UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2020**

OR

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

For the transition period from to

Commission file number: 001-33137

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

400 Professional Drive Suite 400
Gaithersburg, Maryland 20879
(Address and zip code of Principal Executive Offices)

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

As of October 30, 2020 the registrant had 52,999,139 shares of common stock outstanding.

Emergent BioSolutions Inc.
Index to Form 10-Q

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

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

NOTE REGARDING COMPANY REFERENCES

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

NOTE REGARDING TRADENAMES

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

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 415.0	$ 167.8
Restricted cash	0.2	0.2
Accounts receivable, net	196.1	270.7
Inventories, net	270.1	222.5
Prepaid expenses and other current assets	77.4	25.0
Total current assets	958.8	686.2
Property, plant and equipment, net	606.5	542.3
Intangible assets, net	678.1	712.9
In-process research and development	—	29.0
Goodwill	266.5	266.6
Other assets	106.4	90.3
Total assets	$ 2,616.3	$ 2,327.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 102.8	$ 94.8
Accrued expenses	34.9	39.5
Accrued compensation	76.9	62.4
Debt, current portion	30.9	12.9
Other current liabilities	53.8	6.7
Total current liabilities	299.3	216.3
Contingent consideration, net of current portion	35.2	26.0
Debt, net of current portion	848.5	798.4
Deferred tax liability	64.0	63.9
Contract liabilities, net of current portion	60.4	85.6
Other liabilities	57.4	48.6
Total liabilities	1,364.8	1,238.8
Stockholders' equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.001 par value; 200.0 shares authorized, 54.2 and 53.0 shares issued; 53.0 and 51.7 shares outstanding, respectively	0.1	0.1
Treasury stock, at cost, 1.2 common shares	(39.6)	(39.6)
Additional paid-in capital	770.9	716.1
Accumulated other comprehensive loss, net	(21.4)	(9.9)
Retained earnings	541.5	421.8
Total stockholders' equity	1,251.5	1,088.5
Total liabilities and stockholders' equity	$ 2,616.3	$ 2,327.3

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 202.2	$ 256.2	$ 648.9	$ 592.7
Contract development and manufacturing services	157.1	20.0	251.4	54.6
Contracts and grants	25.9	35.6	72.1	98.4
Total revenues	385.2	311.8	972.4	745.7
Operating expenses:				
Cost of product sales and contract development and manufacturing services	149.0	108.0	355.7	300.7
Research and development	84.4	53.4	175.0	163.4
Selling, general and administrative	75.5	65.0	221.2	201.3
Amortization of intangible assets	15.0	14.7	44.8	43.9
Total operating expenses	323.9	241.1	796.7	709.3
Income from operations	61.3	70.7	175.7	36.4
Other income (expense):				
Interest expense	(7.6)	(10.3)	(22.6)	(29.3)
Other, net	1.3	(1.5)	1.3	(1.2)
Total other income (expense), net	(6.3)	(11.8)	(21.3)	(30.5)
Income before provision (benefit) for income taxes	55.0	58.9	154.4	5.9
Income tax provision (benefit)	15.5	15.7	34.7	(1.7)
Net income	$ 39.5	$ 43.2	$ 119.7	$ 7.6
Net income per common share				
Basic	$ 0.75	$ 0.84	$ 2.28	$ 0.15
Diluted	$ 0.73	$ 0.83	$ 2.23	$ 0.15
Shares used in computing income per share				
Basic	53.0	51.6	52.5	51.4
Diluted	54.3	52.3	53.6	52.3

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income	$ 39.5	$ 43.2	$ 119.7	$ 7.6
Other comprehensive income (loss), net of tax:				
Foreign currency translation	(0.2)	(1.1)	(0.6)	0.6
Unrealized gains (losses) on hedging activities	1.0	(3.0)	(10.9)	(4.2)
Total other comprehensive income (loss)	0.8	(4.1)	(11.5)	(3.6)
Comprehensive income	$ 40.3	$ 39.1	$ 108.2	$ 4.0

During the three and nine months ended September 30, 2020 there were tax (expense) benefits related to unrealized gains (losses) on hedging activities of $(0.2) and $3.4, respectively; the tax effects of foreign currency translations were de minimus. During the three and nine months ended September 30, 2019 the tax effects of other comprehensive (loss) income were de minimus.

See accompanying notes.

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows provided by operating activities:		
Net income	$ 119.7	$ 7.6
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation expense	41.0	21.0
Depreciation and amortization	85.6	82.8
Impairment of IPR&D intangible asset	29.0	—
Change in fair value of contingent consideration, net	31.3	12.4
Amortization of deferred financing costs	2.4	2.2
Deferred income taxes	(4.4)	(5.7)
Other	0.6	0.7
Changes in operating assets and liabilities:		
Accounts receivable	74.6	(18.6)
Inventories	(47.6)	(24.4)
Prepaid expenses and other assets	(61.8)	(36.5)
Accounts payable	10.6	2.5
Accrued expenses	4.4	5.2
Accrued compensation	14.5	(2.4)
Contract liabilities	(9.0)	19.1
Net cash provided by operating activities:	290.9	65.9
Cash flows used in investing activities:		
Purchases of property, plant and equipment and other	(105.0)	(50.8)
Milestone payment from prior asset acquisition	(10.0)	(10.0)
Net cash used in investing activities:	(115.0)	(60.8)
Cash flows provided by financing activities:		
Proceeds from revolving credit facility	—	130.0
Principal payments on revolving credit facility	(373.0)	(95.0)
Proceeds from senior unsecured notes	450.0	—
Principal payments on term loan facility	(8.4)	(8.4)
Debt issuance costs	(8.4)	—
Proceeds from exercise of stock options	26.6	5.7
Taxes paid for share-based compensation activity	(12.8)	(6.6)
Contingent consideration payments	(2.2)	(3.7)
Net cash provided by financing activities:	71.8	22.0
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.5)	(0.1)
Net increase in cash, cash equivalents and restricted cash	247.2	27.0
Cash, cash equivalents and restricted cash at beginning of period	168.0	112.4
Cash, cash equivalents and restricted cash at end of period	$ 415.2	$ 139.4
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 14.0	$ 27.6
Cash paid during the period for income taxes	87.3	21.2
Supplemental information on non-cash investing and financing activities:		
Purchases of property, plant and equipment unpaid at period end	$ 9.7	$ 18.1
Reconciliation of cash and cash equivalent and restricted cash at September 30, 2020 and December 31, 2019:		
Cash and cash equivalents	$ 415.0	$ 167.8
Restricted cash	0.2	0.2
Total	$ 415.2	$ 168.0

See accompanying notes.

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

	$0.001 Par Value Common Stock		Additional Paid-In Capital	Treasury Stock		Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balance at December 31, 2019	53.0	$ 0.1	$ 716.1	(1.2)	$ (39.6)	$ (9.9)	$ 421.8	$ 1,088.5
Employee equity plans activity	1.2	—	54.8	—	—	—	—	54.8
Net income	—	—	—	—	—	—	119.7	119.7
Other comprehensive income	—	—	—	—	—	(11.5)	—	(11.5)
Balance at September 30, 2020	54.2	$ 0.1	$ 770.9	(1.2)	$ (39.6)	$ (21.4)	$ 541.5	$ 1,251.5
Balance at June 30, 2020	54.1	$ 0.1	$ 758.5	(1.2)	$ (39.6)	$ (22.2)	$ 502.0	$ 1,198.8
Employee equity plans activity	0.1	—	12.4	—	—	—	—	12.4
Net income	—	—	—	—	—	—	39.5	39.5
Other comprehensive income	—		—	—	—	0.8	—	0.8
Balance at September 30, 2020	54.2	$ 0.1	$ 770.9	(1.2)	$ (39.6)	$ (21.4)	$ 541.5	$ 1,251.5
Balance at December 31, 2018	52.4	$ 0.1	$ 688.6	(1.2)	$ (39.6)	$ (5.5)	$ 367.3	$ 1,010.9
Employee equity plans activity	0.4	—	20.2	—	(0.1)	—	—	20.1
Net income	—	—	—	—	—	—	7.6	7.6
Other comprehensive income	—	—	—	—	—	(3.6)	—	(3.6)
Balance at September 30, 2019	52.8	$ 0.1	$ 708.8	(1.2)	$ (39.7)	$ (9.1)	$ 374.9	$ 1,035.0
Balance at June 30, 2019	52.7	$ 0.1	$ 701.8	(1.2)	$ (39.7)	$ (5.0)	$ 331.7	$ 988.9
Employee equity plans activity	0.1	—	7.0	—	—	—	—	7.0
Net income	—	—	—	—	—	—	43.2	43.2
Other comprehensive income	—	—	—	—	—	(4.1)	—	(4.1)
Balance at September 30, 2019	52.8	$ 0.1	$ 708.8	(1.2)	$ (39.7)	$ (9.1)	$ 374.9	$ 1,035.0

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") or any health agency. The U.S. government (the "USG") is the Company's largest customer and provides the Company with substantial funding for the development of a number of its product candidates.

The Company's product and services portfolio includes:

Vaccines

- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- Vaxchora® (Cholera Vaccine, Live, Oral), the only 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 been reducing its purchases of BioThrax as a result; and

- Trobigard® is a combination drug-device auto-injector procured product candidate that contains atropine sulfate and obidoxime chloride. It has not been approved by the FDA or any similar health regulatory body, but it is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Contract Development and Manufacturing Services

The Company's contract development and manufacturing service offerings cover development services, drug substance manufacturing and drug product manufacturing across the pharmaceutical and biotechnology industries as well as the USG and non-governmental organizations. The Company's technology platforms include mammalian, microbial, viral, plasma and advanced therapies utilizing our core capabilities for manufacturing to third parties on a clinical and commercial (small and large) scale. Additional services include fill/finish formulation and analytical development services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, aseptic filling, lyophilization, final packaging and stability studies, as well as manufacturing of vial and pre-filled syringe formats 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, 2019, as filed with the SEC.

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

Significant accounting policies

During the nine months ended September 30, 2020, there have been no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC. During the nine months ended September 30, 2020, the Company entered into several multi-year CDMO arrangements and further defined our accounting policies around these arrangements in Note 10.

Fair value measurements

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. The Company has cash held in money market accounts (level 1), contingent purchase consideration (level 3) and interest rate swaps arrangements (level 2) that are measured at fair value on a recurring basis (Note 7 and Note 8). As of September 30, 2020 and December 31, 2019, the Company held cash in money market accounts of $290.8 million and $52.2 million, respectively. The Company also records the assets and liabilities of acquisitions at fair value.

On a non-recurring basis, the Company measures its long-lived assets, including IPR&D assets (level 3) using fair value measurements. Goodwill is allocated to the Company's reporting units, which are one level below its operating segment. The Company evaluates goodwill and other indefinite-lived intangible assets for impairment annually as of October 1 and earlier if an event or other circumstance indicates that we may not recover the carrying value of the asset. If the Company believes that as a result of its qualitative assessment it is more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, the quantitative impairment test is not required. If however it is determined that it is not more likely than not that the fair value of a reporting unit or other indefinite-lived intangible asset is greater than its carrying amount, a quantitative test is required. Long-lived assets such as intangible assets and property, plant and equipment are not required to be tested for impairment annually. Instead, long-lived assets are tested for impairment whenever circumstances indicate that the carrying amount of the asset may not be recoverable, such as when there is an adverse change in the market relating to those related assets. The impairment test first requires a comparison of undiscounted future cash flows to the carrying value of the asset. Determining the need for a detailed impairment analysis requires the exercise of judgment about several business factors, including the timing of expected future cash flows and assumptions about the economic environment. During the period ending September 30, 2020, the Company recorded an impairment of its IPR&D intangible assets, which is further discussed in note 6.

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

Recently issued accounting standards

Recently Adopted

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

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

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

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

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

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

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

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

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

Not Yet Adopted

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

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

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

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

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

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

3. Inventories, net

The components of inventory are as follows:

	September 30, 2020	December 31, 2019
Raw materials and supplies	$ 116.8	$ 70.5
Work-in-process	104.3	89.7
Finished goods	49.0	62.3
Total inventories, net	$ 270.1	$ 222.5

Inventories, net is stated at the lower of cost or net realizable value. During the three months ended September 30, 2020, the Company recorded a charge of $13.8 million for inventories associated with the travel health business that are not expected to be realized before expiration following a reduction in travel due to COVID-19. The charge was reflected as a component of cost of product sales and contract development and manufacturing services.

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

4. Property, plant and equipment

Property, plant and equipment consisted of the following:

	September 30, 2020	December 31, 2019
Land and improvements	$ 51.2	$ 46.5
Buildings, building improvements and leasehold improvements	280.6	234.8
Furniture and equipment	352.2	334.2
Software	56.6	55.7
Construction-in-progress	112.8	81.5
Property, plant and equipment, gross	853.4	752.7
Accumulated depreciation	(246.9)	(210.4)
Total property, plant and equipment, net	$ 606.5	$ 542.3

5. Leases

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

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

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

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost:				
Amortization of right-of-use assets	$ 1.1	$ 0.8	$ 3.2	$ 2.1
Interest on lease liabilities	0.2	0.1	0.8	0.4
Total operating lease cost	$ 1.3	$ 0.9	$ 4.0	$ 2.5

Supplemental balance sheet information related to leases was as follows:

(In millions, except lease term and discount rate)	*Balance Sheet location*	September 30, 2020	December 31, 2019
Operating lease right-of-use assets	Other assets	$ 23.4	$ 24.7
Operating lease liabilities, current portion	Other current liabilities	4.4	3.6
Operating lease liabilities	Other liabilities	20.7	22.1
Total operating lease liabilities		$ 25.1	$ 25.7
Operating leases:			
Weighted average remaining lease term (years)		7.4	8.0
Weighted average discount rate		4.2 %	4.2 %

6. Intangible assets

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

		September 30, 2020		
(in millions)	Estimated Life	Cost	Accumulated Amortization	Net
Products	9-22 years	$ 798.0	$ 123.9	$ 674.1
Customer relationships	8 years	28.6	25.6	3.0
Contract development and manufacturing	8 years	5.5	4.5	1.0
Total intangible assets		$ 832.1	$ 154.0	$ 678.1

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

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

During the nine months ended September 30, 2020 and 2019, the Company recorded amortization expense for intangible assets of $44.8 million and $43.9 million, respectively. During the three months ended September 30, 2020 and 2019, the Company recorded amortization expense for intangible assets of $15.0 million and $14.7 million, respectively. As of September 30, 2020, the weighted average amortization period remaining for intangible assets was 13 years.

In-process research and development ("IPR&D") assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the three months ended September 30, 2020, the Company concluded that its IPR&D intangible asset, AP004 (Naloxone prefilled syringe), currently has de minimis value and as such the Company has recorded an impairment charge of $29.0 million during the three and nine months ended September 30, 2020. The impairment charge is reflected as a component of research and development expense on the consolidated statement of operations.

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

Goodwill was $266.5 million and $266.6 million for the periods ended September 30, 2020 and December 31, 2019, respectively. The change in the balance during the period was due to foreign currency translation adjustments.

7. Contingent consideration

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

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

Balance at December 31, 2019	$	29.2
Change in fair value		31.3
Settlements		(2.2)
Balance at September 30, 2020	$	58.3

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 September 30, 2020	Valuation Technique	Unobservable Input	Range	Weighted Average
Revenue milestone and royalty based	$58.3 million	Discounted cash flow	Discount rate	2.5% - 8.6%	4.2%
			Probability of payment	50% - 100%	75.0%
			Projected year of payment	2020 - 2028	2022

8. Derivative instruments and hedging activities

Risk management objective of using derivatives

The Company is exposed to certain 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.

Accounting policy for derivative instruments and hedging activities

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

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

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

	Number of Instruments	Notional
Interest rate swaps	7	$ 350.0

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

	Asset Derivatives				Liability Derivatives			
	September 30, 2020		December 31, 2019		September 30, 2020		December 31, 2019	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Interest Rate Swaps	Other Current Assets	$ —	Other Current Assets	$ —	Other Current Liabilities	$ 5.6	Other Current Liabilities	$ —
	Other Assets	$ —	Other Assets	$ —	Other Liabilities	$ 10.7	Other Liabilities	$ 2.0

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

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

Hedging derivatives	Cumulative Amount of Gain/(Loss) Recognized in OCI on Derivative		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income	
	September 30, 2020	December 31, 2019		Nine Months Ended September 30, 2020	2019
Interest Rate Swaps	$ (16.3)	$ 2.0	Interest expense	$ (2.5)	$ 0.5

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

9. Debt

The components of debt are as follows:

	September 30, 2020	December 31, 2019
Term loan due 2023	$ 427.5	$ 435.9
Revolver loan due 2023	—	373.0
3.875% Senior Unsecured Notes due 2028	450.0	—
2.875% Convertible Senior Notes due 2021	10.6	10.6
Other	3.0	3.0
Total debt	891.1	822.5
Current portion of long-term debt, net of debt issuance costs	(30.9)	(12.9)
Unamortized debt issuance costs	(11.7)	(11.2)
Non-current portion of debt	$ 848.5	$ 798.4

As of September 30, 2020, the Company had approximately $1.8 million and $3.7 million of debt issuance costs associated with the revolver loan that were classified as other current assets and other assets, respectively, on the Company's consolidated balance sheets because there was no outstanding revolver balance at period end. As of December 31, 2019, the Company had approximately $1.8 million and $5.0 million of debt issuance costs associated with the revolver loan that were classified as debt, current portion and debt, net of current portion, respectively, on the Company's consolidated balance sheets because there was an outstanding revolver balance at period end.

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 with a maturity date of October 13, 2023, 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.

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 bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021.

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

10. Revenue recognition

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

	Three Months Ended September 30, 2020			Three Months Ended September 30, 2019		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 102.4	$ 99.8	$ 202.2	$ 170.2	$ 86.0	$ 256.2
Contract development and manufacturing services	85.9	71.2	157.1	—	20.0	20.0
Contracts and grants	24.9	1.0	25.9	35.6	—	35.6
Total revenues	$ 213.2	$ 172.0	$ 385.2	$ 205.8	$ 106.0	$ 311.8

	Nine Months Ended September 30, 2020			Nine Months Ended September 30, 2019		
	U.S. Government	Non-U.S. Government	Total	U.S. Government	Non-U.S. Government	Total
Product sales, net	$ 390.5	$ 258.4	$ 648.9	$ 338.1	$ 254.6	$ 592.7
Contract development and manufacturing services	130.5	120.9	251.4	—	54.6	54.6
Contracts and grants	67.6	4.5	72.1	94.3	4.1	98.4
Total revenues	$ 588.6	$ 383.8	$ 972.4	$ 432.4	$ 313.3	$ 745.7

Contract liabilities

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

December 31, 2019	$ 88.9
Deferral of revenue	60.0
Revenue recognized	(69.0)
September 30, 2020	$ 79.9

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

Transaction price allocated to remaining performance obligations

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

The suite-reservation performance obligations 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 2.5 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 nine months ended September 30, 2020, the Company's lease revenues were $18.1 million, which is included within contract development and manufacturing services in the condensed consolidated statement of operations. The Company did not recognize lease revenue during the three and nine months ended September 30, 2019. The Company has allocated contracted operating lease revenues due under our long-term CDMO service arrangements as follows:

	September 30, 2020
2020 (1)	$ 12.4
2021	74.8
2022	74.8
2023	15.7
	$ 177.7

(1) As of September 30, 2020, amount represents the three months ending December 31, 2020.

As of September 30, 2020, the Company expects future revenues of approximately $2.2 billion associated with all performance obligations described above that have not been satisfied and all other 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 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 September 30, 2020 and December 31, 2019, the Company had contract assets associated with deferred costs of $40.8 million and $34.0 million, respectively, which is reflected as a component of other assets on the Company's consolidated balance sheets.

Accounts receivable

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

	September 30, 2020	December 31, 2019
Billed, net	$ 166.0	$ 227.3
Unbilled	30.1	43.4
Total, net	$ 196.1	$ 270.7

As of September 30, 2020 and December 31, 2019, allowances for doubtful accounts were $0.7 million and de minimis.

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

11. Income taxes

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

The effective tax rate for the Company, which excludes discrete adjustments, was 29% and 27% for the nine months ended September 30, 2020 and 2019, respectively. The effective tax rate for the Company, excluding the impact of the non-deductible contingent consideration expense, was 25% and 24% for the nine months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, the Company recorded a discrete tax benefit of $9.9 million and $2.9 million, respectively. The discrete tax benefits in 2020 were primarily due to activity associated with equity awards while the discrete tax benefits in 2019 were primarily due to return to provision adjustments. For the three months ended September 30, 2020 and 2019, the Company recorded a discrete tax benefit (expense) of $3.3 million and $(0.2) million, respectively, primarily due to the finalization of positions taken on the Company's income tax filings and activity associated with equity awards.

12. Net income per share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net income	$ 39.5	$ 43.2	$ 119.7	$ 7.6
Denominator:				
Weighted-average number of shares—basic	53.0	51.6	52.5	51.4
Dilutive securities—equity awards	1.3	0.7	1.1	0.9
Weighted-average number of shares—diluted	54.3	52.3	53.6	52.3
Net income per share - basic	$ 0.75	$ 0.84	$ 2.28	$ 0.15
Net income per share - diluted	$ 0.73	$ 0.83	$ 2.23	$ 0.15

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 nine months ended September 30, 2020 and 2019.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Anti-dilutive stock awards	—	1.0	—	1.0

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

13. Stock-based compensation

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of product sales and contract development and manufacturing services	$ 2.0	$ 0.9	$ 10.8	$ 2.3
Research and development	0.6	1.1	6.9	3.2
Selling, general and administrative	7.4	4.1	23.3	15.5
Total stock-based compensation expense	$ 10.0	$ 6.1	$ 41.0	$ 21.0

14. Commitments and contingencies

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.), Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Emergent BioSolutions Ireland Limited (formerly known as Adapt Pharma Limited) (collectively, "Adapt Pharma") and Opiant Pharmaceuticals, Inc. (“Opiant”), received notice from Perrigo UK FINCO Limited Partnership (“Perrigo”), that Perrigo had filed an Abbreviated New Drug Application ("ANDA"), with the United States Food and Drug Administration, seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the “‘253 Patent”), 9,468,747 (the “‘747 Patent”), 9,561,177, (the “‘177 Patent”), 9,629,965, (the “‘965 Patent”) and 9,775,838 (the “‘838 Patent”). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the “'937 Patent”). Perrigo’s notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents. On October 25, 2018, Emergent BioSolutions’ Adapt Pharma subsidiaries and Opiant (collectively, the “Plaintiffs”) filed a complaint for patent infringement of the ‘253, ‘747, ‘177, ‘965, and ‘838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo’s ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the ‘937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a nonexclusive license under Adapt Pharma's patents to make, have made, and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo’s license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

On or about February 27, 2018, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) and Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Opiant received notice from Teva Pharmaceuticals Industries Limited and Teva Pharmaceuticals USA, Inc. (collectively "Teva") that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, (the “‘644 Patent”) and U.S. Patent No. 9,707,226, (the “‘226 Patent”). Teva’s notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the ‘644 Patent or the ‘226 Patent, or that the ‘644 Patent and ‘226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant

filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey. This case is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4 mg/spray case.

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) and Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, the '838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the '937 Patent. Closing arguments took place on February 26, 2020. In the complaints described in the paragraphs above, the Plaintiffs sought, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court. On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant in the consolidated case. Emergent filed a Notice of Appeal on July 23, 2020, after the U.S. District Court for New Jersey ruled on June 5, 2020 in favor of Teva, appealing the District Court decision to the Court of Appeals for the Federal Circuit. 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. Emergent, through its subsidiaries, has filed suit within the prescribed time period following notice from Teva of its ANDS filing in Canada.

***Inter Partes Review* ("IPR")**

On or about February 19, 2019, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) and Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Opiant received notice from Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent with the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office. Nalox-1's petitions assert that each of the foregoing patents are unpatentable as obvious in view of prior art. Three of these petitions, IPR Nos. 2019-00685, 2019-00688, and 2019-00694, were instituted on August 27, 2019, September 9, 2019, and September 11, 2019, respectively. The oral hearing for the three instituted IPR proceedings was held before the PTAB on May 19, 2020. On August 21, 2020, the PTAB issued its final written decisions for the above-listed IPRs confirming that claims of U.S. patents in the NARCAN® Nasal Spray patent portfolio are not unpatentable as obvious in view of prior art.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and accompanying notes and other financial information included elsewhere in this quarterly report on Form 10-Q and our audited consolidated financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, includes information with respect to our plans and strategy for our business and financing, as well as forward-looking statements that involve risks and uncertainties. You should carefully review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this quarterly report on Form

10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

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

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

Vaccines

- Anthrax vaccines, including our AV7909 (Anthrax Vaccine Adsorbed with Adjuvant) procured product candidate being developed as a next-generation anthrax vaccine for post-exposure prophylaxis and BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the FDA for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only single-dose smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection;
- Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever; and
- Vaxchora® (Cholera Vaccine, Live, Oral), the only 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 or any similar health regulatory body, but is procured by certain authorized government buyers under special circumstances for potential use as a nerve agent countermeasure.

Therapeutics

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

Highlights and Business Accomplishments for 2020

- On January 13, 2020, received agreement from the EMA and FDA on the company's proposed development plan to use Serum Neutralizing Antibodies (SNA) as surrogate endpoint to predict likely clinical benefit of CHIKV VLP, the company's chikungunya virus virus-like particle (VLP) vaccine candidate, in a Phase 3 safety and immunogenicity study anticipated in late 2020.
- On January 31, 2020, received positive opinion and subsequent approval from EMA of Vaxchora® (Cholera Vaccine, Live, Oral), the company's cholera vaccine, making it the only single-dose oral vaccine indicated for active immunization against disease caused by *Vibrio cholerae* serogroup 01 in adults and children from 6 years of age across all 27 member states of the European Union and the European Economic Area countries.
- On March 10, 2020, signed a development and manufacturing agreement with Novavax, Inc. for an experimental vaccine candidate for COVID-19.
- On March 11, 2020, initiated development of two investigational plasma-derived therapies. COVID-Human Immune Globulin (COVID-HIG) is being developed as a human plasma-derived therapy candidate for potential treatment of COVID-19 in severe hospitalized and high-risk patients, and COVID-Equine Immune Globulin (COVID-EIG) is being developed as an equine plasma-derived therapy candidate for potential treatment of severe disease in humans.
- On March 18, 2020, signed a development and manufacturing agreement with Vaxart, Inc. to produce its experimental oral vaccine candidate for COVID-19.
- On March 31, 2020, signed an agreement with Novavax, Inc. to manufacture NanoFlu™, its seasonal influenza vaccine candidate.
- On April 2, 2020, announced HHS funding valued at $14.5 million to support the development of COVID-Human Immune Globulin (COVID-HIG) for treatment, which will be included in at least one of the studies of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, evaluating potential treatments for COVID-19.
- On April 23, 2020, announced an initial agreement, valued at $135 million, to be the U.S. manufacturing partner of Johnson & Johnson's lead COVID-19 vaccine candidate.
- On May 28, 2020, announced the exercise by the HHS of the first of nine annual contract options, valued at $176 million, to procure doses of ACAM2000® (Smallpox (Vaccine, Live) into the U.S. Strategic National Stockpile (SNS).
- On June 1, 2020, announced an agreement to join the USG's Warp Speed Program in public-private CDMO partnership for COVID-19 vaccine development and manufacturing. The agreement has a contract value of $628 million and includes manufacturing capacity valued at $542.7 million and $85.5 million for expansion of viral and non-viral CDMO drug product fill/finish capacity.
- On June 11, 2020, announced an agreement to be the U.S. manufacturing partner for AstraZeneca's COVID-19 vaccine candidate to provide large-scale manufacturing capacity through 2020. The agreement has a contract value of $87 million.
- On June 18, 2020, announced the $75 million acquisition and planned expansion of a property adjacent to our Canton, Massachusetts live viral drug substance development and manufacturing facility. The expansion will increase advanced therapy (viral vector and gene therapy) capability, which is expected to be available beginning in 2023.

- On July 2, 2020, further announced signing a large scale drug substance manufacturing agreement for Johnson & Johnson's lead COVID-19 vaccine candidate for up to five years beginning in 2021. The first two years are valued at approximately $480 million, with the remaining three years providing flexible capacity.
- On July 6, 2020, announced the award of approximately $34.6 million by the U.S. Department of Defense Joint Program Executive Office and formed collaboration with Mount Sinai Health System and ImmunoTek Bio Centers to advance COVID-Human Immune Globulin (COVID-HIG) for potential post-exposure prophylaxis in populations at high risk of COVID-19.
- On July 14, 2020, announced the exercise by BARDA of the contract option, valued at $258 million, to procure additional doses of AV7909 (anthrax vaccine adsorbed with adjuvant) for delivery into the SNS over 12 months.
- On July 27, 2020, further announced the signing of a large-scale drug substance manufacturing agreement for AstraZeneca's COVID-19 vaccine candidate, valued at approximately $174 million through 2021.
- On August 7, 2020, announced the completion of an offering of $450 million in aggregate principal amount 3.875% Senior Unsecured Notes due in 2028. The Company utilized the proceeds from the offering to repay $353 million outstanding under its revolving credit facility with the remainder to be utilized for general corporate purposes.
- On October 8, 2020, announced the initiation of a Phase 3 clinical trial to evaluate the safety, tolerability, and efficacy of hyperimmune globulin products, including our COVID-19 Human Immune Globulin, as a potential treatment in adult patients hospitalized with COVID-19.

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. 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. During 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.

Critical Accounting Policies and Estimates

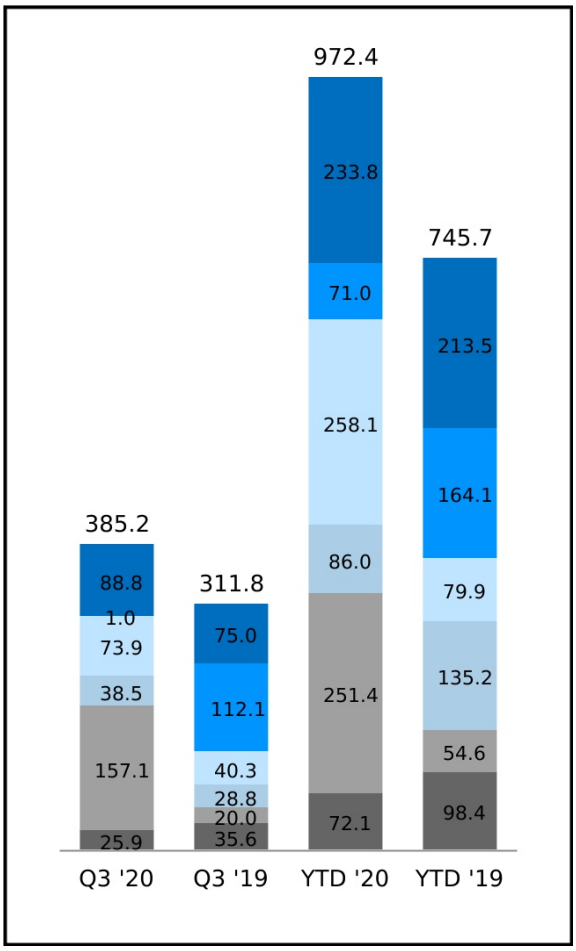
During the nine months ended September 30, 2020, there have been no significant changes to our critical accounting policies and estimates contained in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC, (see Note 2 to the accompanying condensed consolidated financial statements).

Results of Operations

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2020	2019	$ Change	% Change	2020	2019	$ Change	% Change
Product sales net:								
NARCAN Nasal Spray	$ 88.8	$ 75.0	$ 13.8	18 %	$ 233.8	$ 213.5	$ 20.3	10 %
Anthrax vaccines	73.9	40.3	33.6	83 %	258.1	79.9	178.2	NM
ACAM2000	1.0	112.1	(111.1)	(99) %	71.0	164.1	(93.1)	(57 %)
Other product sales	38.5	28.8	9.7	34 %	86.0	135.2	(49.2)	(36) %
Total product sales, net	202.2	256.2	(54.0)	(21) %	648.9	592.7	56.2	9 %
Contract development and manufacturing services	157.1	20.0	137.1	NM	251.4	54.6	196.8	NM
Contracts and grants	25.9	35.6	(9.7)	(27) %	72.1	98.4	(26.3)	(27) %
Total revenues	385.2	311.8	73.4	24 %	972.4	745.7	226.7	30 %
Operating expenses:								
Cost of product sales and contract development and manufacturing services	149.0	108.0	41.0	38 %	355.7	300.7	55.0	18 %
Research and development	84.4	53.4	31.0	58 %	175.0	163.4	11.6	7 %
Selling, general and administrative	75.5	65.0	10.5	16 %	221.2	201.3	19.9	10 %
Amortization of intangible assets	15.0	14.7	0.3	2 %	44.8	43.9	0.9	2 %
Total operating expenses	323.9	241.1	82.8	34 %	796.7	709.3	87.4	12 %
Income from operations	61.3	70.7	(9.4)	(13 %)	175.7	36.4	139.3	NM
Other income (expense):								
Interest expense	(7.6)	(10.3)	2.7	(26 %)	(22.6)	(29.3)	6.7	(23 %)
Other, net	1.3	(1.5)	2.8	NM	1.3	(1.2)	—	— %
Total other income (expense), net	(6.3)	(11.8)	5.5	(47 %)	(21.3)	(30.5)	6.7	(22 %)
Income before provision (benefit) for income taxes	55.0	58.9	(3.9)	(7 %)	154.4	5.9	148.5	NM
Income tax provision (benefit)	15.5	15.7	(0.2)	(1 %)	34.7	(1.7)	36.4	NM
Net income	$ 39.5	$ 43.2	$ (3.7)	(9 %)	$ 119.7	$ 7.6	$ 112.1	NM

NM - Not meaningful

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 nine months ended September 30, 2020 was primarily due to an increase in sales to the U.S. public interest markets.

Anthrax Vaccines

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

ACAM2000

The decrease in ACAM2000 sales for the three and nine months ended September 30, 2020 was due to timing of deliveries to the SNS partially offset by increases in pricing. ACAM2000 product sales are made under a long-term procurement contract. The fluctuations in ACAM2000 revenue are dictated by the timing and delivery of orders to the USG.

Other Product Sales

The Company's other product sales increased during the three months ended September 30, 2020, primarily due to an increase in sales of BAT and VIGIV partially offset by a decline in sales of our travel health vaccines, Vaxchora and Vivotif which were impacted by the reduction of global travel. During the nine months ended September 30, 2020 other product sales decreased primarily due to a decline in sales of raxibacumab, and our travel health vaccines due to the reduction of global travel. These declines were partially offset by an increase in sales of BAT and VIGIV.

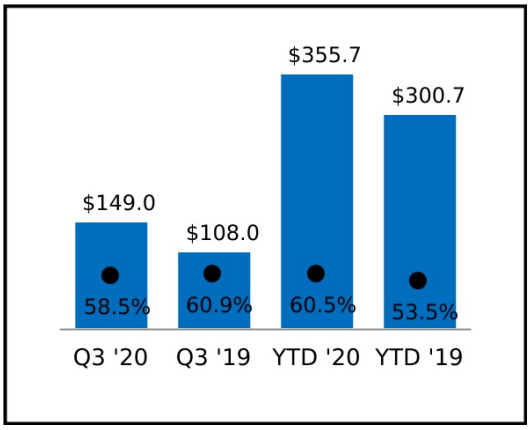
Contract Development and Manufacturing Services

The increase in contract development and manufacturing services revenue for the three and nine months ended September 30, 2020 is largely due to the contribution of recently announced arrangements across development, drug substance, and drug product services with industry and government customers, most notably the Company's public-private partnership with BARDA in support of the USG's Operation Warp Speed Program as well as arrangements with Johnson & Johnson and AstraZeneca.

Contracts and Grants

The decrease in contracts and grants revenue for the three and nine months ended September 30, 2020 is due to the completion of developmental activities associated with our AV7909 procured product candidate partially offset by increases in development awards related to the Company's COVID related product candidates.

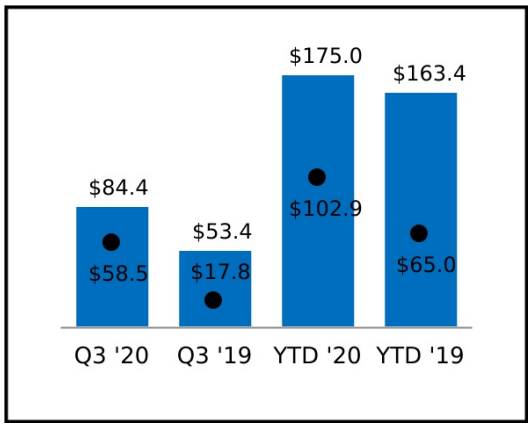
Cost of Product Sales and Contract Development and Manufacturing Services



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

Cost of product sales and contract development and manufacturing services increased for the three and nine months ended September 30, 2020, primarily due to an increase in product sales and contract development and manufacturing services, a charge of $13.8 million related to a write-down of inventory balances due to the expected expiration of a portion of the Company's travel health vaccines, as well as increased charges of $23.3 million and $18.9 million related to the Company's contingent consideration liabilities, as compared to the three and nine months ended September 30, 2019, respectively. Additionally, during the nine months ended September 30, 2020, the Company granted a special broad-based, immediately vested equity award to employees below the senior vice president level which occurred in the second quarter of 2020 contributing to the increase in selling, general and administrative expenses during the period.

