Exhibit 19

AUDITEE	Emergent BioSolutions				
LOCATION	5901 East Lombard St. Baltimore, MD, US 21224			RECORD #	1812490
AUDIT TYPE	External Audit	AUDIT START	09-Jun-2020	AUDIT END	18-Jun-2020

Judith Adair McCorry
Emergent BioSolutions
5901 East Lombard St.
Baltimore, MD, US 21224

Dear Judith Adair McCorry,

As part of the Janssen External Audit program, a(n) Qualification of Emergent BioSolutions was conducted on 09-Jun-2020 - 18-Jun-2020.

Results of the audit have determined that (0) observation(s) meet the definition of Critical observation, (2) observation(s) meet the definition of Major observation, and (5) observation(s) meet the definition of Minor observation. As a result of these observations, a corrective action plan is required.

Please provide responses by 21-Aug-2020. The corrective action plan should be sent to my attention at the address listed below and should include target completion dates.

I would like to take this opportunity to thank you and the staff at Emergent BioSolutions for your assistance and continuous cooperation.

Sincerely,

Stephen Green

AUDIT REPORT COVER PAGE

CONFIDENTIAL:

This audit report may not be shared outside of Johnson & Johnson without written authorization from Emergent BioSolutions

AUDIT DEPARTMENTS:	EQ-SQ- EM LM
AUDITEE DETAILS:	Emergent BioSolutions 5901 East Lombard St. Baltimore, MD, US 21224
LEAD AUDITOR:	Stephen Green SR MANAGER ESI QUALITY AMERICAS
REPORT DISTRIBUTION LIST:	Kathryn Mader - Director, EQ Roberto Cintron - Sr. Director, EQ Andrew Krall - Director, Compliance Armand Jongejan - Director, EQ Curt Graham - Sr. Manager, PES Juan Salas - Sr. Scientist, TechOps Mike Fletcher - Director, VCL
AUDIT DATES:	09-Jun-2020 - 18-Jun-2020

Auditee Contact:	Judith Adair McCorry
Auditee Contact Details:	[redacted]
Company Name:	Emergent BioSolutions
Company Description:	Emergent BioSolutions is an American multinational specialty biopharmaceutical company headquartered in Gaithersburg, Maryland. It develops vaccines and antibody therapeutics for infectious diseases, opioid overdoses, and provides medical devices for biodefense purposes
	Judith Adair McCorry Director, Quality Assurance Emergent Bio Solutions, Bayview site 5901 E Lombard Street Baltimore MD 21224 Office: [redacted]
GMP Certification:	N/A
Record ID:	1812490
Auditor(s):	Stephen Green - SR MANAGER ESI QUALITY AMERICAS (Lead Auditor) ANDREW KRALL - DIRECTOR COMPLIANCE GLOBAL LM API
Other Audit Team Members:	

Internal Site Participant Grid

Row #	Internal Participant Name	External Participant Name	Participant Title	Attend Opening Meeting	Attend the Closing	Audit Participant
1		Chad Anderson	Downstream MFG	Yes	No	Yes
2		Cathy Collins	QA	Yes	Yes	Yes
3		Michele Huggins	QC	Yes	Yes	Yes
4		Cezary Karczewski	QA	Yes	No	Yes
5		Ken Kellner	Facilities	Yes	No	Yes
6		Scott Kelly	MFG/Tech	Yes	No	Yes
7		Amanda McClure	Micro	Yes	No	Yes
8		Judith McCorry	QA	Yes	Yes	Yes
9		Steven Miller	Engineering/Facilities	Yes	No	Yes
10		Lakita Patterson	Warehouse	Yes	No	Yes
11		Joe Rogalewski	QA	Yes	Yes	Yes
12		Leonard Trappanese	BioChem	Yes	No	Yes
13		Dan Zdobinski	QA	Yes	No	Yes
14		Jason Jenkins	Upstream MFG	Yes	No	Yes
15		Amanda Ilioff	Upstream MFG	Yes	No	Yes

I. AUDIT OBJECTIVES

Purpose:

To perform a qualification audit at Emergent Bayview in Baltimore, MD for the manufacture of Ad26COVS1.

Audit Standards:

21 CFR Part 11

J&J Standards

21 CFR Part 210

Relevant cGMP Regulations

JnJ Policies and Procedures

ICH Q7

Quality Agreement

Scope:

The audit will cover the quality systems, upstream and downstream manufacturing process, testing, and supply related to the manufacture of Ad26COVS1 for Janssen Supply Chain.

Qualified Services:

Drug Substance

Not-Qualified Services:

N/A

Material Info:

Row	Material Description	Additional Product Info.	International Name
1	N/A	900L Ad26COVS1	N/A

II. EXECUTIVE SUMMARY

A virtual audit of Emergent Baltimore/Bayview was conducted on 09Jun2020 through 18Jun2020. A virtual tour of common areas was held on 09Jun2020 with participation from AstraZeneca (another Emergent client.) A focused virtual tour of Janssen specific manufacturing areas was held on 10Jun2020 with participation from Janssen EHS. Document review of posted procedures/logs/flow diagrams/trend reports occurred over the following week and a close-out was held on 18Jun2020 with issues and concerns presented to Emergent site management.

It should be considered this was a virtual audit, due to the Covid19 pandemic and limited access to manufacturing sites. An on-site visit has been requested and will be scheduled prior to the first GMP manufacturing run (as access is permitted.)

Emergent Baltimore/Bayview started as an Anthrax manufacturing site owned by the state of Maryland. Emergent acquired the site in 2009 from Lonza. In 2011 the GMP space was gutted and rebuilt into mirror image manufacturing areas (Suites 1 and 2, where Janssen product will be manufactured.) The facility currently has an extended single shift and will be going to a double shift, with split weekends.

The Bayview site was inspected by the FDA in April2020 for QC and general quality systems as part of an Emergent PAI. As of time of preparing this audit report, the FDA has not accepted Emergent's initial responses and Emergent is currently taking steps to ensure they obtain FDA acceptance of the updated 483 responses.

The audit focused on overall quality systems, the buildings/facilities, and data integrity. The assessment included a virtual tour of the warehouse, incoming sampling/ weigh dispense, utilities, and various QC labs along with the sample receipt area. The Janssen specific virtual tour focused on Suites 1 and 2.

Observations Escalated: N/A Escalation Date:

III. QUALITY SYSTEMS/DOCUMENTS REVIEWED

Documents Reviewed:

Refer to attached - documents reviewed Emergent Bayview June2020audit.pdf

The following is an overview of the areas reviewed during the audit:

1) Pre Audit Requests
   - 1.1) List of SOPs
2) Items to be Available for Review during the Audit
   - 2.1) SOPs and Work Instruction List

2.2) Overview of Manufacturing License/Certifications/Recent Inspections

3) Introduction

3.1) Purpose of the Audit

3.2) Organisation Charts and Responsibilities

4) Tour of the site/facilities (following product/material flow)

Warehouses, production workshops and utilties

5) Quality Systems

5.1) Investigations

Complaints, deviations, OOS/OOT, return of material, CAPA system and trending

5.2) Product Release

5.3) Change Management

5.4) Training

5.5) Annual Product Review

5.6) Internal Audits and Management Quality Reviews

5.7) Validation Approach and Master Validation Plan

5.8) Quality Agreement

5.9) IT Systems / Data Integrity

6) Production

6.1) API Process Overview

6.2) Process Validation System

Development reports/product introduction criticality analysis/master batch docs

6.3) Batch Documentation

6.4) Cleaning and Cleaning Validation Practises and Documentations

6.5) Procedures on Contamination and Cross Contamination Prevention

Pre and Post Viral

7) Lab Systems

7.1) Analytical Method and Specifications Overview

7.2) Analytical Method Validation (including methods for cleaning validation)

7.3) Analysis Practises

Raw data management, sample management, Reference standards, reagent controls

7.4) Specifications and Methods Management

7.5) Lab Instrument Qualification, Calibration and Maintenance

7.6) Computer System Validation

8) Material Handling

8.1) Receipt, Labelling, Sampling

8.2) Supplier Management Program

8.3) Distribution of Materials

8.4) Pallet Policy

8.5) Animal Derived Material/Antibiotics/Hormones

9) Equipment and Facilities

9.1) Qualification Practises

9.2) Maintenance and Preventive Maintenance

9.3) Calibration

9.4) Utilities and Water

9.5) Environmental Controls

10) Review Supply Chain Information

10.1) Confirm supply chain documented in Quality Agreement

Verify sub-contractors, warehouse, and shipping department

IV. CONCLUSION

The audit resulted in 0 critical observation(s), 2 major observation(s), and 5 minor observation(s).

Audit Classification: Corrective Actions Indicated

Conclusion:

The audit revealed a total of seven (7) observations; of which zero (0) are critical observations, two (2) are major observations, and five(5) are minor observations. Follow-ups/Recommendations were noted.

As a result of EQ's evaluation of the audit results and Emergent's actions related to the FDA 483, the site rating classification is Corrective Action Indicated - A classification assigned to an audit where the observations cited during the assessment (audit) indicate the quality systems may have weaknesses or gaps that require CAPA.

An on-site visit/follow-up will occur prior to the engineering/GMP run. Emergent Bayview is considered Conditionally Qualified per TV-REF-165226 Janssen External Quality: 2020 Audit Strategy in Response to COVID-19 travel Restrictions 01-APR-2020 to 31-DEC-2020. The AIM record will be changed from Conditionally Qualified to Qualified once an on-site audit occurs resulting in Surveillance Indicated (SI) or Corrective Action Indicated (CAI) with an interim control plan.

Other Recommendations:

General Follow-ups / Recommendations:

Follow-up: Umbrella Change Control has yet to be initiated for introduction of Client 562-001: Janssen COVID-19 Vaccine based on the incoming process gap analysis that is currently being compiled.

a. FRM041871 Biosafety Assessment and FRM041904 and New Product Introduction Package need to be completed

b. Viral VHP Efficacy Evaluation FRM041903 v 1.0 needs to be finalized

c. Viral Spor-Klenz Efficacy Evaluation FRM041902 v 1.0 needs to be finalized

Follow-up: Need to establish and align on EUA GMP expectations with Janssen (and Astra Zeneca) to ensure that while different standards at the site/per client may exist, ensure the differences do not result in compliance gaps, execution errors, or discrepancies. Technology transfer plans have to clearly define and document those requirements and expectations.

Follow-up: Analytical Method Validation Plan PLN004066 ver. 1.0 requires it should be reviewed annually and updated as necessary in consideration of Regulatory Guidelines and industry best practices. This review needs to be captured since the document is effective dating back to Oct. 2015. Subsequent discussion with Emergent informed that SOP025251 Handling of Documents due for Periodic Review v. 5.0 will be updated to include adding a 1 year review of Risk Assessments and Validation Plans.

Recommendation: Reject location in the warehouse shares the same secure area with QT material. Although reject material and QT Material are not comingled on the same rack (SAP hold location is A124 and SAP reject location is A125), it is within the same general cage and should be totally separate as is the expectation of many regulators

Follow-up: Due to mold issues associated with the facility shutdown / startup, inadequate gowning / wipe down procedures for materials coming from the warehouse to weigh and dispense it is especially important that effectiveness of associated CAPAs are assessed and reported in timely manner. It is important that the EC due in August 2020 be completed on time and summarized within the quarterly trend report.

Recommendation: SOP043593 v1.0 - Receiving and Distributing Purchased Materials, is deficient in that it does not include a specified timeframe by which temperature sensitive materials being received must be allocated to proper cold storage locations. The procedure only states that in section 6.1.1.2 "Process temperature sensitive materials first. If temperature sensitive package arrives without temperature-controlled packaging via cold packs, dry ice, etc. notify Quality"

Follow-up: ABEC Bioreactor Control System (BCS) Software DI assessment was performed 28 March 2020 but the approval has not yet occurred. Note: EMOB has not started the DI mitigation for the ABEC BCS yet. ☐As they move into the manufacturing portion of the project, they will be reviewing and approving the assessments for each system prior to starting mitigation activities

Recommendation: Some GMP classified areas have epoxy painted drywall which is not optimal. Drywall is easily damaged in corridors and manufacturing while moving equipment resulting in it being compromised, porous and not cleanable. PMs will be especially important to maintain wall integrity. Site should consider alternative material for vulnerable locations.

Recommendation: The spill / decontamination procedure (BAL - Biological Hygiene Program BOP000706) is currently in approval and could use further enhancements: Sections 5.12.6 (Incident Reporting) and 5.12.7 (Implementation and Operational Control of Biosafety Plan) should be more prescriptive on additional decontamination

steps and sampling and post environmental monitoring / testing of the area depending on the extent of the spill and/or viral contamination.

V. AUDIT FINDINGS

Audit Observation Ratings

Critical

- An observation is defined as "Critical" when any one or more of the following four conditions apply:
- Any non-conformance or non-compliance that will or already has adversely affected product performance meeting specification, safety, therapeutic efficacy, or regulatory requirements
- Any non-conformance or non-compliance that if allowed to continue, may result in product rejection, Field Action, or serious regulatory action (e.g. Warning Letter or similar)
- The observation is a repeat "Critical" or "Major" observation or relates to failure to meet a commitment made to a regulatory authority.The observation represents the complete absence of one or more quality system elements or system components necessary to meet regulatory requirements
- For Pre-approval audits, observations are considered critical if they demonstrate that the process will not be reproducible or if they represent a deficiency that would render the application non approvable.

Major

- An observation is defined as "Major" when any one or more of the following conditions apply:
- Any non-conformance or non-compliance that may or may have adversely affected product performance meeting specifications, safety, therapeutic efficacy, or regulatory requirements (Note: the difference between "Critical" and "Major" in this instance is that for "Critical" observations the outcome is: Will or already Has occurred)
- Any isolated non-compliance in not reporting or reporting late any required regulatory/health authority reports or notifications)Note: Frequent or a trend in not reporting or reporting late to health authorities represents a "Critical" observation).
- Repeat minor observation not appropriately addressed.
- For pre-approval audits this would include any observations that may cause a delay in the approval if not resolved prior to the submission of the application or pre-approval inspection.

Minor

- An observation is defined as "Minor" when it is isolated and will not adversely affect product performance meeting specification, safety, therapeutic efficacy, or regulatory requirements, or is unlikely to impact the approval of the application if corrected promptly.

EM/Supplier Quality Management

Major Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1835740	EM/Supplier Quality Management	Quality Metrics	Process and/or Procedure

Observation Description:

The EM and Utility trending program for the site is deficient based on the following:

a. House isolates were not formally reviewed and documented in the EMOB 2018 Environmental Monitoring Trend Report, RPT045458 v 1.0, to ensure that disinfectants used (i.e. Spor-Klenz) remain effective against these organisms. This is required per EMOB Gap Assessment for Disinfectant Efficacy Qualification Studies for Spor-Klenz, RPT040471 v 2.0, which specifies that the site utilizes routine environmental monitoring data to determine in-house isolates. Additionally, the expectation to perform periodic re-assessment is not specifically covered in EM Trending procedure, SOP000291 v 11.0.

b. EM and Utility trend reports (quarterly and annually) are not completed within designated timeframes per procedure (SOP000291 v 11.0) which specifies that quarterly and annual trend reports must be within 45 & 60 business days respectively (if they cannot, open a CAPA to track completion of the report). A CAPA should not be used as a routine mechanism for tracking overdue trend reports nor should reports routinely be overdue. Timeliness of completing these reports is crucial for evaluating any adverse trends in the facility. In most cases there is a 4-6 month delay in completing reports and it is not appropriate to routinely stipulate delays due to resource constraints. Specifically,

i. 2019 Annual Reports for Utility Monitoring and EM Monitoring Trend Reports for Areas 1 & 2 were not completed as of 6/15/2020. CAPA QN Number 1100002143 was put in place per procedure to track the overdue EM / Utility Trend reports which were all to be completed by end of April 2020. This CAPA was further extended until 15 July 2020 due to resource constraints and impact from Covid-19.

ii. Q4 2019 Utility Monitoring Trend Report, Areas 1 and 2 (RPT052091 v 1.0) not effective until 5/8/2020.

iii. Q3 2019 Utility Monitoring Trend Report, Areas 1 and 2 RPT051810 v 1.0) not effective until 3/27/2020

iv. 2Q 2019 Utility Monitoring Trend Report for Areas 1 & 2 (RPT050723 v 1.0) not effective until 12/19/2019

v. Q4 2019 Environmental Monitoring Trend Report, Areas 1, 2, and Weigh Dispense (RPT051899 v 1.0) not effective until 4/10/2020.

Note: 2019 Annual Utility report RPT052611 is in review in Veeva. The 2019 EM report is started but not ready for review. Emergent did review EM / Utility trend data during the 1Q 2020 Site Management Review to ensure timely management awareness

c. Per the Compressed Air Monitoring Program, SOP001971 v 5.0, section 6.5.1.4, it states that yearly trend reports will be submitted to QA for review and approval by March 31st of the following year. This has not yet occurred as part of the 2019 Utility Monitoring. Also, 60 business days to complete annual trending reports as specified in SOP000291 does not align with the March 31st date specified in SOP001971.

