notebook.

1.2 [**] Study. The goal is to demonstrate the suitability of the selected [**] for [**] of the [**] over a predefined [**] and [**] will be determined [**].

The [**] study will be performed under quality assurance approved protocol to support validation. The process parameters will be based on the finalized process parameter selected for the process performance qualification campaign. Detailed study design and batch records will be approved in writing by both Service Provider and Client. All results will be reviewed by quality and the study report will be approved, in writing, by the appropriate Service Provider and Astra Zeneca quality representative.

2. Deliverables.

2.1 Data summary for [**]

2.2 [**]

2.3 [**]

3. Service Fees

3.1 In addition to fees set forth in Work Order 5997-01, the additional fees due to Service Provider for Services included under this Change Order shall be as follows:

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

3.2 Astrazeneca shall pay Service Provider all fees and costs set forth in this Change Order in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task, with the remaining [**]% payable upon completion of the applicable activity or task; and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services, with the remaining [**]% payable upon Service Provider's receipt of the materials or services. Late payments shall bear interest at the lesser of [**]% per month or the maximum rate allowed by law until such time as paid in full.

4. Estimated Timeline

Service Provider presents the following non-binding estimated timeline to represent the currently expected duration of activities set forth in this Change Order which is subject to change at Service Provider's sole discretion due to the timing of events beyond Service Provider's control, including but not limited to timing of receipt of this executed Change Order. All timelines set forth in this Change Order are estimated and based on a number of assumptions and currently known information. Astrazeneca acknowledges that portions of the work to be performed are experimental in nature and may not have been fully validated within generally accepted standards of the pharmaceutical industry. To the extent assumptions or information change, or there are unexpected results or events or delays, including but not limited to delays in receipt of materials or information from Astrazeneca, timelines may be impacted.

[**]

5. All other terms and conditions of Work Order 5997-01 remain unchanged and in full force and effect.

[Signature Page Follows]

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager, BES
Date: 11 August 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name: Jon Lenihan
Title: Sr. Dir., Head of Sales & BD
Date: Aug 4, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.12

CHANGE ORDER NO. 2 TO WORK ORDER #5997-01 – [**] STUDY AND [**] OF COVID-19 VACCINE DRUG SUBSTANCE

This Change Order No. 2 entitled — [**] STUDY AND [**] OF COVID-19 VACCINE DRUG SUBSTANCE ("Change Order No. 2") effective as of August 04, 2020 ("Change Order No.2 Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No.2 is to further add to the Services set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01(including without limitation, within Change Order No.1), Service Provider will render to Astrazeneca the following Services:

1.1 [**] for AZD1222 drug substance (DS), [**].

1.1.1 Description of Product and Container Closure. The [**].

1.1.2 Storage Conditions. During the stability study, store AZD1222 DS samples at the storage conditions described in Table 3. Specific information regarding the lots to be used for this study will be provided in a separate memo issued by Astrazeneca to the Service Provider.

Table 1: [**] Storage Conditions for AZD1222 Drug Substance

Storage Condition	Storage Description
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

1.1.3 Sample Requirements and Handling. [**].

Table 2: Sample Requirements for AZD1222 Drug Substance

Temperature	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	

Temperature	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	

1.2 [**] Study. [**].

Table 3. Sample pulling window for AZD1222 Drug Substance

Service Provider presents the following non-binding estimated timeline to represent the currently expected duration of activities set forth in this Change Order which is subject to change at Service Provider's sole discretion due to the timing of events beyond Service Provider's control, including but not limited to timing of receipt of this executed Change Order. All timelines set forth in this Change Order are estimated and based on a number of assumptions and currently known information. Astrazeneca acknowledges that portions of the work to be performed are experimental in nature and may not have been fully validated within generally accepted standards of the pharmaceutical industry. To the extent assumptions or information change, or there are unexpected results or events or delays, including but not limited to delays in receipt of materials or information from Astrazeneca, timelines may be impacted.

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

1.2.1 Testing of [**] samples are to [**].

1.2.2 For [**].

1.2.3 [**].