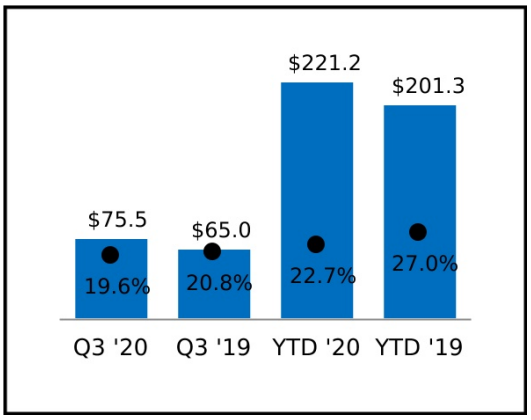
Research and Development Expenses (Gross and Net)



■	Research and Development expense
●	Research and Development expense, net of contracts and grants revenue

The increase in research and development expenses during the three and nine months ended September 30, 2020 is mostly due to the impairment of our IPR&D intangible asset of $29 million. Additionally, the Company increased spending due to COVID-HIG related product candidates. These increases were partially offset by decreases in spending for development activities associated with our AV7909 procured product candidate.

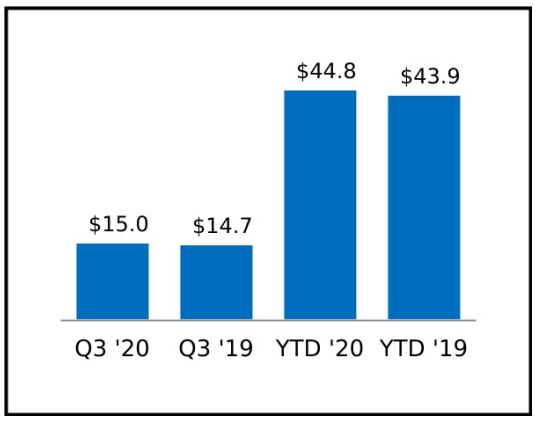
Selling, General and Administrative Expenses



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

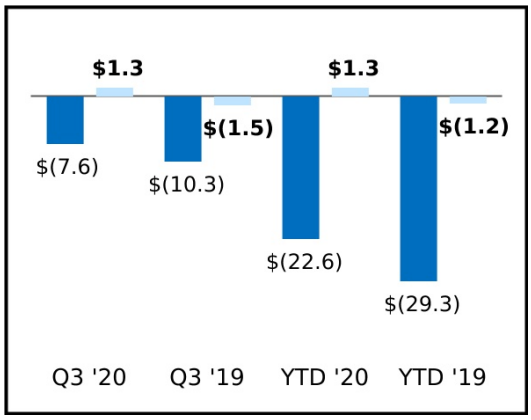
The increase in selling, general and administrative expenses for the three and nine months ended September 30, 2020 is primarily due to an increase in staffing costs to support the Company's growth. Additionally, during the nine months ended September 30, 2020, the Company granted a special broad-based, immediately vested equity award to employees below the senior vice president level which occurred in the second quarter of 2020 contributing to the increase in selling, general and administrative expenses during the period.

Amortization of Intangible Assets



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

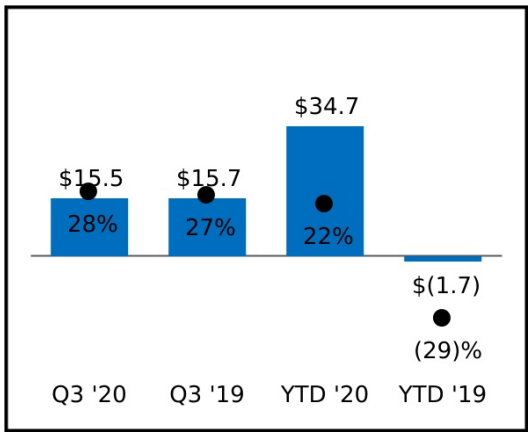
Other Income (Expense), Net



■	Interest expense
■	Other income (expense)

Total other income (expense), net decreased for the three and nine months ended September 30, 2020 due primarily to a decrease in interest expense related to a decline in interest rates period over period offset by an increase in outstanding debt.

Income Tax Provision (Benefit)



■	Income tax provision (benefit)
●	Effective tax rate

During the three and nine months ended September 30, 2020 and 2019, taxes increased mostly because of increases in income. Additionally, the estimated effective tax rate was 29% and 27%, respectively. Excluding the impact of non-deductible contingent consideration expense the effective tax rate was 26% and 25%, respectively. The actual effective tax rate includes the effects of discrete tax benefits of $9.9 million and $2.9 million during the nine months ended September 30, 2020 and 2019, respectively.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and development funding. We also obtain financing from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years through the period ended December 31, 2019. As of September 30, 2020, we had unrestricted cash and cash equivalents of $415.0 million and capacity under our revolving credit facility of $597.1 million. As of September 30, 2020, we believe that we have sufficient liquidity to fund our operations over the next 12 months.

Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ 290.9	$ 65.9
Investing activities	(115.0)	(60.8)
Financing activities	71.8	22.0
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.5)	(0.1)
Net increase in cash, cash equivalents and restricted cash	$ 247.2	$ 27.0

Operating Activities

Net cash provided by operating activities of $290.9 million for the nine months ended September 30, 2020 was due to net income excluding non-cash items of $305.2 million offset by working capital changes of $14.3 million.

Net cash provided by operating activities of $65.9 million for the nine months ended September 30, 2019 was due to net income excluding non-cash items of $121.0 million offset by working capital changes of $55.1 million.

The cash flows from operating activities increased $225.0 million during the nine months ended September 30, 2020 largely due to an increase in net income excluding non-cash items of $184.2 million and changes in working capital of $40.8 million.

Investing Activities

Net cash used in investing activities largely relates to purchases of property, plant and equipment and was $115.0 million and $60.8 for the nine months ended September 30, 2020 and 2019, respectively. We also made a milestone payment related to an asset acquisition of $10.0 million in each of the nine months ended September 30, 2020 and 2019 relating to our acquisition of raxibacumab in October 2017. The cash used in investing activities increased during the nine months ended September 30, 2020 largely due to infrastructure and equipment investments related to our CDMO arrangements and the purchase of a building near our Canton, Massachusetts facility.

Financing Activities

Net cash provided by financing activities of $71.8 million for the nine months ended September 30, 2020 was primarily due to proceeds from the $450.0 million Senior Unsecured Notes and net employee share-based compensation activity of $13.8 million offset by payments of $381.4 on the term loan and revolving credit facility and $8.4 million of debt issuance costs.

Net cash provided by financing activities of $22.0 million for the nine months ended September 30, 2019 was primarily due to net $26.6 million of receipts on the term loan and credit facility, primarily offset by net cash used in employee share-based compensation activity of $0.9 million and payments of $3.7 million related contingent consideration arrangements.

The cash flows provided by financing activities increased $49.8 million during the nine months ended September 30, 2020 due to an increase in net receipts on the Senior Unsecured Notes, term loan and revolving credit facility of $42.0 million and

an increase in net cash provided by net employee share-based compensation activity of $14.7 million.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources:

- existing cash and cash equivalents;
- net proceeds from the sale of our products and contract development and manufacturing services;
- development contracts and grants funding; and
- our Senior Secured Credit Facilities and any other lines of credit we may establish from time to time.

There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

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

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements.

If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our Senior 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.

We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing our ability to make payments on our indebtedness. However, our Senior Secured Credit Facilities restrict our ability to incur additional indebtedness, including secured indebtedness.

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

Unused Credit Capacity

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

(in millions)			
Total Capacity	Outstanding Letters of Credit	Outstanding Indebtedness on Revolving Credit Facility	Unuse Capacity
September 30, 2020			
$600.0	(2.9)	—	$597.1
December 31, 2019			
$600.0	(2.2)	(373.0)	$224.8

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Market Risk

We have interest rate and foreign currency market risk. Because of the short-term maturities of our cash and cash equivalents, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments.

Interest Rate Risk

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

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of September 30, 2020 would increase our interest expense by approximately $0.8 million annually.

Foreign Currency Exchange Rate Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

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 September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

ANDA Litigation - Perrigo 4mg

On September 14, 2018, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.), Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Emergent BioSolutions Ireland Limited (formerly known as Adapt Pharma Limited) (collectively, Adapt Pharma) and Opiant Pharmaceuticals, Inc. (Opiant), received notice from Perrigo UK FINCO Limited Partnership (Perrigo), that Perrigo had filed an Abbreviated New Drug Application (ANDA), with the United States Food and Drug Administration, seeking regulatory approval to market a generic version of NARCAN®(naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, (the ‘253 Patent), 9,468,747 (the ‘747 Patent), 9,561,177, (the

‘177 Patent), 9,629,965, (the ‘965 Patent) and 9,775,838 (the ‘838 Patent). On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937 (the ‘937 Patent). Perrigo’s notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents. On October 25, 2018, Emergent BioSolutions’ Adapt Pharma subsidiaries and Opiant (collectively, the Plaintiffs) filed a complaint for patent infringement of the ‘253, ‘747, ‘177, ‘965, and ‘838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo’s ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the ‘937 Patent. On February 12, 2020, Adapt Pharma and Perrigo entered into a settlement agreement to resolve the ongoing litigation. Under the terms of the settlement, Perrigo has received a nonexclusive license under Adapt Pharma’s patents to make, have made, and market its generic naloxone hydrochloride nasal spray under its own ANDA. Perrigo’s license will be effective as of January 5, 2033 or earlier under certain circumstances including circumstances related to the outcome of the current litigation against Teva (as defined below) or litigation against future ANDA filers. The Perrigo settlement agreement is subject to review by the U.S. Department of Justice and the Federal Trade Commission, and entry of an order dismissing the litigation by the U.S. District Court for the District of New Jersey.

ANDA Litigation - Teva 2mg

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

ANDA Litigation - Teva 4mg

On or about September 13, 2016, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) and Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of the ‘253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the ‘747, the ‘177, the ‘965, the ‘838, and the ‘937 Patents. Teva’s notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the ‘253, the ‘747, the ‘177, the ‘965, the ‘838, or the ‘937 Patent, or that the ‘253, the ‘747, the ‘177, the ‘965, the ‘838, and the ‘937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the ‘253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the ‘747, the ‘177, the ‘965, the ‘838 Patents. All five proceedings have been consolidated. As of the date of this filing, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, have not filed a complaint related to the ‘937 Patent. Closing arguments took place on February 26, 2020. In the complaints described in the paragraphs above, the Plaintiffs sought, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo’s respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court. On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant in the consolidated case. Emergent filed a Notice of Appeal on July 23, 2020, after the U.S. District Court for New Jersey ruled on June 5, 2020 in favor of Teva, appealing the District Court decision to the Court of Appeals for the Federal Circuit. 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. Emergent, through its subsidiaries, has filed suit within the prescribed time period following notice from Teva of its ANDS filing in Canada.

Inter Partes Review ("IPR")

On or about February 19, 2019, Emergent Devices Inc. (formerly known as Adapt Pharma Inc.) and Emergent Operations Ireland Limited (formerly known as Adapt Pharma Operations Limited) and Opiant received notice from Nalox-1 Pharmaceuticals LLC that it had filed fifteen petitions for inter partes review of the '253 Patent, the '747 Patent, the '177 Patent, the '965 Patent, and the '838 Patent with the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office. Nalox-1's petitions assert that each of the foregoing patents are unpatentable as obvious in view of prior art. Three of these petitions, IPR Nos. 2019-00685, 2019-00688, and 2019-00694, were instituted on August 27, 2019, September 9, 2019, and September 11, 2019, respectively. The oral hearing for the three instituted IPR proceedings was held before the PTAB on May 19, 2020. On August 21, 2020, the PTAB issued its final written decisions for the above-listed IPRs confirming that claims of U.S. patents in the NARCAN® Nasal Spray patent portfolio are not unpatentable as obvious in view of prior art.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this Quarterly Report on Form 10-Q when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flows. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flows. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flows. Discussion of these factors is incorporated by reference into and considered an integral part of Part I, Item 2, "Management's Discussion and Analysis of Financial Conditions and Results of Operations."

GLOBAL PANDEMIC RISK

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

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced. Since then, the SARS-CoV-2 virus has been determined to cause the disease COVID-19. COVID-19 has spread worldwide, including in the United States, Canada and Europe. The World Health Organization declared the COVID-19 coronavirus outbreak as a global pandemic on March 11, 2020. The pandemic has caused various governments, including in the United States at Federal and state levels, to impose restrictions on people and businesses, such as quarantines, closures, cancellations and travel restrictions. Significant disruptions due to the COVID-19 pandemic have impacted and in the future could severely impact our business and operations, including as a result of:

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

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

taken in the United States and other countries to mitigate and treat the disease.

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

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from USG procurement of AV7909 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 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 with respect to 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 and eventual FDA licensure in a timely manner or at all. Delays in our ability to achieve a favorable outcome from the FDA could prevent us from realizing the full potential value of our BARDA contract for the advanced development and procurement of AV7909.

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

Notwithstanding, the FDA may decide that our data are insufficient and require additional pre-clinical, clinical or other studies. If we are unsuccessful in obtaining an EUA and, ultimately, FDA licensure, in a timely manner or at all, we may not be able to realize the full potential value of the contract, which could have a material adverse effect on our future business, financial condition, operating results and cash flows. Furthermore, prior to FDA licensure, if we obtain an EUA, the EUA could be terminated if the emergency determination underlying the EUA terminates.

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

The USG is the principal customer for our PHT-focused MCMs and is the primary source of funds for the development of most of our product candidates in our development pipeline, most notably our AV7909 procured product candidate. We anticipate that the USG will also be a principal customer for those MCMs that we successfully develop within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from USG development contracts and grants. Over its lifetime, a USG procurement or development program may be implemented through the award of many different individual contracts and subcontracts. The funding for such government

programs is subject to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. For example, sales of BioThrax to be supplied under our procurement contract with the CDC are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations, changes in priorities due to global pandemics, 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 valued at approximately $200 million. The contract award also includes options for the delivery of additional doses of AV7909 to the SNS and options for an additional clinical study and post-marketing commitments, which, if both were to be exercised in full, would increase the total contract value to up to $1.5 billion. If levels of government expenditures and authorizations for public health countermeasure preparedness decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the USG otherwise declines to exercise its options under our existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows.

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

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 BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as GSK), completed in November 2019. We intend to negotiate follow-on procurement contracts for most of our PHT products upon the expiration of a related procurement contract, including our procurement contract for raxibacumab, but there can be no assurance that we will be successful obtaining any follow-on contracts. Even if we are successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our products could materially and adversely affect our revenues, and our business, financial condition, operating results and cash flows could be harmed.

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

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

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

The USG may choose not to award us future contracts for either the development of our new product candidates or for the procurement of our existing products addressing PHTs and may instead award such contracts to our competitors. If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those contracts. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs or resources that we will be required to secure and, if applicable, perform under such contract awards,

our growth strategy and our business, financial condition and operating results and cash flows could be materially and adversely affected.

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

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

- the Federal Acquisition Regulation (FAR), and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the Defense Federal Acquisition Regulations (DFARs), and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of U.S. Department of Defense (DoD) government contracts;
- the Department of State Acquisition Regulation (DOSAR), which regulates the relationship between a Department of State organization and a contractor or potential contractor;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
- trade controls, including export and import control laws, International Traffic in Arms Regulations (ITAR), U.S. sanctions programs, and anti-boycott laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

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

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

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;

- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders, if funds for contract performance for any subsequent year become unavailable;
- decline, in whole or in part, to exercise an option to purchase product under a procurement contract or to fund additional development under a development contract;
- decline to renew a procurement contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

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

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

REGULATORY AND COMPLIANCE RISKS

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

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

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

However, many of our MCM product candidates, for example, may take advantage of a different regulatory approval pathway under the FDA's "Animal Rule." The Animal Rule provides a regulatory pathway for drug and biologic products targeting indications for which human efficacy studies are not feasible or would be unethical. Instead, efficacy must be demonstrated, in part, by utilizing animal models rather than testing in humans. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our PHT MCM candidates under the Animal Rule. Even if we are able to proceed pursuant to the Animal Rule, it can be a very long process, and the FDA may decide that our data are insufficient to support approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. For example, to the extent feasible and ethical,

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

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process generally may cause delays in the approval or rejection of an application. There is a high rate of failure inherent in this process, and potential products that appear promising at early stages of development may fail for a number of reasons, and positive results from preclinical studies may not be predictive of similar results in human clinical trials. Similarly, promising results from earlier clinical trials of a product candidate may not be replicated in later clinical trials.

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

- Conditions imposed by regulators, ethics committees, or International Review Boards for preclinical testing and clinical trials relating to the scope or design of our clinical trials;
- Restrictions placed upon, or other difficulties with respect to, clinical trials and clinical trial sites, such as clinical holds or suspension or termination of clinical trials due to, among other things, potential safety or ethical concerns or noncompliance with regulatory requirements;
- Delayed or reduced enrollment in clinical trials, or high discontinuation rates;
- Failure by third-party contractors, contract research organizations (CROs), clinical investigators, clinical laboratories, or suppliers to comply with regulatory requirements or meet their contractual obligations in a timely manner;
- Greater than anticipated cost of or time required to complete our clinical trials; and
- Insufficient product supply or inadequate product quality.

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

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

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

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

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

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

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality

assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our collaborators and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

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

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

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

Any product candidate for which we or our collaborators obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

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

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

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

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

- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a

targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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

There have been executive actions to challenge or delay implementation of the ACA. Since January 2017, there have been two Executive Orders issued designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. In addition, the CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On May 16, 2019, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the rule changes allow Medicare Advantage plans to use preauthorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs. The first change took effect in January 2020, while the second change will take effect in January 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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

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

If we fail to comply with foreign, federal, state and local health care laws, including fraud and abuse and health information privacy and security laws, and antitrust laws, we could face substantial penalties and

our business, results of operations, financial condition and prospects could be adversely affected.

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

- the federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, to induce, or in return for, either the referral of an individual, or the purchase, lease, prescribing or recommendation of an item, good, facility or service reimbursable by a federally funded health care program, such as the Medicare or Medicaid program. The term "remuneration" has been interpreted broadly and may constrain our marketing practices, educational programs, pricing policies and relationships with health care providers or other entities, among other activities;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal health care program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $11,181 to $22,363 per false claim;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, health care benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions, as well as standards relating to the privacy, security and transmission of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," or independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, biologics, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Centers for Medicare & Medicaid Services (CMS), certain payments and transfers of value made to U.S. physicians and teaching hospitals, and ownership or investment interests held by physicians and

their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to U.S. physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

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

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

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

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

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

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

these types of investigations and related litigation can result in:

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

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

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

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

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

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

In order for our products to be reimbursed by the primary federal governmental programs, we must report certain pricing data to the USG. Compliance with reporting and other requirements of these federal programs is a pre-condition to: (i) the availability of federal funds to pay for our products under Medicaid and Medicare Part B; and (ii) procurement of our products by the Department of Veterans Affairs (DVA), and by covered entities under the 340B/PHS program. The pricing data reported are used as the basis for establishing Federal Supply Schedule (FSS), and 340B/PHS program contract pricing and payment and rebate rates under the Medicare Part B and Medicaid programs, respectively. Pharmaceutical companies have been prosecuted under federal and state false claims laws for submitting inaccurate and/or incomplete pricing information to the government that resulted in increased payments made by these programs. The rules governing the calculation of certain reported prices are highly complex. Although we maintain and follow strict procedures to ensure the

maximum possible integrity for our federal pricing calculations, the process for making the required calculations involves some subjective judgments and the risk of errors always exists, which creates the potential for exposure under the false claims laws. If we become subject to investigations or other inquiries concerning our compliance with price reporting laws and regulations, and our methodologies for calculating federal prices are found to include flaws or to have been incorrectly applied, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

Regardless of the permissibility and liability risks, in the event a user of one or more of our products suffers an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory

authority of another country, particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact, even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects.

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

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

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

Government regulators enforce cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic and foreign manufacturing facilities without prior notice at reasonable times and in a reasonable manner. Health Canada may conduct similar inspections of our domestic and foreign facilities where Canadian marketed products are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. Following several of these inspections, regulatory authorities have issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators may undertake enforcement action against us, which may include:

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

Similar action may be taken against us should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. Failure to meet potency, stability or other specification requirements could result in delays in distributions, recalls or other consequences. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval. Regulatory approval may also contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. If we experience any of these post-approval events, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Additionally, companies may not promote unapproved products or unapproved uses of approved products (i.e. “off-label” uses or uses that are not described in the product’s approved labeling and that differ from the uses approved by the applicable regulatory agencies). A company that is found to have improperly promoted an unapproved product or unapproved use of an approved product may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity

agreements with the USG), as well as criminal sanctions. If our employees or agents engage in marketing of an unapproved product or the unapproved use of an approved product, we could be subject to civil or criminal investigations and monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our business, financial condition, operating results and cash flows, and damage our reputation.

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

We currently sell certain of our products outside the United States and intend to expand the countries in which we sell our products and have received market authorization under the mutual recognition procedure to sell BioThrax in France, Italy, the Netherlands, Poland, and the United Kingdom. To market our products in foreign jurisdictions under normal circumstances, we generally need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative "emergency use" or other exemptions from general approval and import requirements. Approval by the FDA in the United States or the mutual recognition procedure in the European member states does not ensure approval by all foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA or under the mutual recognition procedure. There is also a risk that a regulatory authority in another country could conclude that we have violated the rules and regulations related to product development, approval or promotion in that country. Therefore, there is a risk that we could be subject to a foreign enforcement action if found to be in violation of such laws and regulations. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products in desired jurisdictions internationally if no alternate procurement pathway is identified for authorized government customers in a particular jurisdiction. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process. Our reliance on third parties can introduce additional uncertainty into the process.

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

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

As we continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of, and must dedicate additional resources towards avoiding inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (FCPA), the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, and other similar foreign laws, which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

regulations, we may be subject to civil and criminal penalties.

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

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

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

MANUFACTURING RISKS

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

An interruption in our manufacturing operations could result in our inability to produce our products 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;
- civil unrest and protests, including by animal rights activists;
- injunctions;
- damage to or destruction of the facility; and
- product contamination or tampering.

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

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities in Camden; facilities in Canton, Massachusetts; Rockville, Maryland, Bern, Switzerland; and Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed products, our product candidates and our ability to produce products for external customers, result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition, operating results and cash flows.

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

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

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

Several of our products, including BioThrax and ACAM2000 and many of our current product candidates, including AV7909, are biologics. Manufacturing 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. In addition, slight deviations anywhere in the manufacturing process, including obtaining materials, maintaining master seed or cell banks and preventing genetic drift, seed or cell growth, fermentation, contamination including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other quality control testing, may result in lot failures or manufacturing shut-downs, delays in the release of lots, product recalls, spoilage or regulatory action. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, as our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-downs, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can also vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, including warning letters and other restrictions on the marketing or manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us, damage our reputation and negatively impact our business.

Additionally, if changes are made to the manufacturing process, we may be required to provide the FDA with pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of any impacted products before and after the changes.

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly and adversely impact our revenues, which would harm our business, financial condition, operating results and cash flows.

Manufacturing delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

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

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

Our operations involve the use of hazardous materials, including chemicals, bacteria and viruses, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials and manufacture our products and product candidates on our behalf, are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with and be inspected by the Centers for Disease Control (CDC) and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer, select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of

registered entities. We are also subject to a variety of environmental and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business, financial condition, operating results and cash flows. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agriculture and the DoD, as well as regulatory authorities in Canada.

RISKS RELATED TO RELIANCE ON THIRD PARTIES

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

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including key components for NARCAN® Nasal Spray. Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

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

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

We depend on certain single-source suppliers for key materials and services necessary for the manufacture of AV7909, BioThrax, ACAM2000, NARCAN Nasal Spray and our other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture AV7909 and BioThrax. We also rely on single-source suppliers for the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. A disruption in the availability of such materials or services from these suppliers, due to their bankruptcy or other unknown factors that may impact these suppliers, or in the quality of the material provided by such suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and product candidates could be adversely affected and could harm our revenues, cause us to fail to satisfy contractual commitments, lead to a termination of one or more of our contracts or lead to delays in our clinical trials, any of which could be costly to us and otherwise materially harm our business, financial condition, operating results and cash flows.

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

We depend on third parties, such as independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also may experience unexpected cost increases that

are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their development efforts, which may not be approved.

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

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

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

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

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential acquisitions that are never completed. Even if we are successful in acquiring a company or product, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial, and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities.

If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our business, financial condition, operating results and cash flows.

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

We may not be able to integrate any acquired business successfully or operate any acquired business profitably, including our prior acquisitions of Adapt Pharma Limited and PaxVax Holding Company Ltd. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

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

- retaining existing customers and attracting new customers;
- retaining key employees;
- diversion of management attention and resources;
- conforming internal controls, policies and procedures, business cultures and compensation programs;
- consolidating corporate and administrative infrastructures;
- successfully executing technology transfers and obtaining required regulatory approvals;
- consolidating sales and marketing operations;
- identifying and eliminating redundant and underperforming operations and assets;
- assumption of known and unknown liabilities;
- coordinating geographically dispersed organizations;

- managing tax costs or inefficiencies associated with integrating operations; and
- the strength of any intellectual property portfolio we may acquire.

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

COMPETITIVE AND POLITICAL RISKS

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

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

There are a number of companies with products or product candidates addressing PHT preparedness that are competing with us for both USG procurement and development resources. Many of our competitors have greater financial, technical and marketing resources than we do. Our competitors may receive patent protection that dominates, blocks or adversely affects our products or product candidates.

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

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

Competition for AV7909, BioThrax, ACAM2000, and our other biological products and product candidates, otherwise referred to as our “Biologic Products,” may be affected by follow-on biologics, or “biosimilars,” in the United States and other jurisdictions. Regulatory and legislative activity in the United States and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars. The specific regulatory framework for this biosimilar approval path and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and could adversely affect our business, financial condition, operating results and cash flows.

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

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

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

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

On June 5, 2020, the U.S. District Court for the District of New Jersey issued an unfavorable ruling against Adapt in the consolidated case. The Company has filed a notice of appeal related to the decision with

the U.S. Court of Appeals for the Federal Circuit. While the case is on appeal, it is possible that Teva could proceed with an at-risk launch of its generic NARCAN® Nasal Spray 4mg/spray. The 2mg/spray is currently stayed pending the outcome of the appeal of the NARCAN® Nasal Spray 4mg/spray case.

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

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

Products developed to counter the potential impact of PHTs are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our business, financial condition, operating results and cash flows.

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

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

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

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

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

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

We are developing two product candidates for the possible prophylaxis or treatment of COVID-19 and we are also providing contract development and manufacturing services for the development and/or manufacture of four vaccine product candidates for

customers. There can be no assurance that any of these product candidates will be safe or effective. There can be no assurance that any of these product candidates will receive approval or be authorized for emergency use by the FDA or any other health regulatory authority. Even if these product candidates are safe and/or effective and receive approval or authorization by a health regulatory authority, the manufacturing processes for these programs are under development and will be complex. As a result, there can be no assurance that we will be able to produce any significant quantity of these products 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.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources in these trials, which may not yield viable products. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, which would adversely affect our business, financial condition, operating results and cash flows.

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

Preclinical and clinical testing for certain of our product candidates addressing CBRNE threats may face additional difficulties and uncertainties because they cannot ethically or feasibly be tested in human subjects. We therefore expect to rely on the Animal Rule to obtain regulatory approval. The Animal Rule permits, in certain limited circumstances, the use of animal efficacy studies, together with human clinical safety and immunogenicity trials, to support an application for marketing approval. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. We have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our product candidates in humans.

Under Project BioShield, the Secretary of HHS can contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA. If our product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms for distribution in the United States.

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

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

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

We continue to evaluate our product development strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. We may change or refocus our existing product development, commercialization and manufacturing activities based on government funding decisions. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or

commercially promising or profitable product candidates or choose candidates for which government development funds are not available. Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better business opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

INTELLECTUAL PROPERTY RISKS

If we are unable to protect our proprietary rights, our business, financial condition, operating results, and cash flows could be materially harmed.

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

Obtaining issued patents relating to our technology or products is not always possible. Even if issued, patents may inadvertently lapse or be challenged, narrowed, invalidated, or circumvented, and such happenings could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. Patent rights are occasionally allowed to lapse in the ordinary course of business as part of alignment with business strategy and resource availability. If circumstances change where such patent rights may have been valuable, our competitive position may be adversely affected. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and in other countries may also impact the value of our intellectual property, For example, by narrowing the scope of our patent protection, or resulting in costly defensive measures. In addition, some countries do not grant patent claims directed to certain subject matter, such as methods of treating humans. Thus, in these countries, patent protection may not be available for protection of certain aspects of our products or product candidates.

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

The cost of litigation to uphold the validity of patents to prevent or stop infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents are subjected to opposition proceedings or validity challenges. Intellectual property lawsuits are expensive and unpredictable and consume management's time and attention and other resources, even if the outcome is successful. In addition, there is a risk that a court could decide that our patents are not valid, are unenforceable, or are not infringed by a competitor product. There is also a risk that, even if the validity of a patent is upheld, a court could refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events occur, our business, financial condition, operating results and cash flows could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such intellectual property rights may be compromised by the acts or omissions of these third parties.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to

market and sell our products, and therefore our business, financial condition, operating results, and cash flows could be materially and adversely affected.

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

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

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

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

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

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

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

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

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

One or more of our products is approved as a drug product under the provisions of the U.S. Food, Drug and Cosmetic Act (FDCA), which may render it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If the patent owner files suit within 45

days of receiving notice from an ANDA filer, the patent owner is entitled to receive a 30 month stay on the FDA's ability to give final approval for the generic product that is the subject of the ANDA.

Generic manufacturers use Paragraph IV certifications to challenge the validity of patents listed in the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products.

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.

Generic manufacturers of biosimilars also have a pathway to challenge innovator products. The 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars.

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 any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate initiatives;
- increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase, to the extent we are unable to offset the risk of such increases through our hedging instruments;
- subjecting us, as under our Senior Secured Credit Facilities 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 $427.5 million and $0 million, respectively, as of September 30, 2020. 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 contract development and manufacturing services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional common stock under any future share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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

Our hedging program is subject to counterparty default risk.

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

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

If our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity or debt offerings, bank loans or collaboration and licensing arrangements. In August 2018, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a “well-known seasoned issuer” under SEC rules (which include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least $700 million of public float or issuing an aggregate amount of $1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 8, 2021, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to August 8, 2021, the existing shelf registration statement will expire, and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

If we raise funds by issuing equity securities, our stockholders may experience dilution. 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. We are not restricted under the terms of the indenture governing our 2.875% Convertible Senior Notes due 2021 (Senior Convertible Notes) from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of diminishing

our ability to make payments on our indebtedness. However, our Senior Secured Credit Facilities restrict our ability to incur additional indebtedness, including secured indebtedness.

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

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability has been substantially dependent on product sales, which historically have fluctuated significantly from quarter to quarter, and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the USG. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

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

OTHER BUSINESS RISKS

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

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

One measure of protection against such lawsuits is coverage under the PREP Act, which was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, ACAM2000, raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures. These declarations expire in 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct or for cases brought in non-U.S. tribunals or under non-U.S. law. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates.

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

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

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

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. Further product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and

we may not be able to obtain insurance coverage that will be adequate to satisfy all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large-scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV, and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Additionally, potential product liability claims related to our commercial products, including NARCAN® Nasal Spray, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

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

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

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

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

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. 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 two proprietary COVID-19 therapeutics 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 success is dependent on our continued ability to attract, motivate and retain key personnel, and any failure to attract or retain key personnel may negatively affect our business.

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

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his substantial beneficial ownership of our common stock. As of September 30, 2020, 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 October 30, 2020, 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 for the foreseeable future.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6 million shares of our common stock outstanding as of September 30, 2020, have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

Exhibit Index

Exhibit Number	Description
4.1	Indenture, dated as of August 7, 2020, by and among the Company, certain subsidiaries of the Company and U.S. Bank National Association, as trustee. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on August 7, 2020).
4.2	Form of 3.875% Senior Unsecured Note due 2028 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on August 7, 2020).
10.1†	Purchase Agreement, dated as of August 4, 2020, by and among the Company, the subsidiaries of the Company named therein as guarantors, and Wells Fargo Securities, LLC, as representative of the several initial purchasers identified therein. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 7, 2020).
10.2	Second Amendment to Amended and Restated Credit Agreement, dated August 7, 2020. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on August 7, 2020).
10.3#†	Modification No. 6, effective July 13, 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).
10.4#†	Modification No. 21, effective June 12, 2020, 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.
10.5#†	Modification No. 22, effective June 12, 2020, to the BARDA ADM Contract.
10.6#†	Modification No. 23, effective July 22, 2020, to the BARDA ADM Contract.
10.7#†	Modification No. 24, effective August 28, 2020, to the BARDA ADM Contract.
10.8#†	Modification No. 25, effective September 25, 2020, to the BARDA ADM Contract.
10.9#†	Modification No. 1, effective August 24, 2020, to task order #75A50120F33007, between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority under the BARDA ADM Contract.
10.10#†	Order for Supplies and Services Between Emergent Manufacturing Operations Baltimore LLC and the BioMedical Advance Research and Development Authority, dated August 6, 2020, under the BARDA ADM Contract (Task Order 75A50120F33008).
10.11#†	Modification No. 1, effective August 24, 2020, to Task Order #75A50120F33008.
10.12#†	Manufacturing Services Agreement, dated July 26, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP. (AZ MSA).
10.13#†	Manufacturing Product Schedule, dated July 26, 2020 to AZ MSA.
10.14#†	Work Order to Manufacturing Services Agreement, dated June 10, 2020, between Emergent Manufacturing Operations Baltimore, LLC and AstraZeneca Pharmaceuticals LP (included as part of AZ MSA).
10.15#†	Amendment No. 1, effective September 30, 2020, to AZ MSA.
10.16#†	Manufacturing Services Agreement, dated July 2, 2020, by and between Emergent Manufacturing Operations Baltimore, LLC and Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson.
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 September 30, 2020, formatted in iXBRL (Inline Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Income, (iv) the Condensed Consolidated Statements of Cash Flows, (v) the Condensed Consolidated Statement of Changes in Stockholders' Equity; and (vi) the related Notes to the Condensed Consolidated Financial Statements.
104 #	Cover Page Interactive Data File, formatted in iXBRL and contained in Exhibit 101.

Filed herewith.

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

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

Date: November 5, 2020

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

Date: November 5, 2020

EXHIBIT 10.3

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 | 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00006	See Block 16C	OS260316	

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)*		
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. 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)* Net Increase: $258,000,000.00
See Schedule

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item
	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 modify ARTICLES B.3 OPTION PRICES, B.5 ADVANCE UNDERSTANDINGS, C.1 STATEMENT OF WORK and SECTION J LIST OF ATTACHMENTS.

Funds Obligated Prior to this Modification: $464,692,203
Funds Obligated with Mod #6: $258,000,000
Total Funds Obligated to Date: $722,692,203

Expiration Date: September 29,2021 (Unchanged)
Period of Performance: 09/30/2016 to 09/29/2021
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)*. Abigail Jenkins SVP, BU Head, Vaccines		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*. Jill M. Johnson	
15B. CONTRACTOR/OFFEROR *Digitally signed by Abigail Jenkins* *Reason: I approve this document* *Date: Jul 13, 2020.13:37 EDT* /s/ Abigail Jenkins *(Signature of person authorized to sign)*	15C. DATE SIGNED Jul 13, 2020	Digitally signed by [**] Date: 2020.07.13 15:10:02 -04'00' 16B. UNITED STATES OF AMERICA /s/ Jill M. Johnson *(Signature of Contracting Officer)*	16C. DATE SIGNED Jul 13, 2020

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

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)
	Add Item 6 as follows:				
					258,000,000.00
6	CLIN 0006 – Option for Additional Surge Capacity AV7909 anthrax vaccine Accounting Info: 2020.199TWNP.26088 Appr. Yr.: 2020 CAN: 199TWNP Object Class: 26088 Funded: $[**] Accounting Info: 2020.1990051.26088 Appr. Yr.: 2020 CAN: 1990051 Object Class: 26088 Funded: $[**] Accounting Info: 2020.1991073.26088 Appr. Yr.: 2020 CAN: 1991073 Object Class: 26088 Funded: $[**]				

The purpose of this modification is to modify ARTICLES B.3 OPTION PRICES, B.5 ADVANCE UNDERSTANDINGS, C.1 STATEMENT OF WORK and SECTION J – LIST OF ATTACHMENTS.

