Exhibit 10

May 12, 2020

# Authorization to Proceed

Sean Kirk
Executive Vice President
Manufacturing & Technical Operations
Emergent BioSolutions
[redacted]

**RE:** Authorization to Proceed to Emergent BioSolutions
Prime Contract # HHSO100201200004I
*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

Mr. Kirk:

This is an Authorization to Proceed (ATP) for your organization to immediately begin performance and incur costs under the subject initiative. All work performed and costs incurred prior to the execution of a subsequent agreement must be in accordance with the terms of this letter and its attachments.

In accordance with FAR 31.109 Advance Agreements, your organization may incur costs in support of this requirement in an amount not-to-exceed $31,412,500. Your organization may not invoice for these costs until the subsequent agreement is in place.

Funds are currently committed for this initiative (requisition no. OS258575) and the services are needed under a valid requirement.

The subsequent agreement will: (1) be a task order awarded under prime contract number HHSO100201200004I; (2) include a period of performance of June 1, 2020 through December 31, 2021; and (3) include a firm-fixed-price of $628,250,000 which will be obligated in full at the time of task order award. The Government anticipates finalizing the subsequent agreement on or before May 31, 2020.

In addition to the terms specified in this letter, the ATP incorporates the terms in the following attachments are incorporated into this letter.

Attachment 1 – Project Objectives, Background, & Description, 2 pages.
Attachment 2 – Contractor Capacity and Pricing, 3 pages.
Attachment 3 – Key Assumptions, 1 page.
Attachment 4 – Mechanism of Action, 1 page.
Attachment 5 – Payment Schedule, 1 page.

Your organization must direct all communications regarding this ATP and the subsequent agreement to Jeffrey Schmidt, Contracting Officer, [redacted] with a copy to Timothy Belski, Contracting Officer's Representative, [redacted].

Please indicate your consent to this agreement by signing and returning this letter.

Regards,

Jeffrey R. Schmidt -S Digitally signed by Jeffrey R. Schmidt -S
Date: 2020.05.12 21:05:53 -04'00'

Jeffrey Schmidt
Contracting Officer
Division of Contract Management & Acquisitions (CMA)
Biomedical Advanced Research & Development Authority (BARDA)

AGREED: [redacted]
Signature

EVP, Manufacturing and Tech Ops
Name and Title

5/13/20
Date

# Attachment 1 – Project Objectives, Background, & Description

*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

## Project Objectives

The objective of this task order is to reserve and expand the capacities and capabilities established at Emergent CIADM.

## Project Background

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

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

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

## Project Description

BARDA is seeking to reserve and expand pharmaceutical manufacturing capacity as soon as possible and reserve this capacity through December 31, 2021 for drug substance and drug product manufacturing. 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. The reserved capacity shall include the facilities and equipment renovated/constructed/purchased as well as services supported through the HHS/BARDA CIADM contracts (IDIQ type contracts). The reservation shall exclude the performance of any work in the reserved capacity without the explicit, written approval from the USG during the reservation period. In addition, the USG seeks to expand the pharmaceutical manufacturing capacity for drug product manufacturing at our CIADM facilities. The new capacity must be operational no later than December 31, 2021. For the purposes of this task, capacity expansion may include: procurement, installation, and commissioning/qualification/validation of new equipment; construction activities associated with expansion of existing facilities/capacities.

Several technically superior vaccine candidates are being targeted by the U.S. Government for accelerated development. As such, large scale manufacturing must be reserved now by for use by BARDA to direct rapid technical transfer and parallel mass-production efforts. As more organizations and companies seek commercial vaccine manufacturing capacity for both COVID-19 and other vaccine products, this capacity is becoming much more limited. BARDA is acting proactively to secure this critical manufacturing infrastructure before other market forces capture it. In addition, the capacity being secured under this action is with a teaming partner well-known to BARDA and has a favorable past performance record, thereby reducing technical and business risk to the government.

## Attachment 2 – Contractor Capacity and Pricing

*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

The Government secures the below capacity at the specified pricing:

1. Drug Substance – Baltimore, MD (Bayview – CIADM) – (please note that this would require the deferral of raxibacumab qualification and production)
    a. Area 3 (2 x 4k scale)
        i. Estimated timeframe: 20 months in total, May 2020 through December 2021
        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 100 batches
        iii. Estimated pricing: $3.0 million / batch for a total of $300 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
    b. Area 4 (1 x 50L scale)
        i. Estimated timeframe: 20 months in total, May 2020 through December 2021
        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 100 batches
        iii. Estimated pricing: $0.7 million / batch for a total of $70 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
    c. Total for Drug Substance: $370 million (excluding raw materials)

2. Drug Product – Baltimore, MD (Camden)
    a. Existing Line 118 (36,000 vials / batch)
        i. Estimated timeframe: 20 months in total, May 2020 through December 2021
        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 100 batches, 3.6 million units

iii. Estimated pricing: $0.325 million / batch for a total of $32.5M. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

b. Existing Line 168 (18,000 vials / batch)
   i. Estimated timeframe: 20 months in total, May 2020 through December 2021
   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 200 batches, 3.6 million units
   iii. Estimated pricing: $0.325 million / batch for a total of $65 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

c. New Line (22,000 vials / batch)
   i. Estimated timeframe: 12 months in total, Jan 2021 through December 2021
   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 150 batches, 3.3 million units
   iii. Estimated CAPEX Acceleration Fee: $7.5 million (best estimate, actual numbers may vary)
   iv. Estimated pricing: $0.325 million / batch for a total of $48.75 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

d. Total for Drug Product: $146.25 million (excluding raw materials) + Capex Acceleration of approximately $7.5 million

3. Drug Product – Rockville, MD
   a. Existing Line (22,500 vials / batch)
      i. Estimated timeframe: 5 months in total, September 2020 through December 2021
      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 40 batches, 900,000 units

iii. Estimated pricing: $0.4 million / batch for a total of $16 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.

b. New Line (150,000 vials / batch)
   i. Estimated timeframe: 3 months in total, October 2021 through December 2021
   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 24 batches, 3.6 million units
   iii. Estimated CAPEX Installation / Acceleration Fee: $78 million (best estimate, actual numbers may vary)
   iv. Estimated pricing: $0.4 million / batch for a total of $9.6 million. This pricing would allow the reservation of associated capacity and manufacturing of product. Please note that raw materials are not included in the foregoing since that will depend on the process and product(s) selected, but these would be passed through to the Government at Contractor's cost.
c. Total for Drug Product: $26.5 million (excluding raw materials) + Capex Installation / Acceleration of approximately $78 million

4. Total Value for Drug Substance and Drug Product Capacity Commitment & Manufacturing: $542.75 million, excluding raw materials

5. Total Value for Capex: approximately $85.5M (best estimate, actual numbers may vary)

## Attachment 3 – Key Assumptions

*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

The following assumptions are applicable to this Authorization to Proceed:

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.

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.

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.

4. The FDA provides expedited multi-product approval for the Rockville, MD site.

## Attachment 4 – Mechanism of Action

*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

The following terms are applicable to this Authorization to Proceed:

1. The Government secures capacity as outlined in Attachment 2 and the reserved capacity is fully available to deployment by the Government.

2. Contractor will act as the Contract Development Manufacturing Organization (CDMO) for priority targets as determined by the Government and the scope will encompass Drug Substance and Drug Product within above network.

3. Upon approval of a direct relationship between Contractor and priority target, the Government will release the associated capacity to Contractor to deploy and contract with identified by the Government.

4. Contractor will negotiate pricing for the identified party for full scope of activities including manufacturing and raw materials.

## Attachment 5 – Payment Schedule

*Emergent CIADM Manufacturing Capacity Reservation and Expansion*

The Government will include the below payment schedule in the subsequent agreement.

Following execution of the subsequent agreement, the Government's approval of invoices will be contingent on delivery and acceptance of a report deliverable submitted each month during the period of performance of the subsequent agreement.

| Reporting Month | Amount |
|---|---|
| May 2020 | $31,412,500* |
| June 2020 | $31,412,500 |
| July 2020 | $31,412,500 |
| August 2020 | $31,412,500 |
| September 2020 | $31,412,500 |
| October 2020 | $31,412,500 |
| November 2020 | $31,412,500 |
| December 2020 | $31,412,500 |
| January 2021 | $31,412,500 |
| February 2021 | $31,412,500 |
| March 2021 | $31,412,500 |
| April 2021 | $31,412,500 |
| May 2021 | $31,412,500 |
| June 2021 | $31,412,500 |
| July 2021 | $31,412,500 |
| August 2021 | $31,412,500 |
| September 2021 | $31,412,500 |
| October 2021 | $31,412,500 |
| November 2021 | $31,412,500 |
| December 2021 | $31,412,500 |
| **Total =** | $628,250,000 |

*payment provided for under this Authorization to Proceed which will be invoiced for following the execution of the subsequent agreement.