1.2.4 All reserve, backup and other unused samples [**]. Emergent will provide notification to the Astrazeneca Global Stability Management team [**].

Table 4. Sample requirement for each analytical method

Method	Number of [**] Samples
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

1.3 Testing Requirements

1.3.1 The tests to be performed during this study are listed in Table 5 and Table 5-2. A description of test methodology can be found in the applicable SOPs for each test method.

1.3.2 Initial [**] results are obtained from QC release data. If a study is initiated later than [**].

Table 5. Testing Schedule for AZD1222 Drug Substance

[**]

Table 6. Testing Requirements for AZD1222 Drug Substance [**]

Test	Method
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

2. Deliverables.

2.1 [**] Results

2.2 [**] Report.

3. Service Fees.

3.1 In addition to fees set forth in Work Order 5997-01 and in Change Order No.1, the additional fees due to Service Provider for Services included under this Change Order No.2 shall be as follows:

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	Previously completed during tech transfer		
Subtotal			[**]	[**]	[**]

Note: [**] will be outsourced.

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

†[**] program for drug substance will be invoiced per [**], assume [**] at [**] estimated pass-through costs per [**]. ††[**] program for drug product will be invoiced per [**], assume [**] in estimated pass-through costs per [**].

The estimated pass through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

Price Matrix Summary			
Task	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
Subtotal	[**]	[**]	[**]

3.2 Astrazeneca shall pay Service Provider all fees and costs set forth in this Change Order in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task, with the remaining [**]% payable upon completion of the applicable activity or task; and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services, with the remaining [**]% payable upon Service Provider's receipt of the materials or services.

4. Miscellaneous. All terms and conditions of Work Order 5997-01 remain unchanged and in full force and effect.

[Signature Page Follows]

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager
Date: Sep 2, 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name: Jon Lenihan
Title: Sr. Dir., Head of Sales & BD
Date: Sep 1, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.13

CHANGE ORDER NO. 4 TO WORK ORDER #5997-01 – [**] STUDY

This Change Order No. 4 entitled — [**] STUDY ("Change Order No. 4") effective as of November 17, 2020 ("Change Order No. 4 Effective Date") to Work Order #5997- 01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby modifies and adds to the scope of Services set forth in Change Order No. 1 to Work Order #5997-01 effective July 31,2020 ("Change Order No. 1") entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No. 4 is to modify and further add to the Services set forth in Change Order No. 1.

2. The line item and task described as "[**]" set forth in Change Order No. 1 has been completed and continues to be subject to the terms and conditions of Change Order No. 1.

3. The following line items and tasks set forth in Change Order No. 1 have not been completed and the Parties remove them from Change Order No. 1:

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

4. In addition to the Services set forth in Work Order #5997-01(including without limitation, within prior Change Orders), Service Provider will render to Astrazeneca the following Services:

A [**] study to be performed by Service Provider. [**].

5. Deliverables.

2.1 Protocol and Report

6. Service Fees.

6.1 In addition to fees set forth in Work Order 5997-01 and in prior Change Orders, the additional fees due to Service Provider for Services included under this Change Order No. 4 shall be as follows:

[**] Study					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

*Per above, this work was completed under Change Order No. 1 and Service Provider will invoice the task and line item pursuant to Change Order No. 1.

The estimated pass through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

6.2 Astrazeneca shall pay Service Provider all fees and costs set forth in this Change Order in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task, with the remaining [**]% payable upon completion of the applicable activity or task; and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services, with the remaining [**]% payable upon Service Provider's receipt of the materials or services.

7. Miscellaneous. Except as amended herein, all terms and conditions of Work Order No. 5997-01 remain unchanged and in full force and effect.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager, BES
Date: December 1, 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ John Lenihan
Name: John Lenihan
Title: Sr. Dir., Head of Sales & BD
Date: December 1, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.14

CHANGE ORDER NO. 5 TO WORK ORDER #5997-01 – [**] STUDY

This Change Order No. 5 entitled — [**] STUDY ("Change Order No. 5") effective as of September 16, 2020 ("Change Order No. 5 Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No. 5 is to further add to the Services set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01(including without limitation, within prior Change Orders), Service Provider will render to Astrazeneca the following Services:

This [**] study will be performed by the Service Provider. The intent of this study will be to evaluate the [**] characteristics.