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

CLIN	Period of Performance	Supplies/Services	Doses	Price per Dose	Total Cost	Additional Doses****
FIXED PRICE						
CLIN 0004 (Option – Funded)***	[**] - 09/29/21	Additional Surge Capacity (EUA)	[**]	[**]	[**]	Dose number TBD

[**]

***CLIN 0004 is funded

****Additional Doses may be delivered to BARDA as consideration under the provision in Article B.5.I. In the event that EBS delivers doses [**] (see Article B.5.I), Emergent will provide a [**]% dose-replacement equivalent of additional doses to the Government. As set forth in Article B.5.I, BARDA may accept [**] if such doses are delivered along with the appropriate number of additional doses ("Additional Doses"). Additional Doses shall be calculated as [**]% of the number of delivered [**].

CLIN	**Period of Performance**	**Supplies/ Services**	**Doses**	**Price per Dose**	**Total Cost**	**Additional Doses****
FIXED PRICE						
CLIN 0006 (Option – Funded)*	**[**] - 07/31/2021**	**Additional Surge Capacity (EUA)**	**[**]**	**[**]**	**$258,000,000**	**Dose number TBD**

*CLIN 0006 is funded

[**]

****As set forth in Article B.5.I, BARDA may accept doses dated [**] if such doses are delivered along with the appropriate number of additional doses ("Additional Doses"). Additional Doses shall be calculated as [**]% of the number of delivered [**].

ARTICLE B.5. ADVANCE UNDERSTANDINGS is hereby modified as follows:

I. Stability

BARDA understands that the stability testing is ongoing to support long-term stability of AV7909. The contractor will continue to perform ICH compliant stability studies on AV7909. While EBS and BARDA believe that a [**] will be achieved, this cannot be confirmed until FDA licensure of the vaccine.

For the agreed upon price, AV7909 will be delivered to the SNS that is [**] from the date of manufacture stamped on the vial label.

i. BARDA does agree to [**] to the [**] limitation, **for CLINs 0004 and 0006**, to allow delivery of approximately [**] doses of AV7909 that were initially manufactured as PPQ material intended for qualification of a Redundant Fill Site at PAR.
ii. For CLIN**s** 0004 **and 0006**, BARDA agrees to allow delivery of and may accept doses dated [**] if such doses are delivered along with the appropriate number of additional doses ("Additional Doses"). Additional Doses shall be calculated as [**]%

of the number of delivered [**]. EBS shall provide the Additional Doses as consideration for BARDA's acceptance of [**] with a [**] for storage in the Strategic National Stockpile. The Additional Doses will be included with delivery of the [**] at no additional cost to BARDA or the US Government.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated **June 26, 2020** 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 June 26, 2020, 10 pages**

10. **AV7909 Delivery Schedule – Amended for CLIN 0006**

Q3 2020	Q4 2020	Q1 2021	Q2 & Q3 2021
Aug - Sep	Oct-Dec	Jan-Mar	Apr-Jul
[**] Doses	[**] Doses	[**] Doses	[**] Doses

***For a total of [**] doses**

All other terms and conditions of this contract remain unchanged.

End of Modification #6

EXHIBIT 10.4

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

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

2. AMENDMENT/MODIFICATION NO. P00021	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. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or

(c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-8 Option to Extend Services. By 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 ____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 execute a no-cost extension for the Base Period; extending the Period of Performance from June 15, 2020 through October 31, 2020. This modification shall provide the adequate lead time to ensure the Contractor meet their obligations under the proposed extended Base Period. Contractor shall provide a technical and business proposal plan for achieving the pandemic influenza objectives which is required in the base period of the contract. Performance milestones must be met by the Contractor and the plan shall also include additional proposed milestones for BARDAs consideration. The plan provided by Emergent will be no later than September 1, 2020.
All other terms and conditions remain the same and in full force and effect.

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*.	16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
Patrick D. Saam VP, Government Contracting & Accounting	Monica Watson

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Patrick D. Saam *(Signature of person authorized to sign)*	Jun 12, 2020	Digitally signed by [**]-S Date: 2020.06.12 12:15:31 -04'00'" /s/ Monica Watson *(Signature of Contracting Officer)*	Jun 12, 2020

STANDARD FORM 30 (Rev. 11/2016)
Previous edition unusable FAR (48 CFR) 53.243

EXHIBIT 10.5

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

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

2. AMENDMENT/MODIFICATION NO. P00022	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)*		
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or

(c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: 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 ____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 exercise Option period VIII associated with CLINS 0031, 0032, 0033 and 0034. The period of performance is from June 15, 2020 through June 14, 2021.
All other terms and conditions remain the same and in full force and effect.
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*.		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
Patrick D. Saam VP, Government Contracting & Accounting		Monica Watson	
15B. CONTRACTOR/OFFEROR /s/ Patrick D. Saam *(Signature of person authorized to sign)*	15C. DATE SIGNED Jun 12, 2020	Digitally signed by [**] Date: 2020.06.12 16:1215:21:36 -04'00" 16B. UNITED STATES OF AMERICA /s/ Monica Watson *(Signature of Contracting Officer)*	16C. DATE SIGNED Jun 12, 2020

STANDARD FORM 30 (Rev. 11/2016)
Previous edition unusable FAR (48 CFR) 53.243

EXHIBIT 10.6

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

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00023	06/15/2020		

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

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE, MD 212246824		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

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

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 correct an administrative error made under Mod P00022. CLINS 0031, 0032, 0033, and 0034 were not activated in PRISM under Mod P00022. This modification activates CLINS, 0031, 0032, and 0034.

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

Chane Item 31 to read as follows (amount shown is the obligated amount) :
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*)	
		Jeffrey R. Schmidt	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	Digitally signed by [**[-S Date: 2020.08.03 13:34:14 -04'00' 16B. UNITED STATES OF AMERICA /s/ Jeffrey R. Schmidt *(Signature of Contracting Officer)*	16C. DATE SIGNED 07/22/2020

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE OF	
	HHSO100201200004I/P00023	2	2

NAME OF OFFEROR OR CONTRACTOR

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC 1410445

ITEM No.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)

	31	Option Period VIII - Core Services Readiness Change Item 32 to read as follows (among shown is the obligated amount): Option Period VIII – Pandemic Influenza Vaccine Readiness				
32						
	33	Change Item 33 to read as follows (amount shown is the obligated amount):				
	34	Option Period VIII – Workforce Development Change Item 34 to read as follows (amount shown is the obligated amount): Option Period VIII – Services Task/Delivery Orders				

Sponsored by GSA
FAR (48 CFR) 53.110

EXHIBIT 10.7

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

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

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P000024	See Block 16C		

6. ISSUED BY CODE	ASPR/BARDA	7. ADMINISTERED BY *(If other than Item 6)* CODE	ASPR/BARDAO2
ASPR/BARDA 200 Independence Ave., S.W. Room 640 - G Washington, D.C. 20201		ASPR-BARDA 330 Independence Ave, SW, Rm G640 Washington DC 20201	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	(x)	9A. AMENDMENT OF SOLICITATION NO.
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103 (a) (3) – 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 ____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 cost modification is to:
A. Incorporate the attached proposal which describes the enhancing of the ADM facility Core Service Capabilities for Bioreactor Infrastructure to the Biomedical Advanced Research and Development Authority (BARDA) under our current Prime Contract No. HHS0100201200004I.
B. This project includes the purchase, installation and qualification of [**]. This acquisition of additional equipment allows for the expansion of the facility with flexibility to be able to increase large scale production.
C. Prime Contract No. HHS0100201200004I is hereby modified as follows in accordance with the
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 & Accounting		Monica Watson	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	Digitally signed by [**] - S 16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Patrick D. Saam *(Signature of person authorized to sign)*	8/28/2020	/s/ Monica Watson *(Signature of Contracting Officer)*	8/28/2020

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	
	HHSO100201200004I/P00024	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)
	Attached proposal.				

NSN 7540-01-152-8067 OPTIONAL FORM 336 (4-86)

Sponsored by GSA
FAR (48 CFR) 53.110

emergent biosolutions™

"Change Order Proposal for Enhancing/Expanding Core Capabilities of the ADM-Bioreactors"

Proposal Submitted for Consideration to:

Biomedical Advanced Research and Development Authority (BARDA) under Contract HHSO100201200004I

Change Order Proposal June 25, 2020

Offeror:
Emergent Manufacturing Operations Baltimore LLC (EMOB)
5901 East Lombard St. Baltimore, MD 21224 DUNS: [**]
CAGE CODE: 6EBP9
Type: Large Business

Proposed Period of Performance:
06/15/2012 – 06/14/2024

Emergent's Program Contact:
Syed Husain
SVP, BU, Head-CDMO
400 Professional Drive
Gaithersburg, MD 20879 Office: [**]
Fax: [**]
Cell: [**]
Email: [**]

Emergent's Contracts Contact:
[**]
400 Professional Drive, Suite 400 Gaithersburg, MD 20879
Phone: [**]
Email: [**]

Prepared for (via email):
[**]
Email: [**]

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of— or in connection with —the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained on all marked pages.

Change Order Proposal

1.0 Introduction

Emergent Manufacturing Operations Baltimore LLC (Bayview) is pleased to submit this proposal for further enhancing the ADM facility's *Core Service Capabilities for Bioreactor Infrastructure* to the Biomedical Advanced Research and Development Authority (BARDA) under our current Prime Contract No. HHS01 00201200004I.

This project includes the [**]. This acquisition of additional equipment allows for the expansion of the facility with flexibility to be able to increase large scale production throughput with parallel suite capability as follows:

- Area [**] and [**]: up to [**] per area, currently up to [**] per area
- Area [**]: up to [**], currently up to [**]

[**].

This Proposal outlines and describes the resources underpinning our approach and the costs of applying those resources.

.1 Contract Type and Period of Performance

.1.1. Line Item Contract Type

Emergent submits this Proposal for incorporation under Contract HHS0100201200004I, awarded June 15, 2012 by BARDA to Emergent.

1.1.1.1. Cost

The Cost SLIN proposed includes only Emergent's Total Cost (with no profit or fee) and is as follows:

subCLIN 0002.7- "Core Service Capabilities–Bioreactor Infrastructure"

1.1.1.2 Cost Share

The Cost-share SLIN proposed with this offer, and the respective share percentage, is as follows:

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

subCLIN 0002.7- "Core Service Capabilities–Bioreactor Infrastructure" [**] (USG/Emergent)

.1.2 Proposal Period of Performance

For the purposes of this proposal, the pricing assumes the Contract itself shall extend the end date for the period of performance for the Base Period from *06/14/2020* to *06/14/2024*.

1.2 Period of Validity

This Proposal shall remain valid for a period of 60 days from the date on the cover page of this submission.

1.3 Commitment

Emergent acknowledges that there may be additional changes required under the current contract to properly incorporate the work proposed and hereby commits that Emergent shall work together in good faith with BARDA's ADM Team to finalize an approach (and subsequent contract modification) acceptable to both parties.

2.0 PRICE TABLES

Set out below is Emergent's proposed price tables detailing the CLIN offered for the new Enhanced Core Service Capabilities for Bioreactors under an additional proposed subCLIN 0002.7 – "Core Service Capabilities – Bioreactor Infrastructure":

subCLIN	Item Description	Cost Share USG/Ktr	Contractor Cost Share	USG Cost Share	Not to Exceed Total Cost
0002.7	Core Service Capabilities - BioReactor Infrastructure	[**]	[**]	[**]	[**]

2.1 CLIN Funding Realignment

Emergent is proposing the addition of this new subCLIN to the contract as a zero-dollar change order proposal assuming that the current funds allocated to existing CLIN 0002 on the contract can be re-allocated to cover the proposed subCLIN 0002.7 amount outlined in the above table. As such, no additional funding is required on the Contract under this proposed change request. The USG current cost share obligation of $[**] shall remain unchanged.

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

Emergent proposes that excess funds that are presently assigned to subCLIN 0002.3 - "Licensure of Pandemic Flu Vaccine at [**] Facility" be allocated to this new CLIN.

Coupled with our prior request for realignment of funds under the ADM CLINs, we request the funding be changed as follows:

Was:

subCLIN	Item Description	Cost Share USG/Ktr	Contractor Cost Share	USG Cost Share	Not to Exceed Total Cost
0002.1	[**] Pilot Plant-Design Construction, CQV	[**]	[**]	[**]	[**]
0002.2	[**]-Design, Construction, CQV	[**]	[**]	[**]	[**]
0002.3	Licensure of Pandemic Flu Vaccine at [**] Facility	[**]	[**]	[**]	[**]
0002.4	Project Management	[**]	[**]	[**]	[**]
0002.5	Security	[**]	[**]	[**]	[**]
0002.6	Workforce Development Program (Plan Development)	[**]	[**]	[**]	[**]
		Totals $[**]	$[**]	$[**]	

Now Read: (all proposed changes in bold font)

subCLIN	Item Description	Cost Share USG/Ktr	Contractor Cost Share	USG Cost Share	Not to Exceed Total Cost
0002.1	[**] Pilot Plant-Design Construction, CQV	[**]	**[**]**	**[**]**	**[**]**
0002.2	[**]-Design, Construction, CQV	[**]	[**]	[**]	[**]
0002.3	Licensure of Pandemic Flu Vaccine at [**] Facility	[**]	**[**]**	**[**]**	**[**]**
0002.4	Project Management	[**]	**[**]**	**[**]**	**[**]**
0002.5	Security	[**]	[**]	[**]	[**]
0002.6	Workforce Development Program (Plan Development)	[**]	[**]	[**]	[**]
0002.7	**Core Service Capabilities – BioReactor Infrastructure**	**[**]**	**[**]**	**[**]**	**[**]**

"The subcontractor identified in the attached proposal are approved by the government for purposes of performance of subCLIN 0002.27"

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

3.0 Assumptions

3.1 Proposed Assumptions

Pricing for the overall program is based on the following assumptions:

- Emergent's schedule and pricing are based on the activities proposed. Any changes to the scope, quantity and type of equipment and/or services to be provided may necessitate a change to the proposed prices and schedule.
- This offer assumes that the period of performance for the Base CLINs 0001, 0002 and 0003 shall be extended as cited in Section 1.1.2, or as amended.
- As both parties have successfully done in the past on this contract, Emergent assumes that as we progress further on the scope of work under CLIN 0002, that the re-alignment of the cost share funding listed for each subCLIN under CLIN 0002s may be required to be adjusted in future.

4.0 Cost Narrative

4.1 Direct Labor

4.1.1. Uncompensated Overtime

Uncompensated overtime has not been proposed for this effort.

4.1.2. Productive Man-Year

The productive man-year proposed for this effort is 2,080. The calculation is based on the available hours in a calendar year (52 weeks x 40 hours per week).

4.1.3. Level of Effort (LOE)

The LOE proposed for each position was estimated based on the work requirements and Emergent's experience with similar tasks.

4.1.4. Direct Labor Escalation

Direct labor rates have been escalated by [**]% commencing January 1st of each contract year which is consistent with industry standard. Emergent issues annual merit/cost of living adjustments to its employees and takes account of any anticipated promotions for proposed personnel on January 1st. Emergent does not always award a [**]% annual merit/cost of living adjustments.

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

4.2 Other Direct Costs

4.2.1 Subcontractors

Proposed subcontractors and subcontractor costs for the following are based on estimated pricing used as a basis of estimate for tasks similar in scope. Breakdowns of Subcontractor costs with task description are included in Table 1, below.

Table 1 – "Emergent's Proposed Subcontractors" below, lists our proposed subcontractors and provides the following information: Subcontractor name, SLIN, basis of selection, and total cost and summary of the source used:

subCLIN	Subcontractor	Basis of Selection	Total Costs	Source
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]
0002.7	[**]	[**]	[**]	[**]

Subcontractor costs are based on estimates from similar work performed by existing or anticipated vendors.

4.2.2. Travel

Emergent is not proposing any costs for travel in this offer.

4.2.3. Materials/Supplies

Emergent is not proposing any costs for materials or supplies in this offer.

4.2.4. Equipment

Emergent shall require the acquisition of certain equipment in the fulfillment of the work proposed. We have included *Table 2* below detailing the equipment and the direct cost proposed. Quotes for this equipment is on file at Emergent.

Equipment cost share assumes that Emergent will own and have title to the equipment purchased as part of this proposed effort.

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

EQUIPMENT COSTS

Task Description	ITEM	Direct $s
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
subCLIN 0002.7	[**]	[**]
Grand Total		**$ [**]**

Table 2: Equipment Proposed

4.3 Indirect Costs

The methodology used to calculate Emergent's proposed Total Cost/Cost Share pricing utilized indirect costs detailed in the sections below and are based on rates from the 2019 Forward Pricing Rates for Emergent BioSolutions – Federal Segment submitted to the National Institute of Health (NIH) Division of Financial Services (DFAS) on July 22, 2019. This Forward Pricing Indirect rate proposal provides forward pricing to be used from the date of submittal onward and provides rates for our indirect cost elements (Fringe, OH, Material & Subcontractor Handling and G&A). A pdf copy is embedded in this submission for your reference, as follows:

[**]

.3.1 Fringe

Emergent's fringe rate is [**]%. The fringe rate is applied to all direct labor costs. This fringe rate as calculated by dividing the projected cost of fringe benefits by the projected salary base.

.3.2 Development Overhead

Emergent has utilized its overhead rate titled "R&D Overhead (Bayview)" for this effort in concert with our disclosed practices, which is [**]% and has been applied to all direct labor and fringe benefit costs. This rate was calculated by dividing the projected cost of overhead expenses by the projected salary base plus applicable fringe benefits.

.3.3 General and Administrative

Emergent's General and Administrative (G&A) rate is [**]% and has been applied to all direct costs and equipment costs proposed herein (excluding Subcontractor and material costs, which are not part of the basis of allocation). This rate was calculated by dividing projected

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

G&A costs by a base composed of direct project cost (excluding subcontracts and materials) and Federal Acquisition Regulation (FAR) unallowable costs.

L.3.4 Material and Subcontractor Handling

Emergent's Material and Subcontractor Handling (M&SH) rate is [**]% and has been applied to subcontractor and material costs proposed herein. This rate includes the costs associated with personnel responsible for aspects of purchasing materials, issuing solicitations, processing subcontractor's agreements and purchase orders. The base used to calculate this rate consists of materials and subcontractor cost (except for subcontractor cost related to capital assets).

L.3.5 Indirect Cost Rates, Forward Pricing/Outyears

Emergent has straight-lined the indirect ceiling rates and as such, there is no variance in the indirect cost rates proposed for each contract year.

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

5.0 COST SUMMARIES

1. Cost Summary

The following tables shows the total for the subCLIN 0002.7, by Element of Cost proposed, and broken down per the proposed Cost Share percentages;

SUMMARY - By Element of Cost

Description	Rate	Grand total	Government Portion ([**]%)	Emergent ([**]%)
TOTAL [**] DEVELOPMENT LABOR HOURS		[**]		
TOTAL HOURS		[**]	[**]	[**]
TOTAL [**] DEVELOPMENT LABOR COST		[**]	[**]	[**]
TOTAL DIRECT LABOR COST		[**]	[**]	[**]
FRINGE BENEFITS [**] DEVELOPMENT LABOR	[**]	[**]	[**]	[**]
TOTAL FRINGE BENEFITS		[**]	[**]	[**]
TOT DIRECT LABOR & FRINGE BENEFITS BALTIMORE DEVELOPMENT		[**]	[**]	[**]
TOTAL DIRECT AND FRINGE		[**]	[**]	[**]
[**] DEVELOPMENT OVERHEAD	[**]	[**]	[**]	[**]
TOTAL OVERHEAD		[**]	[**]	[**]
MATERIALS AND SUPPLIES				
PROFESSIONAL TRAVEL				
EQUIPMENT		[**]	[**]	[**]
CONSULTANTS				
OTHER DIRECT COSTS – SHIPPING				
SUBCONTRACTORS		[**]	[**]	[**]
TOTAL OTHER DIRECT COSTS		[**]	[**]	[**]
SUBTOTAL OTHER DIRECT AND TOTAL LABOR		[**]	[**]	[**]
EXCLUSION FROM BASE FOR G&A		[**]	[**]	[**]
ADJUSTED BASE FOR G&A		[**]	[**]	[**]
G&A	[**]	[**]	[**]	[**]
MATERIAL AND SUBCONTRACTOR HANDLING	[**]	[**]	[**]	[**]
TOTAL PROPOSED COST EXCLUDING PROFIT CPFF		[**]	[**]	[**]
PROPOSED FEE CPFF			[**]	[**]
GRAND TOTAL PRICE		[**]	[**]	[**]

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Change Order Proposal

2. Labor Detail – The following tables shows the calculations for labor costs proposed, by labor category:

LABOR DETAIL

		2020		
Task Description	**Labor Category**	**Hourly Rate**	**Hours**	**Direct Labor $s**
subCLIN 0002.7	[**]	[**]	[**]	[**]
	[**]	[**]	[**]	[**]
	[**]	[**]	[**]	[**]
	[**]	[**]	[**]	[**]
	[**]	[**]	[**]	[**]
	[**]	[**]	[**]	[**]
subCLIN 0002.7				
Grand Total			[**]	[**]

3. Subcontractor Cost Detail

The following tables is a list of the subcontractor costs included in the proposed prices:

SUBCONTRACTOR COSTS

Subcontractor	Task Decsription	Direct $s
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
[**]	subCLIN 0002.7	
[**]		**[**]**
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
[**]	subCLIN 0002.7	[**]
[**]		**[**]**
Grand Total		**[**]**

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

6.0Pricing File (MS EXCEL)

Emergent is submitting as an embedded file, to this volume in MS EXCEL format, the costing buildup worksheet from which the proposed price is generated. Each table displayed in Section
5.0 of this offer is a separate tab within the file.

[**]

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

Appendix A – Statement of Work for subCLIN 0002.7

Statement of Work (SOW)

The proposed subCLIN 0002.7 includes the purchase, installation and qualification of [**] additional bioreactors for Areas [**] of Emergent's CIADM facility at our Bayview location.

The bioreactors are designed to be [**].

This SOW also includes estimates for labor associated with installation, engineering and qualification activities as well as contract automation support. Additional miscellaneous costs include required bioreactor support equipment

Emergent Manufacturing Operations Baltimore LLC. – PROPRIETARY Use or disclosure of the data contained on this sheet is subject to the restriction on the title page of this Proposal

EXHIBIT 10.8

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

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

2. AMENDMENT/MODIFICATION NO. P00025	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. HHSO100201200004I
		10B. DATED *(SEE ITEM 13)* 06/15/2012
CODE 1410445 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or

(c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43 .103 (a) (3) Bilaterial 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:
1.Extend the due date for the submission of the Plan for Achieving the Pandemic Influenza Objectives
2.Correct the error on the base contract end date.
3.Revise Contractor's Key Personnel.
4.Revise BARDA's Contracting Personnel.
See the attached following pages for details.
All other terms and conditions remain in full force and effect.
Period of Performance: 06/15/2012 to 06/14/2021

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)*. Patrick D. Saam VP, Government Contracting & Accounting	16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Patrick D. Saam *(Signature of person authorized to sign)*	Sep 23, 2020	/s/ Carol C. Lavrich *(Signature of Contracting Officer)*	09/23/2020

STANDARD FORM 30 (Rev. 11/2016)
Previous edition unusable FAR (48 CFR) 53.243

This is Modification No. 0025 to Contract No. HHSO100201200004I.

The purpose of this modification is to:

1. Approve the request by the Contractor for an extension of the submission date from September 1, 2020 to October 15, 2020 to provide the technical and business proposal plan agreed upon in modification P00021 for achieving the pandemic influenza objectives which are required in the base period of the contract performance milestones. In addition, the plan shall also include additional proposed milestones for BARDA's deliberation.

2. To revise the administrative information erroneously written in the change order proposal, under section *1.1.2 Proposal Period of Performance*, by correcting the end date for the period of performance Base Period, see the attachment to modification P00024. The correct end date for the period of performance for the base period is hereby changed from June 14, 2024 to October 31, 2020.

3. To replace the key personnel table identified under section *H.15* of the referenced contract. [**]. The following table will replace the previous key personnel changes:

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

Contractor Key Personnel (Base Period of Contract)				
[**]	[**]	[**]		
[**]	[**]	[**]		

4. BARDA's Contracting Personnel is changed to [**] as Contracting Officer and [**] as the Contract Specialist, administrative change to section **D.3. REPORT DELIVERABLES** as follows:

REPORT DELIVERABLES		
Position	***Current***	***Revision required***
Contract Officer(CO)	[**]	[**] OS/ASPR/BARDA 330 Independence Ave., SW RM [**] Washington DC 20201
Contract Specialist(CS)	[**]	[**] OS/ASPR/BARDA 330 Independence Ave., SW RM [**] Washington DC 20201

5. 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) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 | 6

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	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 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)*
CODE 1410445	FACILITY CODE		05/24/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: 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 _____ 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 upgrade task order#75A50120F33007 to priority rating for Defense Priorities and Allocations System. See attachment..
Period of Performance: 05/13/2020 to 12/31/2021

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*)	
Patrick D. Saam VP Gov't Contracting		Carol C. Lavrich	
15B. CONTRACTOR/OFFEROR /s/ Patrick D. Saam *(Signature of person authorized to sign)*	15C. DATE SIGNED 8/22/20	16B. UNITED STATES OF AMERICA Digitally signed by [**]-S Date: 2020.08.24 12:10:01 -04'00' /s/ Carol C. Lavrich *(Signature of Contracting Officer)*	16C. DATE SIGNED 08/24/2020

A. This is Modification No. P00001 to 75A50120F33007.

The purpose of this no cost bilateral modification P0001 is to provide notice that this is a priority DO-H5 rated task order #75A50120F33007 under Contract # HHS010020120004I with a Period of Performance 05/13/2020 to 12/31/2021 certified for national defense use.

B. Accordingly, the following changes are made to the contract:

a. Emergent Manufacturing Operations Baltimore LLC and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this task order is certified for national defense and emergency preparedness use. The authority for this rating is attached (Attachment A). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.

b. *Required Delivery Date from the Contractor:* The date for the operational readiness for the Camden facility is [**] and for the Rockville facility is [**].

c. The Parties agree that this change from an unrated Task Order to a DO-H5 priority rated Task Orders is a no cost change.

d. Upon execution of this modification, Emergent Manufacturing Operations Baltimore LLC and its subcontractors must give the appropriate preferential treatment to the Task Order as of the date of the modification. Emergent Manufacturing Operations Baltimore LLC shall accept, perform, and prioritize this Task Order issued under the contract.

e. The Parties agree that this modification to rate this Task Order does not significantly alter the production or delivery schedule required by the Task Order already in existence.

f. This Task Order shall take precedence over any and all other orders or contracts that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.

g. This priority rating allows Emergent Manufacturing Operations Baltimore LLC to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expediently.

h. This priority rating automatically expires at the end of the Task Order period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of any Task Order period of performance at no cost to the USG.

i. If the Emergent Manufacturing Operations Baltimore LLC and/or its subcontractors are unable to comply fully with the terms of this rated order, Emergent Manufacturing Operations Baltimore LLC must immediately notify the Assistant Secretary for Preparedness and Response in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.

j. Emergent Manufacturing Operations Baltimore LLC agrees that the Government's right to exercise priorities and allocations authority with respect to this Task Order to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is provided. The signature, manual or digital, certifies that the rated order is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order and subcontracts by modification, if previously awarded.

C. No additional funding is incorporated into the task order under this modification.

D. All other terms and conditions remain the same.

The Parties agree that this modification includes the following documents:

Attachment Number	Title	Date
A	Request Authorization to priority rate. Emergent Manufacturing Operations Baltimore LLC. task order for "Manufacturing Capacity Reservation and Expansion"	August 17, 2020
	Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent Manufacturing Operations Baltimore LLC	August 19, 2020

Exhibit 10.10

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

ORDER FOR SUPPLIES OR SERVICES				PAGE OF PAGES	
IMPORTANT: Mark all packages and papers with contract and/or order numbers.				1	18

1. DATE OF ORDER	2. CONTRACT NO. *(if any)*
07/23/2020	HHSO100201200004I

3. ORDER NO.	4. REQUISITION/REFERENCE NO.
75A50120F33008	OS261273

5. ISSUING OFFICE *(Address correspondence to)*

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. SHIP TO

a. NAME OF CONSIGNEE

HHS/OS/ASPR

b. STREET ADDRESS

200 C St SW
Washington DC 20201

c. CITY	d. STATE	e. ZIP CODE
WASHINGTON	DC	20201

7. TO:

a. NAME OF CONTRACTOR

EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC

b. COMPANY NAME

c. STREET ADDRESS

EMERGENT MANUFACTURING OPERATIONS B
5901 E LOMBARD ST

d. CITY	e. STATE	f. ZIP CODE
BALTIMORE	MD	212246824

f. SHIP VIA

8. TYPE OF ORDER

☐ a. PURCHASE
REFERENCE YOUR:

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.

☐ 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.

9. ACCOUNTING AND APPROPRIATION DATA	10. REQUISITIONING OFFICE
See Schedule	BARDA

11. BUSINESS CLASSIFICATION *(Check appropriate box(es))*

☐ a. SMALL ☐ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone

☐ f. SERVICE-DISABLED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ☐ h. EDWOSB

VETERAN-OWNED ELIGIBLE UNDER THE WOSB PROGRAM

12. F.O.B. POINT

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION	b. ACCEPTANCE		12/31/2020	
Destination	Destination			

17. SCHEDULE *(See reverse for Rejections)*

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: [**] DUNS Number: [**] Task Order Title: “Emergent CIADM Manufacturing Capacity Reservation” See attached Continued . . .					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.	$30,000,000.00	17(h) TOTAL *(Cont. pages)*
	21. MAIL INVOICE TO:				
	a. NAME PSC/FMS				
	b. STREET ADDRESS PSC_invoices@psc.hhs.gov (or P.O.Box)				17(i) GRAND TOTAL
	c. CITY	d. STATE	e. ZIP CODE	$30,000,000.00	

Digitally signed by Monica Watson -S
Date: 2020.08.06 17:17:02 -04'00'

22. UNITED STATES OF AMERICA BY *(Signature)*
/s/ Monica Watson

23. NAME *(Typed)*
MONICA WATSON
TITLE: CONTRACTING/ORDERING OFFICER

AUTHORIZED FOR LOCAL REPRODUCTION **OPTIONAL FORM 347** (Rev.. 2/2012)
PREVIOUS EDITION NOT USABLE Prescribed by GSA/FAR 48 CFR 53.213(f)

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

DATE OF ORDER	CONTRACT NO.	ORDER NO.
07/23/2020	HHSO100201200004I	75A50120F33008

ITEM No. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
1	Period of Performance: 10/01/2020 to 12/31/2020 To expand the public-private partnership with Emergent to reserve the capacities and capabilities at their Bayview CIADM facility. (1 of 2). Accounting Info: 2020.199C001.25103 Appr. Yr.: 2020 CAN: 199C001 Object Class: 25103 Funded: $[**]				[**]	
2	To expand the public-private partnership with Emergent to reserve the capacities and capabilities at their Bayview CIADM facility. (2 of 2). Accounting Info: 2020.199COV1.25103 Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25103 Funded: $[**] The total amount of award: $30,000,000.00. The obligation for this award is shown in box 17(i). Contractor to sign below: Syed T Husain Electronically signed by : Syed T Husain Reason: I approve this document Date: Aug 6, 2020 12:56 EDT				[**]	
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))				$30,000,000.00	

B. COST / PRICE SCHEDULE

B.1 Prices

The total fixed price of this task order is $30,000,000.

B.2 Payment Schedule

Following delivery and acceptance of the work described in **SECTION C.3** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

Item Description	Reporting Period	Due Date	Unit Price
Monthly Report #1	October 2020	11/15/2020	$10,000,000
Monthly Report #2	November 2020	12/15/2020	$10,000,000
Monthly Report #3	December 2020	12/31/2020	$10,000,000
		Total =	$30,000,000

C. SCOPE OF WORK

C.1 Project Background

BARDA established a Center for Innovation in Advanced Development and Manufacturing (CIADM) with a subsidiary of Emergent BioSolutions Inc. (including all of its subsidiaries, “Emergent”), as a public-private partnership to ensure domestic vaccine manufacturing surge capacity to address national preparedness and response priorities. HHS/BARDA requires the services of Emergent to provide core advanced development (“industrialization”) and manufacturing services to other commercial partners under contract to the U.S. Government (USG) for development of biopharmaceuticals against public health threats. Additionally, HHS/BARDA requires Emergent to provide manufacturing facilities utilizing flexible manufacturing and modem platform technologies to produce vaccines for outbreaks of an emerging infectious pathogens.

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 (“the virus”) was first detected in Wuhan, Hubei Province, People’s Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Under the President's Operation Warp Speed Mission, HHS is leading a whole of nation effort with the primary goal to execute on a well-defined portfolio of COVID-19 vaccine candidates to maximize probability of having one or more safe and effective vaccines as fast as possible for mass distribution. As such, it is a national security concern to quickly make available safe and effective COVID-19 vaccines. To this end, BARDA must reserve existing manufacturing capacity in order to ensure adequate domestic capabilities are established and ready.

C.2 Objectives

The objective of this task order is to expand the public-private partnership with Emergent to reserve the capacities and capabilities at Contractor's Bayview CIADM facility.

C.3 Tasks

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the tasks described below and in Attachment 1 – Contractor Capacity and Pricing.

The Contractor shall reserve drug substance manufacturing capacity at the Contractor's Bayview CIADM facilities for the exclusive use of the USG for the duration of the period of performance of this task order. The Contractor's facilities shall have the capability of producing the number of batches specified as follows in each applicable calendar month. In the event the Contractor is not tasked with producing batches in a given month, the capacity shall lapse and the unused batch production capacity cannot be allocated to a future period. Specifically, the areas to be reserved and number of batches over the period of performance associated with each area under the reservation, shall be as follows (number of batches is based upon a generic manufacturing process):

Area Description	Estimated Number of Batches	Monthly Full Period of Performance
Bayview CIADM [**] Drug Substance	[**]	[**]
Bayview CIADM [**] Drug Substance	[**]	[**]

D. PACKAGING AND MARKING

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

E. INSPECTION AND ACCEPTANCE

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the Contractor's CIADM facility or subcontractor facility, by the Contracting Officer or the duly authorized representative of the Government.

The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this task order.

F. PERFORMANCE / DELIVERABLES

F.1 Period of Performance

The period of performance of this task order shall be from October 1, 2020 through December 31, 2020.

F.2 Deliverable Requirements

F.2.1 Manufacturing Schedule with Allocated Capacity through Period of Performance

A Manufacturing Schedule shall be provided that includes the utilization and non-utilization of the reserved manufacturing capacities (Bayview [**] Drug Substance) for the entire period of performance. The schedule shall include:

- Length of time for manufacturing in each area.
- Name of the priority target (i.e. Janssen, AstraZeneca, etc.).
- Vaccine/product technical information (i.e. cell line expression system, live viral, subunit, etc.).
- Batch Size or Scale.
- Number of batches.

F.2.2 Monthly Report

Each monthly report must include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. Specific to Task 1, each monthly report must include a summary of capacity availability and utilization / non-utilization, as well as any issues that impact the operational availability of the reserved capacity

F.3 Schedule of Deliverables

Satisfactory performance of the task order shall be deemed to occur upon performance of the work described in **SECTION C** of this task order and upon delivery and acceptance of the following items.

Item	Deliverable	Delivery Method	Due Date
1	Manufacturing Schedule with Allocated Capacity through Period of Performance	Electronically to CO and COR	[**] after TO award
2	Monthly Report	Electronically to CO and COR	[**] day of every month throughout the task order period of performance

F.4 Meeting Requirements

F.4.1 Routine Update Teleconferences

The Contractor shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the Contractor and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held [**]. The Contractor is responsible for securing a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within [**] after each teleconference, or as otherwise authorized by the Contracting Officer.

F.4.2 Person-in-Plant

Contractor shall accommodate up to [**] BARDA personnel at an agreed upon time throughout the performance of this task order. On-site BARDA personnel will provide support of the work and technical consultation in alignment with Contractor and per guidance from the BARDA program office in Washington, D.C.

F.4.3 Periodic Site Visits

The Contractor shall accommodate for periodic site visits by BARDA on an ad hoc basis or as agreed upon, with at least [**] prior written notice. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the CO.

F.4.4 Kick-Off Meeting

The Contractor shall participate in a kick-off meeting, within [**] of task order award; content, format, and location to be determined by the USG and the Contractor. The Contractor is responsible for securing a physical

location or a suitable call in number for relevant participants and be responsible for moderating the meeting. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after the meeting is held, or as otherwise authorized by the Contracting Officer.

G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The following CO will represent the Government for the purpose of this Contract:

[**]

The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, or other stipulations of this Contract.

The CO is the only person with the authority to act as agent of the Government under this contract. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this Contract; and (5) otherwise change any terms and conditions of this Contract.

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

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2 Contracting Officer's Representative

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

[**]

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances

required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

G.3 Key Personnel

Key personnel specified in this task order are considered to be essential to work performance. At least [**] prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement, and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than [**] notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace or announce any such change to key personnel without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The task order will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel.

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

G.4 Invoicing Instructions

Invoices for payment shall be submitted electronically and shall include an SF-1034 and all supporting documentation.