Exhibit 11

# ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 18

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

| | |
|---|---|
| 1. DATE OF ORDER: 07/23/2020 | 2. CONTRACT NO. (If any): HHSO100201200004I |
| 3. ORDER NO.: 75A50120F33008 | 4. REQUISITION/REFERENCE NO.: 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: WASHINGTON | d. STATE: DC | e. ZIP CODE: 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: BALTIMORE | e. STATE: MD | f. ZIP CODE: 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: See Schedule | 10. REQUISITIONING OFFICE: BARDA |

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT:

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

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: [redacted]<br>DUNS Number: [redacted]<br>Task Order Title: "Emergent CIADM Manufacturing Capacity Reservation"<br><br>See attached.<br>Continued ... | | | | | |

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

22. UNITED STATES OF AMERICA BY (Signature): [redacted]

23. NAME (Typed): [redacted]
TITLE: CONTRACTING/ORDERING OFFICER

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION NOT USABLE

OPTIONAL FORM 347 (Rev. 2/2012)
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) |
|---|---|---|---|---|---|---|
| | Period of Performance: 10/01/2020 to 12/31/2020 | | | | | |
| 1 | To expand the public-private partnership with Emergent to reserve the capacities and capabilities at their Bayview CIADM facility. (1 of 2).<br><br>Accounting Info:<br>2020.199C001.25103 Appr. Yr.: 2020<br>CAN: 199C001 Object Class: 25103<br>Funded: $28,366,924.00 | | | | 28,366,924.00 | |
| 2 | To expand the public-private partnership with Emergent to reserve the capacities and capabilities at their Bayview CIADM facility. (2 of 2).<br><br>Accounting Info:<br>2020.199COV1.25103 Appr. Yr.: 2020<br>CAN: 199COV1 Object Class: 25103<br>Funded: $1,633,076.00 | | | | 1,633,076.00 | |
| | The total amount of award: $30,000,000.00. The obligation for this award is shown in box 17(i).<br><br>Contractor to sign below:<br><br>[redacted] | | | | | |

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 Area 1 Drug Substance | 12 | 3 |
| Bayview CIADM Area 2 Drug Substance | 12 | 3 |

## 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 Areas 1 and 2 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 | 30 days after TO award |
| 2 | Monthly Report | Electronically to CO and COR | 15th 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 bi-weekly or monthly. 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 three (3) business days after each teleconference, or as otherwise authorized by the Contracting Officer.

### F.4.2 Person-in-Plant

Contractor shall accommodate up to three (3) 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 three (3) business days prior written notice. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within three (3) business days 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 14 days 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 three (3) business days 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 30 days 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 30 day 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 |
|---|---|
| Syed Husain | Principal Investigator |
| Dino Muzzin | Head of Manufacturing |
| Scott Kelly | Head of Manufacturing, Science & Technology |
| John Ducote | Head of Global Quality |

## G.4 Invoicing Instructions

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

## G.5 Evaluation of Contractor Performance

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

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

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

*Contractor Review:* A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days 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 3 years 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 monthly 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 five (5) calendar days 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 fifteen (15) calendar days 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. Area 1 (2 x 2k scale)

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 12 batches

iii. Estimated reservation pricing: $1.25 million / batch for a total of $15 million. 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. Area 2 (2 x 2k scale)

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 12 batches

iii. Estimated reservation pricing: $1.25 million / batch for a total of $15 million. 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 12

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

| 1. CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 3 |

| 2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. *(If applicable)* |
|---|---|---|---|
| P00002 | See Block 16C | | |

| 6. ISSUED BY | CODE | 7. ADMINISTERED BY *(If other than Item 6)* | CODE |
|---|---|---|---|
| ASPR-BARDA | ASPR-BARDA | ASPR-BARDA | 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

CODE 1410445 FACILITY CODE

(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

**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 ACKNOWLEDGEMENT 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

Net Decrease: -$10,000,000.00

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

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

**E. IMPORTANT:** Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: [redacted]
DUNS Number: [redacted]
The purpose of this modification is to reduce the reserved drug substance manufacturing capacity at the Contractor's Bayview CIADM facility. As a result, $10,000,000 is deobligated from the task order.

See attached for specifics on the changes to the task order.

All other terms and conditions remain unchanged.
Period of Performance: 10/01/2020 to 12/31/2020

Continued ...

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

| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* |
|---|---|
| Syed T Husain Syed T Husain | [redacted] |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| [redacted] *(Signature of person authorized to sign)* | Nov 25, 2020 | [redacted] | |

Previous edition unusable

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

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) |
|---|---|---|---|---|---|
| | Change Item 1 to read as follows(amount shown is the obligated amount): | | | | |
| 1 | To expand the public-private partnership with Emergent to reserve the capacities and capabilities at their Bayview CIADM facility.<br><br>Accounting Info:<br>2020.199C001.25103 Appr. Yr.: 2020 CAN: 199C001<br>Object Class: 25103<br>Funded: -$8,366,924.00 | | | | -8,366,924.00 |
| | Cancel Item 2 in its entirety. | | | | |

On the effective date of this modification, the following changes are made to Task Order 75A50120F33008, Contract Number HHSO100201200004I/

**SECTION B. COST / PRICE SCHEDULE** is superseded by the following:

**B.1 Prices**

The total fixed price of this task order is $20,000,000.

**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 | $0 |
| | | **Total =** | $20,000,000 |

**Subsection c. of ATTACHMENT 1 – Contractor Capacity and Pricing** is modified to reflect the $10,000,000 reduction.

Was: "Total for Drug Substance: $30 million"

Now reads: "Total for Drug Substance: $20 million"

Exhibit 13

**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)* |
|---|---|---|---|
| P00006 | See Block 16C | OS273933 | |

| 6. ISSUED BY | CODE | 7. ADMINISTERED BY *(If other than Item 6)* | CODE |
|---|---|---|---|
| ASPR-BARDA | ASPR-BARDA | ASPR-BARDA | 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

CODE 1410445 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSO100201200004I
75A50120F33007

10B. DATED *(SEE ITEM 13)*
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 ACKNOWLEDGEMENT 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)*
2021.199C035.25103

Net Increase: $22,815,445.00

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

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

**E. IMPORTANT:** Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: [redacted]
DUNS Number: [redacted]
The purpose of this modification is to provide funding for equipment procurement and acquisition to facilitate operational readiness of the Janssen manufacturing process within Area 3 of the Contractor's Bayview location. The Government intends to issue a subsequent modification for the installation and operational qualification of the equipment and area.

See attached.

Appr. Yr.: 2021 CAN: 199C035 Object Class: 25103
Period of Performance: 05/13/2020 to 12/31/2021
Continued ...

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

| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* |
|---|---|
| Syed T Husain SVP and CDMO BU Head | JEFFREY R. SCHMIDT |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| [redacted] | Mar 24, 2021 | [redacted] | |
| *(Signature of person authorized to sign)* | | *(Signature of Contracting Officer)* | |

Previous edition unusable

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

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) |
|---|---|---|---|---|---|
| | Add Item 4 as follows: | | | | |
| 4 | Equipment procurement and acquisition to facilitate operational readiness of the Janssen manufacturing process within Area 3 of the Contractor's Bayview location. | | | | 22,815,445.00 |

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

**Paragraph B.1. Prices** is superseded by the following:

**B.1 Prices**

**B.1.1.** The total fixed price of this task order (sum of Task 1, Task 2, and Task 3) is $650,795,445.

**B.1.2.** The total fixed price of Task 1: Capacity Reservation is $542,480,000.

**B.1.3.** The total fixed price of Task 2: Pharmaceutical Manufacturing Capacity Expansion is $85,500,000.

**B.1.4.** The total fixed price of Task 3: Janssen Equipment is $22,815,445.

**Paragraph B.4. Task 3 Payment Schedule** is added:

Following delivery and acceptance of the work described in **SECTION C.3.3** and the deliverables described in **SECTION F**, and on submission of a proper invoice, the Government will pay the Contractor as follows:

| Item Description | Unit Price |
|---|---|
| Confirmation of Equipment Order Placement | $11,407,723 |
| Confirmation of Initial Equipment Arrival | $5,703,861 |
| Confirmation of Final Equipment Arrival | $5,703,861 |
| **Total =** | $22,815,445 |

**Paragraph C.3.3 Task 3: Janssen Equipment** is added:

**To accommodate Janssen's process within Area 3 manufacturing suite, the contractor shall acquire Janssen's specified equipment. The list of required equipment is included as an** attachment to the contract.

**Paragraph F.2.6 Confirmation of Equipment Order Placement** is added:

The contractor shall provide to the Government executed purchase orders for each of the pieces of equipment listed in Attachment 2 – Task 3 List of Required Equipment.