[**].

	[**]					
Test	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]

2. Deliverables.

2.1 Certificate of Analysis (COA) and a final study report

3. Service Fees.

3.1 In addition to fees set forth in Work Order 5997-01 and in prior Change Orders, the additional fees due to Service Provider for Services included under this Change Order No. 5 shall be as follows:

[**]					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

The estimated pass through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

3.2 Astrazeneca shall pay Service Provider all fees and costs set forth in this Change Order in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task, with the remaining [**]% payable upon completion of the applicable activity or task; and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services, with the remaining [**]% payable upon Service Provider's receipt of the materials or services.

4. Miscellaneous. Except as amended herein, all terms and conditions of Work Order 5997-01 remain unchanged and in full force and effect.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager
Date: Oct 2, 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name Jon Lenihan
Title: Sr. Dir., Head of Sales & BD
Date: Sep 30, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.15

CHANGE ORDER NO. 6 TO WORK ORDER #5997-01 – [**] STUDY

This Change Order No. 6 entitled — [**] STUDY ("Change Order No. 6") effective as of October 13, 2020 ("Change Order No. 6 Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No. 6 is to further add to the Services set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01(including without limitation, within prior Change Orders), Service Provider will render to Astrazeneca the following Services:

This study will be performed by the Service Provider. The intent of this study [**].

2. Deliverables.

2.1 Protocol and Report

3. Service Fees.

3.1 In addition to fees set forth in Work Order 5997-01 and in prior Change Orders, the additional fees due to Service Provider for Services included under this Change Order No. 6 shall be as follows:

Study					
Qty	Task	Deliverable	Direct Fees	Est. Pass Through Costs	Line Total
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

The estimated pass through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

3.2 Astrazeneca shall pay Service Provider all fees and costs set forth in this Change Order in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task, with the remaining [**]% payable upon completion of the applicable activity or task; and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services, with the remaining [**]% payable upon Service Provider's receipt of the materials or services.

4. Miscellaneous. Except as amended herein, all terms and conditions of Work Order 5997-01 remain unchanged and in full force and effect.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager, BES
Date: November 17, 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name: Jon Lenihan
Title: Sr. Dir., Head of Sales & BD
Date: Nov 9, 2020

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.16

CHANGE ORDER NO. 10 TO WORK ORDER #5997-01 -

[**] TESTING

This Change Order No. 10 entitled — [**] TESTING ("Change Order No. 10") effective as of March 10, 2021 ("Change Order No. 10 Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("AstraZeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order No. 10 that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No. 10 is to further add to the Services, and to clarify the specific [**] testing Services, set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01 (including without limitation, within prior Change Orders), Service Provider will render to AstraZeneca the following Services:

Work Order #5997-01 had listed [**] testing [**] testing [**] testing.

[**]	[**] Testing Deliverable	Testing ID
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

[**]	[**] Testing Deliverable	Testing ID
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
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[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

[**] (as per Table 1 below (reference is made to [**]) or as a [**] as per Table 2 below (reference is made to [**]) after [**] review and any associated [**] reports will be provided.

Table 1: [**] Testing[**]

Method Description*	Testing Identification
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

*Note: For clarity, the method descriptions for [**] testing [**] Service Provider are not as set forth in the table in paragraph 1.9 in Work Order #5997-01 but are as set forth in Table 1 above.

Table 2: [**] Testing [**]

Method Description*	Testing Identification
[**]	[**]

*Note: For clarity, the method descriptions for [**] testing [**] by Service Provider are not as set forth in the table in paragraph 1.9 in Work Order #5997-01 but are as set forth in Table 2 above.