G.5 Evaluation of Contractor Performance

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

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

Performance Evaluation Factors: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

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

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

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

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

Retention Period: The agency will retain past performance information for a maximum period of [**] after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL REQUIREMENTS

H.1 Advance Understandings

H.1.1 The Government recognizes that Contractor's operations are essential as a matter of national security and, as such, Contractor is directed to maintain operations to the extent practicable regardless of state or local restrictions to the contrary. In addition, all Contractor employees, independent contractors, and subcontractors are considered essential personnel supporting critical infrastructure as set forth in DHS CISA Memorandum dated March 19, 2020.

H.1.2 Government confirms that all activities conducted by Contractor, any independent contractors and subcontractors under the task order as well as all general operations necessary to ensure execution of activities under the task order are subject to that certain declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) issued by the Secretary of Health and Human Services on March 10, 2020.

H.1.3 Government reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

Emergent BioSolutions agrees that the Government's right to exercise priorities and allocations authority with respect to this order, to include the use of directives in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System, constitutes a no-cost change to this order.

H.1.4 Contractor will act as the Contract Development Manufacturing Organization (CDMO) for priority targets as determined by the Government and the scope will encompass Drug Substance.

H.1.5 Government hereby approves of a direct relationship between Contractor and the following priority targets: Astra Zeneca and Janssen (Johnson and Johnson), and the Government hereby releases the associated capacity to Contractor to deploy and contract with the aforementioned priority targets. In the event that less than all of the capacity reserved under this task order is deployed to such priority targets during the period of performance, any remaining capacity released by the Government to Contractor must be released to another priority target that Government approves of Contractor having a direct relationship with.

H.1.6 Contractor will negotiate pricing with the priority targets for full scope of activities including manufacturing and raw materials.

H.1.7 BARDA secures capacity as outlined above and the reserved capacity is fully available to deployment by BARDA as outlined above.

H.1.8 BARDA will be responsible for the total value for capacity commitment. Ongoing balance would be reviewed on [**] basis subject to whether or not capacity has been deployed. If none of the capacity has been deployed, the payment will be allocated to non-utilization of capacity reserved. If some or all of the capacity has been deployed, then the reservation payment from BARDA for the associated capacity will be credited on a pro rata basis toward either manufacturing costs negotiated with a priority target identified by BARDA, or Government, at Government's sole discretion.

H.2 Intellectual Property

Execution of a subsequent task order for utilization of capacity reserved under this task order may require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the "MCM IP Holder"), and the firm providing the Core Services under the task order (the "CIADM"). The relationship must reflect the Parties' rights to all IP developed and/or IP used in performance of the task order, and be consistent with HHS' IP rights per the Federal Acquisition Regulations (FAR) clauses described in the base contract. Prior to any performance of work, the MCM IP Holder and/or the CIADM shall provide the Contracting Officer with a written description of all IP necessary to develop (the "Description"). The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in performance of the task order. The Description shall also include written verification of the rights provided to HHS to any and all IP utilized or developed during performance of the task order as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of the task order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the "FAR Clauses").

The MCM IP Holder and the CIADM will remain free to negotiate any agreement of their own regarding their use of any of the IP utilized or developed during performance of an task order, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under the task order. The agreement shall be furnished to the Contracting Officer within [**] after the agreement is finalized. In addition, this task order incorporates FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

H.3 Consultants and Sub-Contractors

As a firm fixed price arrangement, BARDA acknowledges that Contracting Officer authorization is not required for use of subcontractors or consultants.

H.4 Non-Personal Services and Inherently Governmental Functions

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H.5 Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO. The

Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

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

H.6 Confidentiality of Information

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

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

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

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

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

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

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

All above requirements MUST be passed to all Sub-contractors.

H.7 Organization Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary

information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within [**] of execution.

I. CONTRACT CLAUSES

Only the clauses incorporated in the base contract that are applicable to fixed price contracts and task orders are in full effect at the task order level. This section or other parts of this task order (TO) may incorporate one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. In addition, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/.

J. ATTACHMENTS

Attachment 1 – Contractor Capacity and Pricing

ATTACHMENT 1 - Contractor Capacity and Pricing

Emergent CIADM Manufacturing Capacity Reservation and Expansion

A. Capacity and Pricing. The following facility and their estimated capacity for reservation & commercial pricing would be as follows:

1. Drug Substance – Baltimore, MD (Bayview - CIADM)

a. [**]

i. Estimated timeframe: 3 months in total, October 2020 through December 2020

ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc.): up to [**] batches

iii. Estimated reservation pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity. Please note that the actual manufacturing including raw materials, lot release testing is not included in the foregoing since that will depend on the process and product(s) selected.

b. [**]

i. Estimated timeframe: 3 months in total, October 2020 through December 2020

ii. Estimated number of batches (assuming generic process parameters, process readiness, availability of raw materials, process specific equipment procurement / installation, approved regulatory pathway, etc.): up to [**] batches

iii. Estimated reservation pricing: $[**] / batch for a total of $[**]. This pricing would allow the reservation of associated capacity. Please note that the actual manufacturing including raw materials, lot release testing is not included in the foregoing since that will depend on the process and product(s) selected

c. Total for Drug Substance: $30 million

EXHIBIT 10.11

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES 1 / 6

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

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

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I 75A50120F33008
		10B. DATED *(SEE ITEM 13)* 07/23/2020
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).
x	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103 (a) (3) – Bilateral Mutual Agreement
	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 the modification is to upgrade task order #75A50120F33008 to priority rating for Defense Priorities and Allocations System. See attachment..
Period of Performance: 10/01/2020 to 12/31/2020

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 Gov't Contracting		Carol C. Lavrich	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	Digitally signed by [**] Date: 2020.08.24 11:07:51 -04'00' 16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Patrick D. Saam *(Signature of person authorized to sign)*	8/22/20	/s/ Carol C. Lavrich *(Signature of Contracting Officer)*	08/24/2020

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

A. This is Modification No. P00001 to 75A50120F3308.

The purpose of this no cost bilateral modification P00001 is to provide notice that this is a priority DO-H5 rated task order #75A50120F33008 under Contract #HHS010020120004I with a Period of Performance 10/01/2020 to 12/31/2020 certified for national defense use.

B. Accordingly, the following changes are made to the contract:

1. Emergent Manufacturing Operations Baltimore LLC and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this task order is certified for national defense and emergency preparedness use. The authority for this rating is attached (Attachment A). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.

2. *Required Delivery Date from the Contractor: December 31, 2020*

3. The Parties agree that this change from an unrated Task Order to a DO-H5 priority rated Task Orders is a no cost change.

4. Upon execution of this modification, Emergent Manufacturing Operations Baltimore LLC and its subcontractors must give the appropriate preferential treatment to the Task Order as of the date of the modification. Emergent Manufacturing Operations Baltimore LLC shall accept, perform, and prioritize this Task Order issued under the contract.

5. The Parties agree that this modification to rate this Task Order does not significantly alter the production or delivery schedule required by the Task Order already in existence.

6. This Task Order shall take precedence over any and all other orders or contracts that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.

7. This priority rating allows Emergent Manufacturing Operations Baltimore LLC to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expediently.

8. This priority rating automatically expires at the end of the Task Order period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of any Task Order period of performance at no cost to the USG.

9. If the Emergent Manufacturing Operations Baltimore LLC and/or its subcontractors are unable to comply fully with the terms of this rated order, Emergent Manufacturing Operations Baltimore LLC must immediately notify the Assistant Secretary for Preparedness and Response in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.

10. Emergent Manufacturing Operations Baltimore LLC agrees that the Government's right to exercise priorities and allocations authority with respect to this Task Order to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is provided. The signature, manual or digital, certifies that the rated order is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order and subcontracts by modification, if previously awarded.

C. No additional funding is incorporated into the task order under this modification.

D. All other terms and conditions remain the same.

The Parties agree that this modification includes the following documents:

Attachment Number	Title	Date
A	Request Authorization to priority rate. Emergent Manufacturing Operations Baltimore LLC. task order for “Manufacturing Capacity Reservation and Expansion” Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract Emergent Manufacturing Operations Baltimore LLC	August 17, 2020 August 19, 2020

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

MASTER SERVICES AGREEMENT

between

ASTRAZENECA PHARMACEUTICALS LP

and

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

DATE: July 24, 2020

TABLE OF CONTENTS

Page

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "**Agreement**") is entered into as of July 24, 2020 (the "**Effective Date**") by and between:

(1) **ASTRAZENECA PHARMACEUTICALS LP**, a Delaware limited partnership with offices at 1800 Concord Pike, Wilmington, Delaware 19803, USA ("**AstraZeneca**"); and

(2) **EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC**, a Delaware limited liability company, with an office at 5901 East Lombard Street, Baltimore, Maryland, 21224 ("**Service Provider**").

Background

(A) AstraZeneca intends to research, develop, manufacture and commercialize its vaccine product candidate known as ChAdOx1 nCOV-19 (AZD1222) (the "**Product**").

(B) AstraZeneca and Service Provider are parties to that certain Master Services Agreement, dated June 10, 2020 (the "**Short Form Agreement**") and adjoining Work Order #5997-01 ("**Work Order #5997-01**"), pursuant to which Service Provider is currently providing AstraZeneca technology transfer, scale-up, process performance qualification, and capacity commitment services in respect of manufacturing Product bulk drug substance by Service Provider.

(D) The Short Form Agreement contemplated that AstraZeneca and Service Provider would use commercially reasonable efforts to agree a more detailed master services agreement setting forth certain additional services and activities to be performed by Service Provider.

(E) AstraZeneca and Service Provider now wish to enter into this Agreement, with the effect that the Short Form Agreement shall be superseded and replaced in its entirety in respect of ongoing activities as of the Effective Date; provided that Work Order #5997-01 shall remain in full force and effect and be incorporated in its entirety, and made a part of, this Agreement as a Product Schedule, with all references to Product Schedule or Development Product Schedule in this Agreement applying to Work Order #5997-01.

Integral Agreement

This Agreement is comprised of (i) Part A (*General Terms*), (ii) Part B (*Ways of Working*), (iii) Part C (*Definitions*), (iv) Part D (*Flowdown Terms*) and Part E (*[**] License Requirements*), each of which is an integral part of this Agreement and which, taken together, and subject to the provisions of Clause 18.7, form the entirety of this Agreement.

Execution

This Agreement is executed as of the Effective Date by the authorized representatives of the Parties.

SIGNED for and on behalf of

AstraZeneca Pharmaceuticals LP

By: /s/ Jarrett Palmer

Name: Jarrett Palmer

Title: Operations – BES Director

SIGNED for and on behalf of

Emergent Manufacturing Operations Baltimore, LLC

By: /s/ Syed T Husain

Name: Syed T Husain

Title: SVP & CDMO BU Head

Agreement

The Parties, intending to be legally bound, agree as follows:

PART A: GENERAL TERMS

1. Agreement and Product Schedules

1.1. Agreement. This Agreement sets out the terms on which Service Provider agrees to perform certain activities related to the manufacture of the Product, and under which AstraZeneca agrees to engage Service Provider to perform such services pursuant to the applicable Product Schedules.

1.2 Product Schedules.

1.2.1 AstraZeneca and Service Provider may enter into:

(a) Development Product Schedules for the development activities and services in relation to the Product;

(b) Manufacturing Product Schedules for the manufacture of commercial Batches of the Product;

(c)Tech Transfer Product Schedules pursuant to which Service Provider would provide technology transfer services as described in Clause 1.4.3

1.2.2 Each Product Schedule, once signed, shall be incorporated into, and form a part of this Agreement. Notwithstanding any other provisions, in case of any conflict between a Product Schedule and this Agreement, the Product Schedule shall prevail, provided that the QAA shall prevail for all matters concerning quality.

1.2.3 As of the Effective Date, Work Order #5997-01 is hereby incorporated in its entirety, and made a part of, this Agreement as a Product Schedule, with all references to Product Schedule or Development Product Schedule in this Agreement applying to Work Order #5997-01.

1.2.4 The Parties intend to enter into their first Manufacturing Product Schedule effective as of the Effective Date ("**Product Schedule #5997-02**") for the manufacturing of the number of commercial Batches of Product as set forth in Product Schedule #5997-02, on the terms set forth herein and in Product Schedule #5997-02.

1.3 Capacity Reservation.

1.3.1 The Parties acknowledge that AstraZeneca reserved the Initial Period Capacities of Service Provider for AstraZeneca pursuant to Section 1.3(a) of the Short Form Agreement. Service Provider hereby acknowledges its obligation to reserve the capacity to manufacture up to the number of Batches of the Product specified on Work

Order #5997-01 constituting the Initial Period Capacities in exchange for payment of the AZ Initial Capacity Commitment Fee as set forth in Work Order #5997-01. Pursuant to Product Schedule #5997-02, AstraZeneca is purchasing and Service Provider is agreeing to manufacture, the initial Batches of Product drug substance (the "**Initial Batches**"), the capacity for which was reserved by the Initial Period Capacities, and in respect of [**] for which the credit of the AZ Initial Capacity Commitment Fee is applied. For clarity, the Initial Batches are comprised of [**] of Service Provider's Bayview facility and [**] of Service Provider's Bayview facility.

1.3.2 Pursuant to Product Schedule #5997-02, in addition to the Initial Batches, AstraZeneca is purchasing and Service Provider is agreeing to manufacture, (a) [**] of Service Provider's Bayview facility and [**] of Service Provider's Bayview facility (collectively, the "**Additional Batches**"). The fees and costs for the Additional Batches are set forth on Product Schedule #5997-02 and will be payable by AstraZeneca in accordance with the terms of this Agreement and Product Schedule #5997-02.

1.3.3 Furthermore, AstraZeneca, may, subject to the approval of the United States Government, and otherwise at its sole option, and in accordance with the terms set forth in Product Schedule #5997-02, elect to purchase, and upon such election, Service Provider agrees to manufacture, [**] of Service Provider's Bayview facility (which Batches, the "**Extended Batches**", shall be in addition to the Initial Batches and the Additional Batches), by delivering written notice to Service Provider (the "**Batch Exercise Notice**") on or before [**] (the "**Option Deadline**"). Notwithstanding the foregoing, the Parties acknowledge and agree that: (i) the United States Government may require or direct Service Provider to offer or use the capacity for the Extended Batches to or for third party(ies) at any time, including prior to the Option Deadline; and (ii) if the United States Government does not consent (or indicates to AstraZeneca or Service Provider it will not provide such consent) or AstraZeneca does not deliver the Batch Exercise Notice by the Option Deadline, Service Provider may offer and/or use the capacity for the Extended Batches to or for other customers of Service Provider or use such capacity for its own products at no additional cost to AstraZeneca and at no penalty to Service Provider. Pursuant to the Task Order, the United States Government has agreed to pay Service Provider the price to reserve the capacity for the Extended Batches.

1.3.4 The AZ Initial Capacity Commitment Fee is non-refundable, but fully creditable against the Service fees (but not the pass-through costs or other out-of-pocket costs or expenses), on a per-Batch of Product basis, as specifically allocated to the AZ Initial Period Capacity and as set forth in Product Schedule #5997-02. Capacity commitment fees indicated to be funded by the United States Government (in this Master Services Agreement and/or in a Product Schedule) ("**BARDA Capacity Commitment Fees**") are also fully creditable, solely upon the consent (and then only to the extent of the consent) of the United States Government, and the Service fees set forth in Product Schedule #5997-02 assume such United States Government consent and are net of such credit (i.e. have already been reduced to account for the credit) on a per-Batch of Product basis. For clarity, it is the intent of AstraZeneca and Service Provider that (i) subject to

the terms of this Clause 1.3.4 and payments due upon termination in accordance with Clause 14.7, the entire amount of the AZ Initial Capacity Commitment Fee and any BARDA Capacity Commitment Fees on a Product Schedule are intended as upfront amounts and, with respect to such BARDA Capacity Commitment Fees, subject to the consent of the United States Government to be credited against future Service fees payable by AstraZeneca, and (ii) notwithstanding the foregoing, Service Provider may be required to credit some or all of the BARDA Capacity Commitment Fees to the US Government, and nothing in this Clause 1.3.4 (or a Product Schedule) shall require Service Provider to credit to AstraZeneca any amount of such BARDA Capacity Commitment Fees that Service Provider is required to credit to the United States Government. The mechanics by which the BARDA Capacity Commitment Fees are creditable against Service fees pursuant to this Clause 1.3.4 will be set forth in the applicable Product Schedule.

1.4 Technology Transfer.

1.4.1 Service Provider acknowledges that pursuant to the Short Form Agreement and Work Order #5997-01, AstraZeneca is transferring certain AstraZeneca Background Technology and technologies of AstraZeneca to Service Provider to enable Service Provider to commence specific activities in connection with the development and/or manufacture of the Product, including the Services (as defined in the Short Form Agreement) thereunder.

1.4.2 During the Term, AstraZeneca shall undertake such additional technical transfer services as are necessary and agreed with respect to a Product Schedule to enable Service Provider to provide the Services contemplated by such Product Schedule.

1.4.3 The Parties agree that AstraZeneca may, during the term of this Agreement or upon termination or expiration of this Agreement, designate and qualify a Third Party to manufacture bulk drug substance Product. In connection therewith, Service Provider shall provide the assistance and support described in this Clause 1.4 for a period not to exceed [**]. If AstraZeneca, using commercially reasonable efforts, is unable to qualify a Third Party without participation by Service Provider, Service Provider shall provide AstraZeneca reasonable assistance and support (including providing AstraZeneca Background Technology in Service Provider's possession and technical assistance and cooperation by employees of Service Provider) as necessary to assist in qualifying such Third Party as set forth in a Tech Transfer Product Schedule executed by both Parties which shall provide for the scope of services and fees and expenses to be paid to Service Provider by AstraZeneca for such consultation and assistance. AstraZeneca shall pay Service Provider for all fees charged and expenses incurred in providing such services, which fees and expenses shall be documented in such Tech Transfer Product Schedule.

1.5 Grant Funding and Sublicense Requirements.

1.5.1 The Parties acknowledge and agree that this Agreement will be considered to be a US Government subcontract pursuant to AstraZeneca OTA (Other Transactional Agreement) with the U.S. Department of Health and Human Services ("**HHS**"), Contract

(provided upon the OTA execution), and Service Provider further understands that its performance of services under this Agreement will be subject to certain additional government requirements. These requirements will be outlined in AstraZeneca OTA with US Government, upon its execution. To the extent applicable to Service Provider's activities under this Agreement, the Service Provider agrees to comply with relevant US Government terms and conditions, as documented in an amendment to this Agreement adding such terms and conditions to Part D1 of this Agreement (the "**AstraZeneca Flowdown Terms**").

1.5.2 The Parties acknowledge and agree that, in the event this Agreement is considered to be a United States Government subcontract pursuant to the Task Order, this Agreement will be considered to be a United States Government subcontract pursuant to the Task Order and AstraZeneca further understands that its performance under this Agreement may be subject to certain additional government requirements. To the extent applicable to AstraZeneca's activities under this Agreement, AstraZeneca agrees to comply with relevant United States Government terms and conditions, as documented in an amendment to this Agreement adding such terms and conditions to Part D2 of this Agreement as notified to it by Service Provider as set forth in Part D2 of this Agreement (the "**Service Provider Flowdown Terms**").

1.5.3 While not known with any particularity at this time, it is understood by the Parties that in addition to Clauses 1.5.1 and 1.5.2, certain government agencies may require, in connection with funding requirements in support of a Product Schedule, that AstraZeneca and/or Service Provider comply with applicable and additional contractual provisions (the "**Additional Flowdown Terms**"). In such event, the Parties agree during the Term of this Agreement to consider in good faith and not unreasonably refuse to enter into an amendment to this Agreement to include any mutually agreed upon Additional Flowdown Terms. If the Parties do not, after such good faith consideration, enter into an amendment to this Agreement to include any mutually agreed upon Additional Flowdown Terms, the matter shall be escalated for consideration to a senior management member of each Party.

1.5.4 Service Provider acknowledges that any use of [**] cell line ("**[**] Cells**") in the course of performing its obligations under the Agreement is subject to the additional conditions set forth in Part E of this Agreement ("**[**] Cell Licence Requirements**"). To the extent applicable to Service Provider's activities under this Agreement, the Service Provider agrees to comply with the [**] Cell Licence Requirements. In the event of a conflict between the [**] Cell Licence Requirements and the terms of this Agreement, the [**] Cell Licence Requirements will control.

1.6 QAA. Within [**] of execution of this Agreement, and in any event, prior to the release of any Product by Service Provider pursuant to this Agreement or any Product Schedule, the Parties will enter into a QAA setting forth, as appropriate, quality assurance provisions, the respective roles and allocation of responsibility of the Parties with respect

to the applicable processes and standards and procedures for handling deviations and related matters.

1.7 AstraZeneca Materials. AstraZeneca shall deliver to Service Provider the items specifically set forth in the Product Schedule as being provided by AstraZeneca to Service Provider, together with any other tangible items, information or documentation in AstraZeneca's possession which is necessary to assist Service Provider in connection with the Services, including but not limited to any active pharmaceutical ingredient, master cell bank, plasma, component or raw materials (collectively, the "**AstraZeneca Materials**"). Unless otherwise stated in a Product Schedule, AstraZeneca shall deliver to Service Provider the AstraZeneca Materials free of charge in a timely manner and in sufficient quantities to perform the Services. AstraZeneca shall at all times retain legal title and risk of loss to the AstraZeneca Materials. AstraZeneca is responsible for ensuring any components and materials that are necessary or used by Service Provider to perform the Services, including but not limited to the AstraZeneca Materials, are suitable and of appropriate quality for the Product, regardless of whether such components or materials are supplied to Service Provider directly by the applicable material manufacturer or by AstraZeneca. The Product Schedule and the Quality Agreement set forth any testing to be performed by Service Provider on such components and materials. Subject to such testing obligations, Service Provider shall not be liable for any defect in AstraZeneca Materials or any defect in any other components or materials existing as of the date of delivery to Service Provider ("**AstraZeneca Defective Materials**").

1.8 Delays. The Parties acknowledge 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. If Service Provider anticipates any delay in the timelines specified in any Product Schedule, whether beyond the reasonable control of either Party, due to a Force Majeure, or otherwise (a "**Delay**"), or Service Provider becomes aware of any actually occurring Delay, it shall promptly notify AstraZeneca in writing. If AstraZeneca anticipates any Delay or becomes aware of any actually occurring Delay, AstraZeneca will promptly notify Service Provider in writing. Unless Service Provider is reasonably able to eliminate an anticipated Delay such that the deliverables under any applicable Product Schedule will be delivered in accordance with the estimated schedule set forth on such Product Schedule, the Parties shall promptly convene to discuss steps that can be taken to mitigate such Delay and agree upon revised timeline(s).

1.9 Development Under Work Order #5997-01. Notwithstanding Clause 8.1.2, AstraZeneca acknowledges that certain portions of the Services to be performed under Work Order #5997-01 are experimental in nature and/or may not have been fully validated within general accepted standards of the pharmaceutical industry, including without limitation any non-cGMP Batches. Service Provider shall not be considered to be in breach of its obligations under this Agreement or otherwise held responsible for not

reaching the desired outcome as set forth in Work Order #5997-01 for such non-cGMP Services under Work Order #5997-01 and AstraZeneca shall be responsible for all fees and costs associated with such Services, except to the extent such failure was caused by Service Provider's gross negligence or willful misconduct. If it is determined that failure to reach the desired outcome for the non-cGMP activities as set forth in Work Order #5997-01 was caused by Service Provider's gross negligence or willful misconduct, then Service Provider shall, at AstraZeneca's request and option, as AstraZeneca's sole and exclusive remedy (subject to Clause 12.5.5) and as soon as it is commercially practical to do so following receipt of any required materials at Service Provider's sole cost and expense (excluding, subject to Clause 12.5.1, costs or expenses for AstraZeneca's Materials but including shipping and transport costs), either (i) re-perform such Services; or (ii) provide AstraZeneca a credit for the amounts paid by AstraZeneca to Service Provider for such Services. AstraZeneca is solely responsible for determining suitability of product for use in humans and final release of product for use in humans.

1.10 PPQ Batches. If it is determined that a process performance qualification ("**PPQ**") Batch does not meet the Product specifications set forth in the master batch record ("**Specifications**") as a result of Service Provider's failure to follow cGMP, then Service Provider shall, at AstraZeneca's request and option, and as AstraZeneca's sole and exclusive remedy (subject to Clause 12.5.5), and as soon as it is commercially practical to do so following receipt of any required materials at Service Provider's sole cost and expense (excluding, subject to Clause 12.5.1, costs or expenses for AstraZeneca's Materials including shipping and transport costs), either (i) re-perform such PPQ Batch; or (ii) provide AstraZeneca a credit for the amounts paid by AstraZeneca to Service Provider for such PPQ Batch. If a PPQ Batch fails to meet Specifications for any cause other than Service Provider's gross negligence, willful misconduct or failure to follow cGMP, then Service Provider shall have no liability to AstraZeneca with respect to such Batch and AstraZeneca shall pay Service Provider for such Batch.

1.11 Non-Exclusive. The engagement of the Service Provider by AstraZeneca for Product related manufacturing services shall be on a non-exclusive basis. AstraZeneca shall at all times have the right, at its sole discretion, to engage suppliers and other service providers in relation to the Product. The Parties further acknowledge and agree that Service Provider and/or its Affiliates may develop and manufacture products competitive to the Products. Except for the intellectual property provisions, obligations of confidentiality and non-use and capacity reservation requirements set forth in this Agreement, nothing herein restricts Service Provider and/or its Affiliates from developing, manufacturing, supplying or in any other manner exploiting any and all such competitive products.

1.12 Duration. AstraZeneca and Service Provider may enter into Product Schedules at any time during the Term.

2. Affiliates

2.1 Affiliates. Affiliates of the Parties may enter into:

2.1.1 Development Product Schedules for the development activities in relation to the Product;

2.1.2 Manufacturing Product Schedules for the manufacture of commercial Batches of the Product;

2.1.3 Tech Transfer Product Schedules for technology transfer services as described in Clause (any Product Schedule described in Clauses 2.1.1, 2.1.2 or 2.1.3 an "**Affiliate Product Schedule**").

Each Affiliate Product Schedule, once signed, shall be incorporated into, and form a part of this Agreement. For so long as any Affiliate Product Schedule remains in force, each Affiliate of a Party that has entered into such Affiliate Product Schedule shall be deemed to be bound by the terms of this Agreement. For the avoidance of doubt, no Affiliate of a Party shall be bound by the terms of this Agreement unless such Affiliate has entered into an Affiliate Product Schedule.

3. Service Provider Obligations

3.1 Service Provider's Performance. Service Provider shall perform the specific services and activities set forth in each Product Schedule ("**Services**"), in accordance with all of the terms of this Agreement and the applicable:

3.1.1 Purchase Order; provided such Purchase Order is consistent with, does not modify or add to the terms (including with respect to aggregate quantities of Product and estimated timelines) of this Agreement or Product Schedule;

3.1.2 QAA; and

3.1.3 Product Schedule.

3.2 Changes. Any amendments or modifications to the scope of Services or pricing shall be set forth in writing in a Change Order mutually agreed upon and signed by both Parties. Furthermore, any change or modification to the manufacturing process or Specifications for Product will be made only in accordance with the change control provisions of the QAA. The Change Order shall detail the requested changes to the Services, responsibility, duty, cost, estimated timelines or other relevant matters to be modified and shall only become effective when executed by both Parties. Both Parties agree to act in good faith and promptly when considering a Change Order request proposed by the other Party. Notwithstanding the foregoing, each Party shall respond to all Change Order requests submitted by the other Party within [**] (or a longer period agreed upon by the Parties in writing) of such other Party's submission of a written Change Order request to such Party. Unless otherwise agreed to by the Parties, Service Provider will continue performing the Services as set forth in the applicable Product Schedule to the extent reasonably practicable and will not implement the Services as outlined in a Change Order request unless and until such Change Order is signed by both

Parties. All mutually executed Change Orders will be implemented as soon as commercially practicable to do so. AstraZeneca shall be responsible for payment of any price increase resulting from any such Change Order.

4. Intellectual Property

4.1 Background Technology of Service Provider. All Intellectual Property, results, data, inventions and information (i) owned or otherwise controlled by Service Provider on the effective date of the Short Form Agreement, or (ii) developed by Service Provider independently of this Agreement or the Short Form Agreement (collectively, "**Service Provider Background Technology**") shall be and remain the sole and exclusive property of Service Provider.

4.2 Background Technology of AstraZeneca. All Intellectual Property, results, data, inventions and information (i) owned or otherwise controlled by AstraZeneca on the effective date of the Short Form Agreement, or (ii) developed by AstraZeneca independently of this Agreement or the Short Form Agreement (collectively, "**AstraZeneca Background Technology**") shall be and remain the sole and exclusive property of AstraZeneca. AstraZeneca grants to Service Provider a royalty-free, nonexclusive right for the Term (with no right to sub-license, except to Service Provider's Affiliates) to use AstraZeneca's Background Technology to the extent necessary and for the sole purpose of performing its obligations under this Agreement.

4.3 Ownership of Foreground Technology:

4.3.1 All Intellectual Property and Improvements discovered or developed in the performance of the Services ("**Foreground Technology**"), solely by or on behalf of Service Provider or jointly with AstraZeneca, that relate to and are not severable from: (i) the Product or (ii) any AstraZeneca Materials or AstraZeneca Confidential Information, and which do not relate generally to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally, will (in the case of (i)-(ii) herein) be solely owned by AstraZeneca ("**AstraZeneca Foreground Technology**"). As between the Parties, Service Provider will own any and all Foreground Technology that is not owned by AstraZeneca in the preceding sentence, including but not limited to any improvements or modifications to Service Provider Background Technology ("**Service Provider Foreground Technology**"). Service Provider hereby grants to AstraZeneca a nonexclusive, perpetual, fully paid-up, royalty-free, worldwide, sub-licensable license to use the Service Provider Foreground Technology, but only to the extent necessary or useful for AstraZeneca or its Affiliates to develop, manufacture, commercialize or otherwise exploit the Product manufactured by Service Provider under this Agreement.

4.3.2 Service Provider will ensure that AstraZeneca acquires, to the extent legally permissible, all rights, title and interest in and to any AstraZeneca Foreground Technology generated by Service Provider employees or agents, and hereby assigns to AstraZeneca all rights, title and interest in and to any and all AstraZeneca Foreground Technology.

AstraZeneca will ensure that Service Provider acquires, to the extent legally permissible, all rights, title and interest in and to any Service Provider Foreground Technology generated by AstraZeneca employees or agents, and hereby assigns to Service Provider all rights, title and interest in and to any and all Service Provider Foreground Technology. Each Party agrees that such technology of each Party is commercially valuable to such Party and agrees not to disclose such technology of the other Party to any other party without the other Party's prior written consent. AstraZeneca hereby grants to Service Provider a royalty-free nonexclusive license to the AstraZeneca Background Technology and/or the AstraZeneca Foreground Technology during the Term as useful or necessary for Service Provider to provide the Services or Deliverables.

4.4 Know-How and Improvements:

4.4.1 If AstraZeneca provides AstraZeneca's Know-How or other AstraZeneca Information to Service Provider to enable it to manufacture and supply the Product, Service Provider shall use any such AstraZeneca Know-How or other AstraZeneca Information provided by AstraZeneca solely for the purpose of performing its obligations under this Agreement.

4.4.2 Service Provider shall promptly disclose to AstraZeneca all Improvements that Service Provider develops or discovers in the performance of this Agreement relating to the Product.

4.5 Trademark. Except as is otherwise licensed under Clauses 4.2, 4.3 or 4.4, neither Party shall acquire any rights or license on the other Party's trademarks, unless such other Party provides prior written consent.

5. Delivery

5.1 Time of Delivery: Within [**] after the Release Date, Service Provider shall deliver the Product or cause the Product to be delivered as set forth in Section 6.3 below.

5.2 No Early Delivery: Service Provider shall not deliver Product before the Release Date unless specifically authorized in writing by a representative of each Party to deliver under quarantine.

5.3 Delivery: Any Product delivered by Service Provider to AstraZeneca hereunder shall be delivered Ex Works Service Provider's facility (INCOTERMS 2020). Title to and risk of loss of Product delivered hereunder will transfer from Service Provider to AstraZeneca when the Service Provider makes the Batch available for pick up by AstraZeneca's designated carrier, Ex Works Service Provider's facility. AstraZeneca is solely responsible for all shipping costs. For clarity, Batches delivered hereunder will be deemed to be delivered on the date that all requirements for release of such Batch that are within Service Provider's control are completed, even if Service Provider agrees to store the delivered Product. Service Provider shall have no obligation to store any Batch of Product at its facility for a period longer than [**] after its applicable Release Date, except

as agreed upon by Service Provider in writing, including in respect of the mutually agreed storage fee.

6. Non-Conformance

6.1 Service Provider shall not be liable to AstraZeneca for any failure of Product to meet Specifications except (i) with respect to PPQ Batches as specified in Clause 1.10, or (ii) with respect to all other Batches, as specified in this Clause 6.

6.2 Defects. Subject to Clause 7, AstraZeneca shall notify Service Provider in writing of any Product that fails to meet Specifications (a "**Defect**") within [**] of discovery of such Defect by AstraZeneca, but no later than [**] after delivery of such Product to AstraZeneca.

6.3 Investigation of a Defect. In any case where AstraZeneca provides Service Provider with a notice in respect of a Defect in accordance with Clause 6.2, AstraZeneca shall provide Service Provider with a reasonable opportunity to inspect and/or test such Product, such period not to exceed [**]. In the event that AstraZeneca does not notify Service Provider of a Defect within the notification periods set forth in Clause 6.2, AstraZeneca will be deemed to have accepted the applicable Batch(es). In the event that Service Provider does not notify AstraZeneca of the results of its inspection and/or test of a Product Defect within the foregoing [**] period, Service Provider will be deemed to have accepted that the subject Product has a Defect.

6.4 Testing for Defects. In the event of any dispute as to whether the Product may be rightfully rejected by AstraZeneca by reason of a Defect, such Product shall be tested for conformance with the applicable Specifications by an independent testing organization mutually acceptable to both Parties which analysis shall be binding on AstraZeneca and Service Provider solely for the purpose of determining whether such Product met Specifications. The Party who was wrong pays for the costs associated with the independent testing. AstraZeneca shall not under any circumstances dispose of any Product claimed by AstraZeneca or determined by independent testing organization to be non-conforming to Specifications without Service Provider's prior written consent. All or part of any delivery of Product determined to have been rightfully rejected by AstraZeneca shall be held by AstraZeneca for disposition by Service Provider, at Service Provider's expense.

6.5 Liability for Defective Product. If AstraZeneca provides notice of a Defect within the time periods set forth in Clause 6.2 and it is determined that such Batch does not meet Specifications solely as a result of Service Provider's negligence, willful misconduct and/or failure to follow cGMP, then Service Provider shall, at Service Provider's option, as AstraZeneca's sole and exclusive remedy and subject to Clause 12.5, either: (i) replace the non-conforming Batch at no additional charge to AstraZeneca other than the original Batch price as soon as commercially practicable to do so following receipt of any required AstraZeneca-supplied materials at no cost to Service Provider; or (ii) credit or refund to AstraZeneca the amount paid by AstraZeneca for such defective

Batch. If a Batch fails to meet Specifications for any cause other than solely Service Provider's negligence, willful misconduct and/or failure to follow cGMP, then Service Provider shall have no liability to AstraZeneca with respect to such Batch and AstraZeneca shall pay Service Provider for such Batch and any fees associated with any dispute regarding such Batch (including any arbitration fees). The Parties agree that manufacturing deviations and investigations that occur during the Services and do not cause a Batch to be non-compliant with Specifications shall not be deemed to cause a Batch to be non-conforming. Service Provider shall not be liable for any non-conformity arising from AstraZeneca's written instructions or AstraZeneca Defective Materials, unless Service Provider utilized such AstraZeneca Defective Materials in manufacturing the Product despite the fact the Service Provider knew or should have known as a result of Service Provider's testing obligations referenced in Clause 1.7 that such AstraZeneca Materials were Defective AstraZeneca Materials.

6.6 Exclusive Remedies: AstraZeneca's remedies under Clause 1.10, this Clause 6 and Clause 12.5 (as applicable) shall be AstraZeneca's exclusive remedies with respect to Defects.

7. Product Recall

As set forth in the QAA, AstraZeneca shall notify Service Provider promptly if any Product manufactured by Service Provider hereunder is the subject of a recall, market withdrawal, field alert or correction, or seizure (a "**Recall**"). AstraZeneca shall (a) bear the cost of, and be responsible for conducting or responding to, all Recalls of Product, (b) remain obligated to pay Service provider in accordance with this Agreement for any Services provided by Service Provider related to the Product Batches that are subject to a Recall, and (c) reimburse Service Provider for its out-of-pocket expenses related to the Recall, if any; provided, however, that if the Recall is the result of an undiscovered Defect the provisions of Clause 6.5 shall apply in respect of subclause (b) and to the extent the Recall is caused solely by Service Provider's failure to follow cGMP, subclause (c) shall not apply.

8. Representations and Warranties

8.1 Service Provider represents, warrants and undertakes that:

8.1.1 Service Provider is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

8.1.2 The Services will conform to industry standards of workmanship, Applicable Laws and Regulations, and if applicable, cGMP and the QAA, by individuals who are appropriately trained and qualified.