**Paragraph F.2.7 Confirmation of Receipt of Equipment** is added:

The contractor shall provide to the Government written confirmation that the pieces of equipment listed in Attachment 2 – Task 3 List of Requirement Equipment have been received at **the contractor's Bayview facility.**

**Paragraph F.3. Schedule of Deliverables** is superseded by the following:

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

| Item | Task | Deliverable | Delivery Method | Due Date |
|---|---|---|---|---|
| 1 | 1 | Manufacturing Schedule with Allocated Capacity through Period of Performance | Electronically to CO and COR | 30 days after TO award; every 3 months thereafter |
| 2 | 2 | Integrated Master Schedule | Electronically to CO and COR | 06/30/2020 |
| 3 | 2 | Work Breakdown Structure | Electronically to CO and COR | 06/30/2020 |
| 4 | 2 | Validation Master Plan | Electronically to CO and COR | 06/30/2020 |
| 5 | 1 & 2 | Monthly Report | Electronically to CO and COR | 15th day of every month throughout the task order period of performance |
| 6 | 3 | Confirmation of Equipment Order Placement | Electronically to CO and COR | Within 15 days following the execution of Modification 6 |
| 7 | 3 | Confirmation of Receipt of Equipment | Electronically to CO and COR | Within 15 days following the receipt of the final piece of equipment |

**Section J. ATTACHMENTS** is superseded by the following:

Attachment 1 – Contractor Capacity and Pricing

Attachment 2 – Task 3 List of Required Equipment

**ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.**

**Attachment 2 – Task 3 List of Required Equipment**

| Qty | Task | Unit Price | Total | Extended Price |
|---|---|---|---|---|
| 2 | Virus Thaw Baths | $1,550 | $3,100 | $3,193 |
| 4 | 200L WAVEs | $305,852 | $1,223,407 | $1,260,109 |
| 4 | SUMs (200L) | $203,713 | $814,853 | $839,299 |
| 8 | SUMs (1500L) | $203,713 | $1,629,707 | $1,678,598 |
| 20 | SUMs (2000L) | $203,713 | $4,074,267 | $4,196,495 |
| 2 | Harvest Settling Tanks | $41,331 | $82,662 | $85,142 |
| 4 | 1" TFFs | $604,100 | $2,416,400 | $2,488,892 |
| 8 | Sartobind Q Trolleys | $2,308 | $18,464 | $19,018 |
| 20 | 1000L Totes | $540 | $10,800 | $11,124 |
| 4 | Powder Lift Bags | $21,965 | $87,860 | $90,496 |
| 2 | Bulk Filler Systems | $340,000 | $680,000 | $700,400 |
| 4 | Bag & Filter Carts | $23,900 | $95,600 | $98,468 |
| 4 | ILD Skids | $347,250 | $1,389,000 | $1,430,670 |
| 2 | AKTA Skids | $750,000 | $1,500,000 | $1,545,000 |
| 2 | CE Instruments (for QC) | $59,124 | $118,248 | $121,795 |
| 2 | Water Baths (for QC) | $6,709 | $13,418 | $13,821 |
| 1 | 7500 Fast qPCR (for QC) | $47,430 | $47,430 | $48,853 |
| N/A | Area 3 Drain Mods | $111,596 | $111,596 | $114,944 |
| 2 | A3 WFI Valves | $9,995 | $19,990 | $20,590 |
| 1 | Freezer System and associated charges | N/A | $4,209,271 | $4,209,271 |
| 4 | 650L SUM and associated charges | N/A | $3,368,764 | $3,368,764 |
| 80 | Freezer carts | $5,710 | $456,800 | $470,504 |
| | | | Grand Total: | $22,815,445 |

Key Contractor Pricing Assumptions for Task 3 List of Required Equipment:

- **Final pricing subject to change post Modification award and prior to Contractor's final supplier** order placement. The Contractor and Government agree to true-up final prices using the executed purchase orders.

  If the true-up results in a total price that is excess of the firm fixed price of this modification, the Government agrees to make a good faith effort to locate and obligate the additional funds. The Contractor understands the Government cannot guarantee it will be able to locate and obligate the additional funds.

  Any true-up of costs will occur prior to approving the final invoice associated with this Modification.

- Quantities/sizes of equipment subject to change based on final layout (freezers, SUMs, totes, etc.) Additional QC and miscellaneous equipment may need to be included (heat sealers, crimpers, etc.)

Exhibit 14

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

CODE 1410445 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSO100201200004I
75A50120F33007

10B. DATED *(SEE ITEM 13)*
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 ACKNOWLEDGEMENT 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 ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| X | FAR 43.103(a)(3) - Bilateral 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: [redacted]
DUNS Number: [redacted]
The purpose of the 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 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* |
|---|---|
| Patrick D. Sapp VP Govt Contracts | [redacted] |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| [redacted] *(Signature of person authorized to sign)* | 8/22/20 | [redacted] *(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 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 12/31/2021certified 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:* The date for the operational readiness for the Camden facility is January 1, 2021 and for the Rockville facility is October 1, 2021.

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"<br><br>Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent Manufacturing Operations Baltimore LLC | August 17, 2020<br><br>August 19, 2020 |

Attachment A (3 additional pages)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

**DATE:**

**TO:** Alex M. Azar II, Secretary

**THROUGH:** Ann C. Agnew, Executive Secretary

**FROM:** Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

**SUBJECT:** Request authorization to priority rate Emergent contract for industrial resources – **DECISION**

## ACTION REQUESTED

This memorandum requests Secretarial approval to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

## SUMMARY

As part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, Operation Warp Speed (OWS) aims to be prepared to deliver 300 million doses of COVID-19 by January 2021, to ensure rapid scale-up, production, and delivery as soon as a safe and effective vaccine is developed. Through the direction of OWS leadership, manufacturing of vaccine components and finished vaccine products will occur in parallel with vaccine clinical development and testing. OWS implemented these concurrent work streams to speed the delivery of a safe and effective vaccine for responding to the COVID-19 pandemic since large scale bio manufacturing has traditionally had long lead times which are actively being mitigated through early activation of manufacturing.

Candidate vaccines under development as part of the OWS portfolio will be manufactured domestically within a mix of company-owned facilities, contract development and manufacturing organizations (CDMOs), and two HHS Centers for Innovation in Advanced Development and Manufacturing (CIADMs) - the Texas A&M University System (TAMUS) CIADM and the Emergent BioSolutions CIADM. Domestic manufacturing capacity for the candidate vaccines remains limited, given the number of doses required and accelerated timeframe established by OWS, as well as use of the facilities by other organizations outside the OWS portfolio that are developing COVID-19 and other vaccines. In order to prepare manufacturing facilities for commercial-scale production of a vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccines.

BARDA determined that the Emergent CIADM possesses the required experience and available capacity to be ready to manufacture Ad-vectored vaccine components at a commercial scale and within the OWS-required timeline. HHS has a contract in place with Emergent BioSolutions CIADM (Contract #HHSO100201200004I) and two relevant task orders have been awarded:

In order to prepare manufacturing facilities for commercial-scale production of a COVID-19 vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccine. DPAS priority rating is requested for vaccine pre-production activities and accelerated facilities expansion to ensure the readiness of the Emergent facility within the OWS-established timeframe by prioritizing orders for the production of BARDA- or OWS-supported vaccines or therapeutics and aiding the Contractor and its subcontractors in securing needed raw materials or equipment.

**ANTICIPATED REACTION**
No impacts expected for other US healthcare needs (e.g., hospitals, seasonal flu response).

**ROLLOUT**
If approved, this request will be briefed to the Operation Warp Speed Board for review.

**RECOMMENDATION**

I recommend that you approve the request to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

[redacted]

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

**DECISION**

Approved ✓ Disapproved _____ Need More Information _____

[redacted]

Alex M. Azar II
Secretary

AUG 17 2020
Date

**Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent**

On August 19, 2020, the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) was granted, from the U.S. Department of Commerce, rating authority under the Defense Priorities and Allocations System (DPAS) regulation (15 C.F.R. part 700) for contracts and orders for "industrial resources" supporting Operation Warp Speed (OWS) projects. The U.S. Department of Commerce's Bureau of Industry and Security (DOC/BIS) authorized HHS to use the "DO-H5" priority rating on OWS contracts or orders to support private domestic production through August 31, 2022. HHS will monitor all acquisitions that carry a priority rating to ensure that each is in compliance with the DPAS regulation, and will inform DOC/BIS of any alleged violations of the DPAS of which it may become aware. HHS will also report quarterly to DOC/BIS on the contracts assigned priority ratings and their dollar value.

OWS was formed by HHS and the Department of Defense (DOD) to ramp up and expand domestic production capacity of critical health and medical resources in response to the coronavirus (COVID-19), and are funded through the Defense Production Act of 1950 (DPA) Title III authority, Coronavirus Aid, Relief, and Economic Security (CARES) Act, and/or other HHS funding sources.

Pursuant to this authority, I authorize the Contracting Officer to issue a DPAS priority rating on the Emergent BioSolutions Center for Innovation in Advanced Development and Manufacturing (CIADM) facility ("the Company") contract for industrial resources supporting the OWS Task Orders. The order or contract issued pursuant to this authorization is subject to the following restrictions:

1. The Company shall accept, perform, and prioritize this order or contract for vaccine produced under OWS-related task orders under Contract #HHSO100201200004I in order to ensure the delivery within the OWS-established timeframe.
2. This order or contract shall take precedence over any and all orders for the Products 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.
3. This order or contract shall allow the Company to priority rate orders to its suppliers for purposes of fulfilling the priority-rated contracts or orders expediently.

This authorization automatically expires at the end of the contract period of performance.