Facilities (Facilities, Utilities & Equipment)

Major Observations:

Count	Record ID	Category 1	Category 2	Category 3

Count	Record ID	Category 1	Category 2	Category 3
1	1835745	Facilities (Facilities, Utilities & Equipment)	Environmental Controls & Monitoring	Process and/or Procedure

Observation Description:

The disinfectant program used in the facility is deficient based on the following:

a. Spor-Klenz is the only approved disinfectant that is currently used within the facility due to LpH and Vesphene being no longer commercially available. Normally multiple disinfectants are applied that have a different mechanism for disinfecting properties (e.g. quaternary ammonium compounds, Chlorine compounds, phenolic compounds, peracetic acid, hydrogen peroxide, etc.) to ensure that the entire spectrum of organisms are routinely covered. EU Annex 1 requires that more than one type of disinfectant be used and monitored to detect the development of resistant strains. These principles are applicable to bioburden controlled environments. A sporicidal (e.g. Spor-Klenz) agent should be used on a certain frequency or as needed to address spore forming organisms. Spor-Klenz can be extremely corrosive to equipment if used routinely over time and could create other concerns with regards to stainless steel appearance / cleanability of surfaces.

b. The DE study (EMOB Gap Assessment for Disinfectant Efficacy Qualification Studies for Spor-Klenz RPT040471 v 2.0) leveraged from multiple Emergent sites and a supplemental study (Surface Sanitizer Efficacy Study for Spor-Klenz Concentrate, performed by WuXi AppTec for addressing the house mold isolate Paecilomyces variotii) needs further clarification:

i. Acceptance criteria for greater than 2-3 log reduction (per USP) is not clearly specified and no rationale provided in the referenced studies

ii. It is not clear how Spor-Klenz Concentrate (Wuxi Apptec study) would perform against the USP organisms.

iii. Studies do not address use of 70% IPA, EtOH (ethanol) and its effectiveness

iv. Studies do not address effectiveness of using RTU Spor-Klenz at its expiry period

v. It is not clear what neutralization validation data is available for leveraged reports.

vi. Disinfectant Efficacy via In-vitro Inoculation for In-house Organisms, and its final report, RPT040316 were completed using LpH, Vesphene, and Spor-Klenz for the applicable isolates appearing in Table 2. These studies were performed by inoculating the isolates in liquid disinfectant as opposed to coupon studies performed at other Emergent sites. Bayview studies were only performed on coupons for the mold isolate and there is no rationale provided for the different approaches.

c. Emergent does not currently have data available to support expiration dating for RTU bottles once opened and does not have a procedure in place instructing to how reassign a bottle after opening. Note: Steris has data to support opened RTU up to 14 days that could be leveraged.

d. Material and Waste Flow for Areas 1 and 2 SOP001518 v 13.0 does not specify contact time details concerning the use of RTU Spor-Klenz for wiping materials at line of demarcation (i.e. 10 minute contact time per the DE study).

e. Cleanroom Behaviors and Contamination Control in the Area 1 & 2 Production Envelope SOP000390 v 7.0 specifies throughout the document "70% IPA, EtOH, Spor-Klenz RTU or other approved disinfectant" but it is not clear what other approved disinfectants that could be used.

Minor Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1835800	Facilities (Facilities, Utilities & Equipment)	Environmental Controls & Monitoring	Process and/or Procedure

Observation Description:

Re-validation program for the utilities / water systems is lacking. Per Requalification Program, SOP025461 v 3.0, utilities should be reviewed quarterly as part of the review of EM data and trends per SOP000291. The quarterly trend reports focus only on EM results,and do not specifically include an assessment / statement with regards to re-qualification status for each

Count	Record ID	Category 1	Category 2	Category 3

utility, nor does this document include review of other information that could impact validated status (e.g. impact from additive changes, increase in non-routine work orders, failed calibrations, industry / regulatory expectations, etc.)

Management Responsibility/Organization Management, Organization & Personnel

Minor Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1844973	Management Responsibility/Organization Management, Organization & Personnel	Management Review	Failure to Follow Procedure

Observation Description:

Quality Management Review process is deficient in that:

a. Not all the elements as defined by SOP001748 v. 7.0, Appendix A (e.g. Product & Raw Material Release, Quality Objectives, Test method status, release cycle time, first pass success, and Manufacturing Yields) were specifically covered in the 1Q 2020 QMR.

b. QMR slide deck and/or meeting minutes do not summarize that overall the Quality Management System is adequate and effective.

c. SOP001748 does not establish the maximum timeframe in which the QMR must occur (e.g. within the next quarter)

Materials Control

Minor Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1845494	Materials Control	Handling/Storage	Process and/or Procedure

Observation Description:

During review of SOP040331 v 4.0, Release of Cell Banks and Viral Seed Banks and SOP041831 v 3.0, Cell Bank and Virus Seed Program, there is no process for the hand-over from warehouse to manufacturing. Per the Emergent SMEs, there is a Quality SOP that governs how to bring in a cell bank (what the requirements are). As for the transport, once Supply Chain receives the request, we will coordinate a time with Manufacturing. Manufacturing will come to the Warehouse to pick up the cell bank. Supply Chain does not transport it to Manufacturing. A process for the interaction, control, and documentation between warehouse and manufacturing should be addressed.

Production and Packaging Processes

Minor Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1835793	Production and Packaging Processes	Process Control (includes process inspections)	Process and/or Procedure

Count	Record ID	Category 1	Category 2	Category 3

Observation Description:

The site virus contamination control strategy is deficient in that:

a. Bayview Facility Viral Cross Contamination Risk Assessment, RPT044360 v 1.0, from 2018 did not account for virus in the downstream of areas 1 and 2 and it was never updated to next version to evaluate if all CAPAs identified appropriately mitigated residual risk.

b. The risk assessment is required to be updated periodically to capture the completion and effectiveness of the mitigation activities outlined within, but this did not happen post the October 2018 assessment. This is not aligned with the internal yearly review requirement for Risk Assessments per SOP000263 v 3.0. Note: A draft version was provided with some of the initial risks identified being mitigated.

c. There is not a formal Bayview contamination control strategy for the site which summarizes the overall control strategy as required in the contamination risk assessment and as is the industry expectation.

Quality/Compliance Systems

Minor Observations:

Count	Record ID	Category 1	Category 2	Category 3
1	1844976	Quality/Compliance Systems	Risk Management	Process and/or Procedure

Observation Description:

Emergent currently does not have a risk register established and reviewed periodically by quality management per ICH Q9.

Note: Emergent has developed a process and template has been agreed upon but not implemented.

VI. ACTIVITY MILESTONES

* Audit Report Completed By: Stephen Green
* Audit Report Approved By: KATHRYN MADER

Audit Report Completed On: 21-Jul-2020 10:36 pm

Audit Report Approved On: 22-Jul-2020 9:43 pm

Audit Report Issued On: 24-Jul-2020 8:24 am

*** denotes electronic signature generated from validated ETS system**

Exhibit 20

emergent
biosolutions

April 30, 2021

Via Electronic Mail
[redacted]

Confidential

Attention: Lisa Harlan, Acting Staff Director, Investigations Branch
Office of Biological Products Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
[redacted]

Re: Emergent Manufacturing Operations Baltimore, LLC's Initial Response to the Form FDA 483 Issued on April 20, 2021 to the Bayview Facility (FEI: 3015448605) Investigators Debra M. Emerson and Cody Rickman, and Senior Advisor Jeremy Wally

Dear Ms. Harlan:

Enclosed please find Emergent Manufacturing Operations Baltimore, LLC's (Emergent or the company) initial response to the Form FDA 483 (483) issued on April 20, 2021 to its Bayview facility ([redacted] Please know that Emergent remains committed to meeting the unprecedented challenge of manufacturing novel Covid-19 vaccines to meet the nation's and the world's needs.

Emergent also knows that it must do everything within its power to ensure appropriate controls are in place to assure product quality. We are doing just that. As described in more detail below, Emergent is establishing a Quality Enhancement Plan that will, among other things:

- Implement ***enhanced contamination controls*** at the Bayview facility prior to initiating new production. These enhanced controls are based on a comprehensive assessment of site operations.

- Institute effective ***interim controls***, including Emergent corporate quality, Johnson & Johnson (J&J), and independent third-party oversight and monitoring, to ensure compliance while longer-term improvements are developed and implemented.

- Guide the development and execution of ***continuous improvement*** initiatives to ensure sustainable compliance.

Emergent believes that the implementation of the activities described below fully addresses the 483 observations and ensures that adequate controls are in place to support resumption of new manufacturing at the Bayview facility and authorization of the Bayview facility to manufacture drug substance for the Janssen Covid-19 vaccine under the existing Janssen EUA.

Emergent's Role in the Fight against Covid-19

Emergent understands the critical role the company is playing in the fight against Covid-19 and takes FDA's observations very seriously. Emergent is uniquely situated to supply critical drug substance for Covid-19 vaccine. The Bayview facility is capable of supporting production of greater than one billion vaccine dose-equivalents per year. Accordingly, the company has been working closely with FDA, other government agencies, and our pharmaceutical clients to deliver on the common goal of expeditiously manufacturing safe and effective Covid-19 vaccines doses.

With the unprecedented challenge of establishing manufacturing processes for novel Covid-19 vaccines and rapidly scaling up production to meet the nation's and world's needs, challenges will inevitably arise.

The recent events at the Bayview facility, including the 483 observations, have given Emergent renewed focus. Emergent is fully aware of its responsibility to public health and has openly and transparently collaborated with FDA and J&J to ensure that appropriate and effective measures are implemented. The company knows that speed is essential to confront the on-going Covid-19 pandemic and that the quality of Covid-19 vaccine drug substance is paramount. Emergent is confident it can pursue and achieve these two objectives simultaneously.

The Quality Enhancement Plan

The April 2021 inspection was triggered by an out-of-specification (OOS) result involving the contamination of a single drug substance lot intended for further drug product manufacturing and use in Janssen's Covid-19 vaccine. Emergent, in close collaboration with J&J, is committed to comprehensively investigating the cause of the contamination event and preventing such events from occurring in the future.

Emergent would like to make clear that, as communicated to FDA during the inspection, the company will implement significant improvements at the Bayview facility before initiating any new manufacturing. Specifically, in collaboration with J&J, Emergent is implementing a Quality Enhancement Plan (QEP). The QEP—developed following a comprehensive assessment of manufacturing operations at the facility by Emergent and J&J—includes immediate actions and interim controls that will assure the safety and quality of drug substance manufactured at the Bayview facility while longer term improvements are implemented. Emergent's interim control strategy includes engaging independent third-party experts to provide continuous oversight of

critical activities and to perform batch certification for all Covid-19 vaccine drug substance batches manufactured at the Bayview facility.

As FDA is aware, the company has ceased manufacturing Covid-19 vaccine drug substance for AstraZeneca and decommissioned the Bayview facility manufacturing suite previously used to manufacture AstraZeneca's product, thereby eliminating the risk of cross-contamination during production going forward. The enhancements detailed in the QEP will further address potential routes of contamination from other sources. These include:

- Performing additional cleaning, disinfection, and repairs throughout the facility;
- Ensuring enhanced segregation of personnel, material and waste flows;
- Enhancing material handling practices;
- Extensively improving waste handling practices and procedures;
- Expanding training and skill development for site personnel;
- Strengthening oversight; and
- Implementing interim controls.

Emergent recognizes the need for effective and timely implementation of these improvements and we are working collaboratively to execute the remediation process. Individual workstreams are being jointly led by identified subject matter experts (SMEs) in the Emergent and J&J organizations. Program leaders from Emergent and J&J are meeting twice daily to review remediation activities and escalate issues, as necessary. A Steering Committee, comprised of Emergent and J&J quality and operations leadership meet daily with program leads for further accountability and oversight.

Consistent with Emergent's commitment to continuous improvement, the QEP also includes a Sustainable Compliance Plan, detailing on-going actions to maintain a robust culture of quality at the Bayview facility. The company understands that sustainable compliance is achieved through consistent evaluation and improvement of quality activities. Emergent expects nothing less than the consistent adoption of industry best practices in the company's manufacturing and quality operations.

To that end, in November 2020, Mary Oates, Ph.D., joined the company as Senior Vice President, Global Quality. Dr. Oates brings over 30 years of biopharmaceutical experience in Quality, Manufacturing Operations and Regulatory Affairs, including as head of Global Quality Operations for Pfizer Inc. Dr. Oates reports directly to Emergent's Chief Executive Officer and is firmly in charge of quality operations at the Bayview facility. Under Dr. Oates's leadership,

Emergent has significantly strengthened the Bayview facility quality leadership with external hires in recent months, including:

- Edward Elmore, Senior Director of Quality. Mr. Elmore has over 30 years of experience in pharmaceutical manufacturing and quality, including as Executive Director of Quality Assurance at Elanco and Senior Director of Quality Assurance at Eli Lilly and Company. Mr. Elmore joined Emergent in April 2021.

- James Kirk, Director of Quality Assurance. Mr. Kirk has over 25 years of quality leadership experience and joined Emergent from Janssen Pharmaceuticals in March 2021.

- William Hatcher, Director of Quality Control. Mr. Hatcher has more than 15 years of experience in Quality Control focusing on drug product and drug substance from clinical to commercial manufacturing. Mr. Hatcher joined Emergent in March 2021 after serving as Director of Quality Control for Catalent Pharma Solutions.

Emergent's new corporate and Bayview facility quality leadership are fully engaged in the enhancement efforts underway at the facility and will provide direct oversight of quality operations at the facility.

The QEP targets efficient, effective, verifiable measures that will provide confidence in Emergent's drug substance and lays the foundation for continuous improvement. Emergent is confident that the QEP and associated corrective and preventive actions (CAPA), described in detail in the attached 483 response, will assure that the Bayview facility is continuously operated in a state of control.

Details regarding the investigation into the OOS contamination event are provided in **Section I** of the enclosed response. The QEP is provided in **Section II** of the enclosed response. The specific responses to the 483 observations are provided in **Section III** of the enclosed response. For ease of reference, the responses are formatted as follows: each response begins with a restatement of FDA's observations in *italic* text. This is followed by Emergent's response to the observations(s). At the conclusion of each observation response, planned CAPAs are detailed with target completion dates, as appropriate.

The company will provide periodic updates to FDA on the status of its ongoing actions and QEP implementation. Emergent will also keep FDA updated of any new actions undertaken.

This document contains confidential commercial and trade secret information that is protected from public disclosure under the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act, FDA's implementing regulations, and the Trade Secrets Act. Recognizing the need for public information in the context of a global pandemic, Emergent will be submitting a redacted copy of this response reflecting information Emergent believes to be exempt from disclosure. If there are no concerns with those redactions, Emergent consents to the public

disclosure of such redacted version. In accordance with FDA's implementing regulations, if a request for disclosure is received that would exceed the scope of the foregoing consent, or FDA determines for any other reason that it must publicly disclose any of the information that Emergent has designated for redaction, Emergent asks that it be notified and provided an opportunity to address why the information or materials should not be released.

Sincerely,

[redacted]

Dino Muzzin
SVP Manufacturing and Interim General Manager
Emergent Manufacturing Operations Baltimore, LLC's

I. Batch [redacted] and the Corresponding Investigation

A. Emergent BioSolutions

By way of background, Emergent BioSolutions (Emergent) is one of a limited number of specialty biopharmaceutical companies focused on developing vaccines and other medical countermeasures for biodefense purposes. Founded in 1998, Emergent began as a small anthrax vaccine manufacturing facility that manufactured vaccines primarily and the US military. Since this time, the company's capabilities and expertise has expanded to include numerous other vaccines, including for smallpox and typhoid, antibody therapeutics, and opioid overdose treatments. We are steadfast in our commitment to government service and national security, and are proud to say that we are one of the largest manufacturers of medical countermeasures for the US government.

Emergent's history of collaboration with the US government to develop vaccines to address public health emergencies also includes a long-standing collaboration with the Biomedical Advanced Research and Development Authority (BARDA). In 2012, Emergent's Bayview facility was established as a Center for Innovation in Advanced Development and Manufacturing (CIADM) with the goal of providing a significant domestic infrastructure in the United States capable of producing medical countermeasures to protect Americans from the health impacts of bioterrorism as well as pandemic influenza and other disease in response to public health emergencies.

Following BARDA's designation of the Bayview facility as a CIADM, Emergent invested approximately $60 million modernizing manufacturing areas 1 and 2 to incorporate flexible, innovative manufacturing platforms that can be used to manufacture multiple products with a focus on medical countermeasure manufacturing. Since 2012, areas 1 and 2 have been used in connection with a development-stage influenza vaccine, in response to task orders from the US government related to Ebola and Zika outbreaks, and for development of other clinical-stage drug development manufacturing both for Emergent as well as a limited number of contracted clients.

In addition to modernizing manufacturing areas 1 and 2, Emergent also built a third manufacturing suite for the sole purpose of manufacturing vaccines in response to a potential pandemic. Following the successful completion of construction activities and the qualification of the clean rooms, area 3 came on-line for cGMP manufacturing activities in May 2017.

Emergent's Bayview facility was constructed to facilitate the use of disposable manufacturing equipment at a very large scale—*i.e.*, batch sizes up to 2,000L. The facility was also designed and constructed to enable live virus vaccine manufacturing. This combination of excess capacity, use of disposable manufacturing equipment at a large scale, and ability to manufacture live virus vaccines makes the Bayview facility unusual among domestic biologic manufacturers.

B. Emergent's Role in Combating the COVID-19 Pandemic

In April 2020, Emergent executed an initial agreement for ramping up drug substance manufacturing for Janssen's Covid-19 vaccine, Ad26.COV2.S, at the Bayview facility, and on July 6, 2020, the companies announced a five-year manufacturing services agreement.