8.1.3 Service Provider, its employees and agents, have, and will continue to have the knowledge, experience and skill to provide, and will provide, the Services in a professional and timely manner.

8.1.4 Service Provider will use commercially reasonable efforts to sufficiently staff each project set forth in a Product Schedule to ensure the completion of the Services as set forth in the applicable Product Schedule.

8.1.5 The performance of Service Provider's obligations to AstraZeneca under this Agreement will not breach or be in conflict with any contractual obligation it has to any Third Party.

8.1.6 Solely to the extent Service Provider incorporates Service Provider Background Technology into the Product, to the best of Service Provider's knowledge, the Service Provider Background Technology does not infringe any Intellectual Property rights of any Third Party.

8.1.7 Title to the Product will not be subject to any security interest, lien or other encumbrance due to any action or inaction of Service Provider.

8.1.8 All manufactured Product will, as at date of delivery by Service Provider, conform to the Certificate of Analysis.

8.1.9 All materials supplied by AstraZeneca shall be handled in accordance with the Safety and Data Sheet and safety regulations as supplied in writing by AstraZeneca.

8.1.10 EXCEPT FOR THE REPRESENTATION AND WARRANTY AND COVENANTS SET FORTH IN THIS CLAUSE 8.1, SERVICE PROVIDER HEREBY DISCLAIMS ALL REPRESENTATIONS, CONDITIONS, WARRANTIES, AND STATEMENTS IN RESPECT OF THE SERVICES AND PRODUCT PROVIDED HEREUNDER, WHETHER EXPRESS OR IMPLIED, CUSTOM OF THE TRADE OR OTHERWISE, INCLUDING WITHOUT LIMITATION, ANY SUCH REPRESENTATIONS, CONDITIONS, WARRANTIES OR STATEMENTS RELATING TO MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE. SERVICE PROVIDER HAS NOT PARTICIPATED IN THE RESEARCH AND DEVELOPMENT OF THE PRODUCT, NOR HAS SERVICE PROVIDER IN ANY WAY EVALUATED THE PRODUCT'S SAFETY OR EFFICACY IN HUMANS OR OTHERS.

8.2 AstraZeneca represents, warrants and undertakes that:

8.2.1 AstraZeneca is duly formed and validly existing under the laws of its jurisdiction of formation and has all requisite power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

8.2.2 The execution, delivery or performance of this Agreement will not contravene Applicable Laws and Regulations and AstraZeneca shall perform its obligations and responsibilities hereunder in accordance with all Applicable Laws and Regulations.

8.2.3 AstraZeneca shall act to ensure the timely delivery of data and materials, including the AstraZeneca Materials, to Service Provider, so as to permit Service Provider to perform its obligations hereunder, in all cases in accordance with the applicable Product Schedule.

8.2.4 AstraZeneca shall not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and shall not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of Service Provider.

8.2.5 AstraZeneca owns or has the right to provide to Service Provider in connection with the performance of the Services all AstraZeneca Materials.

8.2.6 All AstraZeneca Materials have been or will be manufactured in accordance with cGMP and relevant specifications, and no specific safe handling instructions are applicable to any such items, except as disclosed to Service Provider in writing by AstraZeneca in sufficient time for review by Service Provider and prior to delivery to Service Provider.

8.2.7 All Product delivered by Service Provider to AstraZeneca will be stored, labeled, distributed, sold and/or used or disposed of by AstraZeneca in a safe and responsible manner, and in accordance with all Applicable Laws and Regulations.

8.2.8 The Product and the manufacturing, processing, use or distribution thereof, will not, to AstraZeneca's knowledge, violate the intellectual property rights of any third party, and AstraZeneca is not, to its knowledge, engaged in the theft or misuse of any third party's confidential or trade secret information regarding the manufacturing, processing, use or distribution of Product, nor does AstraZeneca have notice of any claim of a third party regarding any such violation, theft or misuse.

8.3 Promptly Inform AstraZeneca: Service Provider shall endeavor to inform AstraZeneca promptly in writing of any event that to the best of Service Provider's knowledge may adversely affect Service Provider's ability to perform its obligations under this Agreement.

8.4 DISCLAIMER: EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN CLAUSE 8.2 AND THE COVENANTS SET FORTH IN CLAUSE 1.7, ALL OTHER WARRANTIES OR (WITH RESPECT TO THE ASTRAZENECA MATERIALS, COVENANTS), BOTH EXPRESS AND IMPLIED, CUSTOM OF THE TRADE OR OTHERWISE ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS, CONDITIONS, WARRANTIES OR STATEMENTS OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

9. Payment

9.1 The Price payable by AstraZeneca in respect of the Product:

9.1.1 is set forth and payable as set forth in the applicable Product Schedule;

9.1.2 is based on the assumptions and information set out in the applicable Product Schedule;

9.1.3 unless otherwise set forth in the applicable Product Schedule, shall remain fixed for the term of the applicable Product Schedule; and

9.1.4 is payable in United States Dollars.

9.2 Purchase Orders: AstraZeneca, or an Affiliate of AstraZeneca, shall submit to Service Provider one or more Purchase Orders in respect of the Services under each Product Schedule in accordance with the applicable timelines set forth therein. For clarity, (i) AstraZeneca is obligated to purchase (i.e. and to pay for, regardless of whether AstraZeneca purchases) all Services set forth in a Product Schedule pursuant to the terms of this Agreement (and subject to Clause 14.7) and the Product Schedule; and (ii) Service Provider has no obligation to accept Purchase Orders for Services not set forth in a Product Schedule.

9.3 Invoices: Service Provider shall issue an invoice to AstraZeneca or the Affiliate of AstraZeneca issuing the Purchase Order, as applicable, for the Price of all Services delivered in respect of the Product Schedules in accordance with the timing set forth in the Product Schedule. Each invoice shall contain a reference to the relevant Purchase Order number, shall comply with Applicable Laws and Regulations regarding information required on a valid invoice and shall state Service Provider's registered Tax number. The Parties agree that amounts due under a Product Schedule shall not be set off against another or applied to sums due as a result of the performance of other Product Schedules without the prior written consent of the other Party.

9.4 Payment Period: AstraZeneca shall pay all invoices within [**]. The payment period begins on the date of receipt of the invoice, except:

9.4.1 Pursuant to Clauses 1.10 or 6.5; or

9.4.2 Where AstraZeneca has a bona fide dispute in respect of the invoice, in which case AstraZeneca shall pay all undisputed amounts within the time period set forth above and shall pay any amount found to be due upon resolution of a dispute promptly upon resolution of the dispute (or as otherwise determined under Clause 17.11).

9.5 Interest: If a Party fails to pay any amount due under this Agreement within [**] after payment is due and a written reminder has been sent, the other Party may be entitled to charge interest until actual payment at no more than [**] percent per annum above the base lending rate of the Bank of England prevailing from time to time until payment is made. Such interest shall accrue on a daily basis from the due date until the

date of actual payment of the overdue amount and shall be payable on demand. Interest shall not accrue on payments that are contested in good faith.

9.6 Right to Suspend: Except as set out and agreed in a Product Schedule or pursuant to Clause 17.2 (Force Majeure), Service Provider shall not be entitled at any time to suspend the provision of the whole or any part of the supply of Product.

10. Taxes

10.1 Taxes: The Parties agree that all charges under this Agreement are exclusive of all taxes, levies, duties, contribution, withholding or impost of whatever nature (including related fines, penalties, surcharges of interest) ("**Taxes**", each "**Tax**") imposed or payable to any government, state or municipality or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world ("**Tax Authority**") including (but not limited to) value added or goods and service taxes or other similar taxes computed by reference to turnover that are required by law to be disclosed as a separate item on the relevant invoice ("**GST**") that are the responsibility of AstraZeneca under this Agreement. Notwithstanding the foregoing, Service Provider shall be responsible for any taxes payable to any Tax Authority based on its income.

10.2 GST Invoice: Where either Party is required under this Agreement to make a supply ("**GST Supplying Party**") to the other Party ("**GST Receiving Party**") for Tax purposes, and Tax is chargeable on such supply, the GST Supplying Party shall provide the GST Receiving Party with an invoice ("**Tax Invoice**") including such particulars as are required by any law imposing Tax and such other information as required to claim any credit allowed under a law imposing Tax in respect of such supply. All Prices are exclusive of GST, which, if payable, shall be borne and paid against provision by the Service Provider of a valid Tax Invoice.

10.3 Excess: To the extent, in any circumstances, the GST Receiving Party has paid GST to the GST Supplying Party which it subsequently transpired was in excess of the GST actually due, the GST Supplying Party shall repay to the GST Receiving Party the excess amount.

10.4 Tax Deductions: If a deduction or withholding for or on account of Tax ("**Tax Deduction**") is required by law to be made by AstraZeneca, the amount of payment due from AstraZeneca to Service Provider shall be equal to the payment which would have been due if no Tax Deduction had been required less the Tax Deduction. AstraZeneca shall not be required to make an increased payment to Service Provider for a Tax Deduction. AstraZeneca shall co-operate reasonably with Service Provider to notify Service Provider when AstraZeneca believes a Tax Deduction is required and in connection with any proposed actions of Service Provider to reduce or recover the Tax Deduction (e.g., by completing prescribed forms) provided that AstraZeneca shall not dispense or apply a reduced rate of Tax Deduction unless Service Provider has provided evidence, in a form satisfactory to AstraZeneca of authorization to do so.

10.5 Audits; Disputes; Requests for Information: The Parties shall reasonably work together with respect to audits, disputes or requests for information with respect to Taxes (e.g., provision of relevant information and documents) in connection with this Agreement.

11. Confidentiality and Use of Name

11.1 Confidential Information: Neither Party shall, at any time, without the other Party's prior written consent, disclose to any Third Party any of the other Party's Confidential Information or the fact that the Services are being conducted hereunder. Each Party shall use such Confidential Information solely for the purposes for which it was provided, including provision of the Services. Each Party shall take all reasonable precautions to prevent any unauthorized use or disclosure of the Confidential Information. For clarity, Confidential Information shall include any information (a) relating to the terms of this Agreement, and (b) defined as "Confidential Information" in the Short Form Agreement, and this Clause 11 shall likewise apply to any such information disclosed under the Short Form Agreement. All Service Provider Information is the Confidential Information of Service Provider. All AstraZeneca Information is the Confidential Information of AstraZeneca. The financial terms of this Agreement are the Confidential Information of the Parties. Confidential Information does not include any information that (i) the receiving Party can prove was known to it prior to the date of this Agreement and any other agreement between the Parties hereto; (ii) the receiving Party can prove was lawfully obtained from a Third Party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving Party; or (iv) is independently developed by the receiving Party without use of or reference to the disclosing Party's Confidential Information, as evidenced by the receiving Party's business records.

11.2 Required Disclosure: Notwithstanding other provisions of this Agreement, a Party may disclose Confidential Information of the other Party to the extent and to the Persons required under Applicable Laws and Regulations, provided that such Party (a) first gives prompt notice of such disclosure requirement to the other Party so as to enable the other Party to seek any limitations on or exemptions from such disclosure requirement, (b) reasonably cooperates at the other Party's request and expense in any such efforts by the other Party, and (c) only discloses that portion of such Confidential Information as is legally required.

11.3 Authorized Disclosure:

11.3.1 Notwithstanding other provisions of this Agreement, a Party or its Affiliate may also disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, lenders, insurers or licensors on a need-to- know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement or any Product Schedule; provided that in each case, the recipient is bound by obligations of confidentiality and non-use no less stringent than

those contained in this Agreement. For clarity, and in furtherance of the foregoing, a Party may disclose Confidential Information of the other Party to any Person that has executed a written definitive agreement with AstraZeneca that pertains to the research, development, manufacture or commercialization of the Product; provided that, the recipient is bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement; and provided further, AstraZeneca shall not be permitted to disclose any Service Provider Background Technology and neither Party shall be permitted to disclose the financial terms of this Agreement and/or any Product Schedule.

11.3.2 Service Provider understands and acknowledges that AstraZeneca is in negotiations of a proposal in response to HSS Request for Proposal Number BAA-18-100-SOL-00003 "Broad Agency Announcement for the Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures": Area of Interest #8.3, ChAdOx1: Manufacturing and Clinical Evaluation of a COVID-19 Vaccine (the "**RFP**").

11.3.3 Service Provider further understands and agrees that AstraZeneca may provide Confidential Information provided in response to this RFP (including information exchanged pursuant to an existing confidentiality or nondisclosure agreement) to representatives or agents of the U.S. Government in connection with AstraZeneca's proposal for the Product. AstraZeneca further understands and agrees that Service Provider may provide Confidential Information provided under this Agreement (including information exchanged pursuant to an existing confidentiality or nondisclosure agreement) to representatives or agents of the U.S. Government in connection with the Task Order. Each Party takes commercially reasonable steps to restrict their disclosure by the U.S. Government under applicable public disclosure / transparency laws. Each Party, however, shall have no liability for the U.S. Government's release of any Confidential Information.

11.4 Return of Confidential Information: Upon the earlier of the termination of this Agreement or at a Party's request for any reason at any time, the other Party shall (a) immediately cease all use of the other Party's Confidential Information disclosed thereunder and (b) promptly, at the requestor's instruction, either return to the requestor or destroy the other Party's Confidential Information disclosed thereunder, including any copies, extracts, summaries or derivative works thereof, and certify in writing to the requestor the completion of such return and/or destruction, provided, however, that such Party may retain one copy solely for archival purposes.

11.5 Publicity: Except as required by Applicable Laws and Regulations, neither of the Parties shall use the name of the other Party (or of the other Party's Affiliate) for promotional purposes without the prior written consent of the Party whose name is proposed to be used, such consent not to be unreasonably withheld or delayed, nor shall either Party disclose the existence or substance of this Agreement (except as already previously disclosed through a prior written mutually agreed disclosure). In particular, neither Party shall make any publications, presentations or public disclosures related to this Agreement and the subject matter thereof without the other Party's prior review and

written approval, such approval not to be unreasonably withheld or delayed; provided, for clarity, AstraZeneca is in no way restricted by this Section from making any publications, presentations or public disclosures related to the Product or AstraZeneca's COVID-19 program generally, which do not specifically include details of this Agreement or Service Provider's performance hereunder.

12. Indemnity

12.1 Indemnification by AstraZeneca: AstraZeneca shall indemnify, defend and hold harmless Service Provider, its Affiliates, and their respective directors, officers, employees and agents (the "**Service Provider Indemnitees**") from and against any and all losses, damages, costs and expenses, including reasonable attorneys' fees arising out of claims by third parties as a result of: (i) [**] or (ii) AstraZeneca's breach of this Agreement, including without limitation, any representations, warranties and covenants herein, or (iii) any use, handling or disposal of any product produced by Service Provider for AstraZeneca, including without limitation, any product liability claim; or (iv) any alleged or actual infringement or misappropriation of third party intellectual property rights in the Product or any portion thereof, or manufacture of the Product, or resulting from, use of any AstraZeneca provided information, data, or property in the performance of the Services; except in each case to the extent that (A) such third party claim is based upon the negligence or willful misconduct of Service Provider or a Service Provider Indemnitee or breach of this Agreement by Service Provider; (B) Service Provider is indemnified by the U.S. Government in respect of any such losses, damages, costs or expenses; or (C) Service Provider has an obligation to indemnify AstraZeneca pursuant to Clause 12.2, as to which third party claims each Party shall indemnify the other to the extent of its respective liability for such third party claims. Service Provider must promptly notify AstraZeneca of a covered claim, must tender to AstraZeneca (and/or its insurer) full authority to defend or settle (for monetary damages) the claim, and must reasonably cooperate with the defense at AstraZeneca's request and expense.

12.2 Indemnification by Service Provider: Subject to Clause 12.5, Service Provider shall indemnify, defend and hold harmless AstraZeneca, its Affiliates, and their respective directors, officers, employees, and agents (the "**AstraZeneca Indemnitees**") from and against any and all losses, damages, costs and expenses, including reasonable attorneys' fees arising out of claims by third parties as a result of (i) [**]; or (ii) Service Provider's breach of this Agreement, including without limitation, any representations, warranties and covenants herein; or (iii) any alleged or actual infringement or misappropriation of third party intellectual property rights resulting from use of any Service Provider provided information, data or property in the performance of the Services, except in each case to the extent that (A) such third party claim is based upon the negligence or willful misconduct of AstraZeneca or a AstraZeneca Indemnitee or breach of this Agreement by AstraZeneca; (B) AstraZeneca is indemnified by the U.S. Government in respect of any such losses, damages, costs or expenses, or (C) AstraZeneca has an obligation to indemnify Service Provider pursuant to Clause 12.1, as to which third party claims each Party shall indemnify the other to the extent of its respective liability for such third party claims.

AstraZeneca must promptly notify Service Provider of a covered claim, must tender to Service Provider (and/or its insurer) full authority to defend or settle (for monetary damages) the claim, and must reasonably cooperate with the defense at Service Provider's request and expense.

12.3 The foregoing indemnification rights shall apply only to Third Party Losses.

12.4 All indemnification obligations in this Agreement are conditioned upon the Party seeking indemnification:

12.4.1 promptly notifying the indemnifying Party in writing of any claim or liability of which the Party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such written notice within a reasonable period shall not relieve the indemnifying Party of its obligations under this Clause 12 except to the extent, if any, the indemnifying Party is prejudiced by such failure,

12.4.2 allowing the indemnifying Party, if the indemnifying Party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense); provided, that the indemnifying Party shall promptly provide and continuously maintain such defense,

12.4.3 cooperating with the indemnifying Party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying Party's expense) and

12.4.4 not compromising or settling any claim or liability without prior written consent of the indemnifying Party.

12.5 LIMITATION OF LIABILITY. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED BY LAW:

12.5.1 EXCEPT TO THE EXTENT CAUSED SOLELY BY SERVICE PROVIDER'S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, IN NO EVENT SHALL SERVICE PROVIDER HAVE ANY LIABILITY FOR THE LOSS OR DAMAGE, THE REPLACEMENT, OR THE COST OR VALUE, OF ANY ASTRAZENECA MATERIALS (AS DEFINED ABOVE). WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, AND EXCEPT TO THE EXTENT CAUSED SOLELY BY SERVICE PROVIDER'S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, SERVICE PROVIDER HAS NO LIABILITY FOR THE ASTRAZENECA MATERIALS DURING THE PROCESSING OR MANUFACTURING OF PRODUCT NOR FOR ANY LOSS OR DAMAGE OF ASTRAZENECA MATERIALS CAUSED BY A CONFORMING OR NONCONFORMING BATCH.

12.5.2EXCEPT WITH RESPECT TO A PARTY'S MATERIAL BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER CLAUSE 11.1, IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT TO THE OTHER PARTY FOR THE COST OF SUBSTITUTE SERVICES, DAMAGES FOR DELAYS, LOSS OF USE, DATA, REVENUE OR PROFIT OR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL OR PUNITIVE DAMAGES, INCLUDING ANY DAMAGES FOR BUSINESS INTERRUPTION, WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. FOR AVOIDANCE OF DOUBT, THE PARTIES AGREE THAT ANY CLAIM BY SERVICE PROVIDER FOR ANY PORTION OF THE CAPACITY COMMITMENT FEE OR ANY OTHER FEES OWED BY ASTRAZENECA AND NOT PAID IN ACCORDANCE WITH THIS AGREEMENT SHALL NOT BE EXCLUDED BY THIS CLAUSE 12.5.

12.5.3 IN ADDITION TO THE FOREGOING, EXCEPT FOR SERVICE PROVIDER'S (A) BREACH OF ITS RESERVED CAPACITY OBLIGATION HEREUNDER WHICH SHALL BE AS SET FORTH IN CLAUSE 12.5.4 BELOW, SERVICE PROVIDER'S AGGREGATE LIABILITY TO ASTRAZENECA HEREUNDER, FOR ANY REASON WHATSOEVER, INCLUDING WITHOUT LIMITATION FOR ANY AND ALL BREACHES OF ITS OBLIGATIONS UNDER THIS AGREEMENT, IS LIMITED TO [**].

12.5.4 FURTHERMORE, SERVICE PROVIDER'S AGGREGATE LIABILITY TO ASTRAZENECA SOLELY WITH RESPECT TO A BREACH BY SERVICE PROVIDER OF ITS OBLIGATION TO RESERVE CAPACITY PURSUANT TO WORK ORDER #5997-01 SHALL BE LIMITED TO [**]. FOR CLARITY, SERVICE PROVIDER SHALL HAVE NO LIABILITY TO ASTRAZENECA FOR A BREACH OF RESERVED CAPACITY OBLIGATIONS TO THE EXTENT CAUSED BY A UNITED STATES GOVERNMENT DIRECTION OR REQUIREMENT.

12.5.5 NOTWITHSTANDING THE PROVISIONS OF THIS CLAUSE 12.5.5, NOTHING IN THIS AGREEMENT SHALL OPERATE TO EXCLUDE OR RESTRICT EITHER PARTY'S LIABILITY FOR FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

13. Insurance

Each Party agrees to keep in full force and effect and maintain at its sole cost and expense insurance coverage in types and amounts commensurate in its industry for the performance of services substantially similar to the services by similarly-sized companies, and as otherwise prudent or required by law. Each Party agrees to provide the other party with certificates of insurance if requested to do so by the other Party.

14. Term and Termination

14.1 Term of the Agreement: This Agreement shall commence on the Effective Date and shall end on the third (3rd) anniversary of the Effective Date unless sooner terminated in accordance with the terms hereof (the "**Term**"). The Term may be extended upon written agreement by AstraZeneca and Service Provider. Any uncompleted Product Schedules shall continue notwithstanding the expiry of this Agreement.

14.2 Term of Product Schedule: Each Product Schedule shall remain in force for the period set forth in the Product Schedule, unless terminated earlier under this Clause 14.

14.3 Termination for Convenience: This Agreement or a Product Schedule may be terminated by AstraZeneca at any time upon thirty (30) days prior written notice to Service Provider.

14.4 Material Breach: This Agreement or a Product Schedule may be terminated by either Party, either in whole or in part with respect to all or a portion of any Product Schedule, upon the material breach of this Agreement by the other Party, which material breach continues unremedied for [**] after delivery to the non-breaching Party of notice of the material breach.

14.5 Insolvency Events: This Agreement and all Product Schedules may be terminated by either Party immediately upon written notice to the other Party in the event the other Party suffers an Insolvency Event.

14.6 Illegal Trade, Money Laundering: This Agreement and all Product Schedules may be terminated by a Party immediately upon written notice to the other Party if the other Party or any employee of the other Party with the knowledge of the other Party is convicted of a crime involving illegal trade, counterfeiting or money laundering or is not so convicted but there is sufficient evidence of their involvement in illegal trade or counterfeiting including negligence or failure to establish necessary preventive controls.

14.7 Payment upon Termination: In the event of a termination of this Agreement or a Product Schedule pursuant to this Clause 14, AstraZeneca shall pay all outstanding amounts for all work performed and in process in accordance with the terms of this Agreement and any Product Schedule through the date of termination, plus all reasonable, bona fide and duly documented non-cancellable out-of-pocket costs and expenses incurred by Service Provider on behalf of AstraZeneca in connection with this Agreement and the Product Schedule and/or as a result of such termination (collectively "**Accrued Amounts**"). In addition, if this Agreement is terminated for any reason other than by AstraZeneca pursuant to Clauses 14.4, 14.5 or 14.6, AstraZeneca shall pay Service Provider: [**].

14.8 Survival of Rights and Obligations: The expiration or termination of this Agreement or a Product Schedule shall be without prejudice to any rights or obligations that may have accrued prior to such expiration or termination. Notwithstanding expiration or termination of this Agreement for any reason, the rights and obligations under Clauses 4, 7, 8.1.10, 8.4, 9.4, 9.5, 10, 11, 12, 13, 14.7, 14.8, 16, 17, 18, 20.1, 20.2, 23, Part C

(solely to the extent the definitions contained therein are used in provisions that expressly survive the expiration or termination of this Agreement), Parts D and E (solely to the extent the provisions therein expressly survive the expiration or termination of this Agreement) will survive.

15. Assignment, Transfer and Subcontracting

15.1 Assignment: Neither Party may assign this Agreement or any of its rights or obligations without the prior written consent of the other Party and any purported assignment in contravention of this Clause shall be null and void, provided, however, that either Party may assign this Agreement to a corporate Affiliate or to any corporation with which it may merge or consolidate or to which it may assign substantially all of its assets or that portion of its business to which this Agreement pertains without obtaining the agreement of the other Party. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns. Any attempted assignment, delegation or subcontracting in violation of this Clause 15.1 shall be void and of no effect.

15.2 Subcontracting: Service Provider may subcontract its obligations under this Agreement to an Affiliate and to any non-Affiliate who is identified in a Product Schedule. Otherwise, Service Provider shall not subcontract its obligations under this Agreement to any Person without the prior written consent of AstraZeneca. Such consent shall not relieve Service Provider from any liability or obligation under this Agreement and Service Provider shall be responsible for the acts or omissions of its subcontractors as fully as if they were its own. Service Provider's subcontractors shall comply with all the applicable terms and conditions of this Agreement. Service Provider shall be liable for any breach of its obligations under this Agreement resulting from actions and/or omissions of its Third Party subcontractors, unless otherwise agreed in this Agreement or the Product Schedule.

16. Notices

16.1 Form of Notice: Any notices given hereunder shall be sent by email (with a confirmation copy sent via overnight courier) or via overnight courier to the following addresses (or such other address as a Party may designate as a notice address in a prior written notice to the other Party) and shall be deemed delivered when received (or if received on a weekend or holiday, on the next Business Day thereafter) as follows. This Clause 16.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

16.2 Address for Notice:

Service Provider	To: Emergent Manufacturing Operations Baltimore, LLC 400 Professional Drive, Suite 400 Gaithersburg, MD 20879 Attention: Syed Husain, Senior Vice President, BU Head, CDMO	With a copy to: Emergent BioSolutions Inc. 400 Professional Drive, Suite 400 Gaithersburg, MD 20879 Attention: General Counsel
AstraZeneca	To: AstraZeneca Pharmaceuticals LP 1800 Concord Pike, Wilmington, Delaware 19803, USA Attention: [**]	With a copy to (which shall not constitute effective notice): Email: legalnotices@astrazeneca.com Attention: Legal Department

17. Regulatory Matters

17.1 Regulatory Documentation. Any AstraZeneca requests for documents or other work product that do not exist as of the date of such request, or other substantive requests for assistance in compiling any filing for a Regulatory Authority, shall be subject to a

mutually agreeable Product Schedule (or amendment thereto) setting forth additional Services and the amounts payable by AstraZeneca therefor.

17.2 Regulatory Communications and Correspondence. Any and all communications from the FDA or other Regulatory Authorities related to the manufacture of the Product at the Service Provider facility that are addressed to Service Provider shall be handled in accordance with the terms and conditions of the QAA (if applicable), or shall be handled by Service Provider, incorporating any and all reasonable comments from AstraZeneca as necessary after provision by Service Provider with, to the extent regulatory timelines reasonably permit, a sufficient period of time for such review and comment.

17.3 Regulatory Authorities. AstraZeneca shall be solely responsible for handling all filings with, and complaints and communications from, Regulatory Authorities with respect to the Product. As reasonably requested by AstraZeneca, Service Provider shall cooperate in resolving such complaints and responding to such communications to the extent they pertain to Service Provider's manufacture of the Product, and AstraZeneca shall reimburse Service Provider for all reasonable costs and expenses incurred by Service Provider in connection with any such assistance. For clarity, under no circumstance shall Service Provider be required to sign, as an applicant or in any other capacity, any filing with any Regulatory Authority in any country relating to the approval, sale, use or distribution of Product.

18. General

18.1 Relationship of Parties: All employees and agents of Service Provider that perform Services under this Agreement are employees and agents, respectively, of Service Provider and not AstraZeneca during the Term and shall at all times be directed solely by Service Provider. Service Provider is acting in the capacity of independent contractor hereunder and not as employee of AstraZeneca.

18.2 Force Majeure. If either Party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an event of Force Majeure, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the Parties to resume performance under the affected Product Schedule. In the event of Force Majeure, the provisions of Clause 1.8 shall apply.

18.3 Independent Contractor. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers nor of principal and agent between the Parties. Neither Party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

18.4 Allocations of Risk. Each provision of this Agreement that provides for a limitation if liability, disclaimer of warranties or exclusion of damages is to allocate the risks of this Agreement between the Parties and each Party acknowledges that such allocation of risk is reflected in the pricing offered by Service Provider to AstraZeneca and is an essential element of the basis of the bargain between the Parties.

18.5 Waivers: No failure or delay by any Party in enforcing any provision of this Agreement shall be deemed a waiver of that Party's rights to later enforce that provision or any other provision of this Agreement. To be effective, any waiver must be in writing and signed by the waiving Party. No single or partial exercise of any right or remedy provided under this Agreement shall prevent or restrict the further exercise of that or any other right or remedy.

18.6 Severability: If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deleted. Any modification to or deletion of a provision or part-provision shall not affect the validity and enforceability of the rest of this Agreement.

18.7 Entire Agreement: This Agreement, the Product Schedules and the QAA constitute the entire agreement between the Parties, and supersedes all prior agreements, arrangements and understandings between them, whether written or oral, with respect to the subject matter hereof.

18.8 No Reliance: Each Party confirms that it is not relying on any statement, assurance, warranty or representation (whether made innocently or negligently) of the other Party except as specifically set out in this Agreement. This Clause 18.8 is not intended to limit or exclude liability for fraud or fraudulent misrepresentation.

18.9 Amendments and Modifications: This Agreement, or any of its Exhibits, may not be altered, amended or modified except by a written document signed by the Parties. Each Agreement formed by the entry into a Product Schedule or an Affiliate Product Schedule may only be amended or modified by way of the authorized representative of the relevant entities signing an amendment or modification to the relevant Product Schedule or Affiliate Product Schedule and such amendment or modification shall not impact any other Product Schedule or Affiliate Product Schedule. AstraZeneca's use of purchase orders is for its convenience only and no purchase order shall modify or supersede the terms of this Agreement or of any Product Schedule. If the terms of a Product Schedule conflict with the terms of this Agreement, the terms of this Agreement shall control over the conflicting terms of the Product Schedule, unless specifically stated otherwise in the Product Schedule. If this Agreement conflicts with the terms of the QAA with respect to any quality-related matters, then the QAA shall control. If this Agreement conflicts with the QAA with respect to any matters not related to quality, then this Agreement shall control.

18.10 Third Parties: The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons except as otherwise provided in this Agreement. No one other than a Party to this Agreement, their successors and permitted assigns, has any right to enforce any of its terms.

18.11 Performance Through Affiliates: Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

18.12 Counterparts: This Agreement may be executed in two counterparts, each of which will be deemed an original and all of which will together be deemed to constitute one agreement. The Parties agree that the execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

18.13 Waiver of Jury Trial. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HERETO HEREBY IRREVOCABLY WAIVE THE RIGHT TO A TRIAL BY JURY IN ANY ACTION RELATED TO THIS AGREEMENT.

18.14 Choice of Law; Dispute Resolution.

18.14.1 Choice of Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

18.14.2 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Clause 16.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in or before any court or other tribunal, including in respect of the alternative dispute resolution procedures contemplated by Clause 18.14.3.

18.14.3 Dispute Resolution.

a. If a dispute arises between the Parties in connection with or relating to this Agreement, a Product Schedule, a Purchase Order or any other document or instrument delivered in connection herewith (a "**Dispute**"), then either Party shall have the right to refer such Dispute to representatives of the Parties who have the authority to settle the Dispute for attempted resolution by good faith negotiations during a period of [**]. Any final decision mutually agreed to by such representatives in writing shall be conclusive and binding on the Parties.

b. If such representatives are unable to resolve any such Dispute within such [**] period, either Party shall be free to institute binding arbitration in accordance with Clause 18.14.3(c) upon written notice to the other Party (an "**Arbitration Notice**") and seek such remedies as may be available.

c. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three (3) experts with relevant industry experience (the "**Arbitrators**"). Each of Service Provider and AstraZeneca shall promptly select one (1) Arbitrator, which selections shall in no event be made later than [**] after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Service Provider and the Arbitrator chosen by AstraZeneca, but in no event later than [**] after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the dispute. The arbitration shall be administered by the American Arbitration Association (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in Wilmington, Delaware, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within [**] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Laws and Regulations in the State of Delaware or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform,

modify or materially change this Agreement or any other agreements contemplated hereunder.

d. Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Clause 18.14.3, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Clause 18.14.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges or travel expenses) or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Clause 18.14.3 is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide application to prevent irreparable harm involving a Party's Confidential Information, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. All arbitration proceedings and decisions of the Arbitrator under this Clause 18.14.3 shall be deemed Confidential Information of both Parties under Clause 11.

18.15 Interpretation: Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation," (c) the word "will" shall be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to include the Person's successors and assigns, (f) the words "herein," "hereof" and "hereunder," and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Clauses Parts shall be construed to refer to Clauses and Parts of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) all references to a number of days, unless otherwise specified, such number refers to calendar days, (i) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by email, written agreement, letter, approved minutes or otherwise (but excluding instant messaging), (j) references to any specific law, rule or regulation, or article, section or other

division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or," (l) section headings are for convenient reference and shall not affect the interpretation of this Agreement and (m) any monetary amounts in this Agreement and in any Product Schedules are, unless otherwise indicated, denominated in United States Dollars.

PART B: WAYS OF WORKING

19. AstraZeneca Expectations

19.1 Authorization: Service Provider recognizes AstraZeneca's commitment to work only with suppliers and service providers who embrace the standards of ethical behavior consistent with AstraZeneca's Expectations of Third Parties Handbook, a copy of which can be found on www.astrazeneca.com or by clicking the "Resources" tab on https://www.astrazeneca.com/sustainability.html, as amended from time to time, and in particular those principles in the Section "Anti-Bribery and Anti-Corruption" as amended from time to time.

19.2 Service Provider Conduct: Each party shall comply with all Applicable Laws and Regulations in connection with its obligations under this Agreement including applicable cGMP standards. Each Party (i) shall perform this Agreement to ethical standards consistent with those set out in its respective Code of Conduct (its "**Ethical Standards**"), (ii) will not take any action that will cause the other Party to be in breach of any Applicable Laws and Regulations for the prevention of fraud, bribery and corruption, racketeering, money laundering, terrorism, including the US Foreign Corrupt Practices Act and the UK Bribery Act, (iii) will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and will not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of such Party, and (iv) will use reasonable efforts to cause its Affiliates, suppliers and subcontractors performing services for such Party or its Affiliates to operate their business in compliance with all Applicable Laws and Regulations, as amended from time to time.

19.3 Improvement Plan: In the event a Party fails to meet or maintain its Ethical Standards, the Parties will agree upon what measures should be taken by such Party to improve such Party's performance (the "**Improvement Plan**"). If the Parties are unable to agree upon an Improvement Plan or the relevant Party does not implement the Improvement Plan within an agreed reasonable timescale (not to exceed [**] months), the other Party will be entitled to terminate this Agreement with immediate effect and be relieved of any obligations under this Agreement.

19.4 Trade Controls: Each Party represents, warrants and undertakes that it is not on any applicable official national or international sanctioned party lists and that performance of this Agreement will not violate applicable embargo regulations. Each Party has the right, at such Party's sole expense, to conduct screening checks of the other

Party, including verification of the other Party's identity, including full name, country location and address, against official national and international sanctioned party lists and embargo regulations.

19.5 Export Controls. This Agreement is made subject to any restrictions under the export control laws, rules and regulations concerning the export of products, materials or technical information either from the United States of America or to a foreign national within the United States of America (e.g., a "deemed export" applying to transfers solely within the United States of America) which may be imposed upon or related to Service Provider or AstraZeneca from time to time by the government of the United States of America. AstraZeneca shall be responsible for performing all activities and procedures as may be necessary for the importation of the AstraZeneca Materials required to be provided by AstraZeneca to Service Provider hereunder, and for any and all exportation of Product. AstraZeneca shall be solely responsible for, and shall pay, all associated duties, taxes and costs and shall comply with all applicable import and export laws.

20. Product Security

20.1 Destruction of Waste: Service Provider shall destroy all Waste which is not delivered to AstraZeneca so it cannot be used or enter the supply chain on AstraZeneca and Service Provider mutually acceptable timelines, during and upon termination or expiry of the Term. Such Waste shall be secured and reconciled by Service Provider pending destruction. Service Provider shall keep a record of destruction of any Waste and promptly issue certificates of destruction. The records shall be kept for a period of at least [**] and made available to AstraZeneca on request.

20.2 Standard Operating Procedures: Service Provider shall maintain standard operating procedures and full records detailing production amounts and the delivery of produced Product bulk drug substance to AstraZeneca to ensure that the security of the supply chain is secured, maintained and controlled. Such records and standard operating procedures relating to Product security shall be kept for a period of at least [**] and made available to AstraZeneca on request.

20.3 Subcontractors: Service Provider shall include in all of its contracts with its subcontractors involved in the manufacture, supply or handling (including, to the extent any such Services are included in a Product Schedule, storage, warehousing, distribution and transportation) of Product or AstraZeneca Materials, provisions substantially identical to this Clause 20.