Gary L. Disbrow -S

Digitally signed by Gary L. Disbrow -S
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=20000124 25, cn=Gary L. Disbrow -S
Date: 2020.08.19 13:02:08 -04'00'

Gary L. Disbrow, Acting Director
HHS/Biomedical Advanced Research and Development Authority
Date:

Exhibit 15

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

| 1. CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 of 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 | 7. ADMINISTERED BY *(If other than Item 6)* | CODE |
|---|---|---|---|
| ASPR-BARDA | ASPR-BARDA | ASPR-BARDA | ASPR-BARDA02 |
| 200 Independence Ave., S.W. | | 330 Independence Ave, SW, [redacted] | |
| [redacted] | | | |
| Washington DC 20201 | | 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<br>EMERGENT MANUFACTURING OPERATIONS B<br>5901 E LOMBARD ST<br>BALTIMORE MD 212246824 | | 9B. DATED *(SEE ITEM 11)* |
| | X | 10A. MODIFICATION OF CONTRACT/ORDER NO.<br>HHSO100201200004I<br>75A50120F33008 |
| | | 10B. DATED *(SEE ITEM 13)*<br>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 ACKNOWLEDGEMENT 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 ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| X | 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 _____ 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: [redacted]
DUNS Number: [redacted]
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 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* |
|---|---|
| PATRICK D. SAAM VP GovtContracts | [redacted] |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| [redacted] | 8/22/20 | [redacted] | 08/24/2020 |
| *(Signature of person authorized to sign)* | | *(Signature of Contracting Officer)* | |

Previous edition unusable

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

A. This is Modification No. P00001 to 75A50120F33008.

The purpose of this no cost bilateral modification P0001 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"<br><br>Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent Manufacturing Operations Baltimore LLC | August 17, 2020<br><br>August 19, 2020 |

Attachment A (3 additional pages)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

**DATE:**

**TO:** Alex M. Azar II, Secretary

**THROUGH:** Ann C. Agnew, Executive Secretary

**FROM:** Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

**SUBJECT:** Request authorization to priority rate Emergent contract for industrial resources – **DECISION**

## ACTION REQUESTED

This memorandum requests Secretarial approval to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

## SUMMARY

As part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics, Operation Warp Speed (OWS) aims to be prepared to deliver 300 million doses of COVID-19 by January 2021, to ensure rapid scale-up, production, and delivery as soon as a safe and effective vaccine is developed. Through the direction of OWS leadership, manufacturing of vaccine components and finished vaccine products will occur in parallel with vaccine clinical development and testing. OWS implemented these concurrent work streams to speed the delivery of a safe and effective vaccine for responding to the COVID-19 pandemic since large scale bio manufacturing has traditionally had long lead times which are actively being mitigated through early activation of manufacturing.

Candidate vaccines under development as part of the OWS portfolio will be manufactured domestically within a mix of company-owned facilities, contract development and manufacturing organizations (CDMOs), and two HHS Centers for Innovation in Advanced Development and Manufacturing (CIADMs) - the Texas A&M University System (TAMUS) CIADM and the Emergent BioSolutions CIADM. Domestic manufacturing capacity for the candidate vaccines remains limited, given the number of doses required and accelerated timeframe established by OWS, as well as use of the facilities by other organizations outside the OWS portfolio that are developing COVID-19 and other vaccines. In order to prepare manufacturing facilities for commercial-scale production of a vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccines.

BARDA determined that the Emergent CIADM possesses the required experience and available capacity to be ready to manufacture Ad-vectored vaccine components at a commercial scale and within the OWS-required timeline. HHS has a contract in place with Emergent BioSolutions CIADM (Contract #HHSO100201200004I) and two relevant task orders have been awarded:

In order to prepare manufacturing facilities for commercial-scale production of a COVID-19 vaccine (in the case that FDA authorization or approval is received), accelerated facility expansion and facility reservation for domestic vaccine manufacturing is required in order to compress the timeline to make the production facility space ready for manufacturing the new vaccine. DPAS priority rating is requested for vaccine pre-production activities and accelerated facilities expansion to ensure the readiness of the Emergent facility within the OWS-established timeframe by prioritizing orders for the production of BARDA- or OWS-supported vaccines or therapeutics and aiding the Contractor and its subcontractors in securing needed raw materials or equipment.

**ANTICIPATED REACTION**
No impacts expected for other US healthcare needs (e.g., hospitals, seasonal flu response).

**ROLLOUT**
If approved, this request will be briefed to the Operation Warp Speed Board for review.

**RECOMMENDATION**

I recommend that you approve the request to priority rate the Operation Warp Speed Emergent contract for vaccine preproduction activities under the Defense Priorities and Allocations System (DPAS).

[redacted]

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

**DECISION**

Approved ✓ Disapproved _____ Need More Information _____

[redacted]

Alex M. Azar II
Secretary

AUG 17 2020
Date

**Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent**

On August 19, 2020, the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) was granted, from the U.S. Department of Commerce, rating authority under the Defense Priorities and Allocations System (DPAS) regulation (15 C.F.R. part 700) for contracts and orders for "industrial resources" supporting Operation Warp Speed (OWS) projects. The U.S. Department of Commerce's Bureau of Industry and Security (DOC/BIS) authorized HHS to use the "DO-H5" priority rating on OWS contracts or orders to support private domestic production through August 31, 2022. HHS will monitor all acquisitions that carry a priority rating to ensure that each is in compliance with the DPAS regulation, and will inform DOC/BIS of any alleged violations of the DPAS of which it may become aware. HHS will also report quarterly to DOC/BIS on the contracts assigned priority ratings and their dollar value.

OWS was formed by HHS and the Department of Defense (DOD) to ramp up and expand domestic production capacity of critical health and medical resources in response to the coronavirus (COVID-19), and are funded through the Defense Production Act of 1950 (DPA) Title III authority, Coronavirus Aid, Relief, and Economic Security (CARES) Act, and/or other HHS funding sources.

Pursuant to this authority, I authorize the Contracting Officer to issue a DPAS priority rating on the Emergent BioSolutions Center for Innovation in Advanced Development and Manufacturing (CIADM) facility ("the Company") contract for industrial resources supporting the OWS Task Orders. The order or contract issued pursuant to this authorization is subject to the following restrictions:

1. The Company shall accept, perform, and prioritize this order or contract for vaccine produced under OWS-related task orders under Contract #HHSO100201200004I in order to ensure the delivery within the OWS-established timeframe.
2. This order or contract shall take precedence over any and all orders for the Products 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.
3. This order or contract shall allow the Company to priority rate orders to its suppliers for purposes of fulfilling the priority-rated contracts or orders expediently.

This authorization automatically expires at the end of the contract period of performance.

Gary L. Disbrow -S

Digitally signed by Gary L. Disbrow -S
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=20000124 25, cn=Gary L. Disbrow -S
Date: 2020.08.19 13:02:08 -04'00'

Gary L. Disbrow, Acting Director
HHS/Biomedical Advanced Research and Development Authority
Date:

Exhibit 16

4. A description of any payments made to Emergent or any of its subsidiaries or affiliates pursuant to the $628 million task order awarded by HHS on May 24, 2020 (PIID 75A50120F33007), including the date(s) and amount(s) of any payments, as well as a description of the completed task, work, or milestone for which the payments were made.

| No. | Date* | Amount | Description | Comments/Notes |
|---|---|---|---|---|
| 1 | 07/21/2020 | $27,137,500.00 | Task 1 – Monthly Report** (May 2020) | |
| 2 | 08/06/2020 | $27,137,500.00 | Task 1 – Monthly Report (June 2020) | |
| 3 | 08/20/2020 | $23,250,000.00 | Task 2 – Delivery of IMS, WBS, VMP<br>Task 2 – Arrival of Camden Equipment | |
| 4 | 09/21/2020 | $29,012,500.00 | Task 1 – Monthly Report (July 2020)<br>Task 2 – Completion of Camden Construction | |
| 5 | 09/17/2020 | $27,137,500.00 | Task 1 – Monthly Report (August 2020) | |
| 6 | 11/09/2020 | $27,137,500.00 | Task 1 – Monthly Report (September 2020) | |
| 7 | 12/01/2020 | $27,137,500.00 | Task 1 – Monthly Report (October 2020) | |
| 8 | 01/04/2021 | $27,137,500.00 | Task 1 – Monthly Report (November 2020) | |
| 9 | 02/23/2021 | $27,137,500.00 | Task 1 – Monthly Report (December 2020) | |
| 10 | 03/10/2021 | $1,875,000.00 | Task 2 – Completion of Camden CQV | |
| 11 | 03/10/2021 | $27,137,500.00 | Task 1 – Monthly Report (January 2021) | |
| 12 | 04/28/2021 | $26,867,500.00 | Task 1 – Monthly Report (February 2021) | USG and Contractor mutually agree to reduce the price for the February 2021 monthly report to account for the onsite DoD personnel support (See Mod Nos. P00003 & P00005). |

*Represents the date that BARDA entered receiving into the Oracle system (the last “BARDA step” in the invoice approval process). The HHS Program Support Center and the US Department of Treasury are responsible for next steps.

**Monthly Report Description (see Task Order paragraph F.2.5 Monthly Report): “Each monthly report must include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. Specific to Task 1, each monthly report must include a summary of capacity availability and utilization / non-utilization, as well as any issues that impact the operational availability of the reserved capacity. Specific to Task 2, each monthly report must include a summary of the progress in establishing the expanded drug product capacities at the Camden and Rockville facilities, including updates to IMS.”