At the time, there was significant uncertainty with regard to which, if any, of the investigational Covid-19 vaccines would successfully demonstrate safety and efficacy to FDA's satisfaction. Accordingly, Emergent was engaged in active negotiations with another vaccine manufacturer to be their drug substance manufacturer. These negotiations, which were being conducted in parallel with the negotiations with J&J, ended when Emergent received a task order from the US government in early June 2020. The task order requires Emergent to reserve manufacturing capacity that was not being allocated to J&J for the US government. Subsequently, the US government directed Emergent to release the capacity to AstraZeneca for large-scale drug substance manufacturing of its Covid-19 vaccine candidate, AZD1222.

Immediately after entering into drug substance manufacturing agreements, Emergent began working around the clock with its partners to transfer the manufacturing processes and related technologies to the Bayview facility as quickly as possible due to the severity of the pandemic. Given the critical need for Covid-19 vaccine, the decision was made to manufacture both drug substances at full-scale immediately.

C. The Batch [redacted] Out-of-Specification Result and Initial Laboratory Investigation

On March 5, 2021, a suspected OOS test result was reported for drug substance Batch [redacted] for Janssen's Covid-19 vaccine during in-process and finished product testing. Batch [redacted] was manufactured at Emergent's Bayview facility between January 19 and February 21, 2021 and sent to J&J's laboratory in Leiden, The Netherlands for quality control testing. Also, on March 5, an *in vitro* adventitious agents assay test conducted by BioReliance Ltd., reported a suspected OOS result for the same drug substance batch.

J&J and BioReliance immediately initiated laboratory investigations, determining that the OOS results were not due to laboratory error and were valid OOS test results. On March 11, 2021 and March 15, 2021, additional investigational testing on the impacted control cell test sample confirmed the presence of a recombinant adenoviral vector that was not the J&J Ad26 vector. These results indicated a possible contamination with another adenoviral vaccine vector. At the time of the deviation, drug substance manufacturing for the J&J vaccine was in operation in manufacturing Area 2, and AstraZeneca drug substance manufacturing was operating in Area 3, which is independent and separated from Areas 1 and 2. However, the manufacturing of drug substance of both vaccine candidates in the same facility raised the possibility that the contaminant was the AstraZeneca vector.

On March 16, 2021, J&J notified Emergent of the test results for Batch [redacted] and preliminary identification of the contaminant.

D. Emergent's Root Cause Analysis and Overall Impact Assessment

Upon notification by J&J, in accordance with its standard quality control protocols, Emergent immediately self-initiated a manufacturing investigation, opening deviation [redacted] on March 17, 2021. Emergent and J&J approved the investigation plan for the OOS on March 24, 2021. At all times, Batch [redacted] remained under Emergent's control and was not sent for further processing into drug product.

Emergent conducted a root cause analysis that included review of Batch [redacted] in-process testing results and data, finished product data, and a review of the manufacturing campaign timeline with a focus on activities impacting Batch [redacted] This included a review of potential ingress points and common areas shared by Areas 1/2 and Area 3. On March 24, 2021, investigational testing performed by Emergent indicated the presence of a viral vector similar to that of the AstraZeneca vector. The following day, Emergent contacted J&J to notify J&J of the investigational results of a positive identification of an alternate adenovirus vector in the DS testing article.

An investigation report was issued and provided to FDA on April 5, 2021. The root cause analysis determined that the most probable contributing root cause was that the bioreactor media prepared for use in the Stage 2 cell expansion process of Batch [redacted] was contaminated in the Weigh and Dispense Area through contact with the waste path for materials from Area 3. Emergent notes that the QEP, described below, is based on a comprehensive review of potential sources of contamination at the Bayview facility, and includes actions to address the most probable root cause identified in deviation 3[redacted] as well as other potential sources of contamination, including those identified in the 483 observations.

An impact assessment was also conducted, and enhanced characterization testing was performed on all batches manufactured at the Bayview facility. Using [redacted], the presence of the Ad26 capsid and core proteins were confirmed for all batches within scope of this evaluation. The results of [redacted] testing confirmed that the incident had no impact on the other batches tested. FDA has been provided with details of these analyses and all underlying data.

An extended comparability assessment was conducted for the previous batches and two additional batches manufactured according to the same manufacturing process variant as Batch [redacted] Batch [redacted] was the only batch exhibiting viral contamination.

E. FDA Inspects the Bayview Facility

Subsequent to receipt of the investigation report on April 5, 2021, FDA conducted an inspection of the Bayview facility from April 12 to April 20, 2021 (the April 2021 inspection). The inspection resulted in the issuance of a Form FDA 483 with nine observations, which is addressed in **Section III** below.

II. Emergent's Quality Enhancement Plan

Emergent fully understands its responsibility to promote public health by assuring the safety, efficacy and quality of the company's critical drug products. Accordingly, Emergent remains steadfastly committed to using its unique manufacturing capacity, expertise in vaccine manufacturing, and technical capability to produce high-quality drug substance for Covid-19 vaccines. Emergent's Bayview facility stands ready to produce drug substance for more than one billion urgently needed Covid-19 vaccines a year to help combat the on-going pandemic.

Emergent is committed to doing so in a way that meets Emergent's and FDA's quality and compliance expectations. To meet the urgent requirements of today, as the world continues to battle resurgent Covid-19 infections, Emergent has initiated a series of immediate actions to address the inspectional observations, enhance operations at the Bayview facility, and minimize the potential for contamination or cross-contamination going forward. These actions, developed and implemented with the support of J&J, address FDA's concerns, as documented on the 483, and will provide assurance of the quality of the Bayview facility's drug substance.

In particular, upon receipt of the 483, Emergent, along with J&J, performed an in-depth analysis of potential sources of contamination and cross-contamination across the Bayview facility. Emergent's comprehensive assessment was organized into three separate workstreams:

- **Establishing a Detailed Process Map to Identify Potential Sources of Contamination.** Emergent created a detailed map identifying every activity performed in the facility relating to the manufacture of J&J's bulk drug substance. The map starts with materials receipt and concludes with transportation of both product and waste from the facility. The purpose was to identify mechanisms by which a contaminant could be introduced and the corresponding controls that must be in place to eliminate the possibility that contamination will occur.

- **Developing and Implementing Actions to Address the Inspectional Observations.** In addition to establishing a detailed process map, Emergent also closely analyzed each of the investigators' inspectional observations and developed an action plan to address them. Based on Emergent's analysis of the 483 and discussions with the FDA investigators, the company has initiated actions in each of the following categories:

    - Repairing, cleaning, and disinfecting the manufacturing facility, including the warehouse;
    - Further segregating personnel, material, and waste flows;
    - Enhancing material handling practices, including containers used, transportation and storage, and personnel gowning;
    - Ensuring that SOPs are updated to reflect the enhanced processes implemented at the site; and

- Providing enhanced training to site personnel.

Emergent's specific actions within each of these categories are detailed in the company's specific responses to the 483 observations, below.

- **Strengthening the Quality Investigation and Root Cause Analysis.** Emergent also worked closely with J&J to strengthen the quality investigation relating to the OOS. As detailed below in the response to Observation 1(a), this included a detailed and expanded review of over twenty separate elements that could have played a role in the contamination event and the implementation of additional CAPAs. By expanding the scope of the quality investigation, Emergent ensured that additional routes of contamination and cross-contamination have been evaluated, and that appropriate actions to address such routes have been implemented. Emergent is confident that these actions further reduce any potential risk of contamination at the Bayview facility.

The findings were used to create the holistic QEP, set forth in sections A and B below. Emergent's QEP is divided into two phases. The first phase is focused on developing and implementing actions that must be complete before the company initiates new manufacturing; the second phase is focused on continuous improvement initiatives to ensure sustainable compliance.

Emergent is working around the clock with J&J subject matter experts and third-party cGMP consultants to implement the actions required. Emergent is confident that these actions will minimize the chances of contamination in the Bayview facility in a way that meets or exceed industry standard. Emergent is also working with J&J subject matter experts and third-party cGMP consultants to develop and implement actions aimed at continuous improvement and achieving sustainable compliance throughout the Bayview facility.

A. QEP Phase 1: Actions Prior to Initiating New Manufacturing

At the outset, Emergent wishes to emphasize the company's commitment to full transparency with FDA, including throughout the course of its collaboration with the agency to ensure access to critical Covid-19 vaccines.

In order to meet the demand for Covid-19 vaccine drug substance, the Bayview facility must operate at full capacity twenty-four hours per day, seven days per week. With the recent pause of manufacturing activities at the plant, as requested by FDA, Emergent has accelerated corrective and preventive measures and developed additional improvements. Emergent is pleased to report that, in cooperation with J&J, important steps to enhance the Bayview facility are being implemented and verified.

Based on Emergent's detailed process map, the inspectional observations, and Emergent's and J&J's quality investigations, Emergent has included the below actions in Phase 1 of the QEP. Emergent believes that the implementation of these actions ensures that the Bayview facility is

continuously operating in state of control and supports the authorization of the Bayview facility to manufacture drug substance for the J&J vaccine under J&J's existing EUA.

Focus on Janssen Vaccine Drug Substance Production

At the outset, Emergent wishes to emphasize that at the US government's request, on April 11, 2021, Emergent permanently ceased drug substance manufacturing activities for the AstraZeneca Covid-19 vaccine. The Bayview facility is now dedicated to manufacturing drug substance for Janssen's Covid-19 vaccine.

While Emergent is confident that the Bayview facility's contamination control program together with the enhancements noted below will prevent recurrence of the quality event resulting in the rejection of drug substance batch [redacted], the company also believes that by dedicating the Bayview facility to manufacturing drug substance for Janssen's Covid-19 vaccine, any theoretical risk of cross-contamination is eliminated.

Cleaning, Disinfection, and Repairs

Prior to initiating new manufacturing, the facility, including the warehouse, will be repaired, cleaned and disinfected to eliminate conditions that may result in contamination. The following actions have been or will be completed:

- The manufacturing suite formerly occupied by the second client (Area 3) will be decontaminated according to an approved protocol [redacted] to ensure that the second viral vector, if present, is eliminated.

- The floors in the warehouse and in Areas 1 and 2 (J&J manufacturing suites) are being repaired and/or replaced, depending on their current condition. There will be no paint on the warehouse floor and surfaces will be easily cleanable.

- Walls are being repaired as needed and will be easily cleanable.

- After the repairs are completed, the entire facility will be cleaned and disinfected according to an approved protocol.

- Materials in the facility will be evaluated according to an approved protocol to determine if they must be discarded based upon a risk of exposure to contamination. Only those materials that can be cleaned and decontaminated and pose no risk of contamination will be used in future production.

Personnel, Material, and Waste Flow Segregation

Changes are being implemented to ensure that waste does not cross paths with materials or personnel involved in manufacturing operations. In addition to modifying flows, a new airlock has

been installed that will provide a dedicated egress path for waste from the facility. Additional gowning and de-gowning requirements will be defined and enforced throughout the facility.

Material Handling Practices

In addition to optimizing material flow, Emergent is significantly enhancing the Bayview facility's practices and procedures for material handling. An assessment was performed of containers (e.g., totes, bins) used during the manufacturing process. The yellow buckets previously used to contain materials from the weigh dispense area will be replaced with single use bags, reducing the potential for contamination. In addition, a visual inspection process will be broadened to ensure that containers and totes are clean and in a good state of repair before use. This will be described in SOP001518.

Additionally, the weigh dispense material airlock has been enlarged to allow for the entry of materials on pallets, preventing the need to move materials across the floor. These enhancements, which will be in place prior to initiating new manufacturing, will ensure that material handling does not introduce a risk of contamination.

Waste Handling Practices

Emergent is committed to ensuring that waste can be removed from the facility in a way that does not introduce contamination. To accomplish this, the decontamination [redacted] have been functionally qualified and validated [redacted] These will be clearly described in the governing SOP. Emergent is also establishing additional controls relating to the removal of biowaste from the facility that has not gone through [redacted] decontamination. These will be defined in SOPs. Employees will be trained on these waste removal procedures prior to initiating new manufacturing.

Procedural Updates and Expanding Training and Skill Development for Site Personnel

As described above, Emergent is implementing significant enhancements to the requirements in Bayview's procedures.

The above-described procedural enhancements will ensure that the facility continuously meets FDA's and Emergent's own expectations for quality compliance. In order to assure that the strengthened facility procedures are correctly and consistently executed, Emergent is using the current pause in new production to deliver comprehensive training to facility personnel.

This training will be instructor-led and will be provided to cross-functional cohorts of employees, ensuring that those who execute, verify, review, and/or oversee the activities are fully knowledgeable regarding both the requirements and why the expectations are critical to quality. In addition, the training materials will be approved by a subject matter expert and there will be oversight of both the training delivery and the execution of the activities to ensure training effectiveness.

Upon completion, and prior to initiating new manufacturing, Emergent personnel will be fully prepared to execute their responsibilities correctly and consistently.

Enhanced Oversight

Prior to initiating new manufacturing at the Bayview facility, Emergent is also enhancing the facility's quality oversight. As an immediate measure, Emergent is leveraging corporate and third-party resources and expertise to provide additional quality resources and oversight. This includes oversight of critical activities, a quality-on-the-floor initiative, and enhanced Emergent corporate quality.

Emergent is working in close collaboration with J&J on all aspects of Phase 1 of the QEP. Each party has identified SMEs from their respective organizations to serve as leads for project workstreams. These SMEs report into the Project Leads, comprised of three Bayview facility quality leaders and a J&J quality leader, who meet twice daily to oversee implementation effectiveness and project status. A Steering Committee, comprised of Emergent and J&J quality and operations leadership, join end-of-day meetings with the Project Leads to provide additional accountability and ensure oversight, and to ensure that appropriate resources are available to meet project goals.

In addition to the above meetings, J&J will now to provide 24/7 oversight of all production areas in addition to the suites in which their vaccine is manufactured. Further, J&J will now provide full oversight of change controls, qualifications, and process items, including final approval. Emergent has also engaged Quantic Group (Quantic) to provide independent oversight and re-enforcement of new procedural and process revisions for material and people flow through the facility (e.g., airlocks and waste flow). In addition, Quantic will ensure that there is proper documentation and training for these activities.

Quantic is also supporting the implementation of interim controls. Quantic personnel will be on-site at the Bayview facility to observe the following activities and ensure compliance with site procedures:

- Movement of materials into and out of the Weigh Dispense area and the QC sampling area
- Movement of materials into the material airlocks for Areas 1 and 2
- Movement of waste from the [redacted], including verifying that the correct cycle was run, prior to moving the waste from the facility
- As necessary, movement of waste that is not decontaminated into the facility's [redacted]
- Movement of waste from the QC laboratory

Additionally, as described in more detail in the response to Observation 7, below, Quantic will review and approve training materials and observe training sessions to ensure training effectiveness. Quantic will also observe and enforce gowning requirements, documentation requirements, cleaning, cleanliness, and the state of repair and maintenance across the facility.

Emergent believes that the above-described enhancements significantly strengthen operations at the Bayview facility. Through the implementation of facility-wide enhancements, interim controls and independent oversight, Emergent is confident that the Bayview facility will be continuously operating in a state of control.

B. QEP Phase 2: Sustainable Compliance Plan

Emergent recognizes the importance of continuous quality improvement to achieving sustainable compliance and will be using information and learnings from Phase 1 of the QEP to drive sustainable compliance initiatives. The Sustainable Compliance Plan will ensure a robust culture of quality at all levels of the Bayview facility through:

- **Facility leadership engagement.** Emergent understands that consistent, visible support from site leadership is critical to ensuring quality and compliance across the facility. Emergent notes that the site currently has open positions for General Manager and Head of Manufacturing. The company is committed to filling these roles with individuals who share Emergent's commitment to quality, including holding individuals accountable for consistently following site policies and procedures.

  Demonstrating the company's commitment to oversight at the Bayview facility, the Interim General Manager position is being filled by Dino Muzzin, Senior Vice President for Manufacturing Operations. Emergent will continue to fill leadership positions with individuals with a strong quality mindset. In particular, Emergent has communicated its expectation that site leadership will be routinely present in the manufacturing area, including performing routine facility walks to observe manufacturing operations and facility maintenance. Leadership engagement will also be demonstrated through accountability for personnel who fail to adhere to site policies and procedures, up to and including termination.

- **Quality culture initiative.** Emergent understands the importance of instilling a robust culture of quality at the Bayview facility at all levels of the organization. To enhance site quality culture maturity, Emergent is reinforcing the foundation of compliance at the site, through skill building, increasing technical and quality expertise, quality and oversight on the floor, and implementing best practices by leveraging third-party expertise. For example, shift supervisors will be expected to remain on the floor for all or nearly all of each production shift. To increase quality culture maturity, these supervisors will be provided enhanced training on all aspects of their responsibilities, including technical skills, compliance, and viral containment, among other subjects.

The site has rapidly evolved and grown, and Emergent recognizes the need to ensure that Bayview facility personnel understand and share the company's commitment to quality. Emergent also understands the need to give personnel the resources they need to consistently and effectively perform their responsibilities. The Bayview facility is currently engaging the expertise of third-party experts Quantic to oversee implementation of interim controls. The company will leverage these third-party resources to raise the understanding of site personnel and enable them to assume responsibility for quality at the site long term.

- **Quality unit assessment.** Emergent is committed to ensuring an effective and efficient quality unit at the Bayview facility. As described above, the company has recently brought on new facility and corporate quality leaders to lead the transformation of the Bayview quality unit. In addition, the quality unit has grown rapidly as site operations have expanded to meet the need for Covid-19 vaccine production. The company recognizes the opportunity to evaluate the performance of the quality unit and identify areas for improvement, including areas to develop subject matter expertise. This initiative will be led by the new site quality leader with support from Emergent corporate quality.