20.4 Security Measures: Service Provider will implement reasonable security precautions to prevent any loss or theft of, or damage or unauthorized access to the Product while in the control of Service Provider and shall ensure that stocks of Product are kept separate from and clearly distinguished from other stocks and supplies held by Service Provider.

20.5 Suspect Samples: At the request of AstraZeneca, Service Provider shall support AstraZeneca in the authentication of suspect samples, including batch checks, responding to requests for information, for example to be sent to AstraZeneca operations sites for use in authentication work, so as to enable prompt authentication in accordance with AstraZeneca standards and strategy.

20.6 IT Security: In performing its obligations and exercising its rights under this Agreement, each Party will ensure that it and each of its Affiliate(s) performing or requiring Services hereunder will maintain administrative, technical, and physical measures, controls, tools, systems, policies and procedures which it deems to be appropriate for the protection of the other Party's Confidential Information and to prevent interference with its obligations hereunder. Service Provider shall work with AstraZeneca in good faith to mitigate the potential occurrence of any Security Incidents and any risks related thereto or arising therefrom, in connection with the Services, including working with key government agencies from the United States who may provide cyber security services to AstraZeneca and AstraZeneca's supply chain partners, including Service Provider. Each Party will notify the other Party, in writing, of any Security Incident affecting or which may affect any information technology infrastructure and data and/or facilities owned, leased and/or used by and/or provided for use by such Party or any Affiliate, which may affect the delivery of the Services, without undue delay and in any event within [**] after such Party becomes aware of such Security Incident. Such notification will be, in the first instance, sent by e-mail to the following e-mail address: [**] and immediately followed up by telephone to [**].

20.7 Security Breaches: Any diversion, theft, tampering, substitution or other breach of the security of the Product (including suspicious returns), machinery, other tools of production or product security information pertaining to this Agreement or the relevant Product Schedule shall be reported to AstraZeneca (copying the AstraZeneca [**]) within [**] of discovery of such incident. Service Provider shall, at AstraZeneca's cost and expense, provide all reasonable assistance to AstraZeneca during any investigation that AstraZeneca may initiate in relation to such incident.

21. Health, Safety and Environment

21.1 Service Provider will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any Waste used in or generated by the Services. Service Provider, in consultation with AstraZeneca, will develop safety and handling procedures for Product; provided, however, that AstraZeneca will have no responsibility for Manufacturer's health and safety program.

21.2 Incident Reporting: Service Provider shall as soon as it becomes aware promptly report to AstraZeneca in writing any event or occurrence at the Service Provider's site where Services are being performed under a Product Schedule which is reasonably likely to affect the provision of the Product or the performance of this Agreement.

22. FFDCA Requirements

Each Party represents, warrants and undertakes to the other Party that it: (a) is not currently excluded, debarred, suspended or otherwise ineligible to participate in U.S. federal healthcare programs or in federal procurement or non-procurement programs pursuant to Section 306 of the FFDCA, and no debarment is pending or no debarment proceedings have been initiated, (b) has not been charged with or convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a 7(a), 1320a-7(b)(1)-(3) related to the provision of healthcare items or services, but has not yet been excluded, debarred, suspended or otherwise declared ineligible, (c) is not debarred or subject to debarment under 21 U.S.C. §335(a), and (d) is not otherwise subject to any restrictions or sanctions by the FDA (an "**Ineligible Person**"). Each Party agrees to promptly disclose in writing to the other Party if it becomes aware that it or any of its employees or agents is or becomes an Ineligible Person, or if any action or investigation is pending or, to the best of such Party's knowledge, threatened, relating thereto, at which point the other Party shall have the right to terminate this Agreement for material breach pursuant to Clause 14.6.

23. Records and Inspections. Monitoring and Right to Audit.

23.1 Records: For purposes of this Agreement, "**Records**" will mean information created, received or recorded in any format by Service Provider in the performance of Service Provider's obligations under this Agreement. Service Provider will maintain and retain complete organized and accurate Records of all equipment and sites used and services provided, including records of raw materials, manufacture, testing, storage and delivery of the Product.

23.2 Protection Against Destruction. Service Provider will act consistently with industry standards to ensure that Records are protected from destruction or damage and are maintained within Service Provider's control during the term of the relevant Product Schedule for [**] thereafter, or for a longer period of time as requested by AstraZeneca and agreed to by Service Provider and as otherwise specified in the relevant QAA or this Agreement. AstraZeneca or its authorized representatives, will be permitted to examine and obtain copies of such Records at AstraZeneca's expense.

23.3 Audit: During the Term, and for a period of [**] thereafter, upon reasonable advance notice to Service Provider and on mutually agreed upon dates and during normal business hours, during the term of this Agreement, AstraZeneca shall have the right to perform, directly or, subject to a confidentiality agreement through its representatives, one (1) general audit/inspection of the facility(ies) used to perform Services hereunder per [**], and perform "for cause" audit(s) of such facility(ies) in accordance with the terms of the QAA. Such audits shall (i) be limited to a maximum of [**] AstraZeneca personnel or representatives, (ii) not occur in areas of the facility(ies) when Service Provider is conducting activities for other customers, and (iii) be a maximum of [**] in duration per audit. All Product and/or Product manufacturing process specific audits or inspections by Regulatory Authorities other than the FDA or EMA associated with the territories/countries in which AstraZeneca has marketing/sales responsibility must be agreed upon in

advance by Service Provider, such agreement not to be unreasonably withheld, conditioned or delayed, and any such agreed upon audits will be invoiced to AstraZeneca in the amounts set forth in a Product Schedule. AstraZeneca shall be solely responsible for all third party costs of all audits. Service Provider may require all AstraZeneca personnel or representatives visiting or having access to the facility(ies) to agree in writing to abide by all relevant Service Provider standard policies, operating procedures, and security procedures as established by Service Provider and communicated to AstraZeneca.

23.4 Audit Assistance: Service Provider shall provide or procure all cooperation and assistance during normal working hours reasonably required by AstraZeneca for the purposes of an audit. AstraZeneca shall procure that any auditor enters into a confidentiality agreement with AstraZeneca substantially equivalent to Clause 11 in all material respects. AstraZeneca shall instruct any auditor or other Person given access in respect of an audit to cause the minimum amount of disruption to the business of Service Provider, its Affiliates and sub-contractors and to comply with relevant building and security regulations.

23.5 Audit Costs: The Parties shall bear their own costs of an audit or rendering assistance under this Clause 23. Any report generated in connection with any such audit conducted in relation to Clause 23.3 shall be the property of Service Provider. However, to the extent relevant to the Services, Service Provider agrees that AstraZeneca shall be entitled to review any such audit report and all supporting documents in relation to the audit.

24. Change Procedure

24.1 Change Procedure: Service Provider shall only make changes to the Product or in the manufacturing process, manufacturing facilities or sub-contractors or materials used by Service Provider to manufacture the Product by following the change control procedure as set out in the QAA.

24.2 Costs of Change: All costs for any change of Product (or manufacturing process, manufacturing facilities or sub-contractors or materials) due to continuous improvements or otherwise, shall be, unless otherwise agreed by the Parties in the Change Order, allocated as follows:

24.2.1 Pursuant to Clause 3.2, when the changes are to the manufacturing process or Product Specifications, AstraZeneca shall bear all of its costs;

24.2.2 when the changes are to the manufacturing facilities or Service Provider's subcontractors, Service Provider shall bear all of its costs; except to the extent such changes are requested or required solely by AstraZeneca or the Product, in which case AstraZeneca shall bear all of its costs; or

24.2.3 where the changes are necessary to comply with a Change in Law which does not apply generally to Service Provider's business, AstraZeneca shall bear all of the costs of such required changes, otherwise Service Provider shall bear such costs.

PART C: DEFINITIONS

Definitions: In this Agreement

Accrued Amounts	has the meaning set out in Clause 14.7.
Additional Batches	has the meaning set out in Clause 1.3.2.
Additional Flowdown Terms	has the meaning set out in Clause 1.5.3.
Affiliate	means, with respect to a Party, any Person that Controls, is Controlled by or is under common Control with such Party from time to time.
Affiliate Product Schedule	means a Product Schedule entered into by Service Provider and AstraZeneca and any Affiliate of AstraZeneca or Service Provider, as described in Clause 2.1.3.
Agreement	has the meaning set out in the preamble of this Agreement.
Applicable Laws and Regulations	means all national, supra-national, federal, state, local, foreign or provincial laws, rules, directives, regulations, including case law, as well any guidance, guidelines and requirements of any Regulatory Authorities, including but not limited to export controls and economic sanctions, and any industry codes of practice, in effect from time to time applicable to the activities performed under this Agreement.
Arbitration Notice	has the meaning set out in Clause 18.14.3(b).
Arbitrators	has the meaning set out in Clause 18.14.3(c).
AstraZeneca	has the meaning set out in the preamble of this Agreement.
AstraZeneca Background Technology	has the meaning set out in Clause 4.2.
AstraZeneca Defective Materials	has the meaning set out in Clause 1.6.
AstraZeneca Flowdown Terms	has the meaning set out in Clause 1.5.1.
AstraZeneca Foreground Technology	has the meaning set out in Clause 4.3.1.
AstraZeneca Indemnitees	has the meaning set out in Clause 12.2.
AstraZeneca Information	means all data and information related to or comprised in Intellectual Property as well as other proprietary or confidential information in relation to AstraZeneca's and its Affiliates' general business operations, technology and products, including the Product or their manufacture or packaging, or trade secrets in each case which is owned or controlled by AstraZeneca or its Affiliates and which AstraZeneca or its Affiliates are entitled to disclose.
AstraZeneca Materials	has the meaning set out in Clause 1.7.
AZ Initial Capacity Commitment Fee	means the price for the AZ Initial Period Capacity, in the amount and on the payment terms set forth on Work Order #5997-01.
AZ Initial Period Capacity	means up to [**] at the Bayview facility [**] July 01, 2020 and September 30, 2020.
BARDA Capacity Commitment Fees	has the meaning set out in Clause 1.3.4.
BARDA Initial Period Capacity	means up to [**] at the Bayview facility [**] July 01, 2020 and December 31, 2020.
Batch	means a lot resulting from a single run of Product produced by a single execution of the instructions specified in the master batch record.
Batch Exercise Notice	has the meaning set out in Clause 1.3.3.
Business Day	means any Monday, Tuesday, Wednesday, Thursday or Friday that is not a public holiday in England.
Certificate of Analysis	means the certificate of analysis to accompany all cGMP-manufactured Product delivered to AstraZeneca as set out in the QAA.
cGMP	means those laws and regulations applicable to the manufacture of medicinal products for human use, including current good manufacturing practices as specified in the US Federal Food Drug and Cosmetic Act at 21 CFR (Chapters 210, 211, 600 and 610), the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC and the good manufacturing practicing regulations of any other territory to be agreed upon in the relevant Product Schedule.
Change in Law	means any change in any Applicable Laws and Regulations that: (i) impacts on the

Change in Law	means any change in any Applicable Laws and Regulations that: (i) impacts on the Product, (ii) comes into force after the date that the relevant Product Schedule came into effect, and (iii) was not known about, and could not reasonably have been known about, before that date.
Change Order	means a document generated by Service Provider and agreed to by signature of both Parties that alters or changes one or more aspects of the scope of Services performed by Service Provider, the Specifications for a Product and/or price as designated within a Product Schedule.
CMC	means the "Chemistry, Manufacturing and Controls" the FDA's term to describe the clause of the new drug application which details the pharmaceutical development and the stability as well as the manufacturing processes and the analytical controls used in the production of a drug substance and a drug product, and/or equivalent Regulatory Authority requirements outside the USA.
Confidential Information	means all AstraZeneca Information and all Service Provider Information, respectively, including the intention to enter into a Product Schedule and related discussions, which information (including all written, oral, visual or other information or data, reports, studies, drawings, designs, specifications, analyses or other material recorded in whatever form or medium) is disclosed to or obtained by one Party or any of its Affiliates from the other Party or any of its Affiliates, either directly or indirectly, or which the Party disclosing it indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary or which such recipient knows or ought reasonably to know is information of a confidential or proprietary nature.
Control	means: (i) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (ii) to own, directly or indirectly, fifty percent (50%) or more of the outstanding voting securities or other ownership interest of such Person, or (iii) in the case of a partnership, control of the general partner, and "**Controls**" and "**Controlled**" shall be construed accordingly.
Defect	has the meaning set out in Clause 6.2.
Delay	has the meaning set out in Clause 1.8.
Development Product Schedule	means a schedule completed and entered into between the Parties for the development of Product bulk drug substance, substantially in the form of the first development product schedule entered into pursuant to this Agreement.

Dispute	has the meaning set out in Clause 18.14.3(a).
Documents	means reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, computer programs and documents, computer information storage means, samples of material other graphic or written data and any other media on which Know-How can be stored.
Effective Date	has the meaning set out in the preamble of this Agreement.
EMA	means the European Medicines Agency.
Ethical Standards	has the meaning set out in Clause 19.2.
Extended Batches	has the meaning set out in Clause 1.3.3.
FDA	means the USA Food and Drug Administration.
FFDCA	means the Federal Food, Drug, and Cosmetic Act of the USA.
Flowdown Terms	means, collectively, the AstraZeneca Flowdown Terms and the Service Provider Flowdown Terms.
Force Majeure	means any failure of a Party to fulfil its obligations hereunder when such failure is due to an act of God, emergency order of government or other circumstances beyond its reasonable control, whether or not foreseeable, including but not limited to facility shutdown, supplier delays or failures, equipment failure, fire, flood, civil commotion, epidemic or pandemic, riot, war (declared and undeclared), revolution, action by government including delays in obtaining governmental approvals or embargoes.
Foreground Technology	has the meaning set out in Clause 4.3.1.
GST	has the meaning set out in Clause 10.1.
GST Receiving Party	has the meaning set out in Clause 10.2.
GST Supplying Party	has the meaning set out in Clause 10.2.
HHS	has the meaning set out in Clause 1.5.1.
Improvement	means any invention, improvement, discovery, extension of Know-How, upgrading or modification and all other Intellectual Property rights (whether patentable or not) arising in the performance of this Agreement made, generated, developed or arising from, or related directly or indirectly to, the Confidential Information. Improvements include any manufacturing processes, any new indication, dosage forms, formulations or delivery systems.
Improvement Plan	has the meaning set out in Clause 19.3.
Ineligible Person	has the meaning set out in Clause 22.
Initial Batches	has the meaning set out in Clause 1.3.1.
Initial Period Capacities	means the AZ Initial Period Capacity and the BARDA Initial Period Capacity.
Insolvency Event	means that a Party: (i) suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due, (ii) commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors, (iii) is the subject of a petition, notice, resolution or order for its winding up, (iv) has an administrator, administrative receiver or receiver appointed over it or its assets or is the subject of any formal step taken as part of the process of making such an appointment, (v) has assets that a creditor or encumbrancer has attached or taken possession of, or in respect of which a distress, execution, sequestration or other such process is levied or enforced on or sued against, or (vi) is subject to any similar event or proceeding in any jurisdiction.
Intellectual Property	means Know-How, Patent Rights, trademarks, service marks, trade names, design rights, copyright (including rights in computer software) and any similar or equivalent rights or property or forms of protection in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.
Know-How	means technical information, data and other information which is not in the public domain including: (i) information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), processes (including manufacturing processes, specifications and techniques), laboratory records, chemical,

	pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries, (ii) practices and instructions of, and scientific, analytical and technical data and studies for, synthesis, manufacturing, pharmaceutical processing, formulation, packaging, labelling, storage and transportation, and (iii) non-clinical and clinical data and studies. Know-How includes Documents containing Know-How. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public. Know-How includes any rights including trade secrets, copyright, database or design rights protecting such Know-How.
[**] Cells	has the meaning set out in Clause 1.5.4.
[**] Cell Licence Requirements	has the meaning set out in Clause 1.5.4.
Losses	means any and all liabilities, claims, demands, causes of action, damages, loss, costs and expenses, including interest, penalties, reasonable professional fees and reasonable lawyers' fees on a solicitor client basis together with disbursements.
Manufacturing Product Schedule	means a schedule completed and entered into between the Parties under which Service Provider would manufacture commercial Batches of Product bulk drug substance, substantially in the form of the first Product Schedule entered into pursuant to this Agreement but for services including for the manufacture of commercial Batches.
MHRA	means the Medicines and Healthcare Products Regulatory Agency.
Option Deadline	has the meaning set out in Clause 1.3.2.
Parties	means AstraZeneca and Service Provider, and "**Party**" means either of AstraZeneca or Service Provider.
Patent Rights	mean patent applications and patents (including but not limited to inventions, utility models and industrial designs), inventors' and authors' certificates, improvement patents, and patents of addition and administrative protection (such as pipeline protection) and all foreign counterparts of them in any and all countries, and including any divisional applications and patents, re-filings, renewals, continuations, continuations-in-part, extensions (including patent term extensions), reissues, re-examinations, substitutions, confirmations, registrations, revalidation, importation and additions, and any equivalents in any and all countries, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them in any and all countries.
Person	means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a Regulatory Authority.
PPQ	has the meaning set out in Clause 1.10.
Price	means the amount payable from time to time for Services, as determined in accordance with the terms of this Agreement and the relevant Product Schedule.
Product	has the meaning set out in the Background of this Agreement.
Product Schedule	means a Development Product Schedule, a Manufacturing Product Schedule or a Tech Transfer Product Schedule.
Product Schedule #5997-02	has the meaning set out in Clause 1.2.4.
Purchase Order	means a document issued and signed by AstraZeneca or an Affiliate of AstraZeneca, ordering a specified Batch or number of Batches of Product or other Services, from Service Provider according to the provisions of this Agreement. Each Purchase Order for the manufacture of Batches must include (a) a reference to this Agreement, (b) the number of Batches ordered, and (c) the agreed upon price for such order as set forth in the applicable Product Schedule. If any terms or requirements are included in the Purchase Order that are in addition to or in conflict with the terms of this Agreement, such additional or conflicting terms are of no force and effect and are superseded by the terms and requirements of this Agreement.
QAA	means the Quality Assurance Agreement entered into by the Parties and/or their Affiliates from time to time.
Records	has the meaning set out in Clause 23.1.
Regulatory Authority	means FDA, MHRA and EMA or any court or government body, whether national, supra-national, federal, state, local, foreign or provincial, including any political subdivision, including any department, commission, board, bureau, agency or other regulatory or administrative governmental authority or instrumentality, and further including any quasi-governmental person or entity exercising the functions of any of these

these.

Release Date	means the date on which: (a) Service Provider's Batch record, (b) the Certificate of Analysis; and (c) Service Provider's deviation/investigation report(s) have been signed by Service Provider and submitted to AstraZeneca.
RFP	has the meaning set out in Clause 11.3.2.
Security Incident	means any incident in which a Party discovers or reasonably suspects that a Person has, without authorization, accessed any information technology infrastructure, data and/or facilities owned, leased and/or of, used by and/or provided for use by such Party or any Affiliate performing Services, which may affect the delivery of the Services.
Service Provider Background Technology	has the meaning set out in Clause 4.1.
Service Provider Foreground Technology	has the meaning set out in Clause 4.3.1.
Services	has the meaning set out in Clause 3.1.
SHE	means safety, health and environmental.
Service Provider	has the meaning set out in the preamble of this Agreement.
Service Provider Flowdown Terms	has the meaning set out in Clause 1.5.2.
Service Provider Indemnitees	has the meaning set out in Clause 12.1.
Service Provider Information	means all data and information related to or comprised in Intellectual Property, as well as other proprietary or confidential information in relation to Service Provider's general business operations and manufacturing processes and trade secrets, which is owned or controlled by Service Provider or its Affiliates and which Service Provider or its Affiliates are entitled to disclose.
Short Form Agreement	has the meaning set out in the Background of this Agreement.
Specifications	has the meaning set out in Clause 1.10.
Subsequent Period Capacity	means up to [**] batches of drug substance at the Bayview facility in Area [**] assuming a cadence of [**] batches per reactor per month during the period between [**] and [**].
Task Order	means that certain task order #75A50120F33007 issued pursuant to that certain prime agreement (Contract #HHS010020120000) between Service Provider and the United States Government.
Tax Authority	has the meaning set out in Clause 10.1.
Tax Deduction	has the meaning set out in Clause 10.4.
Tax Invoice	has the meaning set out in Clause 10.2.
Taxes or Tax	has the meaning set out in Clause 10.1.
Tech Transfer Product Schedule	Means a schedule completed and entered into between the Parties for the Services to be performed by Services Provider associated with a transfer of technology to an alternative service provider.
Term	has the meaning set out in Clause 14.1.
Third Party	means any party other than AstraZeneca, Service Provider or their respective Affiliates.
United States Government	means Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health & Human Services.
Waste	means waste material from Service Provider's manufacture, supply or handling of the Product bulk drug substance, including damaged or defective bulk drug substance and Product bulk drug substance not conforming to Specification
Work Order #5997-01	has the meaning set out in the Background of this Agreement.

PART D1: ASTRAZENECA FLOWDOWN TERMS

PART D2: SERVICE PROVIDER FLOWDOWN TERMS

PART E: USE OF [**] CELL LINE

Pursuant to Clause 1.5.4 of this Agreement, Service Provider agrees to comply with the terms and conditions set forth in this Part E of this Agreement in respect of its use of the [**] Cells.

1. Use of [**] Cells. Service Provider agrees that:

1.1 it shall only use [**] Cells in the course of performing its obligations under this Agreement;

1.2 it shall not transfer [**] Cells to, or use [**] Cells on behalf of, any Third Parties other than Permitted Subcontractors; and

1.3 it shall not use [**] Cells for its own benefit other than in the course of performing its obligations under this Agreement.

2. Termination of Service Provider's Rights to Use [**] Cells. If Service Provider uses [**] Cells other than as permitted under this Part E, AstraZeneca may terminate Service Provider's right to use [**] Cells upon [**] written notice, unless Service Provider cures the non-compliant activities and provides clear written evidence of such cure to AstraZeneca.

3. Consequences of Termination. Following any termination of Service Provider's rights to use [**] Cells pursuant to paragraph 2, or following expiry or termination of this Agreement, Service Provider will return to AstraZeneca or destroy all [**] Cells in its possession within [**] of and will certify such return or destruction in writing to AstraZeneca.

4. Compliance with Laws. Service Provider shall comply with all Applicable Laws and Regulations and cGMP in connection with its performance of Services involving the use of [**] Cells.

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

MANUFACTURING PRODUCT SCHEDULE #5997-02 – LARGE SCALE

MANUFACTURING OF COVID-19 VACCINE DRUG SUBSTANCE

Pursuant to the Master Services Agreement dated July 24, 2020, by and between AstraZeneca Pharmaceuticals LP ("**AstraZeneca**") and Emergent Manufacturing Operations Baltimore, LLC ("**Service Provider**") (the "Master Services Agreement") and in consideration of the mutual promises contained therein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree to enter into this Manufacturing Product Schedule entitled – LARGE SCALE MANUFACTURING OF COVID-19 VACCINE DRUG SUBSTANCE, which is designated Product Schedule #5997- 02 (this "**Product Schedule**"). This Product Schedule is effective as of July 24, 2020 and shall terminate upon completion of the Services set forth in this Product Schedule, unless earlier terminated as permitted in the Master Services Agreement. Capitalized terms used in this Product Schedule that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

1. Services. AstraZeneca shall purchase and Service Provider will render to AstraZeneca the following Services:

1.1. Raw Materials. Service Provider and AstraZeneca will identify quantities and lead time of raw materials that comprise the bill of materials ("BOM") for the scale up from [**] to [**] as well as the implementation of process changes being implemented by AstraZeneca, referenced as "Process [**]". Work Order #5997-01 only included, as pass-through costs, raw materials for [**] and "Process [**]" for [**] Batches in Area [**] and [**] Batches in Area [**]. Estimated pass-through costs shall be updated based on the change in scale, process and number of Batches.

1.2 Drug Substance Manufacturing. The GMP Batches will be executed using a master batch record approved in writing by both Parties. The GMP Batches will be evaluated for release based upon the executed batch records, analytical release assays, and Product Specifications. Additionally, the drug substance manufacturing process will be scaled-up to [**] based upon Process [**].

1.3 Drug Substance Testing. The GMP Batches will be characterized, tested for in-process quality attributes, quality assurance ("QA") reviewed and evaluated for release using phase appropriate validated analytical methods. Analytical testing results will be provided as a Certificate of Analysis (CoA) after QA review and any associated deviation reports will be provided.

2. Deliverables, AstraZeneca Materials and Subcontractors.

2.1 Deliverables for Drug Substance Manufacturing: executed batch record per Batch, test results per Batch, CoA per Batch.

2.2 AstraZeneca Materials: AstraZeneca will provide to Service Provider the following materials for the Services (specifically for, Process [**]): [**], [**], lab notebooks, master batch records and other materials describing the current lab scale process, current lab scale bill of material, formulation description, formulation development history, stability data, as available, manufacturing process details, analytical methods, as available, corresponding primers, probes, and reference standards (when applicable).

2.3 Approved Subcontractors: Approved non-Affiliate subcontractors Service Provider will and/or may use to perform Services include:

[**]

3. Timeline.

The Service Provider presents the following nonbinding estimated timeline to represent the currently expected duration of activities which is subject to change at the Service Provider's sole discretion and/or due to the timing of events beyond the Service Provider's control, including but not limited to (i) the timing of the receipt of this executed Product Schedule and valid purchase order, and/or (ii) acquisition of materials and receipt of AstraZeneca Materials. All timelines set forth in this Product Schedule 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.

[**]

4. Service Fees.

4.1 The fees due to Service Provider for Services under this Work Order shall be as follows:

Area [**]

Drug Substance Manufacturing (Area [**] Initial Batches)					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**[**]**

Drug Substance Manufacturing (Area [**] Additional Batches)					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**[**]**

[**]

The capacity window to manufacture up to [**] Batches at the Bayview facility in Area [**] assuming Process [**] is [**] through [**] and assumes both an agreed upon campaign start date of [**] and availability of required raw materials. If the start date is adjusted, the Parties will agree, in writing via a Change Order, on the revised number of Batches to be manufactured during the available capacity window.

Area [**]

* [**] are subject to United States Government approval and all pricing set forth herein is in addition to payments payable to Service Provider by BARDA for Services under the Task Order such as BARDA Capacity Commitment Fees.

Drug Substance Manufacturing (Area [**] Initial Batches)					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**[**]**

Drug Substance Manufacturing (Area [**] Additional Batches)					
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, including raw materials.

The capacity window to manufacture up to [**] batches at the Bayview facility in Area [**] assuming Process [**] is [**] through [**], 2021 and assumes both an agreed upon campaign start date of [**] and availability of required raw materials and equipment. If the start date is

adjusted, the Parties will agree, in writing in a Change Order, on the revised number of Batches to be manufactured during the available capacity window.

Drug Substance Manufacturing (Area [**] Extended Batches)					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**$63,248,100**

[**]

The provisions in Clause 1.3.2 of the Master Services Agreement apply to the Extended Batches set forth in the table above. The Extended Batches shall only be included in the number of Batches of Product identified in this Product Schedule upon AstraZeneca's issuance of the Batch Exercise Notice in accordance with Clause 1.3.2 of the Master Services Agreement.

The Extended Batches capacity window to manufacture up to [**] batches at the Bayview facility in Area [**], subject to acceptance assuming Process [**] is [**] through [**] and assumes both a continuation of the previous campaign ending in [**], 2021 and availability of required raw materials and equipment. If the start date is adjusted and it is not an extension of the previous campaign, the Parties will agree, in writing in a Change Order, on the revised pricing and number of Batches to be manufactured during the available capacity window.

Summary

Total			
Task	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
Area [**] Manufacturing Summary	[**]	[**]	[**]
Area [**] Manufacturing Summary	[**]	[**]	[**]
Total	**[**]**	**[**]**	**$174,306,844**

4.2 AstraZeneca shall pay Service Provider all fees and costs set forth in this Product Schedule in accordance with the following payment schedule: (a) Service Provider will issue invoices for [**]% of all fees upfront upon initiation of the specified activity or task, with Service Provider issuing an invoice for the remaining [**]% upon completion of the applicable activity or task; and (b) Service Provider will issue invoices for [**]% of all pass-through costs plus the administrative fee of [**]% upon order placement for the materials, with the remaining [**]% to be invoiced upon Service Provider's receipt of the materials. Invoices shall be payable in accordance with the terms of the Master Services Agreement.

4.3 For clarity, AstraZeneca agrees to pay Service Provider to manufacture the number of Batches of Product identified in this Product Schedule. If, for any reason other than Service Provider's breach of the Master Services Agreement or Service Provider's inability to manufacture the number of Batches set forth herein within the time period(s) specified above, Service Provider manufactures less than the

number of Batches set forth herein, then AstraZeneca shall pay Service Provider a fee equal to the Batch price for the Product multiplied by the number of Batches set forth herein, less the total price paid for the manufacture of Product Batches actually manufactured.

5. Miscellaneous. All terms and conditions of the Master Services Agreement apply to this Product Schedule.

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Jarrett Palmer

Name: Jarrett Palmer
Title: Operations – BES Director

EMERGENT MANUFACTURING OPERATIONS

BALTIMORE, LLC

BY: /s/ Syed T Husain

Name: Syed T Husain
Title: SVP & CDMO BU Head

Exhibit 10.14

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

WORK ORDER #5997-01 - TECHNOLOGY TRANSFER, SCALE-UP, PPQ AND CAPACITY COMMITMENT OF COVID-19 VACCINE DRUG SUBSTANCE MANUFACTURING

Pursuant to Section 1.1 of the Master Services Agreement dated June 10, 2020, by and between AstraZeneca Pharmaceuticals LP ("**Client**") and Emergent Manufacturing Operations Baltimore, LLC ("**Service Provider**") and in consideration of the mutual promises contained therein and for other good and valuable consideration the receipt and adequacy of which each of the Parties does hereby acknowledge, the Parties hereby agree to amend Exhibit B by adding this Work Order entitled – TECHNOLOGY TRANSFER, SCALE-UP, PPQ AND CAPACITY COMMITMENT OF COVID-19 VACCINE DRUG SUBSTANCE MANUFACTURING, which is designated Work Order #01 (this "**Work Order**"). This Work Order is effective as of June 10, 2020 and shall terminate upon completion of the Services set forth in this Work Order, unless earlier terminated as permitted in the Master Services Agreement. Capitalized terms used in this Work Order that are not otherwise defined herein have the meanings given to them in the Master Services Agreement.

1. Services. Service Provider will render to Client the following Services:

1.1 Transfer the existing manufacturing process using an established technology transfer process, which leverages previous experience in transfer, scale-up and production. Additionally, a gap analysis will be performed covering knowledge and/or skill, equipment and material gaps, also a risk analysis and a risk management plan.

1.2 Drug Substance Scale-up Development. The Service Provider will generate a development cell bank (DCB) from a vial of master cell bank (MCB) or working cell bank (WCB). [**].

1.3 Bulk DS Concentration and Formulation Development. The current manufacturing process [**].

1.4 Analytical Development. Service Provider [**].

1.5 Method Robustness. [**].

1.6 Process Characterization. [**].

1.7 Drug Substance Manufacturing. [**].

1.8 Method Validations. [**].

1.9 DS and Optional DP Testing. [**].

[**].

1.10 Process Performance Qualification. [**].

2. Deliverables.

2.1 Development Services: [**].

2.2 Drug Substance Manufacturing: [**].

2.3 Materials: Client will provide to Service Provider the following materials for the Services: [**]; [**]; artwork and product information for label, carton and product insert; lab notebooks; master batch records and other materials describing the current lab scale process; current lab scale bill of material; formulation description; formulation development history; stability data, as available; manufacturing process details; analytical methods, as available; corresponding primers; probes; and reference standards (when applicable).

2.4 Timeline. The Service Provider presents the following nonbinding estimated timeline to represent the currently expected duration of activities which is subject to change at the Service Provider's sole discretion and/or due to the timing of events beyond the Service Provider's control, including but not limited to (i) the timing of the receipt of this executed Work Order and valid purchase order, and/or (ii) acquisition of materials and receipt of AstraZeneca Materials. All timelines set forth in this Work Order are estimated and based on a number of assumptions and currently known information. The Client 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 Client, timelines may be impacted.

[**]

3. Capacity Reservation.

3.1 For [**] through [**] in Area [**] (the AZ Initial Period Capacity).

Drug Substance Capacity Commitment				
Qty	**Task**	**Deliverable**	**Direct Fees**	**Line Total**
[**]	[**]	[**]	[**]	[**]
Subtotal				[**]

This total non-refundable, and except as expressly set forth in the Master Services Agreement, non-creditable capacity commitment fee of $[**] is payable at [**]% within [**] of execution of the Master Service Agreement by both parties. The remainder of the capacity commitment fee will be payable by [**]. The parties acknowledge and agree that the Service Provider is, in exchange for this payment, reserving capacity to perform services for the Client for up to [**] batches of drug substance at the Bayview facility in Area [**] assuming a cadence of [**] batches per reactor per month during the period between [**] and [**] and that this fee is in addition to the fees associated with such services and is in no circumstances refundable to Client.

3.2 For [**] through [**] in Area [**] (the BARDA Initial Period Capacity).

Drug Substance Capacity Commitment				
Qty	**Task**	**Deliverable**	**Direct Fees**	**Line Total**
[**]	[**]	[**]	Funded by USG	Funded by USG
Subtotal				Funded by USG

The reserved capacity to perform services for the Client for up to [**] batches of drug substance at the Bayview facility in Area [**] assuming a cadence of [**] batches per reactor per month during the period between [**] and [**] is funded by the USG.

3.3 For [**] through [**] in Area [**] (the Subsequent Period Capacity).

Drug Substance Capacity Commitment				
Qty	**Task**	**Deliverable**	**Direct Fees**	**Line Total**
[**]	[**]	[**]	Funded by USG	Funded by USG
Subtotal				**Funded by USG**

The reserved capacity to perform services for the Client for up to [**] batches of drug substance at the Bayview facility in Area [**] assuming a cadence of [**] batches per reactor per month during the period between [**] and [**] is funded by the USG.

4. Service Fees.

4.1 The fees due to Service Provider for Services under this Work Order shall be as follows:

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

Drug Substance Tasks: Tech Transfer					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			[**]	[**]	[**]

CONFIDENTIAL AND PROPRIETARY

Drug Substance Tasks: Manufacturing					
Engineering Run					
Qty	**Task**	**Deliverable**	**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**[**]**

Process Validation & PPQ Runs					
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
Subtotal			**[**]**	**[**]**	**[**]**

[**].

Optional Drug Product Tasks: Release Testing					
Qty	**Task**	**Deliverable**	**Direct Fees (Per Batch)**	**Est. Pass Through Costs (Per Batch)**	**Line Total (Qty x Per Batch)**
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

Price Matrix Summary				
Task		**Direct Fees**	**Est. Pass Through Costs**	**Line Total**
2020 Area [**] Capacity Commitment	Drug Substance	[**]		[**]
2020 Area [**] Capacity Commitment	Drug Substance	[**]		[**]
Development Services		[**]	[**]	[**]
Drug Substance Technical Transfer		[**]	[**]	[**]
Drug Substance Engineering		[**]	[**]	[**]
Drug Substance Manufacturing & PPQ		[**]	[**]	[**]
Subtotal		**[**]**	**[**]**	**$87,453,649**

4.2 The total non-refundable capacity commitment fee of $[**] is payable at [**]% within [**] of execution of the Master Service Agreement by both parties. The remainder of the capacity commitment fee will be payable by [**]. Client shall pay Service Provider all other fees and costs set forth in this Work Order (i.e. all fees and costs other than the capacity commitment fee) 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.

5. Miscellaneous. All terms and conditions of the Master Services Agreement apply to this Work Order.

[***Signature Page Follows***]

ASTRAZENECA PHARMACEUTICALS LP

BY: /s/ Jarrett Palmer

Name: Jarrett Palmer
Title: Operations – BES Director

EMERGENT MANUFACTURING OPERATIONS

BALTIMORE, LLC

BY: /s/ Syed T Husain

Name: Syed T Husain
Title: SVP & CDMO BU Head

CONFIDENTIAL AND PROPRIETARY

Exhibit 1: Total [**] volume and # bags [**].

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

Exhibit 2: Schematic of the Development Process

[**]

Exhibit 3: Characterization assays for [**] and process development

Method Description	Development
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

[**]

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

AMENDMENT TO MASTER SUPPLY AGREEMENT

This Amendment ("**Amendment**"), effective as of September 30, 2020 (the "**Amendment Effective Date**"), is to the Master Supply Agreement, effective as of July 24, 2020 (the "**Agreement**"), by and between AstraZeneca Pharmaceuticals LP, a Delaware limited partnership with offices at 1800 Concord Pike, Wilmington, Delaware 19803 ("**AstraZeneca**") and Emergent Manufacturing Operations Baltimore, LLC a Delaware limited liability company, with an office at 5901 East Lombard Street Baltimore, Maryland 21224 ("**Service Provider**"). AstraZeneca and Service Provider are sometimes referred to herein individually as a "**Party**" and, collectively, as the "**Parties**." Capitalized terms used but not defined herein shall have the meaning ascribed to them in the Agreement.