Exhibit 17

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| Baltimore District (BLT-DO)<br>6000 Metro Drive, Suite 101<br>Baltimore, MD 21215<br>[redacted] | 4/12/2021 – 4/20/2021 |
| | FEI NUMBER<br>[redacted] |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Dino S. Muzzin, Senior Vice President Manufacturing Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Emergent Manufacturing Operations Baltimore, LLC. | 5901 East Lombard Street |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Baltimore, MD 21224 | Vaccine Drug Substance Manufacturer |

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

## Observation 1

Failure to conduct thorough investigations into unexplained discrepancies.

Specifically,

a. The cross-contamination of client [redacted] viral vaccine drug substance batch [redacted], which was manufactured between 1/19/2021 and 2/21/2021, with the virus from client [redacted] as described in deviation 3100012112 initiated on 3/17/2021 has not been thoroughly investigated. Specifically,

   i. The deviation did not include consideration of operator [redacted] who is recorded on the batch record as weighing and dispensing the raw materials for media batch [redacted] used in the manufacture of DS batch [redacted] on 2/4/2021. This batch of media is implicated by your firm in the deviation as the most probable cause of the cross-contamination event. Operator [redacted] also entered both manufacturing areas where client [redacted] viral vaccine drug substance and client [redacted] viral vaccine drug substance are respectively manufactured on 2/4/2021, prior to weighing and dispensing these raw materials based upon badge access data and video surveillance. Operator [redacted] was observed on the security camera footage dated 2/4/2021 wearing protective gowning and foot protection in the controlled not classified hallway outside the weigh and dispense room before entering the weigh and dispense room through the material airlock.

   ii. The deviation investigation did not include a thorough review of personnel movements in and around the facility as a potential source of contamination.

   iii. The deviation did not include consideration of the potential impact of the continued use of zip-tied plastic bags to store raw materials used to manufacture buffers used in the manufacture of client [redacted] viral vaccine drug substance and client [redacted] viral vaccine drug substance. These plastic bags were identified in the deviation as being not designed to allow for proper decontamination.

   iv. It is not known how long client [redacted] virus will remain viable on a surface. There was no additional cleaning performed other than the routine cleaning in response to this deviation.

   v. There is no assurance that other batches have not been subject to cross-contamination.

b. On 2/12/2021, during the filling of batch [redacted] bulk drug substance for client [redacted] released on 3/10/2021, a [redacted] leak was observed by the operator. The fill recipe was paused and

excess liquid in the spine was pushed into the final two bottles, then the recipe was aborted, and a new recipe was initiated. The practice for aborting a fill is not described within a written procedure and is not a procedural step in the master batch record. Your firm failed to investigate how the operators were trained to perform this recipe abort and initiate a new recipe technique. Your firm also failed to investigate what impact utilizing this technique has on the product during filling operations.

c. On 1/19/2021, freezer room ID# [redacted] and freezer corridor ID [redacted] had logbook entries "fix bag w/tear" and "repair ripped bag". The bulk drug substance batch [redacted] for client [redacted] released on 3/10/2021, was in the freezer at the time of these logbook entries. Your firm failed to initiate a deviation and failed to conduct an investigation to evaluate what impact a tear or ripped bag had on bulk drug substance batch [redacted] or what corrective actions were initiated.

## Observation 2

The building used for the manufacture of the client [redacted] viral vaccine drug substance and client [redacted] viral vaccine drug substance is not maintained in a clean and sanitary condition.

Specifically,

a. Waste generated during the manufacture of the client [redacted] vaccine drug substance and client [redacted] viral vaccine drug substance is not decontaminated using [redacted] that have been qualified for use or a cycle qualified for actual use. Such waste is transported through the warehouse before disposal and has the potential to contaminate the warehouse and adjacent areas

b. The manufacturing rooms and corridors are not cleaned with a cleaner/detergent.

c. The painted floors in the warehouse were observed to be peeling on multiple days during the inspection. Large areas of the painted surface are missing in front of the weigh and dispense and QC raw material sampling rooms. The damaged floors and rough surfaces do not allow for adequate cleaning and sanitization.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Dino S. Muzzin, Senior Vice President Manufacturing Operations

| FIRM NAME | STREET ADDRESS |
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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

d. On 4/14/2021, the paint on the walls of the controlled not classified corridors surrounding the manufacturing rooms for Areas 1 and 2 were observed to be peeling in multiple areas. Paint flecks were observed on the floor all along the sides of these walls. Damage to the wall boards was also observed approximately 6 inches above the floor and approximately 3 feet above the floor. This peeling paint and wall damage impacts the firms' ability to adequately clean and disinfect the area.

e. On 4/14/2021, the following items were observed inside room [redacted], a Grade [redacted] room, during the filling of client[redacted] viral vaccine drug substance batch 21004323:
   i. Paint flecks, loose particles/debris, and a washer were observed on the floor along the sides of the wall
   ii. Brown residue was observed on the wall
   iii. Black residue from a spill-pig was observed on the floor
   iv. Blue peeling paint was observed along the door jam into room [redacted]

**Observation 3**

The building used for the manufacture of the client [redacted] viral vaccine drug substance and client [redacted] viral vaccine drug substance is not of suitable size, design, and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

a. The number and size of decontamination [redacted] used to decontaminate waste generated during the manufacture of client [redacted] viral vaccine drug substance or client [redacted] viral vaccine drug substance are inadequate to ensure that such waste is decontaminated in a timely manner. In addition, an assessment of the building's capacity to decontaminate waste was not performed as part of the incoming process gap assessment prior to introduction of the manufacturing of client [redacted] viral vaccine drug substance into the facility.

   The inadequacy of waste handling is underscored by planned deviation 3100012410 that was opened on 4/9/2021 to change the path of waste out of the building for Areas 1 and 2; and due to an increase in waste from Areas 1, 2, and 3, this waste will not be autoclaved, but it will be double bagged and the exterior of the bag will be sprayed with [redacted]z prior to transport through the warehouse and out of the building for a limited number of days.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

b. The warehouse was observed on 1/27/2021, 2/3/2021 and 2/4/2021 through security camera footage, and on 4/12/2021 and 4/13/2021 through direct observation, to be overcrowded with materials staged for entry into manufacturing as well as material staged for QC sampling.

c. On 4/14/2021, the Area 1 buffer preparation, [redacted], was observed to be congested with tanks and tote-like containers used to hold buffer solutions.

d. On 4/14/2021, the Area 1 downstream, room [redacted], was observed to be congested with carts, transport racks for bottled drug substance, tote-like containers used to hold buffer solutions and drug substance, and various other pieces of equipment. The congestion made it difficult to move without bumping into equipment or totes.

e. The doors into and out of the material pass through into the weigh and dispense area and into the raw material sampling area are too small as operators are unable to use a pallet jack for pallets to move material in large containers. On 4/12 and 4/13/2021, operators were observed pushing and pulling large containers along the floor to move them from weigh and dispense room and QC sampling room into the warehouse.

## Observation 4

Written production and process control procedures to prevent cross-contamination are not followed in the execution of production and process control functions and are not documented at the time of performance.

Specifically,

a. According to security camera footage from 1/27/2021 and 2/3/2021, employees handling special medical waste from manufacturing Area 3, where bulk drug substance for client [redacted] is manufactured, failed to follow SOP041888 v 3.0 (effective 8/21/2020) regarding handling non-disinfected and non-decontaminated special medical waste.

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| | FEI NUMBER<br>[redacted] |

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

i. On 1/27/2021 and 2/3/2021, employees in manufacturing Area 3 where bulk drug substance for client [redacted] is manufactured, were observed throwing unsealed bags of special medical waste into the service elevator accessing the warehouse corridor.

ii. On 1/27/2021 and 2/3/2021, employees in manufacturing Area 3 where bulk drug substance for client [redacted] is manufactured, failed to spray/wipe all special medical waste with disinfectant.

iii. On 1/27/2021 and 2/3/2021, employees were observed carrying unsealed bags of special medical waste from manufacturing Area 3. The unsealed bags were observed contacting containers of staged manufacturing materials, walls, and fence barriers in the weigh and dispense corridor of the warehouse.

iv. On 1/27/2021 and 2/3/2021, employees were observed dragging used materials containers and unsealed bags of special medical waste from manufacturing Area 3 across the floor of the weigh and dispense corridor of the warehouse.

v. On 2/3/2021, employees were observed compacting, using their gloved hands, unsealed bags of special medical waste from manufacturing Area 3 in the warehouse where raw materials were staged for manufacturing in Area 2 for client [redacted].

vi. On 2/3/2021, employees were observed removing their outer protective garments onto the warehouse floor where raw materials were staged for manufacturing in Area 2 for client [redacted] and placing the garments in open garbage containers.

b. According to direct observation and security camera footage from 2/4/2021 and 4/12/2021, employees handling raw materials intended for the use in manufacturing Area 2 where bulk drug substance for client [redacted] failed to follow SOP001518 v 15.0 (effective 4/9/2021) and SOP001518 v 14.0 (effective 9/3/2020) regarding the handling of materials into the weigh and dispense room and the Quality Control sampling room.

i. On 2/4/2021, employees were observed dragging containers of raw materials across the floor of the weigh and dispense warehouse corridor failing to apply disinfectant to the bottom of the container.

ii. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the weigh and dispense warehouse corridor floor failing to apply disinfectant to the bottom of the container.