2. Deliverables.

2.1 For Table 1 testing, [**]

2.2 For Table 2 testing, [**]

3. Service Fees.

3.1 In addition to amounts set forth in Work Order #5997-01 and in prior Change Orders, the additional amounts due to Service Provider for Services included under this Change Order No. 10 shall be as follows:

Price per Lot^

[**] Testing Support						
Qty	Task	Testing ID	Deliverable	Direct Fees	Est. Pass Through Costs*	Line Total
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]

^The above pricing replaces the pricing set forth in Work Order #5997-01 for [**] testing support.
*The estimated pass-through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

Total Price

[**] Testing Support						
Qty	Task	Testing ID	Deliverable	Direct Fees	Est. Pass Through Costs*	Line Total
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]
Sub Total				[**]	[**]	[**]

*The estimated pass-through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

3.2 AstraZeneca shall pay Service Provider all fees and costs set forth in this Change Order No. 10 in accordance with the following payment schedule: (a) all fees are payable [**]% upfront upon initiation of the specified activity or task and (b) all pass-through costs plus the administrative fee of [**]% are payable [**]% upon order placement for the materials or services.

4. Miscellaneous. Except as amended herein, all terms and conditions of Work Order #5997-01 remain unchanged and in full force and effect.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order No. 10 as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

By: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager, BES
Date: Apr 1, 2021

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name: Jon Lenihan
Title: Senior Director, Head of Sales & BD
Date: April 2, 2021

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Exhibit 10.17

CHANGE ORDER NO. 13 TO WORK ORDER #5997-01 – [**]

This Change Order No. 13 entitled — [**] ("Change Order No. 13") effective as of April 23, 2021 ("Change Order No. 13 Effective Date") to Work Order #5997-01 by and between AstraZeneca Pharmaceuticals LP ("Astrazeneca") and Emergent Manufacturing Operations Baltimore, LLC ("Service Provider") hereby adds to the scope of Services set forth in Work Order #5997-01 entered into by the Parties pursuant to the Master Services Agreement dated July 24, 2020 (the "Master Services Agreement"). Capitalized terms used in this Change Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

In consideration of the mutual promises contained therein and herein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree as follows:

1. Purpose and Description of Change. The purpose of this Change Order No. 13 is to purchase certain equipment, [**] (the "Equipment") and add related services to the Services set forth in Work Order #5997-01. In addition to the Services set forth in Work Order #5997-01(including without limitation, within prior Change Orders), Service Provider will render to Astrazeneca the following Services: purchase the Equipment.

2. Service Fees.

2.1 In addition to fees and pass-through costs set forth in Work Order 5997-01 and in prior Change Orders, the additional amounts due to Service Provider for Services included under this Change Order No. 13 shall be as follows:

Total			
Task	Direct Fees	Est. Pass Through Costs*	Line Total
[**]	[**]	[**]	[**]
Grand Total	[**]	[**]	[**]

*The estimated pass through costs are exclusive of the administrative fee. The administrative fee of [**]% will be added to the actual cost of the pass-through costs.

2.2 Astrazeneca shall pay Service Provider all fees and costs set forth in Section 2.1 of this Change Order No. 13 in accordance with the following payment schedule: [**]% upfront upon initiation of the specified activity or task.

3. Ownership and Use of Equipment. The Parties agree that Service Provider shall own the Equipment and such ownership shall survive the expiration or termination of the Agreement. Service Provider may utilize the Equipment to produce [**] provided however, that during the

Term of the Agreement such Equipment will be allocated for manufacturing Product bulk drug substance as necessary to perform Services set forth in Product Schedule(s).

4. Miscellaneous. Except as amended herein, all terms and conditions of Work Order 5997-01 remain unchanged and in full force and effect.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Change Order as of the Change Order Effective Date.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Michelle Vincent
Name: Michelle Vincent
Title: Supplier Relationship Manager, BES
Date: May 26, 2021

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

BY: /s/ Jon Lenihan
Name: Jon Lenihan
Title: Senior Director, Head of Sales & BD
Date: May 26, 2021

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 29, 2021

/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 29, 2021

/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, 2021 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 29, 2021

/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, 2021 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 29, 2021

/s/RICHARD S. LINDAHL
Richard S. Lindahl
Chief Financial Officer