- **Skill development initiative.** Emergent recognizes the need for personnel to have the technical and procedural skills to effectively carry out their responsibilities. The company will develop and implement skill building training, to ensure that site personnel have a holistic understanding of the manufacturing process and key elements that impact product safety and quality. This will include developing and implementing a technical skill tutorial for the manufacturing process in collaboration with J&J SMEs.

- **Facility maintenance.** To ensure the site is consistently maintained in a good state of repair, Emergent will continue to emphasize detecting, escalating, and addressing facility maintenance issues as well as implementing industry best practices for cleaning and disinfecting. The site will also develop and implement a new site master plan to assess and document facility upgrade and construction needs.

- **Enhanced investigations program.** As planned prior to FDA's April 2021 inspection, the Bayview facility will adopt Emergent's new corporate quality procedure on deviation investigations, ensuring appropriately documented investigations with scientifically justified conclusions, including for root cause determinations. Bayview personnel will receive instructor-led training on the new procedure, with modules on root cause analysis techniques and investigation skills. The new procedure includes additional clarity regarding what is and what is not a deviation and more clearly defines escalation requirements, the escalation process, and QA's responsibilities for review and approval of the deviation investigation. Emergent notes that the Bayview facility is scheduled to implement the new corporate investigation procedure no later than June 2021.

- **CAPA effectiveness verification.** To ensure that the CAPA undertaken in response to the 483 are appropriately implemented and effective, and sustainable, Emergent will verify CAPA effectiveness based on defined criteria, as described in the company's global procedure on GxP CAPA management. In addition, Emergent will leverage independent third-party expertise, including from J&J, to verify CAPA implementation, as appropriate.

III. Emergent's Specific Responses to the 483 Observations

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 [redacted] initiated on 3/17/2021 has not been thoroughly investigated. Specifically,*

   i. *The deviation did not include consideration of operator TEC 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* [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.*

Response to Observation 1

Emergent understands the importance of thoroughly investigating deviations, including identifying attributable root causes, where possible. The Bayview facility's investigation SOP, [redacted], *Deviation Investigation Process*, requires that any unexplained discrepancies is thoroughly investigated, root cause(s) determined, where possible, and effective corrective and preventive action (CAPA) implemented. Specifically, SOP000261 requires that deviation investigations include, as applicable:

- A clear statement of the deviation being investigated
- A summary of the process or procedure involved
- Identification of any potentially impacted products
- Risk assessment
- Historical review for prior occurrences
- Documentation of investigation activities
- Assignment of actual or probable cause
- A description of corrective actions taken

SOP000261 also requires QA to perform the initial assessment of event details to determine the deviation criticality. Deviations considered to be major or critical with respect to potential product quality impact must be investigated in accordance with SOP001881 using the root cause analysis tools set forth in that SOP. In addition, any critical deviations are escalated to the Site Head of Quality for review and final approval.

Bayview facility investigations are performed by subject matter experts with QA oversight and approval. All site investigators are trained on SOP000261 and SOP001881, *Root Cause Analysis.*

As described above, Emergent is in the process of a company-wide investigation enhancement initiative. Prior to the cross-contamination deviation that triggered the April 2021 inspection, Emergent had developed and began implementing enhanced global corporate procedures SOP044111, *Global GMP Deviation Management Procedure*, and SOP044112, *Investigation and Root Cause Analysis Procedure for GMP Deviations,* at all Emergent sites, including the Bayview facility. SOP044112 and SOP044111 include detailed instructions for conducting investigations, including the use of robust root cause analysis tools. Under the new procedures, only qualified investigators who have completed the Emergent corporate quality-developed training can lead deviation investigations, ensuring quality and consistency across investigations.

Emergent has also developed and is implementing a global procedure relating to GxP CAPA management: SOP044131, *CAPA Management Procedure*. This global SOP will enhance processes for implementing and ensuring effectiveness of CAPAs across the company.

The Bayview facility is scheduled to receive instructor-led training on SOP044111, SOP04112, and SOP044131 no later than June 2021, including modules on root cause analysis techniques and investigation skills. Emergent is confident that these procedures and accompanying training will strengthen site investigation practices, including root cause analysis.

Pending the implementation and verification of effectiveness of these procedural and training enhancements, all newly initiated J&J drug substance batches will undergo independent third-party certification prior to release. This will include a review of any associated Bayview facility investigation to confirm the adequacy of the investigation, including the root cause analysis, and that conclusions are scientifically sound. Emergent also understands that J&J will perform a separate certification process for every batch of Covid-19 vaccine drug substance manufactured at the Bayview facility.

With respect to Observation 1(a), Emergent would like to reiterate that it takes the contamination event extremely seriously. As described in detail in Section I.D, above, immediately upon notification by J&J of the OOS result, Emergent self-initiated a manufacturing investigation, opening deviation [redacted] on March 17, 2021. Deviation [redacted] was performed in accordance with SOP00261 and SOP001881. Emergent's initial root [redacted] analysis considered, among other things, in-process testing results and data, finished product data, and a thorough review of the manufacturing process. Although SOP00261 provides for critical deviation investigations to be completed within 45 calendar days to ensure a thorough investigation and full consideration of potential root causes, due to the critical nature of the deviation, a report for deviation 3100012112 was issued on April 5, 19 days after the company became aware of the contamination OOS.

Emergent recognizes the opportunity to further strengthen the root cause analysis for deviation 3100012112 and, on April 22, 2021, initiated a new deviation to document the enhanced investigation. Emergent's new investigation included a detailed and expanded review of over twenty separate elements that could have played a role in the contamination event and the implementation of additional CAPAs. These include but are not limited to the following:

- Flow of materials, including buffers, from weigh and dispense to the production area
- Gowning practices throughout the facility
- Flow and control of waste
- Use of zip ties to secure bags
- Handling of viral stock material
- Congestion in the facility
- Personnel movement throughout the facility
- Showering practices

Emergent notes that as part of the investigation, the companies reviewed badge access records, video recordings, and interviewed operators, among other investigation activities. Based on the additional investigation, the following contamination prevention controls were identified:

- The contamination control plan will be updated to ensure that flow paths of raw materials, including buffers, prevent crossover with materials designated for other products
- Methods and controls will be identified for introduction of buffer in the manway, including amending the contamination control in the production envelope procedure SOP000390, *Cleanroom Behaviors and Contamination Control in the Production Envelope*, to include specific instructions on lifting from the inner bag and not from the bottom
- The use of zip-ties for bags will be eliminated through the implementation of [redacted]
- Cryo gloves used for handling the viral stock material will be replaced with new ones
- Updating the personnel gowning procedure SOP001516, *Personnel Flow and Gowning Procedure for Production Envelope*, to state that double gloves will be required when handling viral material, which will be decontaminated, removed and replaced before performing any additional activities

CAPAs identified in the prior assessments were reinforced through the additional investigation, including but not limited to:

- Improved waste flow and waste handling practices
- Enhanced understanding by employees regarding viral containment controls
- Updated gowning procedures
- Updated personnel and material flows
- [redacted] enhancements
- Reduction in congestion in the facility

By expanding the scope of the quality investigation, Emergent is confident that potential routes of contamination and cross-contamination have been evaluated and appropriate actions to address such routes are being implemented. Emergent is confident that these actions further reduce any potential risk of contamination at the Bayview facility.

Emergent also notes that, as described in detail in Section II, above, independent of deviation 3100012112, Emergent and J&J collaborated on a comprehensive review of potential sources of contamination at the Bayview facility. Based on the results of this review, Emergent is implementing the QEP to address potential sources of contamination.

With respect to product impact, an impact assessment of the OOS result was conducted, and enhanced characterization testing was performed on all batches manufactured at the Bayview facility. Using [redacted] the presence and identity of only the Ad26 capsid and core proteins were confirmed for all batches within scope of this evaluation. The results of [redacted] and [redacted] testing confirmed that the incident had no impact on the other batches tested. FDA has been provided with details of these analyses and all underlying data.

An extended comparability assessment was conducted for the previous batches and two additional batches manufactured according to the same manufacturing process variant as Batch [redacted]. Batch [redacted] was the only batch exhibiting viral contamination.

[redacted] *leak*

Regarding Observation 1(b), Emergent recognizes the importance of describing manufacturing steps in site procedures and/or master batch records, as appropriate. For context, the [redacted] increases capacity. Due to the critical need for Covid-19 vaccine drug substance, this piece of

equipment was implemented in an accelerated fashion. Observation 1(b) relates to abortion of the fill process that was initiated to prevent the recovery phase in the event of a valve leak in the bottle filter and dispense system. Emergent wishes to clarify that the Bayview facility initiated a deviation to investigate [redacted] leaks.

Aborting the filling process due to a [redacted] leak was taken based on discussions with the equipment vendor, J&J SMEs, and Emergent QA. Specifically, this cross-functional group determined that the operators should abort the process to prevent initiation of the recovery phase where the pump would reverse and potentially contaminate the mixing tank.

Additionally, in February 2021, Emergent requested that the equipment vendor evaluate whether it would be possible under normal operating conditions for contaminants to enter [redacted]. The vendor performed [redacted] under Emergent's operating conditions, confirming that there would not be [redacted]. Accordingly, Emergent determined that the impact to product was low. In light of the observation, Emergent will re-open the deviation investigation to include this additional information.

Emergent also understands the importance of fully documenting all process steps. With respect to the lack of a specific procedure detailing how to abort a fill recipe and initiate a new recipe, Emergent is revising SOP044115, *Setup and Operation of the* [redacted], and creating a Work Instruction WI042057, *Work Instruction for Filtration and Dispense (Bulkfill) System for Client* [redacted], to detail the process for aborting and documenting abortion of a batch process in the batch record. Relevant site personnel will be trained on the revised SOP and Work Instruction prior to implementation.

Emergent notes that, as described above, corporate procedures SOP044112, SOP044111, and SOP044131 include details regarding the appropriate identification and reporting of deviations. Site personnel will be trained on the procedures, including when to initiate a deviation.

Torn bulk drug substance bottle bag

With respect to Observation 1(c), Emergent would like to clarify that a deviation was in fact opened at the time of the event on January 13, 2021—deviation 3100011147. Unfortunately, the existence of this deviation was not identified during the inspection.

The bulk drug substance is filled into bottles upon completion of the manufacturing process. The individual bottles are then placed into bags in the unlikely event that a bottle is damaged to prevent a spill into the environment. The ripped bag noted in Observation 1(c) was one of the bags into which the integral filled bottles of drug substance had been placed. These bags are not nor are they intended to be a sterile barrier. Further, because the bottle inside the bag was confirmed to be integral during the deviation investigation, it was determined that the rip had no impact on the bulk drug substance in the closed bottle.

Observation 1 Corrective and Preventive Actions

1.1 Emergent has developed global corporate procedures SOP044112, SOP044111, and SOP044131, with detailed instructions for conducting investigations, including the use of robust root cause analysis tools and providing structured approach for identifying, investigating, assessing, and addressing deviations.

Target Completion Date (TCD): Complete

1.2 Emergent will implement and conduct instructor-led training on corporate procedures SOP044112, SOP044111, and SOP044131 at the Bayview facility.

TCD: June 2021

1.3 Newly initiated J&J drug substance batches will undergo independent third-party certification by Quantic prior to release, including a review of any site investigation to confirm adequacy of the investigation and root cause analysis.

TCD: On-going upon resumption of new J&J drug substance manufacturing

1.4 Emergent has initiated a new deviation 3100012594 to document an additional comprehensive investigation of the [redacted] originally investigated under deviation 3100012112. Additional CAPAs with associated target dates will be initiated upon completion of this investigation.

TCD: May 2021 for completion of investigation (prior to resuming new manufacturing)

1.5 Emergent will revise SOP044115, *Setup and Operation of the* [redacted], and creating a Work Instruction WI042057, *Work Instruction for Filtration and Dispense (Bulkfill) System for Client* [redacted], to detail the process for aborting and documenting abortion of a batch process in the batch record. Emergent will train appropriate site personnel on the revised procedure and work instruction on abortion of a batch process and documentation.

TCD: May 2021

1.6 Emergent will re-open the [redacted] leak deviation investigation to include the vendor's impact assessment.

TCD: May 2021

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 of 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.*

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 [redacted]*

    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 was observed on the wall*

    iv. *Black residue from a spill-pig was observed on the floor*

    v. *Blue peeling paint was observed along the door jam into room [redacted]*

Response to Observation 2

Waste Decontamination

Viral containment is of paramount importance, and the Bayview facility's viral containment program includes the use of [redacted] to decontaminate biowaste before removing it from the facility.

In light of Observation 2(a), Emergent is implementing significant enhancements to its [redacted] validation and the practice and procedures related to the use of [redacted] to decontaminate waste from the drug substance manufacturing process. Specifically, Emergent will:

- Demonstrate the functionality of the [redacted] in accordance with a written protocol;
- Optimize and qualify the [redacted] decontamination cycle using [redacted] to demonstrate appropriate viral log reduction.

Emergent notes that the company has also performed facility walkthroughs to identify ways in which waste flow can be enhanced, facility modifications to improve the flow of waste, training on proper waste handling, increased documentation for each step in the waste handling process, and second-person verification for each step in the waste handling process.

Facility Cleaning and Maintenance

Emergent understands the importance of keeping manufacturing areas in clean and sanitary conditions and maintaining the Bayview facility in a good state of repair. Emergent notes that the facility maintenance program is designed to ensure that drug substances are manufactured in a clean and sanitary environment. Specifically, the Bayview facility has established procedures for cleaning Areas 1 and 2, SOP000392, *EMOB Cleaning Program for Controlled Areas 1 and 2* and the warehouse, SOP044245, *Warehouse Cleaning Procedure*, among others. Emergent would like to clarify that all cleaning procedures, including SOP000392, require weekly floor cleaning with [redacted] detergent.

In light of Observations 2(b)-(e), Emergent is further strengthening the facility maintenance program by revising SOP027886, *Quality on the Floor Program*, to include routine checks throughout the facility. This includes checks of the manufacturing suites by the shift lead at the start of every shift, weekly checks by the manufacturing manager, and monthly checks by site leadership team members. This also includes weekly checks of the QC laboratory and the warehouse by the area manager and monthly checks by site leadership team members. These checks will be performed using a checklist to ensure appropriate assessments are performed. Depending on the nature of any identified issue, repairs will be performed prior to initiating or resuming manufacturing activities or a work order will be initiated. Repairs will be tracked in logbooks and verified by site QA. In addition, site leadership will perform routine checks to ensure accountability and oversight.

Further, as part of the QEP, Emergent is upgrading the physical facility and site maintenance and cleaning practices and procedures. Quality and maintenance personnel, in collaboration with J&J, have completed a review of all areas used in drug substance manufacturing and assessed each area for cleaning, sanitization, maintenance and repair needs. In particular, Emergent has completed a comprehensive gap assessment of Bayview's cleaning and sanitization procedures, including for classified and non-classified areas.

Based on the results of the assessment, the Bayview facility will implement enhanced cleaning procedures, including specific procedures for manufacturing areas, warehouse, and weighing and dispensing areas. Emergent notes that as part of the revised procedures, the warehouse area will be cleaned on a daily basis and disinfected at regular intervals. Further, to ensure that cleaning procedures are consistently followed, Emergent will provide on-the-job training to relevant personnel on performing cleaning. The effectiveness of these enhancements will be routinely monitored through increased oversight, including by Emergent QA, J&J SMEs, and Quantic.

Additional QEP Phase 1 activities, which will be completed prior to initiating new manufacturing, include prioritizing material upgrades to ensure that walls and floors throughout the facility are of appropriate construction to allow appropriate cleaning and prevent contamination. These include:

- Cleaning and disinfecting Areas 1/2 and the facility warehouse;
- Installing pre-made wall-panes for the controlled-not-classified corridor supporting Areas 1 and 2 that are impact resistant to eliminate peeling paint and paint flecks;
- Replacing the floors in the controlled not classified (CNC) corridor, Area 2 buffer prep and downstream manufacturing areas, and material airlocks for downstream manufacturing areas with material conducive to cleaning and sanitization;
- Replacing the floors in the warehouse areas where product or raw materials pass through; and
- Decontaminating and decommissioning Area 3

Emergent is confident that the facility is maintained in an adequate state of control and does not present a risk of product contamination.

Observation 2 Corrective and Preventive Actions

2.1 Emergent completed a comprehensive gap assessment of the site's cleaning and sanitization procedures.

TCD: Complete

2.2 Emergent will implement enhanced cleaning procedures that detail the performance of cleaning manufacturing areas. Emergent will provide training to relevant site personnel on the enhanced cleaning procedures.

TCD: May 2021 (prior to resuming new manufacturing)

2.3 Emergent will revise SOP027886, *Quality on the Floor Program*, to include routine checks throughout the facility. This includes checks of the manufacturing suites by the shift lead at the start of every shift, weekly checks by the manufacturing manager, and monthly checks by site leadership team members. This also includes weekly checks of the QC laboratory and the warehouse by the area manager and monthly checks by site leadership team members. These checks will be performed using a checklist to ensure appropriate assessments are performed.

TCD: June 2021

2.4 Emergent will decontaminate and decommission Area 3, including access limitation, material removal, and [redacted].

TCD: May 2021 (prior to resuming new manufacturing)

2.5 Emergent will replace the floors in the Areas 1/2 corridor to utilize more durable surfaces that can support equipment movement and cleaning requirements.

TCD: May 2021 (prior to resuming new manufacturing in the impacted areas)

2.6 Emergent will replace the floors in material flow path in the warehouse with material conducive to cleaning and sanitization.