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| Baltimore District (BLT-DO)<br>6000 Metro Drive, Suite 101<br>Baltimore, MD 21215<br>(410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov | 4/12/2021 – 4/20/2021 |
| | FEI NUMBER<br>3015448605 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Dino S. Muzzin, Senior Vice President Manufacturing Operations

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

iii. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the Quality Control sampling corridor failing to apply disinfectant to the bottom of the container.

c. According to security badge access logs, shower logs, and security camera footage from 1/19/2021 to 2/21/2021, employees were observed entering manufacturing Area 3 where bulk drug substance for client [redacted] and Area 2 where bulk drug substance for client [redacted] in the same day failing to document de-gowning, showering, and gowning activities according to SOP001516 v 23.0 (effective 2/5/2021) and SOP001516 v 22.0 (effective 9/2/2019).

i. According to the security badge access log, security camera footage, and batch record [redacted] on 2/4/2021, a manufacturing associate (Operator upstream MFG) was observed entering manufacturing Area 3 when manufacturing for client [redacted] was taking place, then weigh and dispense for raw materials for client [redacted], and then loading of materials into the bioreactor in manufacturing Area 2 for client [redacted] without documenting de-gowning and showering.

ii. According to security badge access logs between 1/19/21 – 2/21/21, one MFG Bioprocess Associate entered manufacturing Area 3 and manufacturing Area 2 on the same day, during 19 different days, only documenting once in shower logbook on 2/21/21.

iii. According to security badge access logs between 1/19/21 – 2/21/21, one engineer entered manufacturing Area 3 and Area 2 on the same day, during 4 different days, not documenting in shower logbook for any of the days.

iv. According to firm management between 1/19/21 – 1/31/21, approximately 14 different personnel entered manufacturing Area 3 and manufacturing Area 2 on the same day, there was no documentation of a shower.

v. According to firm management between 2/1/21 – 2/11/21, approximately 13 different personnel entered manufacturing Area 3 and manufacturing Area 2 on the same day, there was only one documented in the shower logbook.

vi. According to firm management between 2/12/21 – 2/21/21, approximately 13 different personnel entered manufacturing Area 3 and manufacturing Area 2 on the same day, there were only two documented in the shower logbook.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

d. According to direct observation and security camera footage from 1/27/2021 to 4/12/2021, employees were observed entering the materials airlock for manufacturing Area 2 where bulk drug substance for client [redacted] is manufactured, warehouse, weigh and dispense room, and Quality Control Sample room failing to adhere designated gowning zones according to SOP001516 v 23.0 (effective 2/5/2021) and SOP001516 v 22.0 (effective 9/2/2019).

   i. According to security camera footage on 1/27/2021, employees were observed removing gloves and booties into waste containers located in the warehouse with staged raw materials present after handling special medical waste from manufacturing Area 3.
   ii. According to security camera footage on 2/3/2021, employees were observed removing protective gowns onto the floor of the warehouse and into waste containers located in the warehouse with staged raw materials present after handling special medical waste from manufacturing Area 3.
   iii. Per direct observation on 4/12/21, employees were observed wearing protective gowns and booties into the warehouse and warehouse corridor while conducting activities in the Area 2 materials airlock, weigh and dispense room, and Quality Control Sample room.

## Observation 5

The components, product containers and/or closures were not handled and/or stored in a manner to prevent contamination.

Specifically,

Product components, containers, and closures involved in manufacturing operations, quality control sampling, weigh and dispense operations are not handled and stored to prevent cross contamination of viral bulk drug substances created for client [redacted] and client [redacted].

a. On 3/16/2021, the firm was notified by client [redacted] that bulk drug substance batch [redacted] manufactured between 1/19/2021 and 2/21/2021, was contaminated with a viral vector used in the manufacture of bulk drug substance for client [redacted]. Review of security camera footage found:

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

i. On 1/27/2021 and 2/3/2021, employees were observed carrying unsealed bags of special medical waste from manufacturing Area 3. The unsealed bags contacted containers of staged manufacturing materials, walls, and fence barriers in the weigh and dispense corridor of the warehouse.

ii. On 1/27/2021 and 2/3/2021, employees were observed dragging used materials containers and unsealed bags of special medical waste from manufacturing Area 3 across the floor of the weigh and dispense corridor of the warehouse.

iii. On 2/3/2021, employees were observed compacting unsealed bags of special medical waste from manufacturing Area 3 in the warehouse where raw materials were staged for manufacturing in Area 2 for client [redacted]

iv. On 2/3/2021, employees were observed removing outer protective garments onto the warehouse floor and placing them in open garbage containers where raw materials were staged for manufacturing in Area 2 for client [redacted]

v. On ~~2/3/2021~~ 1/27/2021 CDR 4/20/2021, an employee was observed putting yellow raw material bucket containers on a table in the service elevator accessing manufacturing Area 3, amongst unsealed special medical waste from manufacturing Area 3, then bringing the yellow raw material bucket containers into the weigh and dispense room without decontaminating or disinfecting the yellow raw materials bucket containers.

vi. On 2/4/2021, employees were observed dragging containers of raw materials across the floor of the weigh and dispense warehouse corridor failing to apply disinfectant to the bottom of the container.

b. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the weigh and dispense and Quality Control sampling warehouse corridor floor failing to apply disinfectant to the bottom of the container.

c. On 4/12/2021, we observed yellow raw material bucket containers with cracked or opened closures in the raw materials staging area of the warehouse staged for manufacturing in Area 1/2 for client 562.

d. On 4/14/2021, we observed employees lifting containers of sodium chloride onto a platform, opening the container, and then using a scoop to add the sodium chloride into the manway of a

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| Baltimore District (BLT-DO)<br>6000 Metro Drive, Suite 101<br>Baltimore, MD 21215<br>[redacted] | 4/12/2021 – 4/20/2021<br>[redacted] |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Dino S. Muzzin, Senior Vice President Manufacturing Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Emergent Manufacturing Operations Baltimore, LLC. | 5901 East Lombard Street |
| **CITY, STATE AND ZIP CODE** | **TYPE OF ESTABLISHMENT INSPECTED** |
| Baltimore, MD 21224 | Vaccine Drug Substance Manufacturer |

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

mixing vessel for strip buffer solution batch [redacted] in manufacturing in Area 2. We observed the employees failing to remove or sanitize their gloves after grabbing the bottom of the container.

## Observation 6

Written procedures designed to assure that the drug substances manufactured in the facility have the identity, strength, quality, and purity they purport or are represented to possess are inadequate. Specifically,

a. The procedure for decontamination of waste generated during the manufacture of the client [redacted] viral vaccine drug substance and client [redacted] viral vaccine drug substance described in SOP040195 does not include a description of how the bags containing the waste are to be placed into the [redacted] chamber to ensure that there is adequate penetration of steam into these bags to decontaminate the waste. Such waste is transported through the warehouse, where raw materials are received and staged, prior to disposal.

b. The procedure used for the periodic monitoring of decontamination [redacted] effectiveness described in BOP040102 and documented on FRM042531 does not include a requirement for placement of the biological indicator or chemical indicator in a worst-case location inside the autoclave chamber to support that all of the waste is decontaminated. Such waste is transported through the warehouse, where raw materials are received and staged, prior to disposal.

c. The procedure for cleaning and decontamination of buckets used to store and transport raw materials described in SOP001518 does not include a requirement for cleaning the buckets or to remove residual sterilant/disinfectant sprayed onto the buckets prior to placing plastic bags used to store the raw materials inside the buckets. Such plastic bags were identified in deviation 3100012112 as being able to introduce material on the outside of the bag into a vessel in which buffers used to manufacture the client [redacted] viral vaccine drug substance are formulated.

d. The procedure "Material and Waste Flow for Area 3" SOP041888, version 3.0, effective 21 Aug 2020 does not reflect current operations for the movement of contaminated waste. The procedure states "[redacted] all potentially contaminated waste", however staff in Area 3 were allowed to dispose of potentially contaminated waste without first using the autoclave.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

## Observation 7

Employees were not trained in the particular operation that they performed and/or in CGMPs related to their job function.

Specifically,

The firm has failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross contamination of bulk drug substances created for client [redacted] and client [redacted]

Review of security camera footage found:

a. Personnel involved in manufacturing operations entered manufacturing Area 3 while processing of client [redacted] bulk drug substance was taking place, then entered weigh and dispense rooms where operations for client [redacted] bulk drug substance was taking place without properly adhering to gowning procedures.

b. Personnel involved in manufacturing operations and engineering entered manufacturing Area 3 while processing of client 577 bulk drug substance was taking place, then entered manufacturing Area 2 while processing for client 562 bulk drug substance was taking place without properly adhering to gowning procedures.

c. Personnel involved in manufacturing operations dragged non-disinfected and non-decontaminated special medical waste from manufacturing Area 3 across the warehouse corridor, weigh and dispense corridor, and quality control sampling corridor floors, failing to adhere to materials and waste handling procedures.

d. Personnel involved in manufacturing operations collided with walls, warehouse barriers, weigh and dispense doors, quality control sampling doors, and staged raw material containers with non-disinfected and non-decontaminated special medical waste from manufacturing Area 3, failing to adhere to materials and waste handling procedures.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

e. Personnel involved in manufacturing operations removed protective gowns and foot covers worn in manufacturing Area 3 and handling non-disinfected and non-decontaminated special medical waste from manufacturing Area 3 in the warehouse with staged raw materials, failing to adhere to gowning procedures.