RECITALS

WHEREAS, Section 18.9 (Amendments and Modifications) of the Agreement provides that the Agreement may be amended by a written document signed by the Parties;

WHEREAS, the Parties desire to amend the Agreement, in accordance with the terms set forth in this Amendment, to extend the Option Deadline and modify the definition of "Extended Batches;"

NOW, THEREFORE, the Parties, intending to be legally bound, hereby agree as follows:

1. Section 1.3.3 of the Agreement is hereby amended and restated in its entirety to read as follows:

> 1.3.3 Furthermore, AstraZeneca, may, subject to the approval of the United States Government, and otherwise at its sole option, and in accordance with the terms set forth in Product Schedule #5997-02, elect to purchase, and upon such election, Service Provider agrees to manufacture, up to [**] additional Batches of Product drug substance in 'Area [**]' of Service Provider's Bayview facility (which Batches, the "**Extended Batches**", shall be in addition to the Initial Batches and the Additional Batches), by delivering written notice to Service Provider (the "**Batch Exercise Notice**") on or before [**] (the "**Option Deadline**"). If the number of Extended Batches elected by AstraZeneca pursuant to the Batch Exercise Notice is fewer than [**], the Parties will agree, in writing in a Change Order, on the revised pricing for the number of Extended Batches to be manufactured. Notwithstanding the foregoing, the Parties acknowledge and agree that: (i) the United States Government may require or direct Service Provider to offer or use the capacity for the Extended Batches to or for third party(ies) at any time, including prior to the Option Deadline; and (ii) if the United States Government does not consent (or indicates to AstraZeneca or Service Provider it will not provide such consent) or

AstraZeneca does not deliver the Batch Exercise Notice by the Option Deadline, Service Provider may offer and/or use the capacity for the Extended Batches to or for other customers of Service Provider or use such capacity for its own products at no additional cost to AstraZeneca and at no penalty to Service Provider. Pursuant to the Task Order, the United States Government has agreed to pay Service Provider the price to reserve the capacity for the Extended Batches.

2. Except as expressly amended hereby, the Agreement is in all respects ratified and confirmed and all the terms, conditions and provision thereof shall remain in full force and effect. This Amendment shall be deemed to be in full force and effect from the Amendment Effective Date.

[*Signatures Follow on a Separate Page*]

IN WITNESS WHEREOF, each Party has executed this Amendment as of the Amendment Effective Date.

AstraZeneca Pharmaceuticals LP
By: /s/Jarrett Palmer
Name: Jarrett Palmer
Title: Operations – BES Director

Emergent Manufacturing Operations Baltimore, LLC
By: /s/Syed T Husain
Name: Syed T Husain
Title: SVP & CDMO BU Head

Exhibit 10.16

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

MANUFACTURING SERVICES AGREEMENT

THIS MANUFACTURING SERVICES AGREEMENT is made and entered into July 1, 2020 (the "Effective Date") by and between Janssen Pharmaceuticals, Inc., a corporation organized under the laws of the State of Pennsylvania, with corporate offices at 1125 Trenton-Harbourton Road, Titusville, NJ 08560 ("Buyer"), and Emergent Manufacturing Operations Baltimore, LLC, a limited liability company organized under the laws of the State of Delaware, with offices at 5901 E. Lombard Street, Baltimore, MD 21224 ("Manufacturer").

RECITALS:

WHEREAS, pursuant to a Technology Transfer Letter Agreement between Buyer and Manufacturer dated April 20, 2020 (as amended from time to time, the "Technology Transfer Agreement"), the Parties agreed to work together to negotiate and enter into this Agreement; and

WHEREAS, Buyer desires to engage Manufacturer to perform certain Manufacturing Services, on the terms and conditions set forth below, and Manufacturer desires to perform such Services for Buyer.

AGREEMENT:

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants of all Parties set forth in this Agreement, all the Parties hereto agree as follows:

1. Definitions. Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, have the respective meanings set forth below:

1.1 "Affiliate" means, with respect to a party, any person or entity that controls, is controlled by or is under common control with such party. As used in this definition, "control" means (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity.

1.2 "Agreement" means this Manufacturing Services Agreement, together with all Appendices attached hereto, as amended from time to time by all the Parties in accordance with Section 14.10.

1.3 "Applicable Law" means all applicable ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any kind whatsoever of any Authority, as amended from time to time, including without limitation, cGMP (if applicable).

1.4 "Authority" and "Authorities" means the FDA [**] and any other government or regulatory authority or agency responsible for granting approvals for the performance of Services under

this Agreement or for issuing regulations pertaining to the Manufacture and/or use, distribution, sale, promotion or marketing of Product in the intended country of use as agreed to in writing by the Parties.

1.5 "Background IP" means Intellectual Property existing as of the Effective Date or developed independently of the activities under this Agreement that is under the control of either Party 1 and that is reasonably necessary for performing the activities under this Agreement. For the purposes of this definition "control" means ownership and/or the right to grant access or licenses to Third Parties.

1.6 "Batch" means a lot of bulk drug substance Product resulting from a single run of Product produced by a single execution of the instructions specified in the Master Batch Record.

1.7 "Batch Documentation" means the following documents for each Batch of Product: (a) Batch Record; (b) the Certificate of Analysis; (c) Manufacturer's deviation/investigation report(s); and (d) any other Batch documentation in Manufacturer's possession or control reasonably requested by Buyer.

1.8 "Batch Record" means the batch production and control record containing the set of detailed processing instructions which are to be followed by Manufacturer to produce one Batch of Product.

1.9 "Business Day" means any day that the commercial banks of the United States are open for business.

1.10 "Buyer Indemnitee" has the meaning set forth in Section 11.1.

1.11 "Buyer Supplied Items" means those items supplied by Buyer to Manufacturer in connection with the Services as set forth in Appendix 1, including the Cell Line and Virus Seed.

1.12 Cell Line" means the cell line supplied by Buyer to Manufacturer to perform the Services as identified in Appendix 1.

1.13 "Certificate of Analysis" means a document, signed by an authorized representative of Manufacturer, listing Batch or Product description, Batch or Product number, the Specifications for, and Test Methods applied to, Product, the results thereof, a pass/fail indication and an attestation as to whether the Batch or Product is conforming or non-conforming with the Specifications.

1.14 "cGMP" means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Authority, including any guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines) as may be promulgated by any such Authority including, with respect to the United States, the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 CFR §§ 210 and 211).

1.15 "Change Order" means a document executed by authorized representatives of both Parties that changes the scope of the Services, the Specifications and/or the price of the Services and which references this Agreement.

1.16 "Confidential Information" has the meaning set forth in Section 9.1.

1.17 "Defect" has the meaning set forth in Section 5.3.

1.18 "Drug Product" means the sterile filled vial end product containing the Product.

1.19 "[**]" means the [**].

1.20 "Equipment" means any equipment or machinery used by Manufacturer in the Manufacturing of Product.

1.21 "EXW" or "Ex Works" has the meaning set forth in INCOTERMS 2020.

1.22 "Facility" means the facility of Manufacturer located at 5901 E. Lombard Street, Baltimore, Maryland (Bayview).

1.23 "FDA" means the United States Food and Drug Administration, and any successor agency having substantially the same functions.

1.24 "FDCA" means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 et seq., as amended from time to time.

1.25 "Firm Order" shall have the meaning set forth in Section 2.7.

1.26 *"force majeure"* has the meaning set forth in Section 14.5.

1.27 "Forecast" shall have the meaning set forth in Section 2.6.

1.28 "Foreground IP" means all Intellectual Property discovered or developed in the performance of the activities set forth herein solely by or on behalf of Manufacturer or jointly with Buyer.

1.29 "IND" means an Investigational New Drug application filed with the FDA in accordance with Applicable Law.

1.30 "Intellectual Property" means all patents, trademarks, utility certificates and models, inventors' certificates, copyrights, database rights, designs, domain names, trade secrets, Know-How and any other proprietary rights, priority rights, prior user rights and all other rights of a like nature in each case whether registered or unregistered and in any jurisdiction.

1.31 **"**Know-How" means all of the following: manufacturing protocols and methods, product specifications, analytical methods and assays, processes, formulations, product designs, product plans, trade secrets, flow diagrams, chemical data, pharmacological data, pharmacokinetic data, toxicological data, pharmaceutical data, physical and analytical data, safety data, quality assurance data, quality control and clinical data, techniques, practical knowledge, skills, technical information, proprietary information and materials in possession of or developed by a Party.

1.32 "Manufacture" and "Manufacturing" means any steps, processes and activities necessary to produce bulk drug substance Product, including without limitation, the manufacturing, processing, packaging, labeling, quality control testing, and release of bulk drug substance Product.

1.33 "Manufacturer Indemnitee" has the meaning set forth in Section 11.2.

1.34 "Manufacturing Process" means any and all processes and activities (or any step in any process or activity) used or planned to be used by Manufacturer to Manufacture bulk drug substance Product, as evidenced in the Master Batch Record.

1.35 "Master Batch Record" means a master production and control record, mutually agreed upon by the Parties, containing a written description of the procedure to be followed for Manufacturing a Batch of Product including (but not limited to) the Specifications for the Product and all raw materials, ingredients and components there of (including Raw Materials and Buyer Supplied Items) and Test Methods.

1.36 "[**]" has the meaning set forth in Section [**].

1.37 "[**]" has the meaning set forth in Section [**].

1.38 "Party" and "Parties" means Buyer and/or Manufacturer as applicable.

1.39 "Product" means Ad26COVS1-JNJ-78436735, a recombinant, replication defective adenovirus type 26 (Ad26) vectored vaccine component encoding a SARS-CoV-2 produced in PER.C6® or PER.C6®[**] cells.

1.40 "Quality Agreement" has the meaning set forth in Section 4.3(a).

1.41 "Quality Review" means the review and disposition by Manufacturer's Quality Assurance Department of a Batch and the associated Batch Documentation.

1.42 "Raw Materials" means all cell banks, virus seeds, cell culturing media, single use equipment, chemicals, solvents, inactive ingredients, excipients, labels, bags, liners, tubing, filters and other single use or regularly replaced materials, and ingredients, solvents and other materials (including shipping components) required to be used in order to Manufacture the Product as set forth in the Master Batch Record, but excluding any Buyer Supplied Items.

1.43 "Recall" has the meaning set forth in Section 5.6.

1.44 "Records" has the meaning set forth in Section 4.4(a).

1.45 "Release Date" means the date on which the applicable Batch Documentation documents have been signed by Manufacturer and submitted to Buyer in accordance with Section 6.1 and the Batch is finished and ready to deliver.

1.46 "Services" means the Manufacturing services as described in this Agreement.

1.47 "Shipping Guidelines" means Manufacturer's written procedures approved by Buyer in writing that describe the methods of packaging Batches for shipment.

1.48 "Specifications" means the final release specifications for Product set forth in the Master Batch Record.

1.49 "Storage Guidelines" means Manufacturer's procedures approved by Buyer in writing that describe the methods of packaging, monitoring, and storing the Product, Raw Materials, Buyer Supplied Items and work-in-progress.

1.50 "Supply Committee" has the meaning set forth in Section 2.3.

1.51 "Technology Transfer Agreement" has the meaning set forth in the recitals.

1.52 "Test Methods" means a list of quality control analytical assays to be performed by Manufacturer in connection with Manufacturing the Product, as mutually agreed up by the Parties.

1.53 "Third Party" means any party other than the Parties.

1.54 "Third Party Intellectual Property Right" means all patents, patent applications, trademarks, and trade names, service marks, design rights, utility models, rights in computer software, database rights, moral rights, copyright, rights in inventions, rights in know-how, confidential information and trade secrets, unfair competition rights, in each case whether registered or unregistered and including applications for and renewals or extensions of such rights and any other similar or analogous right or form of protection in any country in the world, together with the right to apply for registration of such rights, which are owned, controlled, or held by a Third Party.

1.55 "Virus Seed" means the virus seed supplied by Buyer to Manufacturer to perform the Services as identified in Appendix 1.

2. Services.

2.1 Services. Manufacturer shall perform the Services in accordance with the terms of this Agreement and the Quality Agreement.

2.2 Changes. Changes to the scope or pricing of the Services (other than adjustments described by Section 7.7) or to the Specifications may be made only in a Change Order. To the extent that any such change affects the relative obligations and rights of the Parties or affects the fees, expenses and/or timelines of the Services, then such effects shall be documented in the Change Order. Both Parties agree to act in good faith when considering a proposed Change Order from the other Party. Each Party agrees to take commercially reasonable efforts to respond to requested Change Orders within [**] of receipt.

2.3 Supply Committee. Promptly following execution of this Agreement, a committee (the "Supply Committee") shall be established with appropriate membership from each Party, which shall (at minimum) include the Parties' respective project managers, which will convene on at least a [**] basis

during the [**] of the term of this Agreement and [**] thereafter, or at such intervals as the Parties may agree.

The purpose of the Supply Committee shall be to facilitate timely, accurate, and complete communication of matters affecting the Services under this Agreement and informal resolution of issues, including discussion of:

1. Forecasts (including deviations from prior Forecasts), trends and factors which have affected and may affect the accuracy of Forecasts;
2. Issues and problems that may affect the ability of the Parties to perform as expected; and
3. External factors which may affect the supply chain, such as material shortages, shipping delays, and the like.

The Supply Committee shall be comprised of production, quality, compliance, planning, and process engineering representatives of both Parties, and/or such other representatives as a Party may reasonably determine appropriate. In any event, the Supply Committee shall consist of an equal number of representatives of Buyer and Manufacturer.

In addition to the [**] meetings of the full Supply Committee, each Party's quality representative(s) on the Supply Committee, as well as any other representatives as a Party may reasonably determine appropriate, shall convene on a [**] basis during the term of the Agreement, or at an alternate interval as the Parties may agree, to review and discuss quality performance and metrics.

2.4 Sale and Purchase of Product. Subject to the terms and conditions of this Agreement, Manufacturer shall sell to Buyer, and Buyer shall purchase from Manufacturer, Product pursuant to Firm Orders as set forth in Section 2.7.

2.5 No Exclusivity. This Agreement is non-exclusive and Buyer may at any time contract with any Third Party(ies) or use its Affiliates for the manufacture of Product and Manufacturer shall not have any exclusive rights to be the sole manufacturer of Product. The Parties further acknowledge and agree that [**], provided that [**].

2.6 Forecasts. Commencing [**] prior to Contract Year 1 (as defined in Section 13.1 below) and thereafter on a [**] basis, Buyer shall submit to Manufacturer a written forecast of the quantity of Product that Buyer expects to order for [**] during the following [**] period, [**] (each, a "Forecast"). The parties agree that, subject to [**] as set forth below, (a) the quantity of Product [**] Forecast [**], and (b) [**] Forecast [**]. The [**] Forecast [**] in a Firm Order. Within [**] after receipt of each Forecast, [**], provided, however, that for Contract Years 3 through 5 [**].

2.7 Firm Orders. All purchases of Services under this Agreement shall be effected solely pursuant to a purchase order or other form agreed by the Parties specifying the number of Batches ordered. [**], Buyer shall submit a purchase order [**] during such Contract Year, [**] as set forth in Section 2.6 above (each a "Firm Order"). The Parties acknowledge that, [**], Buyer is not [**], and

Manufacturer is not [**] Firm Orders. Except as otherwise agreed to by the Parties, Buyer [**] Firm Order.

2.8 [**]. During the term of this Agreement Buyer shall [**], and Manufacturer is [**].

3. Subcontracting; Materials and Equipment.

3.1 Subcontracting. Manufacturer will not subcontract with any Third Party or Manufacturer Affiliate to perform any of its obligations under this Agreement without the prior written consent of Buyer, provided that no such written consent shall be required with respect to any allowed subcontractor under the Technology Transfer Agreement or to any subcontractor identified in Appendix 6 providing the services described therein. If Manufacturer subcontracts any of its obligations under this Agreement it will be solely responsible for the performance of any approved subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by Manufacturer itself under this Agreement. Manufacturer will cause any approved subcontractors to comply with the terms of this Agreement, as applicable, including without limitation, all confidentiality, quality assurance, regulatory and other obligations and requirements of Manufacturer set forth in this Agreement, and for the avoidance of doubt, Manufacturer shall enter into a quality agreement reasonably acceptable to Buyer with any such approved subcontractor, which shall require, among other things, that such subcontractor perform its services at the approved facility, validate equipment, and secure for Buyer the right to audit and inspect such subcontractor in a manner consistent with Buyer's right to audit and inspect Manufacturer.

3.2 Raw Materials. Unless specifically agreed to otherwise by the Parties in writing, Manufacturer will purchase, in accordance with the relevant Raw Materials specifications all Raw Materials insofar as required for Manufacturer to complete the Manufacture and delivery of Batches in accordance with the terms of this Agreement. [**]. The Master Batch Record and/or the Quality Agreement set forth any testing to be performed by Manufacturer on such Raw Materials or Buyer Supplied Items. Manufacturer shall perform such testing. Subject to such testing obligations, [**]. For the avoidance of doubt, [**] of this Agreement, [**] Raw Material.

3.3 Safety Stock. Within [**] following the Effective Date, or a later date mutually agreed to by the Parties, the Parties shall agree upon the types and amounts of safety stock and shall enter into an amendment to this Agreement to include such information in Appendix 1. After the date of such amendment and at all times during the term of this Agreement, Manufacturer shall maintain [**] safety stocks of those Raw Materials identified in Appendix 1 in the amount set forth in in Appendix 1. The Supply Committee shall discuss on a periodic basis the levels of safety stock to determine whether any adjustments with respect thereto are warranted, but no such adjustments may be made without the prior written consent of Manufacturer.

3.4 Buyer Supplied Items and Required Documentation. At least [**] prior to the commencement date of Manufacture for a Firm Order, Buyer, [**], shall cause to be delivered to the Facility the following items: (a) the quantity of Buyer Supplied Items as necessary to Manufacture the quantity of Product identified in a given Firm Order; and (b) if required by the Quality Agreement, a certificate of analysis for the Buyer Supplied Items; (c) if not previously provided, a Safety Data Sheet for the Buyer Supplied Items and the Product; and (d) a signed Master Batch Record if not previously

provided. Buyer shall ensure that all Buyer Supplied Items have been manufactured in accordance with cGMP and the relevant specifications set forth in the Master Batch Record. Manufacturer shall be responsible for maintaining all Buyer Supplied Items in accordance with the Storage Guidelines, Applicable Laws and cGMP. Manufacturer shall not transfer, deliver or otherwise provide or make available the Buyer Supplied Items (or any component thereof) to any Third Party that is not specifically authorized in advance and in writing by Buyer. Manufacturer shall not use the Buyer Supplied Items (or any component thereof) for any purpose except as contemplated by this Agreement, or as otherwise authorized in writing by Buyer. Buyer shall at all times retain legal title to and, [**], the Buyer Supplied Items. Upon Buyer's written request, [**], Manufacturer shall return any remaining Buyer Supplied Items in Manufacturer's possession to Buyer or its designee, Ex Works the Facility.

3.5 Additional Controls for Cell Line. Manufacturer shall implement the following controls and safeguards with respect to the Cell Line it receives:

a. [**].

b. [**].

c. Buyer shall have the right during the term of this Agreement to conduct periodic audits no more frequently than [**] at a mutually agreed upon time and date during Manufacturer's normal business hours to assess adherence to the Cell Line Procedures and Controls, and security controls, including, if applicable, review of inventory logs, access lists and related documentation; notwithstanding the foregoing, there shall be no limit on the number of for cause audits that may be performed by Buyer in a calendar year.

d. Manufacturer shall, [**], implement such additional procedures and controls with respect to the Cell Line as may be reasonably requested by Buyer [**].

e. [**] shall be set forth [**].

3.6 Additional Controls for Virus Seed. Manufacturer shall implement the following controls and safeguards with respect to the Virus Seed it receives:

a. [**].

b. [**].

c. Buyer shall have the right during the term of this Agreement to conduct periodic audits no more frequently than [**] at a mutually agreed upon time and date during Manufacturer's normal business hours to assess adherence to the Virus Seed Procedures and Controls, and security controls, including, if applicable, review of inventory logs, access lists and related documentation; notwithstanding the foregoing, there shall be no limit on the number of for cause audits that may be performed by Buyer in a calendar year.

d. Manufacturer shall, [**], implement such additional procedures and controls with respect to the Virus Seed as may be reasonably requested by Buyer [**].

e. [**] shall be set forth [**].

3.7 Business Continuity Plan. Manufacturer shall allow Buyer to inspect its Business Continuity Plan for the Facility at Manufacturer's location. Such plan shall be considered Confidential Information of Manufacturer.

3.8 Import and Export. Buyer shall be responsible for performing all activities and procedures as may be necessary for the importation of the Buyer Supplied Items required to be provided by Buyer to Manufacturer hereunder, and for the exportation of Product. Buyer shall be solely responsible for, and shall pay, all associated duties, taxes, and costs and shall comply with all applicable import and export laws.

3.9 Supply of Equipment.

a. Except with respect to [**], Manufacturer will supply all Equipment necessary to perform the Services.

b. The parties acknowledge and agree that [**]. The [**] Equipment and [**] Equipment are listed in Appendix 3 hereto. The Parties agree that Manufacturer shall [**] and Buyer shall [**], Manufacturer shall [**], Manufacturer shall [**], the Parties shall mutually determine, [**], whether Manufacturer [**]; provided, however, [**], the Parties agree that Manufacturer [**] of this Agreement [**].

4. Manufacture of Product.

4.1 Applicable Law. Manufacturer will comply with Applicable Law in performing Services.

4.2 Facility.

a. Performance of Services. Subject to Section 3.1, Manufacturer will perform all Services at the Facility, provide all staff necessary to perform the Services in accordance with the terms of this Agreement, hold at such Facility all Equipment and other items used in the Services, and will not change the location of the Facility or use any additional facility for the performance of Services under this Agreement without the prior written consent from Buyer. Manufacturer will maintain, at its own expense [**], the Facility and all Equipment required for the Manufacture of Product in a state of repair and operating efficiency consistent with the requirements of cGMP (if applicable) and Applicable Law.

b. Validation. Manufacturer will be responsible for performing all validation of the Facility, Equipment and cleaning and maintenance processes employed in the Manufacturing Process in accordance with cGMP (if applicable), Manufacturer's SOPs, the Quality Agreement, and Applicable Law. Manufacturer will also be responsible for ensuring that all such validated processes are carried out in accordance with their terms.

c. Licenses and Permits. Manufacturer shall be responsible for obtaining and maintaining any and all licenses or permits required by Authorities for Manufacturer to perform the Services as set forth in this Agreement (including but not limited to the Quality Agreement).

At Buyer's request, Manufacturer will provide Buyer with copies of all such licenses or permits, and Buyer will have the right to use any and all information contained in such licenses or permits in connection with regulatory approval of Product.

d. Access to Facility. With reasonable advance notice to Manufacturer and on mutually agreed upon dates and during normal business hours, during the term of this Agreement, Buyer shall have the right to (a) observe and consult with Manufacturer during the performance of Services under this Agreement, including without limitation the Manufacturing of any Batch of Product, in accordance with the Quality Agreement, (b) perform, directly or, subject to a confidentiality agreement [**], through its representatives, one (1) general audit/inspection of the Facility per [**], and (c) perform "for cause" audit(s) of the Facility in accordance with the terms of the Quality Agreement. Such audits shall (i) be limited to a maximum of [**] Buyer personnel or representatives, (ii) not occur in areas of the Facility when Manufacturer is conducting activities for other customers, and (iii) [**]. All Product and/or Manufacturing Process specific audits or inspections by Authorities other than the FDA or [**] associated with the territories/countries in which Buyer has marketing/sales responsibility must be agreed upon in advance by Manufacturer and any such agreed upon audits will be invoiced to Buyer in the amounts set forth in a Change Order. [**]. Manufacturer may require all Buyer personnel or representatives visiting or having access to the Facility to agree in writing to abide by all relevant Manufacturer standard policies, operating procedures, and security procedures as established by Manufacturer and communicated to Buyer. Buyer will also have the right, [**], to conduct "mock" pre-approval audits at mutually convenient times as documented in a Change Order, and Manufacturer agrees to cooperate with Buyer in such "mock audits" prior to approval of the Drug Product by FDA or [**] in connection with such mock audits.

e. Manufacturing Suite(s). [**], Manufacturer agrees that suites [**] in the Facility used to Manufacture the Product [**].

4.3 Quality.

a. Quality Agreement. Manufacturer and Buyer shall, within [**] following the Effective Date or a later date mutually agreed to by the Parties, enter into a global Quality Agreement regarding the quality assurance and control responsibilities of each Party with respect to the Product ("Quality Agreement").

b. Process/Specifications and Change Control. Any change or modification to the Manufacturing Process or Equipment or Specifications will be made only in accordance with the change control provisions of the Quality Agreement and pursuant to a Change Order. A Change Order shall detail the agreed upon changes and the cost or price associated therewith and shall only become effective when executed by both Parties. Both Parties agree to act in good faith and promptly when considering a Change Order request proposed by the other Party. Unless otherwise agreed to by the Parties, Manufacturer will continue performing the Services as set forth in this Agreement to the extent reasonably practicable and will not implement the Services as outlined in a Change Order request unless and until such Change Order is signed by both Parties. All mutually executed Change Orders will be implemented as soon as commercially practicable to do so. [**].

c. Improvements. Subject to subsections (a) and (b) above, throughout the term of this Agreement, either Party may submit to the other written proposals for the adoption, implementation, or development of any change, improvement or modification to the Manufacturing Process, Equipment or Specifications that would reduce costs or otherwise constitute an improvement in the Manufacture of Product. Any such written proposal shall be provided to all members of the Supply Committee of the other Party. If the parties mutually agree in writing to undertake to test or implement such improvement, the Parties shall enter into a Change Order with respect to such improvement which addresses issues, including but not limited to, regulatory matters, allocation of cost and expenses to test or implement, and any adjustment in price for Product that would result. If any such improvement, [**] of the Agreement [**] such improvement.

4.4 Records, Sample Retention and Stability Testing.

a. Records. Manufacturer shall keep complete and accurate records (including without limitation reports, Batch Documentation, data, and records of all information and results obtained from performance of Services) of the Services performed by it under this Agreement and the Quality Agreement (collectively, the "Records"). For the sake of clarity, Buyer shall own all information contained in the Master Batch Record and the information contained in the documents described in Section 1.7(a), (b) and (c), and all Product-specific information contained in the Records. Manufacturer will not transfer, deliver or otherwise provide any such Records to any Third Party, without the prior written approval of Buyer, unless otherwise required by Applicable Law. Records will be available at reasonable times for inspection, examination and copying by or on behalf of Buyer. Manufacturer shall retain and archive all of its respective original Records of the Manufacture of Product under this Agreement in accordance with cGMP (if applicable), the Quality Agreement, and Applicable Law, but in no case for less than a period of [**] following creation thereof. Upon Buyer's request [**], Manufacturer will promptly provide Buyer with copies of such Records.

b. Sample Retention. Manufacturer shall take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the Quality Agreement, samples of Product from the Manufacturing Process produced under this Agreement. Further, Manufacturer will submit such samples to Buyer, upon Buyer's written request and at Buyer's expense. Manufacturer shall label and store such samples in accordance with the Storage Guidelines, the Specifications, the Quality Agreement, cGMP and all Applicable Laws.

c. Stability Testing. Unless otherwise agreed to in a Change Order, Buyer will be solely responsible for any stability testing of the Product.

4.5 Regulatory Matters.

a. Regulatory Approvals. Buyer will be responsible for preparing, submitting, and obtaining, at its expense, all regulatory and governmental approvals and permits necessary for Buyer or its Affiliates to market, use or sell any Product Manufactured under this Agreement, including, without limitation, IND submissions, new drug applications, and any analogous submissions filed with the appropriate Authority of a country. Manufacturer will be

responsible for providing Buyer with all supporting data and information relating to the Manufacture of Product at the Facility in Manufacturer's possession, custody or control (including in the possession, custody or control of Manufacturer's Affiliates or Third Parties (including subcontractors) which is necessary for obtaining such approvals, including, without limitation, all Records, raw data, reports, authorizations, certificates, methodologies, Batch Documentation, Raw Material specifications, SOPs, standard test methods, Certificates of Analysis, and other documentation in its possession or under its control relating to the Manufacture of Product (or any component thereof). For clarity, under no circumstance shall Manufacturer be required to sign, as an applicant or in any other capacity, any filing with any Authority in any country relating to the approval, sale, use, or distribution of Product.

b. Drug Master Files. The parties agree that Buyer or its Affiliates shall, in Buyer's sole discretion, file any Drug Master Files ("DMFs") as necessary to support Buyer's or its Affiliate's or licensee's applications for marketing authorizations of Product. Manufacturer shall provide Buyer with all supporting data and information in Manufacturer's possession relating to the Manufacture of Product necessary for any DMF.

c. Regulatory Inspections. Manufacturer will permit Buyer or its agents to be present at any visit or inspection by any Authority of a Facility to the extent it relates solely to the Product or the Manufacturing Process in accordance with the Quality Agreement. Manufacturer will give as much advance notice as possible to Buyer of any such visit or inspection.

d. If Buyer requests documents or other work product that do not exist as of the date of such request, or makes other substantive requests for assistance in compiling any filing for an Authority, then the creation of such documents or work product shall be subject to a mutually acceptable Change Order setting forth such additional Services and the amounts payable by Buyer therefore.

4.6 Waste Disposal. The generation, collection, storage, handling, transportation, movement and release of hazardous materials and waste generated in connection with the Services will be the responsibility of Manufacturer at Manufacturer's sole cost and expense. Without limiting other applicable requirements, Manufacturer will prepare, execute and maintain, as the generator of waste, all licenses, registrations, approvals, authorizations, notices, shipping documents and waste manifests required under Applicable Law.

4.7 Safety Procedures. Manufacturer will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services. Manufacturer, in consultation with Buyer, will develop safety and handling procedures for Product; provided, however, that Buyer will have no responsibility for Manufacturer's health and safety program.

4.8 Technology Transfer. The Parties agree that Buyer may, during the term of this Agreement or upon termination or expiration of this Agreement, designate and qualify a Third Party or its Affiliates to manufacture bulk drug substance Product. In connection therewith, Manufacturer shall provide the assistance and support described in this Section for a period not to exceed [**] from the

written request for assistance by Buyer. If Buyer, using commercially reasonable efforts, is unable to qualify a Third Party or its Affiliate without participation by Manufacturer, Manufacturer shall provide Buyer reasonable assistance and support (including providing Manufacturing information in Manufacturer's possession and technical assistance and cooperation by the appropriate employees of Manufacturer) as necessary to assist in qualifying such Third Party or Affiliate. The Parties shall set forth in a Change Order or separate mutually acceptable written agreement executed by both Parties details with respect to the specific services to be provided by Manufacturer as well as the fees and expenses (if any) to be paid to Manufacturer by Buyer in connection therewith. [**].

4.9 Duty to Notify. If Manufacturer, at any time during the term of this Agreement, determines that it will be unable or unwilling to perform or complete the Services, it will promptly notify Buyer thereof. Compliance by Manufacturer with this Section 4.9 will not relieve Manufacturer of any other obligation or liability it otherwise has under this Agreement.

4.10 Failure to Supply. In the event that Manufacturer shall, or anticipates that it shall, fail to deliver [**] Product to be delivered [**], under one or more Firm Orders, [**] and Buyer elects to [**] Manufacturer shall promptly [**] of a Failure to Supply. For clarity, the Parties agree that [**] a Failure to Supply. [**] set forth in this Section 4.10 for a Failure to Supply [**].

4.11 Storage. Manufacturer shall label and store all Product, Raw Materials, Buyer Supplied Items and work-in-progress in its possession from the time of receipt at the Facility until delivery of the Product in accordance with the Storage Guidelines, the Specifications, the Quality Agreement, cGMP and all Applicable Laws. Manufacturer shall use the first-in first-out (FIFO) method of material usage, subject to the prudent and appropriate usage of the first expiring, first-out (FEFO) method, or unless otherwise directed in writing by Buyer. Manufacturer will implement and enforce reasonable security precautions to prevent any loss or theft of, or damage or unauthorized access to, the Products, Buyer Supplied Items, work-in-progress and Raw Materials while in the control of Manufacturer and shall ensure that stocks of Product are kept separate from and clearly distinguished from other stocks and supplies held by Manufacturer. Manufacturer shall store at the Facility a maximum of [**] of Product in final containers (combination of finished Product, work-in-progress and rejected Batches) at one time. Manufacturer shall request an emergency meeting of the Supply Committee if it believes it may exceed any capacity constraints with respect to storing Batches. The Parties agree to meet and discuss in good faith ways to increase storage capacity at the Facility. [**].

4.12 Substitution. In the event that the Parties mutually agree to substitute [**], the Parties shall enter into a written amendment to this Agreement to reflect such substitution, including but not limited to [**]. In such case, Manufacturer shall manufacture such [**] under this Agreement pursuant to any modified and/or additional terms that may be mutually agreed to by the parties in such written amendment.

5. Testing and Latent Defects.

5.1 Testing by Manufacturer. Manufacturer shall comply with cGMP, the Manufacturing Process, and the Quality Agreement in the Manufacture of the Product. Each Batch of Product will be sampled and tested by Manufacturer as set forth in the Master Batch Record using the Test Methods.

For the avoidance of doubt, the final decision and responsibility for use of Product in Drug Product shall remain with Buyer.

5.2 Provision of Records. If, based upon the Test Methods, a Batch of Product is found to have conformed to the Specifications, then a Certificate of Analysis will be completed and issued by the quality assurance department of Manufacturer to Buyer in accordance with the Quality Agreement. The Batch Documentation for each Batch of Product will be made available to Buyer upon request. Upon request, Manufacturer will also make available to Buyer all raw data, reports, authorizations, certificates, methodologies, Raw Material specifications, SOPs, standard Test Methods, and other documentation in the possession or under the control of Manufacturer relating to the Manufacture of each Batch of Product. If Buyer has not received all such Batch Documentation at the time of receipt of the Batch, Buyer will notify Manufacturer in writing. If Buyer requires additional copies of such Batch Documentation, Manufacturer shall provide them to Buyer promptly.

5.3 Latent Defects. Buyer shall notify Manufacturer in writing of any Product that fails to meet Specifications (a "Defect") within [**] of discovery of such Defect by Buyer, but no later than [**] after delivery of such Product to Buyer. In such case, Buyer shall also provide Manufacturer with a reasonable opportunity to inspect and/or test such Product.

5.4 Disputes Regarding Conformity. In case of any disagreement between Buyer and Manufacturer as to whether Product conforms to the applicable Specifications, the quality assurance representatives of Buyer and Manufacturer will attempt in good faith to resolve any such disagreement and Buyer and Manufacturer will follow their respective SOPs to determine the conformity of the Product to the Specifications. If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed [**]), a representative sample of such Product will be submitted to an independent testing laboratory mutually agreed upon by Buyer and Manufacturer for tests and final determination of whether such Product conforms with such Specifications. The laboratory must be of recognized standing in the industry, and consent to the appointment of such laboratory will not be unreasonably withheld or delayed by either Manufacturer or Buyer. Such laboratory will use the applicable Test Methods contained in the Master Batch Record. The determination of conformance by such laboratory with respect to all or part of such Product will be final and binding on all parties absent manifest error. The fees and expenses of the laboratory incurred in making such determination will be paid by Manufacturer, if the determination is made against Manufacturer, or by Buyer, if the determination is made against Buyer. The Parties agree that any dispute with respect to whether Product has been Manufactured in accordance with cGMP shall be subject to Section 14.12 (Governing Law and Dispute Resolution).

5.5 Product Defects and Remedies. If it is determined that Product does not meet the Specifications [**], then Manufacturer shall, [**], and as soon as it is commercially practical to do so following receipt of any required Raw Materials and, [**] Buyer Supplied Items, at Manufacturer's cost and expense, either (a) re-perform the Manufacturing Services for such Product at Manufacturer's sole cost and expense other than the original price for such Services; or (b) provide Buyer a credit for the amounts paid by Buyer to Manufacturer for such Product. [**]. The Parties acknowledge that obtaining a specific quantity of Product with respect to any Batches is not guaranteed by Manufacturer. [**].

5.6 Product Recalls. In the event (a) any Authority issues a request, directive or order that Drug Product be recalled, (b) a court of competent jurisdiction orders such a recall, or (c) Buyer or an Affiliate [**] determines that Drug Product should be recalled (in each case, a "Recall"), then Buyer shall promptly inform Manufacturer of such Recall and shall be responsible for conducting or responding to all Recalls. [**]that is subject to a Recall [**]related to the Recall, [**]any Recalls [**]. The Parties shall, [**], take all appropriate corrective actions, and shall cooperate in any governmental investigations surrounding the Recall. Manufacturer's obligation, if any, to provide replacement Product for recalled Batches is as set forth in Section 5.5.

6. Product Release and Delivery.

6.1 Release Documents. Manufacturer shall prepare the Batch Documentation specific to each Batch of Product, and shall submit them at Manufacturer's cost to Buyer within a reasonable time following completion of Manufacturing. Batch Documentation and applicable test results and results of environmental monitoring shall not be considered final until completion of Quality Review.