TCD: May 2021 (prior to resuming new manufacturing)

2.7 Emergent will install pre-made panels in the [redacted] corridor supporting Areas 1 and 2, warehouse pass-thru, and material air locks.

TCD: May 2021 (prior to resuming new manufacturing in the impacted areas)

2.8 Emergent will clean and disinfect Areas 1/2 and the facility warehouse.

TCD: May 2021 (prior to resuming new manufacturing)

2.9 Emergent will demonstrate the functionality of the [redacted] in accordance with a written protocol.

TCD: Complete

2.10 Emergent will optimize and qualify the [redacted] decontamination cycle [redacted] demonstrate appropriate viral log reduction.

TCD: May 2021 (prior to resuming new manufacturing)

2.11 Emergent will revise the autoclave decontamination SOP000388, *Operation of the Decontamination* [redacted], and will train operators on the revised procedure.

TCD: May 2021 (prior to resuming new manufacturing)

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 [redacted], but it will be double bagged and the exterior of the bag will be sprayed with [redacted] prior to transport through the warehouse and out of the building for a limited number of days.*

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, room [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.*

Response to Observation 3

The Emergent Bayview facility is designed to have adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product

containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. Due to the rapid scale up in order to produce critically necessary drug substance for use in Covid-19 vaccines, the facility experienced a dramatic increase in storage and staging demands as the facility operated at full capacity for the first time. In addition, going to full capacity increased waste production with the full impact beginning in the latter part of December 2020. Accordingly, Emergent implemented an alternative biowaste removal process, which is noted in Observation 3(a).

In light of the investigators' observation and Emergent's investigation, the company will strengthen the Bayview facility's biowaste handling process. Specifically, under SOP044335, *Removal of Special Medical Waste from Manufacturing Areas*, when [redacted] requires waste to be bagged and removed without decontamination, site personnel must disinfect each layer of the bag and follow a defined exit pathway to remove the waste from the facility, with cleaning and disinfection performed along the exit route immediately following waste removal. Documentation of the removal process will be required at every step, including verification by a second person witnessing the activity. As noted above, as an interim control Quantic personnel will monitor and verify any waste removal activity.

With respect to the deviation referenced in Observation 3(a), Emergent wishes to clarify that the planned deviation was initiated to document the waste removal process while a procedure for waste removal without [redacted] decontamination was developed and implemented. This process will now be performed in accordance with SOP 044335. With the optimization of autoclave cycles allowing for more material to be decontaminated, increased [redacted] capacity is available to support decontamination of biowaste.

With respect to Observations 3(b)-(d), as part of Emergent's and J&J's comprehensive review of the manufacturing facility, described in Section 2, above, the companies collaborated on corrective and preventive actions to alleviate congestion and overcrowding at the facility. These include:

- Materials will not be staged for sampling in the warehouse
- For rooms [redacted] and [redacted] ensure that materials and supplies will only enter the respective rooms when needed for production, to avoid congestion with staged materials

With respect to Observation 3(e), Emergent has enlarged the weigh and dispense material airlock to allow for entry of materials on pallets or dollies, avoiding contact with floor surfaces.

Observation 3 Corrective and Preventive Actions

3.1 Emergent will strengthen the Bayview facility's biowaste handling process. Specifically, under SOP044335, *Removal of Special Medical Waste from Manufacturing Areas*, when [redacted] requires waste to be bagged and removed without decontamination, site personnel must disinfect each layer of the bag and follow a defined exit pathway to remove

the waste from the facility, with cleaning and disinfection performed along the exit route immediately following waste removal.

TCD: May 2021 (prior to resuming new manufacturing)

3.2 Emergent will evaluate alternatives to staging raw materials for QC sampling in the warehouse.

TCD: June 2021 (for the evaluation)

3.3 Emergent will ensure that materials and supplies only enter rooms [redacted] and [redacted] when needed for production, to avoid congestion with staged materials. This will be verified during daily shift-lead area walkthroughs.

TCD: May 2021 (prior to resuming new manufacturing)

3.4 Emergent has enlarged the weigh and dispense material airlock to allow for entry of materials on pallets or dollies, avoiding contact with floor surfaces.

TCD: Complete

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 nondisinfected and non-decontaminated special medical waste.*

    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.*

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 21003600 on 2/4/2021, a manufacturing associate (Operator upstream MFG) was observed entering manufacturing Area 3 when manufacturing for client 577 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.*

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.*

Response to Observation 4

Emergent understands the importance of following and documenting adherence to written production and process control procedures to prevent cross-contamination in the execution of production and process control functions. In this regard, Emergent has established robust requirements relating to the flow of personnel and personnel gowning practices to prevent contamination and cross-contamination. From a personnel flow perspective, operators enter the manufacturing suites through a single designated entrance for each manufacturing area. Once inside the manufacturing suites, movement through the suites is unidirectional, and operators exit the manufacturing suites through a single designated exit for each area.

With respect to operator movement between Areas 1 and 2 and Area 3, specifically, Emergent wishes to clarify that, at the time of the inspection, the requirement to shower when moving between Areas 1 and 2 and Area 3 was based on whether an operator had been exposed to a "viral" area within the manufacturing suite. In this context, a "viral" area is one where, based on the

process flow, the operator could have been exposed to live virus. Emergent notes that with the decommissioning of Area 3 and focus on production of drug substance for the J&J vaccine, the Bayview facility is eliminating showering requirements, as they are no longer necessary to prevent cross-contamination. Emergent is also confident that the decommissioning of Area 3 will prevent recurrence of the observations noted in Observation 4(c).

In addition, Emergent has identified a number of procedural, training, and process flow enhancements to prevent contamination. These include:

- Identifying, confirming, and strengthening the process and waste flows across the facility. Specifically, Emergent has conducted a comprehensive assessment to identify changes needed to ensure segregation of flows. As a result of this assessment, Emergent is implementing revised flows that ensure that waste does not cross paths with materials or personnel involved in manufacturing operations. Specifically, SOP001516 will be revised to define relevant requirements, which will be enforced through third-party oversight. Additionally, an airlock has been installed that provides a dedicated egress path for waste. At an operator level, Emergent will define and enforce gowning and de-gowning requirements that will mitigate the risk of contamination.

  Emergent is confident that these actions will prevent recurrence of the observations noted in Observation 4(a).

- Emergent has also enlarged the weigh and dispense material airlock under Change Control 2100006389 to allow for entry of materials on pallets or dollies, thereby avoiding contact with floor surfaces. This includes training on how to transport raw materials.

  In conjunction with this Change Control, Emergent amended SOP1516 for the weighing and dispensing area to reflect the enhanced flow and to more clearly describe operator gowning requirements.

  Emergent is confident that these actions will prevent recurrence of the observations noted in Observation 4(b).

Emergent will not resume new batch starts until these enhancements have been implemented.

Emergent is also using this voluntary shutdown period to provide training to operators across the facility, as discussed below in the response to Observation 7. These trainings include role-specific training modules to ensure that operators engaged in similar critical manufacturing activities—*e.g.*, waste handling—have received the same training. Emergent is confident that this enhanced training program will prevent recurrence of the observations noted in Observation 4(d), as well several of the investigators' other inspectional observations.

The effectiveness of these numerous enhancements will be continuously monitored through Emergent's enhanced QA on the floor program and through the company's implementation of third-party oversight. These CAPAs will also be evaluated through periodic effectiveness checks.

Observation 4 Corrective and Preventive Actions

4.1 Emergent has discontinued production of AstraZeneca Covid-19 vaccine drug substance in Area 3, which will eliminate the risk of cross-contamination presented by movement between Areas 1/2 and Area 3.

TCD: Complete

4.2 Emergent is implementing revised flows that ensure that waste does not cross paths with materials or personnel involved in manufacturing operations.

TCD: May 2021 (prior to resuming new manufacturing)

4.3 Emergent has installed an airlock to provide a dedicated egress path for waste.

TCD: Complete

4.4 Emergent will define and enforce gowning and de-gowning requirements that will mitigate the risk of contamination. Specifically, SOP001516 will be revised to define relevant requirements, which will be enforced through third-party oversight.

TCD: May 2021 (prior to resuming new manufacturing)

4.5 Emergent has enlarged the weigh and dispense material airlock under Change Control 2100006389 to allow for entry of materials on pallets or dollies, avoiding contact with floor surfaces.

TCD: Complete

4.6 The effectiveness of these enhancements will be continuously monitored through Emergent's enhanced QA on the floor program and through the company's implementation of third-party oversight.

TCD: On-going

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 21003600 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:*

    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 [1/27/2021], 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 [redacted].

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 mixing vessel for strip buffer solution batch 21004975 in manufacturing in Area 2. We observed the employees failing to remove or sanitize their gloves after grabbing the bottom of the container.

Response to Observation 5

Emergent recognizes the importance of handling and storing components, product containers, and closures in a manner to prevent contamination. With respect to Observation 5(a) and as detailed above, Emergent has decided to permanently cease drug substance manufacturing activities for the AstraZeneca Covid-19 vaccine and is in the process of decommissioning Area 3, which is where drug substance manufacturing activities for the AstraZeneca Covid-19 vaccine were performed. Emergent's decommissioning activities are being carried out pursuant to a written decontamination protocol. Emergent's Bayview facility is now dedicated to the manufacture of drug substance for Janssen's Covid-19 vaccine, thereby eliminating the risk of cross-contamination going forward.

In addition to permanently ceasing drug substance manufacturing activities for AstraZeneca's Covid-19 vaccine, Emergent has also completed a comprehensive assessment of the Bayview facility's material handling practices. Based on this assessment, Emergent has initiated several additional actions that address Observations 5(b) and (c). These include segregating raw material and waste flows; strengthening procedures and practices around waste decontamination and removal; replacing the yellow raw material bucket containers with single-use sterile bags ([redacted]); and revising SOP001518 to require visual inspection of material totes before each use and to require documentation of this visual inspection in the equipment logbook.

Further, materials in the facility will be evaluated according to an approved protocol to determine if they must be discarded based upon a risk of exposure to contamination (e.g., opened containers of raw materials) or if they can be cleaned and decontaminated (e.g., single use bags in sealed containers). Only those materials that can be cleaned and decontaminated and pose no risk of contamination will be used in future production.

At the operator level, Emergent has also initiated several actions to strengthen material handling practices at the Bayview facility. As discussed below in the response to Observation 7, this includes role-specific training modules to ensure that operators engaged in similar critical manufacturing activities—*e.g.*, raw material handling—have received appropriate training to

perform such activity. Emergent is confident that this enhanced training program will prevent recurrence of the observations noted in Observation 5(d), as well as several of the investigators' other inspectional observations.

The effectiveness of these numerous enhancements will be continuously monitored through Emergent's enhanced QA on the floor program and through the company's implementation of third-party oversight. These CAPAs will also be evaluated through periodic effectiveness checks.

Emergent is confident that the above actions will broadly strengthen materials handling practices across the facility and prevent recurrence of the observations noted in Observation 5.

Observation 5 Corrective and Preventive Actions

5.1 Emergent has discontinued production of AstraZeneca Covid-19 vaccine drug substance in Area 3, which will eliminate the risk of cross-contamination presented by movement between Areas 1/2 and Area 3.

TCD: Complete

5.2 Emergent has implemented revised flows that ensure that waste does not cross paths with materials or personnel involved in manufacturing operations.

TCD: Complete

5.3 Emergent will replace the yellow raw material bucket containers with single-use bags [redacted]

TCD: May 2021 (prior to resuming new manufacturing)

5.4 Emergent will revise the individual media preparation batch records regarding the use of single-use [redacted] and train personnel on the revised batch records.

TCD: May 2021 (prior to resuming new manufacturing)

5.5 Emergent will revise SOP001518 to require visual inspection of material totes before each use and to require documentation of this visual inspection in the equipment logbook.

TCD: May 2021 (prior to resuming new manufacturing)

5.6 Emergent will evaluate materials in the Bayview facility according to an approved protocol to determine if they must be discarded based on risk of exposure to contamination, or if they can be cleaned and decontaminated.

TCD: May 2021 (prior to resuming new manufacturing)

5.7 Emergent will implement enhanced Quality Assurance on the floor and third-party oversight to continuously monitor the effectiveness of the implemented enhancements.

TCD: On-going

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 autoclave 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 autoclave 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 [redacted] o 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 [redacted]*

Response to Observation 6

Emergent understands the need for establishing and following robust 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. Due to the nature of the drug substance manufacturing activities performed at the Bayview facility, such written procedures include a robust cross-contamination risk mitigation plan that describes the flow of processes, people, and

materials into and out of the facility and defines the risk mitigation steps required to reduce the risk of cross-contamination at each step.

Emergent also recognizes that the rapid ramp-up of full-scale manufacturing activities for two live virus Covid-19 vaccine drug substances revealed several areas for further strengthening with respect to the Bayview facility's cross-contamination control procedures. For example, going to full capacity increased waste production with the full impact beginning in the latter part of December 2020. Accordingly, Emergent implemented an alternative biowaste removal process.

In light of the investigators' observations and Emergent's investigation, Emergent is strengthening the Bayview facility's waste management and decontamination procedures. In particular, prior to resuming new batch starts, Emergent will:

- Demonstrate the functionality of the [redacted] in accordance with a written protocol; and
- Optimize and qualify the [redacted] decontamination cycle using [redacted] to demonstrate appropriate viral log reduction.

To address Observation 6(a), Emergent will revise the autoclave decontamination SOP000388, *Operation of the Decontamination* [redacted], based on the autoclave decontamination cycle qualification to describe how the bags containing the waste are to be placed into the autoclave chamber to ensure that there is adequate penetration of steam into these bags to decontaminate the waste.

With respect to Observation 6(b), Emergent will revise BOP040102, *Decontamination Autoclave Efficacy Testing Program*, to include a requirement for placement of the biological indicator or chemical indicator in a worst-case location inside the [redacted] to support that all waste is decontaminated. This activity will be documented in revised FRM042531, *Decontamination* [redacted] *Efficacy Testing Form*.

To address Observation 6(d) and as detailed above, Emergent will strengthen the Bayview facility's biowaste handling process. Specifically, under SOP044335, *Removal of Special Medical Waste from Manufacturing Areas*, when [redacted] capacity requires waste to be bagged and removed without [redacted] decontamination, site personnel must disinfect each layer of the bag and follow a defined exit pathway to remove the waste from the facility, with cleaning and disinfection performed along the exit route immediately following waste removal. Documentation of the removal process will be required at every step, including a second person verification by someone who actually witnessed the step. As noted in Section II, above, as an interim control Quantic personnel will monitor and verify any waste removal activity.

Emergent's waste management plan also incorporates facility modifications and materials and process flow changes to facilitate the segregation of waste from raw materials and finished drug substance, training on proper waste handling, increased documentation for each step in the waste handling process, and second-person verification for each step in the waste handling process.

Adherence to the strengthened decontamination SOPs will be monitored through Emergent's enhanced quality oversight program, including Emergent QA on the floor and third-party oversight.

With respect to the Bayview facility's use of buckets to store and transport raw materials (Observation 6(c)), as detailed above in the response to Observation 5, Emergent has moved to single-use sterile bags [redacted] to address the risk of contamination from a previously-used bucket. This will be documented in the revised individual media preparation batch records. Emergent is confident that replacing the raw material buckets with single-use [redacted] bags addresses the observation noted in Observation 6(c) and also reduces the risk of contamination.

Observation 6 Corrective and Preventive Actions

6.1 Emergent will demonstrate the functionality of the [redacted] in accordance with a written protocol.

TCD: Complete

6.2 Emergent will optimize and qualify the [redacted] decontamination cycle using [redacted] to demonstrate appropriate viral log reduction.

TCD: May 2021 (prior to resuming new manufacturing)

6.3 Emergent will revise the [redacted] decontamination SOP000388, *Operation of the Decontamination* [redacted], to describe 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.

TCD: May 2021 (prior to resuming new manufacturing)

6.4 Emergent will revise BOP040102, *Decontamination* [redacted] *Efficacy Testing Program*, to include a requirement for placement of the biological indicator or chemical indicator in a worst-case location inside the [redacted] chamber to support that all of the waste is decontaminated.

TCD: June 2021

6.5 Emergent will implement SOP044335, *Removal of Special Medical Waste from Manufacturing Areas*, to establish robust controls relating to the disposal of [redacted] biowaste.

TCD: May 2021 (prior to resuming new manufacturing)

6.6 Emergent will revise the individual media preparation batch records regarding the use of [redacted] and train personnel on the revised batch records.

TCD: May 2021 (prior to resuming new manufacturing)

6.7 Emergent will implement enhanced QA on the floor and third-party oversight to continuously monitor the effectiveness of the implemented enhancements.

TCD: On-going

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* [redacted] *bulk drug substance was taking place, then entered manufacturing Area 2 while processing for client* [redacted] *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 nondisinfected and non-decontaminated special medical waste from manufacturing Area 3, failing to adhere to materials and waste handling procedures.*

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.*

Response to Observation 7

Emergent understands the critical importance of having appropriate training for GMP personnel and of ensuring that operators are trained on the necessity of fully understanding and adhering to established procedures. Emergent will enhance training opportunities and requirements for site personnel, with a focus on ensuring employees' understanding of contamination containment. Emergent is using the pause in new manufacturing to provide comprehensive training to facility personnel, to ensure that, upon resumption of operation, site personnel will be prepared to execute their roles in a consistently GMP-compliant manner. Emergent has conducted a comprehensive review and evaluation of its training program and, in light of the 483 observations, is further strengthening the program as described below.