The following was directly observed during the inspection:

f. Personnel involved with weigh and dispense, and quality control sampling operations were observed dragging raw material containers used in manufacturing Area 2 across the weigh and dispense and quality control sampling corridor, failing to adhere to materials and waste handling procedures.

## Observation 8

Equipment used is not of adequate size to facilitate operations for its intended use or for cleaning and maintenance.

Specifically,

a. On 4/13/2021, plates dating back to 2/22/2021 were observed in and on top of a plastic container in the refrigerator inside the microbiology laboratory that is used for testing of client [redacted] viral drug substance. These plates included environmental monitoring plates, raw material bioburden plates, and microbial limit testing for client [redacted] that are to be sent for microbial identification. This refrigerator was overcrowded, and a cleanout had occurred on 4/12/2021.

b. On 4/14/2021, the refrigerator inside the QC lab [redacted] was observed to be overcrowded. Inside this refrigerator the analysts store plates awaiting send out for identification, microbial organisms for growth promotion, retains for client [redacted] bioburden aliquots, conical tubes of in-process and final drug substance samples, and laboratory supplies and plates needing storage under refrigeration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

## Observation 9

Equipment and/or utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug substance.

Specifically,

a. The non-dedicated yellow buckets used to hold weighed bagged raw materials are not required by written procedure to be cleaned after each use. The procedure as described in SOP001518 (version 14) requires that they are externally sprayed with [redacted] when travelling through the material airlock.

b. I observed residue on the bottom of a tote inside the Area 3 suite. Rouging was observed on the metal screws that attach the tote to the wheels below in many of the totes seen in the hallway. These totes are used to transport material in Area 3.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | [redacted] | [redacted] | **4/20/2021** |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Exhibit 18

# OWS Manufacturing & Supply Chain

## Emergent BioSolutions sites visit report

## DRAFT

This report is based on company provided information, a review session with the BARDA team of SMEs who have interacted with the company so far, and a site visit to the Emergent Bayview and Camden facilities performed by CdN, T.Belski and A.Donabedian on June 4, 2020.

**Executive Summary**: The scope of the visit was to assess the company organization and facilities readiness to accept transfer in of the Janssen, AZ and Novavax vaccine candidates, and start manufacturing drug substance and drug product according to the current very aggressive schedule.

The Bayview drug substance plant is currently being reconfigured to accommodate the covid-19 vaccine candidates, and it is not ready yet. Most of the large scale existing equipment is not suitable for the new processes, and will be either removed or mothballed. New 2000lt bioreactors are on order, and will be installed as delivered, together with most ancillary equipment. The plant overall design is modern and suitable for the purpose assessed, with 4 manufacturing suites. The supporting infrastructure is very limited, and will need substantial remediation and expansion to allow manufacturing to proceed at the planned rate. The operations management is knowledgeable and appears self confident.

Risks identified for Bayview

- Scale up risk – limited: the scale up ratios are small, and the organization has the necessary experience/competence. Main risk here is process drifting, to be assessed with strong change control.
- Facilities readiness risk – medium: Most of the critical equipment for the Janssen vaccine has not been received yet, and will have to be installed and qualified. Warehousing must be expanded, and so QC and Utilities. Might require government support for expediting.
- Personnel risk – significant: The staffing plans presented seem inadequate to the level of concurrent activities required for full scale production of 3 programs. In addition, recent FDA and customer audits has highlighted the need for extensive training of personnel, and strengthening of the quality function.
- Compliance risk – significant: Emergent Bayview has been focused on R&D activities for the last 8+ years, and will have to strengthen the change control process, systems audit trails, and quality oversight to address audit observations and ensure products licensure. This will require significant resources and commitment.

Risks identified for Camden

- Facilities readiness risk – limited: Construction work is well advanced, and key equipment is already onsite.

- Personnel risk – medium: Staffing plans seem inadequate to a possible doubling of production volumes, but alternative capacity will exist for fill/finish of most of the products.
- Scale up risk – limited: Fill/finish process tech transfer and scale up is less critical, and the site has experience with multiple products in commercial setting.
- Compliance risk – medium: The site has an existing capacity which is outdated, and constitutes a concern. The new expansion is state of the art, and fully in line with current regulatory expectations.

All of the above mentioned risks can be addressed successfully within the timelines of OWS, enabling successful manufacturing of the products, provided the necessary external support to assess and remediate will be engaged. This is especially true for the compliance risk at Bayview. Material deliveries and construction/qualification progress will also need to be monitored closely and may require intervention. Astra Zeneca has committed to support beyond tech transfer with onsite resources, until delivery of the committed doses. Similar commitment will be asked of J&J/Janssen.

The Emergent B. management is visibly committed to this project, which is a key requisite for success.

**Bayview plant:**

This plant was acquired by Emergent in 2009, and consists today of 4 manufacturing areas. Areas 1 & 2 where gutted and rebuilt in 2011, and the plant was expanded in 2018 with the construction of areas 3 & 4. The partnership with BARDA was established in 2012. The facility has many development programs ongoing, and one commercial filing pending review.

The areas have a good layout, material and people flow, and appear well built, with separate upstream and downstream sub- areas and enough space to operate and maintain the equipment. Some of the existing equipment will be mothballed and replaced with new ones to suit the new products being transferred there.

Airlocks and area classifications allow manufacturing of products requiring BSL2 safety level. Areas 1&2 utilities are segregated from area 3&4, and personnel access is completely independent.

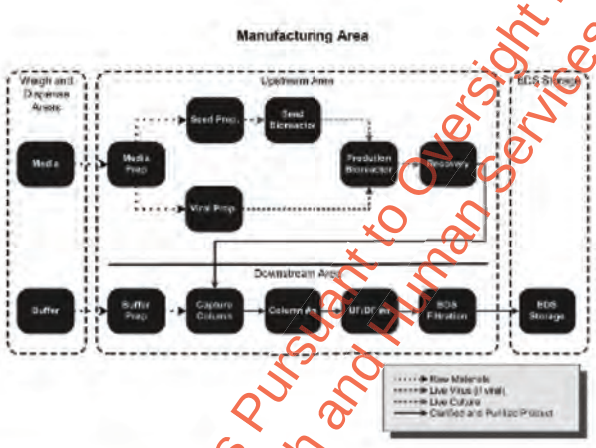
Areas 1&2 are mirror image floor plans, designed for multi-product concurrent manufacturing. Each area has segregated upstream suite, downstream suite and a component prep suite.

Areas 3&4 are single product manufacturing spaces, with different layouts. Area 3 has two downstream suites, while area 4 has a ballroom upstream and a ballroom downstream.

The utilities and the storage space require significant restructuring and expansion to support the volumes we are projecting to manufacture post validation. In addition to that, the Janssen product will require major adaptation in the equipment trains, and the purchase and installation of new equipment both for the upstream and downstream. Some of the existing equipment will be mothballed and left in place.

## Bayview Facility and Process Flow

- The Bayview site consists of four segregated multi-purpose manufacturing suites (Area 1,2,3 and 4).
- Each manufacturing suite is provided with dedicated utilities including WFI distribution, HVAC and process gas distribution.
- Segregated areas for Upstream and Downstream processes




27 BAYVIEW OPERATIONS BARDA/OWS Site Visit - Baltimore Sites

## Large Scale Manufacturing – Equipment and Platforms

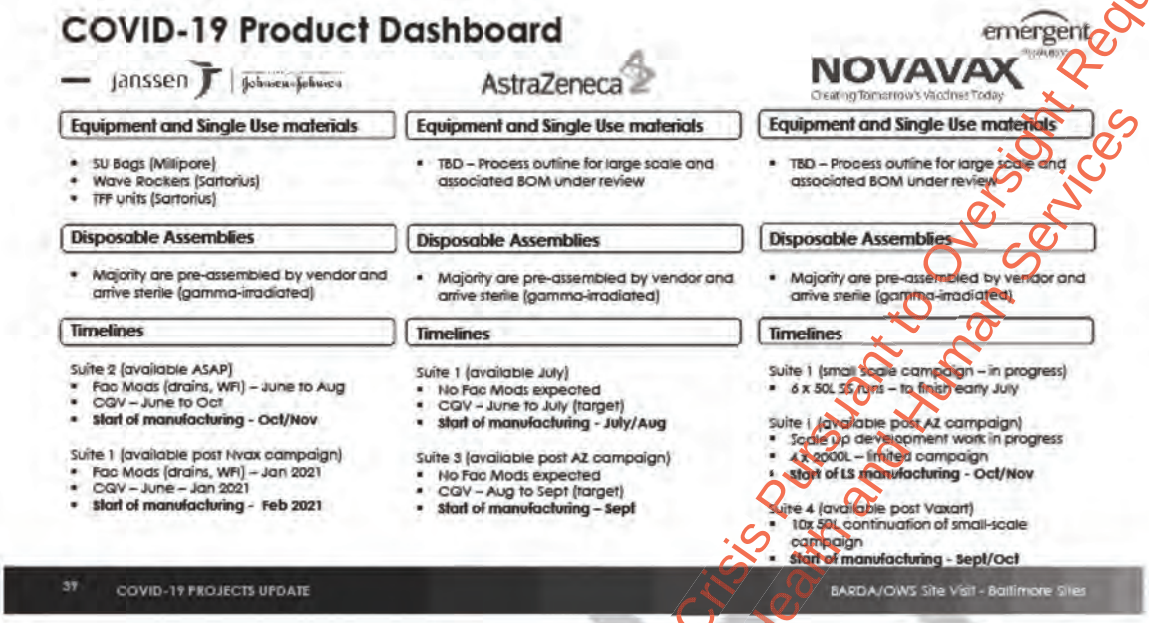
### Process Equipment

- Flexible Single-Use Platform
- Accommodates up to 4000L bioreactors and associated downstream equipment