6.2 Delivery. Manufacturer shall deliver each shipment of Product hereunder Ex Works the Facility within [**] following the Release Date. Title to, and risk of loss of, the Product shall transfer to Buyer when Manufacturer makes the Batch available for pickup by Buyer's designated carrier. Each shipment shall be packed, marked, sealed, and delivered in accordance with the Shipping Guidelines. The shipment shall be labeled with a traceable batch number. The bill of lading shall list the gross weight and net weight of the shipment. Concurrent with each delivery of Product, Manufacturer shall provide Buyer with an electronic copy of the Certificate of Analysis and notice that the Product has been made available for pick up by Buyer's designated carrier, including the quantity of Product made available for shipment. For clarity, Batches delivered hereunder will be [**] the delivered Product.

6.3 Wood Pallets. This clause applies to all Product and/or materials shipped or delivered to Buyer, its Affiliates or authorized locations on wood pallets. Wood pallets must be constructed from lumber sourced from countries that prohibit the treatment of wood with any form of halophenol based chemicals (including but not limited to [**]). Wood pallets used must have been heat treated only in accordance with the Heat Treatment standards set forth in International Standards for Phytosanitary Measures Publication No. 15, 2009 Revision (ISPM 15). Additionally, the sourced lumber or finished pallets shall not be shipped or stored with pallets or materials that may contain the chemicals mentioned above. While ISPM 15 currently provides for the use of Methyl Bromide (MB), the use of pallets fumigated with Methyl Bromide is also prohibited. All wood pallets must be labeled with the HT stamp in accordance with ISPM 15 Annex II. Failure to meet the above requirements of this paragraph may lead to rejection of shipments at Manufacturer's expense.

7. Price and Payments.

7.1 Price. The prices to be paid by Buyer to Manufacturer during the term of this Agreement for Manufacturing each Batch of Product hereunder, and the fees and costs for any additional specified activities, shall be as set forth in Appendix 2 attached hereto, subject to adjustment only as expressly provided therein and in Section 7.7 below.

7.2 Invoice. All invoices must be submitted electronically by Manufacturer to Buyer or its designated Affiliate. Manufacturer shall invoice Buyer for each Batch as follows: [**]. If the Release Date is delayed solely due to the action(s) or inaction by Buyer, Buyer will be invoiced the any portion of the Batch price due to be invoiced on the Release Date when all requirements for release of such Batch which are within Manufacturer's control are complete. [**], Manufacturer shall invoice Buyer [**]. All invoices shall include (i) a reference to this Agreement, (ii) a description of the services or Products to which the invoice relates, (iii) the price, (iv) the relevant purchase order number (v) expenses and pass-through costs and (vi) sales or use taxes, if applicable. Buyer shall pay all undisputed, invoiced amounts by wire transfer to the account designated by Manufacturer within [**] of Buyer's receipt of the invoice.

7.3 Payments. All payments under this Agreement will be made in United States Dollars.

7.4 Invoice Records. Manufacturer will each keep accurate records of the invoice calculations for amounts invoiced by Manufacturer to Buyer for the Services, and, upon the request of Buyer, during the term of this Agreement will permit Buyer or, subject to execution of a confidentiality agreement acceptable to Manufacturer, its duly authorized agents to examine such records during normal business hours on a mutually agreed upon date for the purpose of verifying the correctness of all such invoiced amounts and related calculations.

7.5 Taxes. Duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of Services will be borne by Buyer (other than taxes based upon the income of Manufacturer).

7.6 Shipping. All prices are EXW the Facility. Buyer shall be solely responsible for all shipping costs and charges.

7.7 Pricing Adjustments. Commencing the calendar year after Contract Year [**], the Batch price for the Product and the price for any additional specified activities may be increased upon mutual agreement of the Parties [**] Appendix 2.

8. Intellectual Property Rights.

8.1 Nothing in this Agreement shall affect a Party's rights to its Intellectual Property nor imply grant of any license to a Party's Intellectual Property unless expressly set forth herein. Each Party agrees not to decompile, disassemble or otherwise reverse engineer any or all of the other Party's Background IP.

8.2 Manufacturer acknowledges and agrees that all Foreground IP shall be and shall at all times remain the sole and exclusive property of Buyer. Manufacturer and/or its agents, consultants, subcontractors and employees shall, without delay, inform Buyer of any Foreground IP and hereby assign or shall cause to be assigned free of any restrictions and/or additional remuneration and charges, to Buyer or its designee all rights to the Foreground IP. In the event that such assignment is not possible, for whatever reason, Manufacturer hereby grants, or shall grant, or cause to be granted, as the case may be, to Buyer an exclusive, worldwide, perpetual, irrevocable, unlimited, royalty-free and transferable license, with a right to sublicense, to Foreground IP. [**].

8.3 Buyer hereby grants to Manufacturer the royalty-free right to use its Background IP and any Foreground IP to the extent such is reasonably required for performing Services under this Agreement.

8.4 Manufacture shall not incorporate any Manufacturer Background IP into the Product or the Manufacturing Process. If, after the Effective Date, Manufacturer determines that it must incorporate any Manufacturer Background IP into the Product or the Manufacturing Process, it shall first notify Buyer in writing and obtain Buyer's written consent. If Buyer provides its written consent, and Manufacturer incorporates Manufacturer Background IP into the Product or the Manufacturing Process, Manufacturer grants to Buyer a non-exclusive, perpetual, irrevocable, fully paid-up, worldwide license, with the right to sub-license, to use Manufacturer's Background IP only to the extent necessary for Buyer to Manufacture Product or to have Product manufactured by a Third Party (including an Affiliate of Buyer) on Buyer's behalf. Manufacturer acknowledges and agrees that any license granted to Buyer pursuant to this Section 8.4 shall survive the expiration or termination of this Agreement.

8.5 Buyer will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend at its sole expense, any patents that claim and/or cover the Foreground IP.

8.6 Each Party shall promptly inform the other Party if it receives written notice of any claim or potential claim or allegation relating to infringement or alleged infringement of any Third Party Intellectual Property Right by virtue of Buyer's or Manufacturer's use of the Buyer Supplied Items or the Manufacture of Product.

9. Confidentiality.

9.1 Definition of Confidential Information. As used herein, "Confidential Information" includes all information given to one party (the "Receiving Party") or its Affiliates by the other party or its Affiliates (the "Disclosing Party") or otherwise acquired, whether orally, visually, electronically, in writing or otherwise, by the Receiving Party or its Affiliates, in connection with this Agreement, and all information derived or generated therefrom, including (a) information regarding any of the products of the Disclosing Party or any of its Affiliates, (b) information regarding costs, productivity or technological advances and (c) this Agreement, any services and any other information in connection therewith. Confidential Information also includes any information given to Manufacturer or its Affiliates by Buyer or its Affiliates with respect to any potential manufacturing or other services Manufacturer or its Affiliates may provide, regardless of whether Manufacturer or its Affiliates actually provides any such manufacturing or services, including any discussions between such entities with respect thereto and all information derived or generated therefrom.

9.2 Exceptions. The Receiving Party has no obligation to protect the following categories of Disclosing Party information: (a) information that is or was independently developed by the Receiving Party without use of or reference to any of the Disclosing Party's Confidential Information, (b) information that is or was lawfully received from a third party without any restriction on use; or (c) information that becomes or was a part of the public domain through no breach of this Section 9 (Confidentiality) by the Receiving Party.

9.3 Restrictions on Use and Disclosure. The Receiving Party shall not, except as otherwise provided below (a) use or reproduce the Disclosing Party's Confidential Information for any purpose other than as required to perform the obligations or exercise the rights granted in connection with this Agreement or (b) disclose the Disclosing Party's Confidential Information to any third party, without the prior written approval of the Disclosing Party, except to personnel, consultants, agents and representatives of the Receiving Party or its Affiliates who have a need to know such information in connection with the performance of this Agreement; provided the Receiving Party shall be responsible for any actions of such parties that would be in breach of this Agreement if done by the Receiving Party. Notwithstanding the foregoing, the Receiving Party may disclose the Disclosing Party's Confidential Information to the extent such information is required to be disclosed by law, including a subpoena, or to respond to a regulatory request; provided that the Receiving Party promptly notifies the Disclosing Party in writing prior to any disclosure to allow the Disclosing Party to seek a protective order or similar relief in the Disclosing Party's sole discretion.

9.4 Protection of Confidential Information. The Receiving Party shall (a) use at least the same degree of care that the Receiving Party uses to protect its own proprietary information of a similar nature and value, but no less than reasonable care to protect and maintain the Disclosing Party's Confidential Information and (b) as requested by the Disclosing Party, return or destroy all of the Disclosing Party's Confidential Information in the Receiving Party's possession or control. Nothing in this Section 9.4 shall require the destruction or alteration of computer back-up tapes or similar storage made in the ordinary course of the Receiving Party's business that contain the Disclosing Party's Confidential Information, provided that Receiving Party shall continue to comply with its obligations herein with respect to such Confidential Information. The obligations set forth in Sections 9.3, 9.4 and 9.6 shall survive for a period of [**] from the expiration or termination of this Agreement; provided however, that the obligations shall continue indefinitely for any Confidential Information that qualifies as a trade secret for so long as such information qualifies as a trade secret.

9.5 Ownership of Confidential Information. The Receiving Party acknowledges that, except as otherwise provided below, and as between the Parties (a) the Disclosing Party is the exclusive owner of and has all rights to its Confidential Information, including all intellectual property rights therein, such as patents, copyrights, trade secrets, trademarks, moral rights and similar rights of any type under the laws of any governmental authority, and (b) no right, title, interest or license to the Receiving Party is either granted or implied under any rights outlined in subsection (a) of this Section 9.5 or any other intellectual property rights or other technical and proprietary materials, information and techniques by the disclosure of Confidential Information hereunder.

9.6 Other Customers. Notwithstanding any provision to the contrary in this Agreement, Manufacturer shall not use Buyer's or its Affiliates' Confidential Information to produce (including, without limitation, manufacture, process, package, label, quality control test, stability test, release, store and/or supply) any product for any other customer of Manufacturer.

9.7 No Publicity. Except where required by law, neither Party may originate any publicity, news release, technical article, advertising or other announcement, written or oral, whether made to the public press or others (each, an "Announcement"), relating to performance under this Agreement or the existence of this Agreement between the Parties without the prior written consent of the other Party,

such consent not to be unreasonably withheld or delayed. If required by law to make any Announcement, the Party required to do so shall, to the extent permitted by law (a) consult with the other Party in connection with said Announcement a reasonable time prior to its release to allow the other Party to comment thereon and to prevent its release if so permitted by law; and (b) promptly provide the other Party with a copy of the released Announcement and all materials relating thereto. Without limiting the foregoing, neither Party may use the names, logos or trademarks of the other Party or its affiliates for any advertising or promotional purposes.

9.8 Publications. Notwithstanding any provision to the contrary in this Agreement (including Section 9.7 (No Publicity), Buyer shall have the right to publish or present the results of activities performed under this Agreement and the Technology Transfer Agreement; provided that any such publication or presentation shall not include any Manufacturer Confidential Information.

10. Representations and Warranties.

10.1 Manufacturer's Representations and Warranties. Manufacturer represents and warrants to Buyer that:

a. it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, inconsistent with the provisions of this Agreement;

b. the Services will be performed using a customary professional standard of requisite care, skill and diligence, in accordance with Applicable Law, and by individuals who are appropriately trained and qualified;

c. it will perform the Services in accordance with cGMP and the Quality Agreement;

d. solely to the extent Manufacturer incorporates its Background IP into the Product or Manufacturing Process as contemplated in Section 8.4, to Manufacturer's knowledge the Manufacturer Background IP does not infringe any Third Party Intellectual Property Right;

e. at the time of delivery to Buyer, the Product Manufactured under this Agreement will not, due to the fault of Manufacturer, be adulterated or misbranded under the FDCA or other Applicable Law. Notwithstanding, Manufacturer disclaims any representation or warranty with respect to the Buyer Supplied Items and any components, materials, specifications and instructions provided by Buyer;

f. neither Manufacturer, its Affiliates or approved subcontractors, nor any of their respective officers or any person used by Manufacturer, its Affiliates or approved subcontractors to perform Services under this Agreement, (i) has been debarred, or is subject to a pending debarment, or will use in any capacity in connection with the Services any person who has been debarred pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, (ii) has been listed by any federal and/or state agencies, excluded, debarred, suspended or otherwise been made ineligible to participate in federal or state healthcare programs or federal procurement or non-

procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), (iii) has been convicted of a criminal offense related to the provision of healthcare items or services or (iv) is subject to any such pending action, or is the subject of a conviction or pending action described in such sections. Manufacturer agrees to notify Buyer in writing immediately if Manufacturer, its Affiliates or approved subcontractors, or any of their respective officers or any person used by Manufacturer, its Affiliates or approved subcontractors to perform Services under this Agreement is subject to any of the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Manufacturer's, its Affiliates', or approved subcontractor's knowledge, is threatened;

g. it has, or shall obtain, and shall maintain all Facility licenses and permits (and Manufacturer shall provide Buyer with a copy of all such licenses, and permits upon request) with respect to its manufacturing, packaging and storing processes, facilities or otherwise, to permit the performance of its obligations hereunder in accordance with all Applicable Law;

h. it shall comply with the obligations and requirements set forth in Appendix 5 (Data Safeguards); and

i. in performing under this Agreement, Manufacturer agrees to adhere to the Johnson & Johnson Responsibility Standards for Suppliers which is in effect on the date of this Agreement (posted on JNJ.com: https://www.jnj.com/partners/responsibility-standards-for-suppliers).

10.2 Buyer Representations and Warranties. Buyer represents and warrants to Manufacturer that:

a. it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, inconsistent with the provisions of this Agreement;

b. to the best of Buyer's knowledge at the time of signature of this Agreement, the Buyer Background IP does not infringe any Third Party Intellectual Property Right; and

(c)(i) no Third Party has filed, pursued, maintained, or threatened in writing to file, pursue, or maintain any claim, lawsuit, charge, complaint, or other action alleging infringement of any Third Party Intellectual Property Rights based on the Product or the Manufacture, use, import, export, offer for sale, sale, or distribution of the Product; (ii) its supply to Manufacturer of the Buyer Supplied Items, Buyer Confidential Information and Manufacturing Process, and Manufacturer's use thereof in accordance with the terms of and in performance of its obligations under this Agreement, does not infringe any Third Party Intellectual Property Rights; and (iii) the Product, or the Manufacture, use, import, export, offer for sale, sale, or distribution thereof, does not and will not violate any Third Party Intellectual Property Rights, and Buyer is not engaged in the theft or misuse of any Third Party's trade secret information regarding the Manufacture, use, import, export, offer for sale, sale, or distribution of Product. Subject to Buyer's indemnification obligations hereunder, the Parties agree that

Manufacturer's remedy for a breach of this representation by Buyer shall be limited to termination of this Agreement in accordance with Section 13.2(b)(ii); and

d. as of the Effective Date, there is no action or proceeding by the FDA or any other Authority pending or threatened against Buyer relating to safety or efficacy of the Product.

10.3 Disclaimer of Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT, WHETHER ARISING FROM A COURSE OF DEALING OR FROM CUSTOM IN THE TRADE. MANUFACTURER HAS NOT PARTICIPATED IN THE RESEARCH OR DEVELOPMENT OF THE PRODUCT AND HAS NOT, IN ANY WAY, EVALUATED THE PRODUCT'S SAFETY OR EFFICACY IN HUMANS OR ANIMALS.

11. Indemnification/ Limitation of Liability.

11.1 Indemnification by Manufacturer. Subject to the limitations set forth in Section 11.5, Manufacturer will indemnify, defend and hold harmless Buyer, its Affiliates, and their respective officers, directors, employees, and agents (each a "Buyer Indemnitee") from and against any and all losses, damages, liabilities or expenses (including reasonable attorneys' fees and other costs of defense (collectively "Losses") resulting from any and all actions, suits, claims or demands that may be brought or instituted against any Buyer Indemnitee by any Third Party to the extent based on, arising out of, or resulting from, any (a) breach by Manufacturer of its agreements, representations, warranties or covenants under this Agreement, or (b) negligence or the willful misconduct of any Manufacturer Indemnitees in performing its obligations under this Agreement. Notwithstanding the foregoing, Manufacturer shall not be liable for Losses to the extent such Losses are caused by the negligence or willful misconduct of any Buyer Indemnitee or breach of any of the terms of this Agreement by Buyer.

11.2 Indemnification by Buyer. Buyer will indemnify, defend and hold harmless Manufacturer, its Affiliates and their respective officers, directors, employees and agents (each a "Manufacturer Indemnitee") from and against any and all Losses resulting from any and all actions, suits, claims or demands that may be brought or instituted against any Manufacturer Indemnitee by any Third Party to the extent based on, or arising out of, or resulting from (a) the promotion, handling, distribution, import and export, marketing, sale, or use of Product by Buyer or any Third Party, including without limitation any product liability claim; (b) any breach by Buyer of its agreements, representations, warranties or covenants under this Agreement, (c) negligence or the willful misconduct of any Buyer Indemnitees in performing obligations under this Agreement; (d) any alleged or actual infringement or misappropriation of Third Party Intellectual Property Rights in the performance of the Services, in the Product or any portion thereof, in the Manufacture of the Product, or resulting from the use of any Buyer Supplied Items, in the performance of this Agreement; [**]. Notwithstanding the foregoing, Buyer shall not be liable for Losses to the extent such Losses are caused by the negligence or willful misconduct of any Manufacturer Indemnitee or breach of any of the terms of this Agreement by Manufacturer.

11.3 Procedures. Each indemnifying party agrees to promptly notify the indemnified party (within no more than [**]) of receipt of any claims made for which the indemnifying party might be liable under Section 11.1 or 11.2, as the case may be, provided that the failure of such timely notice shall not bar any claim pursuant to Section 11.1 or 11.2 unless the indemnifying party shall be materially prejudiced by failure to receive such timely notice. Subject to Section 11.4, the indemnifying party will have the right to defend, negotiate, and settle such claims. The party seeking indemnification will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party. The indemnified party shall be entitled to participate in the defense of such matter and to employ counsel at its own expense to assist therein; provided, however, that the indemnifying party shall have final decision-making authority regarding all aspects of the defense of any claim. The parties understand that no insurance deductible will be credited against losses for which an indemnifying party is responsible under this Section 11.

11.4 Settlement. An indemnified party will not be responsible or bound by any settlement of any claim or suit made without its prior written consent; provided, however, that the indemnified party will not unreasonably withhold or delay such consent. If a settlement contains an absolute waiver of liability for the indemnified party, and the indemnified party and indemnifying party have acted in compliance with the other requirements of this Section 11, then the indemnified party's consent will be deemed given. Notwithstanding the foregoing, (a) Manufacturer will not agree to settle any claim on such terms or conditions as would impair Buyer's ability or right (or the ability or right of a Buyer Affiliate or Third Party) to Manufacture, market, sell or otherwise use Product; and (b) Buyer will not agree to settle any claim on such terms or conditions as would impair Manufacturer's ability or right to perform manufacturing services for any Third Party or itself or its Affiliates.

11.5 Limitation of Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED BY LAW:

a. IN NO EVENT [**] HAVE ANY LIABILITY FOR [**] EXCEPT TO THE EXTENT [**], IN WHICH EVENT [**] LIABILITY FOR [**] HEREUNDER [**]. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, [**] LIABILITY FOR [**], EXCEPT TO THE EXTENT [**] IN WHICH EVENT [**] WILL BE SUBJECT TO [**] THIS SECTION 11.5(a).

b. IN NO EVENT SHALL [**] BE LIABLE UNDER THIS AGREEMENT [**] FOR [**], INCLUDING ANY [**]. FOR AVOIDANCE OF DOUBT, THE PARTIES AGREE THAT [**]. THE LIMITATIONS OF THIS SECTION 11.5(b) [**].

c. EXCEPT TO THE EXTENT [**] SHALL BE BORNE BY [**].

d. IN ADDITION TO THE FOREGOING, [**] TO [**] FOR [**] IS [**] TO [**].

e. [**] TO [**] FOR [**] IS [**] TO [**].

12. Insurance.

12.1 Manufacturer Insurance. Manufacturer will secure and maintain in full force and effect throughout the term of this Agreement (and for at least [**] thereafter for claims made coverage), insurance with coverage and minimum policy limits set forth as follows:

a. *Worker's Compensation*, including coverage for occupational disease, with benefits determined by statute;

b. *Comprehensive General Liability*, including coverage for contractual liability assumed by Manufacturer and coverage for Manufacturer's independent contractor(s), with per occurrence limits of [**] each and a general aggregate limit of [**];

c. *Products Liability*, exclusive of the coverage provided by the Comprehensive General Liability policy, with an aggregate limit of [**]; and

d. *Comprehensive Automobile Liability*, *Employer's Liability, and Umbrella Liability*, in such amounts and under such terms as are customary for similar companies providing like services.

12.2 Buyer Insurance. JANSSEN will maintain, at its sole cost, reasonable insurance against liability and other risks associated with its activities contemplated by this Agreement, including but not limited to commercial general liability and product liability consistent with the normal and customary practices of companies of similar size, nature and scope.

12.3 Evidence of Insurance. Each Party will, upon request, furnish to the other Party evidence of insurance in the form of a certificate of insurance upon written request therefor and will provide [**] advance written notice in the event of any insurance cancellation.

13. Term and Termination.

13.1 Term. This Agreement will take effect as of the Effective Date and, unless earlier terminated [**] Appendix 2 [**] this Section 13, will expire at the conclusion of Contract Year 5. Each "Contract Year" is a twelve (12) month period. Contract Year 1 shall begin on [**]. The term of this Agreement may be extended by for an additional two (2) year period upon mutual agreement of the Parties as set forth in an amendment to this Agreement.

13.2 Termination by Either Party.

a. By Buyer. Buyer will have the right to terminate this Agreement by written notice to Manufacturer, upon the occurrence of any of the following:

i. Manufacturer files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [**]);

ii. Manufacturer fails to start and diligently pursue the cure of a material breach by it of this Agreement within [**] after receiving written notice from Buyer of such breach;

iii. a *force majeure* event that will, or continues to, prevent performance (in whole or substantial part) by Manufacturer of any obligation owed by it under this Agreement for a period of at least [**];

iv. the Drug Product fails to meet the primary endpoints of the [**] trials prior to Product approval by an Authority; provided that Buyer shall provide at least [**] prior written notice of any termination under this item (iv); or

v. Buyer decides to withdraw the Drug Product from sale, whether because of Buyer's decision to (partially or completely) stop the sale of the Drug Product or to sell the rights to the Drug Product to a Third Party or for any other reason, provided that Buyer shall provide at least [**] advance written notice of any termination under this item (v).

b. By Manufacturer. Manufacturer will have the right to terminate this Agreement, by written notice by to Buyer, upon the occurrence of any of the following:

i. Buyer files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [**]);

ii. Buyer fails to cure a material breach by it of this Agreement within [**] after receiving written notice from Manufacturer of such breach; or (ii) a *force majeure* event that will, or continues to, prevent performance (in whole or substantial part) by Buyer of any obligation owed by it under this Agreement for a period of at least [**].

13.3 Effect of Termination. Upon notification of termination, Manufacturer will promptly cease performance of the Services and will take all reasonable steps to mitigate the out-of-pocket expenses incurred in connection therewith. In particular, Manufacturer will [**] to:

a. immediately cancel, to the extent possible, any Third Party obligations (unless agreed by Buyer in writing);

b. promptly inform Buyer of any irrevocable commitments made in connection with any pending Firm Order(s) prior to termination;

c. promptly return to the vendor for a refund, to the extent possible, all unused, unopened Raw Materials in Manufacturer's possession that are related to any pending Firm Order for which Manufacturer will not complete Services as of the effective date of the termination;

d. promptly inform Buyer of the cost of any remaining unused, unreturnable Raw Materials ordered pursuant to any pending Firm Order(s);

e. perform only those services and activities mutually agreed upon by Buyer and Manufacturer as being necessary or advisable in connection with the close-out of any pending Firm Order(s); and

f. as mutually agreed by the Parties, place orders for Raw Materials solely as necessary to close out any pending Firm Order.

13.4 Payment upon Termination.

13.4.1 Termination of this Agreement, for whatever reason, shall not affect the obligation of either Party to make any payments for which it is liable prior to or upon such termination.

13.4.2 Upon expiration or termination of this Agreement, Buyer shall be responsible for (a) all amounts due for any Services completed as of the date of termination, including but not limited to the [**] for any Raw Materials purchased by Manufacturer pursuant to Section 3.2 prior to the notice of termination or pursuant to Section 13.3(f) prior to the date of expiration or termination of this Agreement and/or all non-cancelable orders for Raw Materials placed by Manufacturer pursuant to Section 3.2 prior to the notice of termination or pursuant to Section 13.3(f) prior to the date of expiration or termination of this Agreement; and (b) all amounts payable for additional specified activities that have been performed prior to the termination date or are in progress as of the termination date; [**] the Agreement is terminated. Additionally, subject to [**] shall pay to [**] terminates this Agreement [**] shall pay to [**]. For example, [**] terminates this Agreement pursuant to [**] would pay [**]. Manufacturer shall issue an invoice for any payment due under this Section 13.4 within [**] of the termination date and Buyer shall pay [**] within [**].

13.5 Batches in Process; Storage. Batches that are in process as of the effective date of any expiration or termination hereunder shall not be cancelled without the mutual agreement of the Parties and this Agreement shall continue to survive with respect to those in-process Batches. Batches that have been fully Manufactured as of the date of such expiration or termination, but for which Quality Review has not been completed, shall remain subject to the terms of this Agreement. If any such Batches remains at the Facility for a period longer than [**] after its applicable Release Date, Buyer shall pay storage fees for such Batch(es) as set forth in Section 4.11.

13.6 Return of Materials/Confidential Information/Equipment. Upon the expiration or termination of this Agreement, (i) each party will promptly return all Confidential Information of the disclosing party that it has received pursuant to this Agreement except that Manufacturer may retain Batch Documentation as required to comply with cGMP or other Applicable Law; and (ii) Manufacturer shall promptly deliver to Buyer all Specifications (and copies thereof) provided by Buyer except as otherwise required by Applicable Law, all remaining unused Raw Materials paid for by Buyer and Buyer Supplied Items, [**].

13.7 Payment Reconciliation. Within [**] after the close-out of activities mutually agreed upon by the parties upon termination of this Agreement, Manufacturer will

provide to Buyer a written itemized statement of all work performed by Manufacturer in connection with such close-out activities, an itemized breakdown of the fees and costs associated with that work, and a final invoice. [**].

13.8 Licenses and Bankruptcy. If this Agreement is terminated by a Party (the "Non-Bankrupt Party") pursuant to Section 13.2(a)(i) or Section 13.2(b)(i) due to the rejection of this Agreement by or on behalf of the other Party (the "Bankrupt Party") under Section 365 of the United States Bankruptcy Code (the "Bankruptcy Code"), all licenses and rights to licenses granted pursuant to this Agreement by the Bankrupt Party to the Non-Bankrupt Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. All parties agree that the Non-Bankrupt Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code and that the foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other applicable law.

13.9 Survival. Any expiration or termination of this Agreement shall not release any Party from any liability which at such time had already accrued or thereafter accrues from a breach or default prior to such expiration or termination nor affect the survival of any right, duty or obligation of any Party that is stated to survive termination or expiration or by its nature survives termination or expiration. The following Sections shall survive termination or expiration of this Agreement: Sections 3.9(b), 4.8, 5.6, 7.2, 8 through 11, 12 (for the periods specified therein), 13.3 through 13.9, 14.6, 14.12 through 14.13, and 14.17 through 14.19, including the appendices referenced and incorporated therein.

14. Miscellaneous.

14.1 Currency. Unless otherwise indicated, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

14.2 Independent Contractor. All Services will be rendered by Manufacturer as an independent contractor and this Agreement does not create an employer-employee relationship between Buyer and Manufacturer. Neither Party shall in any way represent itself to be a partner or joint venturer of or with the other Party.

14.3 Key Performance Indicators. During the term of this Agreement, the Parties may track and monitor each Party's performance under this Agreement against the "Key Performance Indicators" specified in Appendix 4 and shall use such data for discussion purposes at meetings of the Supply Committee, provided that neither Party shall provide any such data to Third Parties without the other Party's prior written consent.

14.4 Anti-Corruption Compliance. Neither Party shall perform any actions that are prohibited by local and other anti-corruption laws (including the U.S. Foreign Corrupt Practices Act, collectively "Anti-Corruption Laws") that may be applicable to one or both Parties to the Agreement. Without limiting the foregoing, neither Party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate

for political office or to any other Third Party related to the transaction in a manner that would violate Anti-Corruption Laws.

14.5 Force Majeure. Except as otherwise expressly set forth in this Agreement, a Party will not have breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than payment obligations) when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including, without limitation, fire, floods, embargoes, shortages, epidemics or pandemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, acts of God or acts, omissions, or delays in acting, by any governmental authority *("force majeure")*. The Party affected by any event of *force majeure* will promptly notify the other Party, explaining the nature, details and expected duration thereof. Such Party will also notify the other Party from time to time as to when the affected Party reasonably expects to resume performance in whole or in part of its obligations under this Agreement, and to notify the other Party of the cessation of any such event. A Party affected by an event of *force majeure* will use its commercially reasonable efforts to remedy, remove, or mitigate such event and the effects thereof with all reasonable dispatch. Upon termination of the event of *force majeure*, the performance of any suspended obligation or duty will promptly recommence.

14.6 Notices. All notices must be written and sent to the addresses or facsimile numbers identified below or in a subsequent notice. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid internationally recognized courier air delivery service (e.g., Federal Express). Notices will be effective upon receipt or at a later date stated in the notice.

If to Buyer to:
Janssen Pharmaceuticals, Inc.
Attn: President, Janssen Supply Chain
1125 Trenton-Harbourton Road
Titusville, NJ 08560

With a copy to:

With a copy to:
Johnson & Johnson
Office of General Counsel
Attn: Counsel for Janssen Supply Chain
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Janssen Supply Group, LLC
Attn: VP Partnership & External Supply
1125 Trenton-Harbourton Road
Titusville, NJ 08560

If to Manufacturer:

Emergent BioSolutions Inc.
400 Professional Drive, Suite 400
Gaithersburg, Maryland 20879
Attention: SVP, BU Head CDMO
Email: [**]

With a copy to:
Emergent BioSolutions Inc.
400 Professional Drive, Suite 400
Gaithersburg, MD 20879
Attention: General Counsel

14.7 Assignment. This Agreement may not be assigned or otherwise transferred by a Party without the prior written consent of the other Party; provided, however, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part, (a) in connection with the transfer or sale of all or substantially all of its assets or the line of business or Product to which this Agreement relates, (b) to a successor entity or acquirer in the event of a merger, consolidation or change of control, or (c) to any Affiliate. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement. This Agreement shall be binding upon the successors and permitted assigns of the Parties.

14.8 Entire Agreement. This Agreement, including the attached Appendices, each of which are incorporated herein, constitute the entire agreement between the Parties with respect to the specific subject matter hereof and all prior agreements with respect thereto are superseded except for the Technology Transfer Agreement. Each Party hereto confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. As of the Effective Date, (a) the terms of Section 9 (Confidentiality) shall supersede the Mutual Non-Disclosure Agreement by and between Janssen Supply Group, LLC and Emergent BioSolutions Inc. dated as of [**] and the confidentiality terms of the Technology Transfer Agreement; thus, any information disclosed pursuant to either of such agreements by a Party or its Affiliates that was deemed "Confidential Information" under either of such agreements shall be deemed Confidential Information of such Party under this Agreement; and (b) the intellectual property terms of the Technology Transfer Agreement shall be supersede by the terms in Section 8 (Intellectual Property Rights) of this Agreement.

14.9 Conflict Between Documents. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any purchase order, or other form used by the Parties, the terms of this Agreement will control. Pre-printed or additional or conflicting terms on any purchase order or similar document shall have no effect. If this Agreement conflicts with the Quality Agreement with respect to matters related to quality assurance or quality control activities, then the Quality Agreement shall control. In all other matters, this Agreement shall control over the Quality Agreement.

14.10 No Modification. This Agreement and Quality Agreement may be changed only by a writing signed by authorized representatives of all of the Parties.

14.11 Severability; Reformation. Each provision in this Agreement is independent and severable from the others, and no restriction will be rendered unenforceable because any other provision may be invalid or unenforceable in whole or in part. If the scope of any restrictive provision in this Agreement is too broad to permit enforcement to its full extent, then such restriction will be reformed to the maximum extent permitted by law.

14.12 Governing Law and Dispute Resolution.

a. Other than disputes arising under Section 5.4 (which shall be addressed as set forth in Section 5.4), the Parties shall first attempt in good faith to settle any dispute arising hereunder promptly by negotiations between representatives of Buyer and Manufacturer who have authority to settle the controversy. If the Parties are unable to resolve such dispute within [**] following the referral of the dispute to such representatives, such dispute shall be submitted to mediation using a professional mediator selected by agreement from the American Arbitration Association, the CPR Institute for Dispute Resolution or like organization, or absent agreement, through selection procedures administered by the CPR. Within a period of [**] after the request for mediation, the Parties agree to convene with the mediator, with business representatives present, for at least one session to attempt to resolve the matter. In the event that the Parties are unable to resolve the dispute through mediation, the dispute will be solely and finally settled by arbitration, which shall be conducted in New York, New York, by a single arbitrator (the "Arbitrator") designated by the American Arbitration Association. The Parties hereby renounce all recourse to litigation and agree that the award of the Arbitrator shall be final and subject to no judicial review. The Arbitrator shall conduct the proceedings pursuant to the Commercial Arbitration Rules of the American Arbitration Association, as now or hereafter amended. All substantive questions of law shall be determined under the laws of the State of New York, USA (without regard to the principles of conflict of laws of such state). Judgment on the award of the Arbitrator may be entered into any court having jurisdiction over the Party against which enforcement of the award is being sought, and the Parties hereby irrevocably consent to the jurisdiction of any such court for the purpose of enforcing any such award. The Arbitrator shall divide all costs (including, without limitation, fees of counsel) incurred in conducting the arbitration in his/her final award in accordance with what he/she deems just and equitable under the circumstances.

b. Rule 14 of the CPR Rules does not apply to this Agreement. All aspects of the mediation and arbitration shall be treated as confidential.

c. EACH PARTY HERETO [**].

14.13 Waiver. No waiver of any term, provision or condition of this Agreement in any one or more instances will be deemed to be or construed as a further or continuing waiver of any other term, provision or condition of this Agreement. Any such waiver, extension or amendment will be evidenced by an instrument in writing executed by an officer authorized to execute waivers, extensions or amendments.

14.14 Allocations of Risk. Each provision of this Agreement that provides for a limitation of liability, disclaimer of warranties, or exclusion of damages is to allocate the risks of this Agreement

between the Parties and each Party acknowledges that such allocation of risk is reflected in the pricing offered by Manufacturer to Buyer and is an essential element of the basis of the bargain between the Parties.

14.15 Compliance with Applicable Laws. In all activities undertaken pursuant to this Agreement, both Manufacturer and Buyer covenant and agree that each will in all material respects comply with all Applicable Laws, as may be in effect at the time of performance.

14.16 Government Contracting. While not known with any particularity at this time, it is understood by the parties that some aspects of this Agreement may be funded by U.S. Government funding in the future. In such event, the parties agree during the term of this Agreement to consider in good faith and not unreasonably refuse to enter into an amendment to this Agreement to include any mutually agreed upon flowdown provisions required by the Buyer's prime contract with the U.S. Government to be included in this Agreement.

14.17 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument.

14.18 Headings. This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement, and should not be used in the construction of this Agreement.

14.19 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

JANSSEN PHARMACEUTICALS, INC.

By: /s/ Remo J. Colarusso Jr.

Print Name: Remo J. Colarusso Jr.

Title: VP, Janssen Supply Chain

Date: 2 Jul 2020

EMERGENT MANUFACTURING OPERATIONS BALTIMORE, LLC

By: /s/ Syed T. Husain

Print Name: Syed T. Husain

Title: SVP and CDMO BU Head

Date: Jul 1, 2020

Appendix 2

Price [**]

The price of each Batch during the relevant Contract Year [**] is as set forth in the table(s) below.

Price Per Batch for Contract Year [**]:

[**]	**[**]**	**Total Price Per Batch**
[**]	[**]	[**]

[**].

Price Per Batch for Contract Year [**]:

Fees	**[**]**	**Total Price Per Batch**
[**]	[**]	[**]

Price Per Batch for Contract Year **[**]****

[**]	**[**]**	**Total Price Per Batch**
[**]	[**]	[**]

** [**]

[**] Contract Year:

Contract Year	**[**]**
Contract Year 1	[**]
Contract Year 2	[**]
Contract Year 3	[**]
Contract Year 4	[**]
Contract Year 5	[**]

***[**].

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: November 5, 2020

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

EXHIBIT 31.2

CERTIFICATION

I, Richard S. Lindahl, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2020

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

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert G. Kramer, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2020

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

EXHIBIT 32.2

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

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Richard S. Lindahl, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2020

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