In the immediate term, Emergent will conduct specific training to support one-time changes associated with the resumption of manufacturing of new drug substance lots for the Janssen Covid-19 vaccine, such as activities associated with decontamination of Area 3. Emergent will identify personnel who need to be trained, create training materials reviewed and approved by subject matter experts (SMEs), provide training to site personnel, and implement oversight of the training process to ensure the delivery of the training is effective.

Prior to resuming initiation of new Janssen Covid-19 vaccine drug substance lots, Emergent will develop and deliver integrated and instructor-led training related to routine activities, such as gowning, waste handling, cleaning, and disinfection activities. Emergent will develop *role-based* training curricula, again created and approved by SMEs, and train cohorts of cross-functional employees who require knowledge of that curriculum. For example, operators, engineers, QA personnel, and others involved in waste handling will be trained comprehensively on the waste handling curriculum. Moreover, as part of Emergent's interim controls, a third-party will provide oversight of the delivery of training to ensure its effectiveness, including execution of critical activities after training.

To address the observations in the 483, the curricula will include training on GMP principles, microbial contamination prevention, and viral containment. This program will provide specialized additional training specific to the issues identified in the 483 and will include examples from the April 2021 inspection. Education on viral containment will be included in annual training for site personnel.

Observation 7 Corrective and Preventive Actions

7.1 Emergent will conduct specific training to support one-time changes associated with the resumption of manufacturing of new drug substance lots for the Janssen Covid-19 vaccine, such as activities associated with decontamination of Area 3.

TCD: May 2021 (prior to resuming new manufacturing)

7.2 Emergent will develop and deliver integrated and instructor-led training related to routine activities, such as gowning, waste handling, cleaning, and disinfection activities.

TCD: May 2021 (prior to resuming new manufacturing)

7.3 As part of Emergent's interim controls, a third-party will provide oversight of the delivery of training to ensure its effectiveness, including execution of critical activities after training

TCD: On-going

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* [redacted] *viral drug substance. These plates included environmental monitoring plates, raw material bioburden plates, and microbial limit testing for* [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* [redacted] *lab* [redacted] *room* [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] *of inprocess and final drug substance samples, and laboratory supplies and plates needing storage under refrigeration.*

Response to Observation 8

Emergent fully recognizes the importance of ensuring that equipment is of adequate size to facilitate operations for its intended use or for cleaning and maintenance. The sudden scale-up to full-scale manufacturing activities for two different Covid-19 vaccine drug substances strained the capacity of Emergent's existing [redacted] refrigerators described in the observation. As an interim measure, Emergent has taken immediate actions to clean and organize these refrigerators. In addition, the cessation of manufacturing activities in Area 3 will reduce the strain on the capacity of the existing refrigerators.

Emergent will purchase and qualify an additional refrigerator unit for the Area 1 and 2 [redacted] to facilitate sample storage. This action is being performed under Change Control 210006400. Emergent will also purchase and qualify another refrigerator for the [redacted]. This action is being performed under Change Control 2100006142.

Beyond these measures, which will significantly increase refrigerator storage capacity, Emergent will implement measures to prevent future overcrowding and to segregate materials stored in the refrigerators. To that end, Emergent will revise SOP000336, *Operation and Cleaning of Refrigerators and Freezers*, to include:

- Use of visual indicators on the refrigerators to note appropriate placement of items; and
- Segregation requirements for samples storage

Emergent is confident that the addition of two refrigerators in the [redacted] lab and the revision of SOP000336 will address the overcrowding issues noted in Observation 8.

Observation 8 Corrective and Preventive Actions

8.1 Emergent will purchase and qualify two new refrigerators.

TCD: July 2021

8.2 Emergent will revise SOP000336, *Operation and Cleaning of Refrigerators and Freezers,* to provide for visual inspection of refrigerators for overcrowding and sample segregation.

TCD: July 2021

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.*

General Response to Observation 9

Emergent recognizes the importance of cleaning and maintaining equipment and utensils at appropriate intervals to prevent contamination that could alter the safety, identity, strength, quality or purity of a drug substance. Equipment and utensils in Areas 1 and 2 are maintained in accordance with SOP1518.

Emergent recognizes the opportunity to strengthen its equipment and utensil maintenance practices and procedures. Emergent quality and maintenance personnel will review and revise SOP001518. This will include, but not be limited to:

- For the weigh buckets, Emergent will replace the multi-use weigh buckets with single-use bags ([redacted] that will be discarded after each use. This enhanced practice will be documented in the revised individual media preparation batch records.

- For totes, Emergent has clarified the process for inspecting, cleaning, and, if needed, disposal of the totes prior to each use. This process is described in SOP001518. The inspection, cleaning, and disposal of the totes must be documented in the material transfer logbooks, FRM045355, FRM045353, and FRM045354. Emergent will also revise SOP001518 to state that the totes must be visually inspected prior to each use, and that this visual inspection must also be documented in the material transfer logbooks, FRM045355, FRM045353, and FRM045354.

Emergent is confident that the CAPAs described above will strengthen the site's cleaning and contamination mitigation program and will prevent recurrence of the inspectional observations noted in Observation 9. Adherence to the strengthened requirements will be monitored through

Emergent's enhanced quality oversight program, including Emergent QA on the floor and third-party oversight of weighing and dispensing and movement of material into the material airlock.

Observation 9 Corrective and Preventive Actions

9.1 Emergent will replace the multi-use weigh buckets with single-use bags [redacted]) that will be discarded after each use.

TCD: May 2021 (prior to resuming new manufacturing)

9.2 Emergent will revise SOP001518 to state that the totes must be visually inspected prior to each use, and that this visual inspection must also be documented in the material transfer logbooks, FRM045355, FRM045353, and FRM045354

TCD: May 2021 (prior to resuming new manufacturing)

9.3 Adherence to the revised procedures will be monitored through Emergent's enhanced quality oversight program, including Emergent QA on the floor and third-party oversight of weighing and dispensing and movement of material into the material airlock.

TCD: On-going

Exhibit 21

CONSULTING AGREEMENT

This Consulting Agreement ("***Agreement***"), effective as of February 1, 2012 ("***Effective Date***"), is made by and between **Emergent BioSolutions Inc.** ("***Emergent***"), with a principal office at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, and **RPK Consulting Group, Inc.** ("***Consultant***"), with a principal office at [redacted] Emergent and Consultant are hereinafter referred to individually as "***Party***" or collectively as the "***Parties***". The Parties hereby agree as follows:

1. **Services; Work Orders**. Consultant agrees to perform certain services ("***Services***") for Emergent as mutually agreed from time to time in a fully-executed statement of work (each, a "***Work Order***"), substantially similar to the form attached hereto as Exhibit A. Each Work Order shall identify the Services to be performed, the person(s) providing Services, applicable milestones and deliverables, and the fees and total maximum compensation. If Consultant is requested or required to perform work beyond the Services necessarily contemplated by or specifically set forth in an applicable Work Order, any such additional work and an appropriate adjustment to amounts payable shall be negotiated in good faith and mutually agreed upon in writing prior to the performance thereof. If any Affiliate of Emergent enters into a Work Order with Consultant, for purposes of such Work Order and this Agreement "Emergent" shall mean and refer to such Affiliate, and "Parties" shall mean and refer to such Affiliate and Consultant. "***Affiliate***" shall mean any direct or indirect, current or future subsidiary of a Party, or any other entity controlled by, under common control with, or which controls such Party. "***Control***" shall mean direct or indirect possession of at least fifty percent (50%) of another entity's voting equity (or other comparable interest for a non-corporation), or the power to direct or cause the direction of the management or policies of such entity whether through ownership of securities, by contract or otherwise. Unless otherwise explicitly noted in a Work Order, this Agreement supersedes any provision of any Work Order or other document that is inconsistent with this Agreement.

2. **Federally-funded Services.** In the event that Emergent uses a Federal grant or contract as the source of funding for any Services, Emergent shall notify Consultant and may require, as a condition of such grant or contract and for continued eligibility for such federal funding, that the Parties comply with additional contract provisions, including certain clauses of the Federal Acquisitions Regulation, agency supplements, policy directives or other terms and conditions ("***Flowdown Provisions***"). Emergent shall have the right to include applicable Flowdown Provisions in the relevant Work Order, and Consultant shall comply with such Flowdown Provisions. If Flowdown Provisions require Emergent to submit detailed and certified cost or pricing data for Consultant's performance of Services, Consultant shall promptly provide and certify such non-proprietary data as is reasonably required to permit Emergent to comply with the Flowdown Provisions. Consultant shall also provide any other cost or pricing data as is required for Consultant to comply with the Flowdown Provisions. Notwithstanding any indemnification provision(s) of this Agreement to the contrary, unless otherwise specified in the applicable Work Order, Consultant shall indemnify and hold harmless Emergent for any cost or price reduction effected by the Federal Government, to the extent caused by (a) certified cost or pricing data submitted by Consultant or its permitted subcontractors that is not accurate, current or complete as certified by Consultant, or (b) the failure of Consultant or its permitted subcontractors to disclose and consistently follow applicable cost accounting practices and standards or otherwise comply with the Flowdown Provisions (including any regulations promulgated by the Cost Accounting Standards Board).

3. **Performance Standards.** Services shall be provided in accordance with the terms of this Agreement, specific requirements of the Work Order, and best industry standards applicable thereto. Consultant shall (a) provide the facilities and supplies necessary to perform Services unless otherwise specified in an applicable Work Order, (b) report to the authorized contact(s) identified in the applicable Work Order or such other person(s) as Emergent or its Affiliates may designate from time to time in writing, (c) provide Emergent with deliverables and reports described in the applicable Work Order or such other reports as Emergent or its Affiliates may from time to time request, and (d) not subcontract with or otherwise engage or consult any third party to provide Services or any part thereof without Emergent's prior written consent.

4. **Payment**. Emergent shall compensate Consultant for Services rendered based on invoices submitted by Consultant under the applicable Work Order and in accordance with the terms of this Agreement. All invoices shall reference the Emergent Accounting Codes designated in the applicable Work Order, and, if Consultant bills on an hourly basis, be accompanied by a timesheet signed by the Parties that details the hours worked. Invoices shall be payable within forty-five (45) days of receipt by Emergent. Payment of an invoice shall be in full compensation for the corresponding Services performed unless expressly otherwise agreed in writing by the Parties. Consultant shall not receive employee benefits (such as paid vacation, sick leave or any insurance benefits) from Emergent even if Consultant is physically situated at Emergent's offices. Consultant shall be fully responsible for payment of all income taxes, social security taxes, and for any other taxes or payment which may be due and owing by Consultant as the result of fees or amounts paid to it by Emergent under this Agreement, and Consultant shall indemnify and hold harmless Emergent from and against any such tax or payment.

5. **Expenses**. Unless otherwise set forth in an applicable Work Order, Emergent shall reimburse Consultant for out-of-pocket expenses reasonably incurred in the performance of Services in addition to the compensation detailed in the applicable Work Order. Consultant shall submit monthly invoices detailing and categorizing expenses incurred during the immediately preceding month and shall provide supporting documentation as reasonably required by Emergent. Expenses shall not be marked up and shall not exceed fifteen percent (15%) of Maximum Compensation for the applicable invoice period without prior written pre-approval by Emergent. All travel must be in accordance with the Emergent Corporate Travel, Food and Lodging Policy. This Agreement relates to the provision of Services only, and Consultant shall not purchase equipment, goods, software or other tangible or intangible property for which it will seek reimbursement from Emergent without Emergent's express, prior written authorization.

6. **Confidential Information**. Consultant acknowledges that this Agreement creates a confidential relationship between the Parties, and that, in order to perform the Services, Consultant or its members, principals, directors, shareholders, officers, employees, agents, affiliates and advisors (collectively, "***Representatives***") may need to have access to certain commercially valuable, proprietary, and non-public information that Emergent considers to be Confidential Information. "***Confidential Information***" means any and all written, oral, electronic, graphic or other information relating directly or indirectly to Emergent or the business, products, markets, customers, suppliers, condition (financial or otherwise), operations, assets, liabilities, results of operations, cash flows or prospects of Emergent that is delivered, disclosed or furnished by or on behalf of Emergent to Consultant or its Representatives, whether before, on or after the Effective Date hereof, or which Consultant or its Representatives otherwise learns or obtains, through observation or through analysis of such information, and shall also be deemed to include all notes,

analyses, compilations, studies, forecasts, interpretations or other documents prepared by Consultant or its Representatives to the extent such material contains, reflects or is directly based upon, in whole or in part, such information. Confidential Information may include, without limitation, technical information, business plans, identification or characterization of biological or other materials, results and/or design of experiments or preclinical or clinical testing, know-how, trade secrets, methods, methodologies, designs, specifications, clinical protocols, data, inventions, improvements, intellectual properties, devices, processes, procedures, financial analysis, accounting policies and procedures, employee staffing, employee compensation and benefits, manuals and marketing and advertising strategies disclosed directly or indirectly by Emergent to Consultant (whether prepared by Emergent, its advisors or otherwise). The existence, terms and conditions of this Agreement shall also be considered Confidential Information. Consultant agrees to keep confidential and not, without the prior written consent of Emergent, publish, disclose to any third party or use (except for purposes of performance under this Agreement) any Confidential Information. The obligations of this paragraph do not pertain to information which is generally known or hereafter becomes generally known to the public through no fault of Consultant or which is disclosed by Consultant with the written approval of Emergent. Consultant shall return all Confidential Information to Emergent upon completion of the corresponding Services hereunder or upon Emergent's request. Consultant shall be entitled to disclose Confidential Information as required by applicable law, regulation or court order only to the extent necessary to comply therewith; *provided, however*, Consultant shall, if reasonably practicable, provide Emergent an opportunity to seek to prevent disclosure of, or to obtain a protective order for, such Confidential Information by giving advance written notice of such required disclosure; *provided further*, that Consultant shall make such required disclosures in consultation with Emergent and shall cooperate with Emergent in connection with efforts to obtain any protective order or other remedy.

7. **Ownership of Work**. Consultant shall promptly disclose to Emergent in writing all data, information, documents, materials and inventions relating to or arising out of Services, and agrees that all right, title, and interest in and to the foregoing shall belong to and be the property of Emergent. Consultant hereby assigns all its rights in the foregoing to Emergent and agrees, without further payment by Emergent, to make any further assignments and execute all documents necessary to effect Emergent's title thereto in all countries of the world. All documents and materials prepared by Consultant in the performance of Services constitute works-for-hire and shall belong to and be the exclusive property of Emergent, and shall be surrendered by Consultant to Emergent upon request.

8. **Independent Contractor**. With respect to the subject matter hereof, the Parties are and remain independent contractors. This Agreement shall not be deemed to create an employer/employee relationship, joint venture, partnership, association, or agency between the Parties. Consultant is not authorized to incur or create any obligation (express or implied) on behalf of Emergent or to bind Emergent in any manner whatsoever.

9. **Term; Termination**. This Agreement is effective as of the Effective Date and shall continue in effect for three (3) years thereafter or until the Agreement otherwise terminates under this Section ("***Term***"); *provided, however*, that in the event that any Work Order or amendment thereto is then pending, the Term shall be automatically extended until the Services to be provided thereunder are completed. This Agreement (or any Work Order, as applicable) shall terminate upon the expiration of the Term or the first to occur of (a) the date Emergent provides Consultant with written notice (setting out with particularity) that this Agreement is being terminated for "cause" where Consultant: (i) commits any act of embezzlement, theft or fraud against Emergent; (ii) is convicted of a

felony or any crime involving moral turpitude, whether or not related to Services; (iii) commits any act of gross negligence or willful misconduct; or (iv) breaches the representations, warranties or covenants contained in this Agreement; or (b) the date either Party terminates the Agreement for convenience on not less than thirty (30) days' prior written notice. Upon termination of this Agreement, Emergent shall have no further liability other than for payment in accordance with the terms of this Agreement for Services provided prior to the termination date. If this Agreement is terminated by Emergent under the foregoing subsection (a)(iv), in addition to any other rights or remedies available at law or in equity, Consultant will surrender any claim for payment under the Agreement and will refund any payments received under this Agreement. The provisions of Sections 4 – 7, 9, 11 – 15, 16 (only for the applicable period following termination or expiration) and 17 shall survive the expiration or termination of this Agreement for any reason.

10. **Representations and Warranties**. In addition to any other representations and warranties set forth in this Agreement, Consultant represents and warrants that Consultant: (a) will perform Services in a competent, diligent and workmanlike manner consistent with the expected industry standards of professional conduct; (b) has not ever been debarred, and any Consultant representative who provides any portion of the Services has not been debarred, pursuant to the United States Food, Drug and Cosmetic Act, or been excluded from any federal health care program (including Medicare or Medicaid), and Consultant will notify Emergent immediately if any of the foregoing occurs; (c) will perform Services for Emergent and has been advised of the restrictions and obligations set forth in this Agreement, including without limitation, the requirements of confidentiality, compliance with laws and non-solicitation; (d) has full power to enter into and fully perform this Agreement and has the full and unrestricted right to disclose to Emergent any information Consultant makes available to Emergent under this Agreement; and (e) in the event Consultant is employed by a third party, Consultant has verified that the Services do not present a conflict with Consultant's primary employment and that Consultant has the right and authority to enter into this Agreement and to comply with the requirements of Section 7 (Ownership of Work).