### Product Platforms

- Live viral vaccines
- Viral Vector
- Microbial
- Cell Culture

24 BAYVIEW OPERATIONS BARDA/OWS Site Visit - Baltimore Sites




The slide above shows the plan at the time of the visit, on June 4th. This plan has been changed since, and now the Novavax product is no longer planned for scale up and manufacturing at Emergent. The Janssen product will require facilities modifications, and the procurement of several units of downstream equipment, with an extensive lead time of up to 23 weeks. The AstraZeneca product instead will fit the facility without requiring any major change, and the limiting factor to the startup will be the tech transfer. Initial discussion with both companies have already started, and Emergent has received technical information packages to make these assessments.

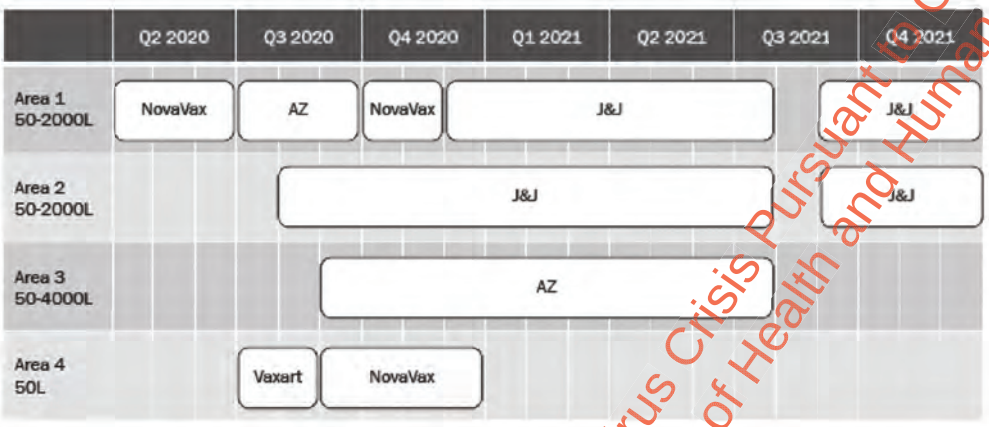
The outcome of these assessments are the manufacturing schedule, and the list of key risks reported in the two following slides. The manufacturing schedule is being optimized, developing a new alternative excluding Novavax and possibly Vaxart (TBC). The schedule seems aggressive, and assumes a smooth tech transfer and no issues with the equipment delivery. BARDA is engaged and has started communicating the priority to the suppliers of disposable components and equipment.

The compression of the timelines has required the tech transfer to start, before the processes are fully defined. The Janssen process is currently being scaled up in the US, and so is the AstraZeneca process. There is a risk that some of the initial assessment on equipment suitability may have to be reviewed. Emergent is aware of this risk and so are the sponsor companies. I believe this risk to be limited, given the experience of the organization of the sponsor companies, and at Emergent.

The equipment and construction risk is more significant. There are a number of construction activities on site and off site which need to be completed and the facilities qualified before the cell line and viral seed can be introduced in the plant. Any restriction related to a new wave of infections may have an impact on the schedule. This risk has been identified, and mitigation actions studied.

The plant does not have enough warehouse space on site, and Emergent is in the process of building/leasing a new warehouse in the Baltimore area to serve all the 4 plants they own in that area. This is a less than ideal solution, given the high production volumes and level of activities expected in the Bayview plant, but unfortunately no better solutions were identified due to space constraints.

## Manufacturing Schedule




32 BAYVIEW OPERATIONS BARDA/OWS Site Visit - Baltimore Sites

## Risks / Issues / Challenges – Bayview

### Long lead times for some Equipment & Components

- Single Use components, i.e. bags
- Process equipment, i.e. 200L rockers/bioreactors, TFF systems
- Action: Escalation process for critical path items, leverage good vendor relationships, emphasize priority with COVID response efforts

### CQV

- Understanding and alignment of requirements for emergency use batches
- Action: Alignment with customer and discussions with regulatory authorities as required

### Rolling Tech Transfers...

- Use of platform processes not fully developed for COVID-19.
- Action: Continued close collaboration with customers to ensure that we appropriately react to process/equipment changes

40 COVID-19 PROJECTS UPDATE BARDA/OWS Site Visit - Baltimore Sites

The two key risks to the plan are linked to the hiring of people and their training, and the remediation of the compliance gaps identified by the FDA inspection held in April 2020. A mere detailed T&E plan was requested and solicited several times from Emergent, and as of 6/17 was not provided yet.

The following slide shows the current hiring plan to support the required production plan. I believe this plan to be inadequate to enable the company to manufacture at the required rate, but I recognize the limits in the plant's ability to grow, and the time required to train new employees. This increases the risk to the schedule obviously, and will have to be monitored closely. Offloading the Novavax program to a different facility will also help reduce the load on Emergent Bayview

The plant will have to operate on a 24/7 schedule, which means 5 teams will be required in manufacturing, QC and some of the other support functions. Keeping into account an attrition rate of the order of 10%-15%/year, we will have to extend the hiring plan and the company has accepted to review it and discuss it with BARDA. Reinforced quality oversight and training to strengthen compliance will also absorb resources.

## Bayview Headcount

emergent

| Department | Current FTEs | Contingency | Additional Temp/Contractors | FTE's Added |
|---|---|---|---|---|
| Manufacturing | 46 | 7 | 0 | 46 |
| QA/Validation | 23 | 4 | 4 | 9 |
| Quality Control | 33 | 2 | 0 | 19 |
| MS&T | 11 | 0 | 0 | 4 |
| AS&T | 8 | 2 | 0 | 0 |
| Eng./Facilities | 28 | 0 | 10 | 4 |
| Supply Chain | 7 | 0 | 0 | 3 |
| Project Mgmt. | 7 | 0 | 1 | 0 |
| Administrative | 8 | 0 | 0 | 1 |
| Total | 171 | 15 | 15 | 86 |
| | | | | 287 |

34 BAYVIEW HEADCOUNT BARDA/OWS Site Visit - Baltimore Sites

**Compliance risk**

The Bayview plant received a pre-approval inspection by the FDA resulting in 5 observations, mostly focused on data integrity in the QC lab, training of operators, and general QA practices. The plant also received a customer audit for cause triggered by some data integrity issues identified in the QC testing of the customer product.

While these observations are not unusual in a startup mostly dedicated so far to development activities, they will require significant effort to be addressed to the agency's satisfaction. The resources and time required should be built into the plan

**Camden Plant :**

The Camden plant is focused on fill finish and packaging operations. It is a relatively old facility acquired by Emergent in 2014. The plant cosmetics have been recently upgraded over the last few years, replacing floor finish, walls coverings and doors in manufacturing, but it is still original in the packaging and ancillary areas. The equipment is mostly obsolete, with manual operations, and very low capacity. The total manufactured volume in 2019 amounted to about 3mm vials.

The plant has 3 filling lines, 2 of which are for vials and one for PFSs. The two vials filling lines have open RABS, and are manually loaded with vials from trays, and manually unloaded. One line has one needle fill station and the other line has 2 needles fill station. The washing of the vials is performed in a separate room, and the vials are manually loaded into trays and put in a dry heat over for depyrogenation. From there the vials are manually loaded onto the filling line.

This set up is obsolete, and the FDA has challenged it since many years around the world.

The company has recently started investing in a new state of the art flexible filling line, which is in process of being installed, and expected to be operational by the end of the year. This new line appears to meet current regulatory expectations, and is equipped with an isolator. It will process vials in tubs pre-sterilized.

Inspection is manual, and so is packaging. Also this plant, like the Bayview facility has very limited storage space, and will require expansion of the warehouse.

People in the plant are mostly long term employees of that plant, and seem knowledgeable. The plant has undergone several regulatory inspection and customer audits. The most recent FDA inspection was successful with no 483 issued, the previous one from 2018 identified similar data integrity and training issues recently identified in Bayview.

**Conclusions:**

The Bayview plant is preparing to accept two of the OWS vaccine processes. Risks can be mitigated with incremental support to the quality organization, and appropriate planning to ensure training is performed.

If the Camden plant is required to perform fill/finish operations, the new line under installation should be used exclusively.

June 17, 2020

Carlo de Notaristefani, Dr. Ing.

OWS Advisor Manufacturing & Supply Chain