11. **Compliance with Laws**. Consultant shall perform its duties and responsibilities hereunder in accordance with the highest standards of ethical business conduct and not engage in any acts or activities that are illegal or that may adversely affect or reflect upon the business, integrity or goodwill of Emergent. Consultant shall take no action that it believes might cause (or be construed as causing) Emergent to be in violation of international, federal, state or local laws or regulations, or Emergent's policies and procedures. Consultant further agrees, to the extent applicable to performance of the Services, to abide by the Emergent BioSolutions Code of Conduct and Business Ethics policy as posted from time to time on the company's website. Without limiting the generality of the foregoing, Consultant represents, warrants and agrees that Consultant will: (a) comply with all applicable laws, rules and regulations, including those governing employment practices (including employee recruiting and hiring), anti-bribery, anti-corruption and anti-gratuities laws or other similar laws; (b) comply with Emergent stated policies and procedures generally applicable to parties operating at Emergent's offices, including those governing safety, health, harassment, and discrimination; (c) prohibit its staff or any representatives from involvement with the payment or giving of anything of value, either directly or indirectly, to an official of any government, political party or official thereof, any candidate for foreign political office, or any official of an international organization, for the purpose of influencing an act or decision in its official capacity, or inducing that official to use influence with any government, to assist Emergent in obtaining or retaining business for or with, or directing business to, any person, or for obtaining an improper advantage; and

(d) certify in writing, at such times as may be requested by Emergent, that Consultant and its Representatives understand, have complied with and are in compliance with the foregoing. Consultant will immediately advise Emergent if Consultant should learn of or have reason to believe that there has been a violation of any of the foregoing undertakings.

12. **Export Control Restrictions**. Each Party acknowledges that, in the course of exchanging Confidential Information, it may desire to have access to certain information about the production and/or development of materials that is subject to export controls by the U.S. Department of Commerce and requires a specific license from that agency before such technology can be transferred outside the United States or disclosed in the United States to nationals of other countries (unless such individuals have been granted U.S. citizenship, permanent residence, or asylee status) ("***Controlled Technology***"). Each Party agrees that Controlled Technology will not be transferred or "released" (as that term is defined in Title 15 CFR Sect. 734.2(b)(3)) to the other Party unless and until the disclosing Party notifies the prospective receiving Party that such information constitutes Controlled Technology and the prospective receiving Party agrees in writing to receive such Controlled Technology, and that any such ultimate disclosure or "release" shall be provided under a license or as may be otherwise authorized by the laws of the United States.

13. **Indemnification**. Consultant shall hold harmless and indemnify Emergent, its employees, agents and representatives, from and against any and all suits, demands, losses, damages, judgments, claims, costs (including reasonable attorneys' fees and costs) or other liabilities (including claims for personal injury or death) to the extent arising from or relating to the performance of Services under this Agreement, or the negligence, acts or omissions of Consultant or any of Consultant's Representatives.

14. **Dispute Resolution**. All disputes or claims arising hereunder that cannot be resolved by the Parties shall be submitted to non-binding mediation for a period of thirty (30) days, which may be extended by written agreement of the Parties. If such dispute is not resolved through mediation or otherwise within the specified period, either Party may pursue remedies available to it at law or in equity, subject to the terms of this Agreement.

15. **Insurance**. Consultant shall maintain, at its sole cost and expense, policies of insurance with respect to the Services provided under this Agreement, and shall provide certificates of insurance evidencing the limits or liability and expiration dates to Emergent upon request. Consultant's level of compliance with such policies of insurance shall not be construed to limit or affect Consultant's obligations or liability hereunder. The following minimum requirements shall apply to Consultant's insurance policies for Services:

(a) Worker's Compensation insurance in accordance with applicable statutory requirements.

(b) Commercial General Liability insurance including coverage for products/completed operations with annual limits of liability not less than $1,000,000 per occurrence; $2,000,000 general aggregate; and $3,000,000 products/completed operations aggregate.

(c) Automobile Liability insurance in an amount not less than $1,000,000 per occurrence.

(d) Applicable Professional Liability insurance in amount not less than $2,000,000 per occurrence.

16. **Non-Solicitation**. Consultant agrees that, during the Term and for a period of twelve (12) consecutive months after termination of the Agreement, Consultant will not knowingly (i) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of Emergent or accept employment with Consultant or any other person or entity, (ii) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of Emergent within the previous six (6) months to accept employment with any person or entity besides Emergent or (iii) solicit, interfere with, or endeavor to cause any customer, client, or business partner of Emergent to cease or reduce its relationship with Emergent or induce or attempt to induce any such customer, client, or business partner to breach any agreement that such customer, client, or business partner may have with Emergent.

17. **Restriction on Insider Trading**. Emergent BioSolutions Inc. is a publicly traded company on the New York Stock Exchange. Consultant acknowledges the existence of laws and regulations prohibiting "insider trading," including the purchase or sale of securities of a company while in the possession of material information that has not been generally disclosed in the marketplace. Consultant acknowledges and agrees that it may have access to certain material nonpublic information of Emergent BioSolutions Inc. or its Affiliates as a result of the Services, and covenants and agrees that it will not engage in insider trading or disclose such information to any third parties.

18. **Force Majeure.** Neither Party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such Party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials. The Party claiming force majeure shall use its commercially reasonable efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement. During such time that the event of force majeure causes such a delay or failure of performance, this Agreement and the Parties' obligations and responsibilities under it shall be deemed suspended until the event of force majeure ceases.

19. **Miscellaneous Provisions.**

(a) Non-Waiver. No delay by or omission of any Party in exercising any right, power, privilege, or remedy shall impair such right, power, privilege, or remedy or be construed as a waiver thereof.

(b) Remedies. The rights and remedies provided in this Agreement are cumulative and are not exclusive of other rights or remedies provided by law.

(c) Notices. Any notice hereunder shall be given by first class mail, express mail, or facsimile (followed by confirmation), addressed to the Parties at the addresses given in the preamble of this Agreement, or to such other address as a Party may later designate in writing to the other Party. Notice of any legal action, claim or other legal matter given by Consultant to Emergent shall be directed to Emergent's General Counsel at 2273 Research Boulevard, Rockville, Maryland, USA 20850.

(d) Use of Name. Neither Party shall use the name, tradename or trademark of the other Party in a press release, advertising, publicity or promotional activity without the prior written consent of the other Party.

(e) Severability. In the event that any section or any part of a section of this Agreement should be declared void, invalid, or unenforceable by any court of law, for any reason, such a determination shall not render void, invalid, or unenforceable any other section or any part of any other section of this Agreement and the remainder of this Agreement shall remain in full force and effect.

(f) Headings. Headings and titles of parts and sections are for convenience only and have no interpretative significance.

(g) Assignability. This Agreement may not be assigned by Consultant without Emergent's prior, express written consent. Emergent may, without Consultant's written consent, assign and transfer this Agreement to any Affiliate, in which event Consultant agrees to continue to perform the duties and obligations according to the terms hereof to or for such assignee or transferee of this Agreement.

(h) Amendments. No modification or amendment to this Agreement or any Work Order shall be effected by or result from the receipt, acceptance, signing or acknowledgement of any purchase order, quotation, invoice, shipping document or other business form containing terms or conditions different from those set forth in this Agreement or any Work Order, and all such additional terms and conditions are hereby specifically rejected by both Parties.

(i) Governing Law and Jurisdiction. This Agreement and its interpretation shall be governed by the laws of Maryland without reference to its conflict of law or choice of law provisions. Any action commenced by a Party to enforce the terms of this Agreement must be brought in the courts of the jurisdiction where the Services were primarily delivered hereunder, and the Parties hereby irrevocably consent to the jurisdiction and venue of such courts to enforce the terms of this Agreement. **The Parties expressly waive any right that they have or may have to a jury trial of any dispute arising out of or in any way related to this Agreement, or any breach thereof**.

(j) Integration; Counterparts; Signatures. This Agreement and any Work Orders (including any corresponding Exhibits), constitute the entire agreement of the Parties, supersede all prior discussions, negotiations and understandings verbal and written, if any, and may only be amended or modified by a written agreement signed by both Parties. In the event of a conflict between the terms of this Agreement and the terms of any Work Order, Exhibit or attachment hereto, proposal, quotation or any Consultant documentation, the terms of this Agreement shall prevail. This Agreement may be signed in multiple identical copies, each of which shall be deemed to be an original copy, and each facsimile or electronic copy shall constitute a legally binding, enforceable document. Electronic signatures shall not be an acceptable means of execution unless both Parties have agreed in writing to the format and standard of such signature.

(k) Advice of Counsel. EACH PARTY ACKNOWLEDGES THAT, IN EXECUTING THIS AGREEMENT, SUCH PARTY HAS HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND HAS READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT SHALL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION HEREOF.

IN WITNESS WHEREOF, Emergent and Consultant have executed this Agreement to be effective as of the Effective Date.

Emergent BioSolutions Inc.

By: [redacted]

Name: Allen M. Shofe

Title: Sr. VP Corp. Affairs

Date: 01/24/12

RPK Consulting Group, Inc.

By: [redacted]

Name: Robert P. Radice

Title: Managing Director RPC

Date: 29 Jan 2012

APPROVED AS TO LEGAL FORM
1/23/2012
K.S.
EMERGENT
K.S.

Work Order

This Work Order, effective as of ***(insert date)*** ("***Effective Date***"), is made by and between **(insert Emergent entity name)** ("***Emergent***") and **<Other Party>** ("***Consultant***"), and is a "Work Order" under the Consulting Agreement dated as of **<Effective Date>**, between Emergent and Consultant ("***Agreement***"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Agreement.

1. Description of Services, Milestones and Deliverables:

2. Period of Performance:

3. Person(s) providing Services:

4. Reports: Consultant shall provide the Emergent Representative with such reports as requested by Emergent from time to time.

5. Fees and Maximum Compensation:

Fees: **Maximum Compensation:**

6. Invoicing and Payment: Invoices shall be sent to and payments made in accordance with the terms of the Agreement, and the following shall apply:

Manner/Location for Payments: First-class mail to Consultant business address

Accounting Codes (Must be noted on invoices for payment to be processed):

G/L No.: **Cost Center:**

Project Code (if applicable):

Emergent Address for Invoices: Emergent BioSolutions Inc.
300 Professional Drive, Suite 250
Gaithersburg, Maryland 20879
Attn: Accounts Payable

7. Expenses: Reimbursable in accordance with the terms of the Agreement.

8. Contacts: **Consultant Notices**:
Emergent Representative:

IN WITNESS WHEREOF, the Parties have executed this Work Order as of the Effective Date.

[Insert Emergent Entity]	**<Other Party>**
By: (form only—do not sign)	By: (form only—do not sign)
Printed Name:	Printed Name:
Title:	Title:
Date:	Date:

Exhibit 22

WORK ORDER NO. 1

This Work Order, effective as of February 1, 2012 ("***Effective Date***"), is made by and between **Emergent BioSolutions Inc.** ("***Emergent***"), and **RPK Consulting Group, Inc.** ("***Consultant***"), and constitutes a "Work Order" under that certain Consulting Agreement dated as of February 1, 2012, between Emergent and Consultant ("***Agreement***"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Agreement.

1. Description of Services, Milestones or Deliverables: Consultant will provide advice limited to international biosecurity and biodefense related issues to Emergent.

   Consultant will assist in developing a strategy, plan and assist in implementation of efforts to raise the awareness and value of general biodefense preparedness for but limited to the Republic of Korea and Saudi Arabia. Such activities would consist of traveling to attend meetings, drafting white papers and providing briefings and assisting in the creation and execution of simulations to key officials. It would also include developing generic as well as tailored educational materials and briefings that could be used to inform senior policy officials concerning the threat of biological warfare and bioterrorism.

2. Period of Performance: February 1, 2012 – January 31, 2013

3. Person(s) providing Services: Dr. Robert P. Kadlec

4. Reports: Consultant shall provide the Emergent Representative with such reports as may be requested by Emergent from time to time.

5. Fees and Maximum Compensation:

   Fees: $10,000.00 per month

   Maximum Compensation: $120,000.00

6. Invoicing and Payment: Invoices shall be sent and payments made in accordance with the terms of the Agreement, and the following shall apply:

   Manner/Location for Payments: First-class mail to primary business address

   Accounting Codes (Must be noted on invoices for payment to be processed):

   G/L No.: 650085 **Cost Center:** 10071 0010

   WBS Code: 200038-0040

   Emergent Address for Invoices: Emergent BioSolutions Inc.
   2273 Research Boulevard, Suite 400
   Rockville, Maryland 20850
   Attention: Accounts Payable

7. Expenses: Reimbursable in accordance with the terms of the Agreement.

8. Contact: Consultant: **Dr. Robert P. Kadlec**
Phone: [redacted]
Email: [redacted]

RPK Consulting Group, Inc
[redacted]

Emergent: **Al Shofe**
Phone: [redacted] Email: [redacted]

Emergent BioSolutions Inc.
2273 Research Boulevard, Suite 400
Rockville, Maryland 20850

IN WITNESS WHEREOF, Emergent and Consultant have executed this Work Order to be effective as of the Effective Date.

Emergent BioSolutions Inc.

By: [redacted]
Name: Allen Shofe
Title: Senior VP Corp. Affairs
Date: 03/02/12

RPK Consulting Group, Inc

By: [redacted]
Name: Robert P. Kadlec
Title: Managing Director
Date: 03/05/12

APPROVED AS TO LEGAL FORM EMERGENT 1/25/2012 K.S

Finance Approved FEB 20 2012 MD

Exhibit 23

WORK ORDER NO. 2

This Work Order No. 2, effective as of February 1, 2013 ("***Effective Date***"), is made by and between **Emergent BioSolutions Inc.** ("***Emergent***"), with a principal office at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, and **RPK Consulting Group, Inc.** ("***Consultant***"), with a principal office at [redacted], and constitutes a "Work Order" under that certain Consulting Agreement dated as of February 1, 2012, between Emergent and Consultant ("***Agreement***"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Agreement.

1. Description of Services, Milestones or Deliverables: Consultant will provide services and advice limited to international biosecurity and biodefense related issues to Emergent.

   Consultant will assist in developing, planning and implementing a strategy to raise the awareness of the value of general biodefense preparedness in the Republic of Korea and Saudi Arabia. Services will include traveling to attend meetings, drafting white papers, providing briefings, and assisting in the creation and execution of simulations to key officials. Services will also include developing generic as well as tailored educational materials and briefings used to inform senior policy officials about the threat of biological warfare and bioterrorism.

2. Period of Performance: February 1, 2013 – January 31, 2014

3. Person(s) providing Services: Dr. Robert P. Kadlec

4. Reports: Consultant shall provide the Emergent Representative with such reports as may be requested by Emergent from time to time.

5. Fees and Maximum Compensation:

   Fees: Emergent will pay Consultant $10,000.00 per month for Services performed.

   Maximum Compensation: $120,000.00, unless otherwise agreed by Emergent in an amendment to this Work Order.

6. Invoicing and Payment: Invoices shall be sent and payments made in accordance with the terms of the Agreement, and the following shall apply:

   Manner/Location for Payments: First-class mail to primary business address

   Accounting Codes (Must be noted on invoices for payment to be processed):

   G/L No.: 650081
   Cost Center: 10075 0010
   WBS Code: 200038-0040

   Emergent Address for Invoices: Emergent BioSolutions Inc.
   2273 Research Boulevard, Suite 400
   Rockville, Maryland 20850
   Attention: Accounts Payable

7. Expenses: Reimbursable in accordance with the terms of the Agreement.

8. Contact: Consultant: **Dr. Robert P. Kadlec**
Phone: [redacted]
Email: [redacted]

Emergent: **Al Shofe**
Phone: [redacted]
Email: [redacted]

IN WITNESS WHEREOF, Emergent and Consultant have executed this Work Order to be effective as of the Effective Date.

Emergent BioSolutions Inc.

By: [redacted]
Name: Allen M. Shofe
Title: Sr VP Corp. Affairs
Date: 02/12/13

RPK Consulting Group, Inc.

By [redacted]
Name: ROBERT P. KADLEC
Title: MANAGING DIRECTOR
Date: 1 Feb 2013

APPROVED AS TO LEGAL FORM
1/30/13
EMERGENT

emergent BioSolutions
TM 1/31/13
FINANCE APPROVED

Exhibit 24

Finance Approval
Michael Orndorff
02/10/2014

Legal Approval
Linda Povinelli
02/10/2014

WORK ORDER NO. 3

This Work Order No. 3, effective as of February 1, 2014 ("***Effective Date***"), is made by and between **Emergent BioSolutions Inc.** ("***Emergent***"), with a principal office at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, and **RPK Consulting Group, Inc.** ("***Consultant***"), with a principal office at [redacted] and constitutes a "Work Order" under that certain Consulting Agreement dated as of February 1, 2012, between Emergent and Consultant ("***Agreement***"). Capitalized terms used but not defined herein shall have the meaning ascribed to such terms in the Agreement.

1. Description of Services, Milestones or Deliverables: Consultant will provide services and advice limited to international biosecurity and biodefense related issues to Emergent.

   Consultant will assist in developing, planning and implementing a strategy to raise the awareness of the value of general biodefense preparedness in the Republic of Korea and Saudi Arabia. Services will include traveling to attend meetings, drafting white papers, providing briefings, and assisting in the creation and execution of simulations to key officials. Services will also include developing generic as well as tailored educational materials and briefings used to inform senior policy officials about the threat of biological warfare and bioterrorism.

2. Period of Performance: February 1, 2014 – January 31, 2015

3. Person(s) providing Services: Dr. Robert P. Kadlec

4. Reports: Consultant shall provide the Emergent Representative with such reports as may be requested by Emergent from time to time.

5. Fees and Maximum Compensation:

   Fees: Emergent will pay Consultant $10,000.00 per month for Services performed.

   Maximum Compensation: $120,000.00, unless otherwise agreed by Emergent in an amendment to this Work Order.

6. Invoicing and Payment: Invoices shall be sent and payments made in accordance with the terms of the Agreement, and the following shall apply:

   Manner/Location for Payments: First-class mail to primary business address

   Accounting Codes (Must be noted on invoices for payment to be processed):

   G/L No.: 650081
   Cost Center: 10074 0010
   WBS Code: 200038-0040

   Emergent Address for Invoices: Emergent BioSolutions Inc.
   2273 Research Boulevard, Suite 400
   Rockville, Maryland 20850
   Attention: Accounts Payable

7. Expenses: Reimbursable in accordance with the terms of the Agreement.

8. Contact: Consultant: **Dr. Robert P. Kadlec**
Phone: [redacted]
Email: [redacted]

Emergent: **Christopher Frech**
Phone: [redacted]
Email: [redacted]

IN WITNESS WHEREOF, Emergent and Consultant have executed this Work Order to be effective as of the Effective Date.

Emergent BioSolutions Inc.

By: [redacted]

Name: Chris Frech

Title: VP Government Affairs

Date: Feb 10, 2014

RPK Consulting Group, Inc.

By: [redacted]

Name: Robert P. Kadlec

Title: Managing Director; RPK Consulting LLC

Date: 9 Feb 2014

Exhibit 25

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, Rm G640	
Room 640-G		Washington DC 20201	
Washington DC 20201			

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST BALTIMORE MD 212246824	(X)	9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201200004I 75A50120F33008
		10B. DATED *(SEE ITEM 13)* 07/23/2020

CODE	1410445	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR 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)*
[redacted]	CAROL C. LAVRICH

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
[redacted]	8/22/20	Carol C. Lavrich -S Digitally signed by Carol C. Lavrich -S Date: 2020.08.24 11:07:51 -04'00' *(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 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" Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – Emergent Manufacturing Operations Baltimore LLC	August 17, 2020 August 19, 2020

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 26

December 22, 2020

To: The Compensation Committee of the Board of Directors
Emergent BioSolutions Inc.

Sue Bailey, Jerome Hauer, George Joulwan, Louis Sullivan

Re: Notice of Compensation Committee Meeting

By authority of the Executive Chairman of the Board of Directors, notice is hereby given that a telephonic meeting of the Compensation Committee of Emergent BioSolutions Inc. will be held on Wednesday, January 20, 2021, commencing at 2:30 p.m. (EDT).

Please use the following information to join the meeting through video or audio. **If you prefer to join via video, please click on the "Click here to join meeting" link in yellow highlighting below. If you prefer to participate via audio only, please use the dial in number and code underneath the "Or call in (audio only)" further down the page.**

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting
Join with a video conferencing device
[redacted]

Find a local number | Reset PIN
Learn More | Meeting options

Should you have any questions, please feel free to contact me at [redacted] or [redacted]

I look forward to speaking with you at the upcoming meeting.

Respectfully,

Daniel Woubishet
Associate General Counsel and Assistant Secretary

protected by emergent biosolutions

Emergent BioSolutions Inc.
Meeting of the Compensation Committee of the Board of Directors
(Louis Sullivan, Sue Bailey, Jerome Hauer, George Joulwan)

Telephonic
Wednesday, January 20, 2021
2:30 p.m. – 4:00 p.m. (EDT)
Agenda

Item No.	Time	Subject Matter	Area of Oversight
		Call to Order	
1	2:30-2:35	Approve Minutes	Board Operations and Corporate Governance
2	2:35-3:00	Review 2020 Corporate Performance Factor	Corporate Performance
3	3:00-3:15	Review 2021 Goals for Executive Officers	Executive Compensation
4	3:15-3:30	Review Individual Weighting for Executive Officer 2021 Bonus Program	Executive Compensation
5	3:30-3:55	Review Competitive Market Data for Executive Officers	Executive Compensation
6	3:55-4:00	Discuss New Business and Recommendations for Future Topics	Board Operations and Corporate Governance
		Proposed Resolutions	Yes
		Adjourn	
		Informational Agenda	
1		2021 Budget	Corporate Performance
2		2021 Salary Structure	Compensation

1/05/2021 (v4)

Draft- December 17, 2020

EMERGENT BIOSOLUTIONS INC.
Minutes of the Compensation Committee

November 11, 2020

Pursuant to notice duly given, a telephonic meeting of the Compensation Committee of the Board of Directors (the "Committee") of Emergent BioSolutions Inc. (the "Corporation") was held on November 11, 2020 at 10:00 a.m. The following members of the Committee, constituting a quorum, participated telephonically or in person at the meeting:

Sue Bailey
Jerome Hauer
George Joulwan
Louis Sullivan

Others in attendance telephonically for all or a portion of the meeting were:

Fuad El-Hibri, Executive Chairman
Robert Kramer, Sr., Director, President and Chief Executive Officer

David Flaherty, VP, Total Rewards
Jennifer Fox, SVP, Legal Affairs and Deputy General Counsel
Elizabeth Petrone, Sr. Corporate Paralegal
Atul Saran, EVP, Corporate Development, General Counsel and Corporate Secretary
Katy Strei, EVP, Human Resources and Chief Human Resources Officer
Daniel Woubishet, Associate General Counsel and Assistant Secretary (*In-person*)

Mitchell Bardolf *(Willis Towers Watson)*
Amy Culbert (*Fox Rothschild*)
Hemant Patel *(Willis Towers Watson)*

Dr. Sullivan served as the chair of the meeting and Mr. Woubishet kept the minutes thereof.

Minutes

The Committee reviewed the minutes of the prior Committee meeting held on August 25, 2020. Upon motion duly made and seconded, it was unanimously:

RESOLVED, that the minutes of the meeting of the Committee held on August 25, 2020 are hereby approved.

2020 Committee Self-Evaluation

All non-director members of management and guests left the meeting except for Mr. Saran, Mr. Woubishet and Ms. Petrone. Dr. Sullivan turned the meeting over to Ms. Culbert to lead a review of the Committee's self-evaluation results. A written summary of the results was distributed to the Committee prior to the meeting. Ms. Culbert described the evaluation process and provided a high-level summary of the results of the self-evaluation. Dr. Sullivan discussed the results with the other Committee members. The Committee thanked Dr. Sullivan for his steady leadership of such a high-functioning committee.

Review Competitive Benchmarking Methodology, 2020 Proxy Peer Comparator Group and Compensation Survey Data

Ms. Culbert left the meeting and other members of management and guests joined the proceedings. Ms. Strei and Mr. Flaherty introduced a discussion regarding the proposed methodology for benchmarking target peer comparator groups as a part of the Section 16 annual executive compensation review process.

Mr. Bardolf led the discussion beginning with an outlined approach of peer proxy data and published survey data. He stated that the most appropriate comparator groups were those that could best match Emergent's evolving business strategy and revenue growth, while recognizing the challenges in assessing the Corporation's unique business model. He discussed the proxy peer group screening criteria and approach. He then presented the results of the proposed proxy peer group, including potential additions as well as companies that no longer fit the peer comparison criteria. He discussed the adjusted criteria range for the Committee to consider and presented the proposed list of companies to retain as proxy peers, as well as proposed companies to remove and those companies for the Committee to consider adding to the group.

Mr. Bardolf noted that finding exact peer group comparators presented challenges because of the Corporation's unique business. He emphasized the focus to identify valid comparables from an executive labor market perspective rather than business strategy match. Ms. Strei spoke about the constant assessment of Emergent's unique mix of business and the delicate balance of biotech pharma and manufacturing mix of peer companies. Mr. Bardolf also summarized the characteristics of companies that underly the published survey data. A discussion ensued. Mr. Bardolf reviewed next steps with the Committee.

Following further discussion, the Committee approved the proposed competitive benchmarking approach, including proxy peers and the published survey data for 2021 in the form presented to the Committee, attached hereto as Exhibit A.

Discuss New Business and Recommendations for Future Topics

Dr. Sullivan asked the Committee members if there were additional topics they would like to discuss at future meetings. There were none presented.

Adjournment

There being no other business, the meeting adjourned at 10: 39 a.m.

Respectfully submitted,

Daniel Woubishet
Associate General Counsel and Assistant Secretary

Exhibit A

Approved Peer Group of Companies for 2020

Proxy Peer Group Review

2020 Proxy Peer Group Recommendation

- The table below summarizes the 20-company proxy peer group resulting from the recommendations outlined on the prior pages – 55% of the peer companies are classified as biotechnology or pharmaceuticals
- A preliminary of the resulting competitive market data indicates potential for somewhat more moderate YoY movement in target TDC relative to last year (i.e., ranging from approximately 5% to 25%)

Recommended 2021 Addition

Company Name	Revenue ($M)	Net Income ($M)	R&D Expense ($M)	R&D as % of Revenue	Spot Market Cap[1] ($M)	12-Month Avg Market Cap[1] ($M)	# of Ees	GICS Industry	Scope (US vs Int'l)[2]
Varian Medical Systems, Inc.	$3,225	$292	$268	8%	$15,747	$11,978	10,082	Health Care Equipment	Int'l
Catalent, Inc.	$3,094	$221	$64	2%	$14,074	$9,890	13,900	Pharmaceuticals	Int'l
PRA Health Sciences, Inc.	$3,066	$243	$0	0%	$6,395	$6,282	17,500	Life Sciences Tools and Services	Int'l
Bio-Rad Laboratories, Inc.	$2,312	$1,759	$203	9%	$15,320	$12,284	8,120	Life Sciences Tools and Services	Int'l
Jazz Pharmaceuticals plc	$2,162	$523	$653	30%	$7,708	$6,990	1,620	Pharmaceuticals	Int'l
Incyte Corporation	$2,159	$447	$1,169	54%	$18,675	$19,119	1,456	Biotechnology	US
Bruker Corporation	$2,073	$197	$189	9%	$5,871	$6,759	7,230	Life Sciences Tools and Services	Int'l
Amneal Pharmaceuticals, Inc.	$1,626	-$362	$235	14%	$626	$567	5,500	Pharmaceuticals	Int'l
Integra LifeSciences Holdings Corp	$1,518	$50	$190	13%	$3,797	$4,476	4,000	Health Care Equipment	Int'l
United Therapeutics Corporation	$1,449	-$105	$1,183	82%	$4,486	$4,440	920	Biotechnology	Int'l
Horizon Therapeutics plc	$1,300	$573	$334	26%	$17,372	$8,392	1,225	Pharmaceuticals	Int'l
Alkermes plc	$1,171	-$197	$513	44%	$2,736	$2,866	2,235	Biotechnology	Int'l
NuVasive, Inc.	$1,168	$65	$72	6%	$2,537	$3,249	2,800	Health Care Equipment	Int'l
Ionis Pharmaceuticals, Inc.	$1,123	$294	$414	37%	$7,013	$7,968	817	Biotechnology	US
Exelixis, Inc.	$968	$321	$337	35%	$7,975	$6,204	617	Biotechnology	Int'l
Masimo Corporation	$938	$196	$93	10%	$12,077	$10,222	1,600	Health Care Equipment	Int'l
OPKO Health, Inc.	$902	-$315	$163	18%	$2,177	$1,596	6,096	Biotechnology	Int'l
Globus Medical, Inc.	$785	$155	$60	8%	$4,822	$5,026	2,000	Health Care Equipment	Int'l
Bio-Techne Corporation	$739	$229	$100	13%	$9,165	$8,659	2,300	Life Sciences Tools and Services	Int'l
Amphastar Pharmaceuticals, Inc.	$322	$49	$69	21%	$892	$880	2,027	Pharmaceuticals	Int'l
n=20									
Summary Statistics									
25th Percentile	**$960**	**$50**	**$88**	**9%**	**$3,532**	**$4,142**	**1,564**		
50th Percentile	**$1,374**	**$209**	**$196**	**14%**	**$6,704**	**$6,521**	**2,268**		
75th Percentile	**$2,160**	**$301**	**$356**	**31%**	**$12,576**	**$8,967**	**6,380**		
Emergent BioSolutions Inc.[3]	**$1,500**	**$365**	**$226**	**15%**	**$5,292**	**$3,779**	**2,200**	**Biotechnology**	**Int'l**
Percentile Rank	57%	81%	57%	54%	39%	23%	46%		

Note: For FY21, EBS management anticipates additional growth beyond FY20 projected revenue, earnings and headcount

Note: Peer financials were extracted from Standard and Poor's Capital IQ (CapIQ) financial database and reflect most recent fiscal year unless noted otherwise.
1. Spot market capitalization as of September 21, 2020. 12-month average is based on the period between September 21, 2019 and September 21, 2020.
2. Reflects US versus international operations based on CapitalIQ business description
3. Emergent revenue and net income reflect guidance as of 7/30/20; R&D expense and employees reflect FYE results per Emergent's FY19 10-K filing

Presenters and Guest Attendees

- **Presenter(s)**
  - Robert Kramer, President and Chief Executive Officer
  - Katy Strei, Executive Vice President and CHRO, Public Affairs

- **Guest Attendee(s)**
  - Dave Flaherty, VP Total Rewards

Agenda

- Background
- Performance Against Corporate Goals
- Additional Factors to Consider
- Corporate Operating Plan Performance
- Historical Trend Analysis

Questions / Issues for the Compensation Committee

Does the Committee have any questions about how corporate performance is being measured?

Does the Committee support management's performance rating assessment and proposed rating?

Background

Evaluation of Corporate Performance

- Historically, the corporate performance factor has been determined based on:
  - Assessment of performance against pre-established annual corporate goals
  - Consideration of how we executed against COP (corporate operating plan) goals
  - Significant additional accomplishments or setbacks

Plan Design

- Under the plan, the maximum bonus payout is capped at 150% of target
- For each separately-weighted corporate goal, our practice has been to cap our assessment of performance at a score of 1.5
  - Thus, achieving the maximum payout (150%) requires performance of 1.5 on every goal

Performance Against Corporate Goals

Corporate Goal	Proposed Rating & Score	Details of Performance Against Goal
Progress 7 pipeline candidate of which at least 5 are in advance stage	Meets 1.0	▪ Achievements – **AV-7909** Ph3 completed – **Vaxchora** received EU approval and 2.0 submission – **FLU-IGIV** data review complete; in discussions with regulators on next development phase – **Trobigard** submitted and approved – Launched **Generation II NARCAN® Nasal Spray** device; NARCAN Nasal Spray shelf-life improvements – **COVID-HIG** candidate in Phase 3 NIAID trial, first patients dosed. PEP study initiated (unplanned) – Shigella-ETEC IND submitted – AP007 (nalmefene LAI) – process development and accelerated – WEVEE Ph2 prep initiated (unplanned) ▪ Disappointments – Chik (Initiation Phase 3 delayed)
Conduct due diligence on at least 3 significant M&A opportunities	Meets 1.0	Goal met despite re-prioritization to focus on CDMO expansion efforts (due diligence projects: Vicuna, Opal, Cobra)

Bold = Advanced Stage; Phase 2 and beyond

Performance Against Corporate Goals

Corporate Goal	Proposed Rating & Score	Details of Performance Against Goal
Enhance commercial efforts, medical/clinical and supply chain capabilities	Exceeds 1.25	**Commercial:** • Project Pinnacle and Pricing Committee: Identified, developed and operationalized policies and ,procedures for International MCM procurement and Pricing Governance for all Products • Enterprise Analytics: Built analytical capabilities for business decision making and performance measurement • Developed Sales and Operations Planning, sourcing and demand planning tools • Established the foundation of a centralized commercial operations **Medical/Clinical:** • **Enhanced medical communication and related processes:** ✓ **Developed Medical Affairs infrastructure and processes** ✓ **Created new Medical communications function** ✓ **Built Medical Affairs training capability** • Strengthened Clinical Dev. infrastructure and processes **Supply Chain** • Established freight and logistics capability to manage global shipping and import/export partner network to reduce freight spend • Implemented system to provide spend analysis and e-sourcing tool • **Advanced Sourcing and Procurement workstream** • **Sustained supply of PPE to manufacturing network** • **Establish MD Centralized Warehouse** • **Improved ERP systems** • **Established Global Policy Board (GPB)**

Bold = Achievements beyond targets.
100% of targeted goals were accomplished.

Performance Against Corporate Goals

Corporate Goal	Proposed Rating & Score	Details of Performance Against Goal
Deliver a meaningful improvement in targeted engagement items through delivery of a comprehensive portfolio of people initiatives	Exceeds 1.25	Notable improvement in Q12 metrics • Engagement Index Ratio increased to 6:1 from 2.83:1 • Engagement grand mean increased from 3.81 to 3.98 surpassing target of 3.91 Increased employee communication and listening efforts: • 14 COVID All Employee Update meetings • 20+ No Agenda Required sessions w EMT reaching nearly 400 employees • 3 Diversity and Inclusion Listening Circles with 3000+ participants Launched key platforms: (1) Arrive onboarding program for new colleagues, (2) Recognize Moments that Matter employee recognition platform
Execute budgeted plan to achieve revenue of $1.274B	Significantly Exceeds 1.5	Final data to come from finance; Guidance provided on 11/5/2020 indicates revenue of $1.52B to $1.58B
Execute budgeted plan to achieve Adjusted EBITDA of $357M	Significantly Exceeds 1.5	Final data to come from finance; Guidance provided on 11/5/2020 indicates $575M to $615M
	Unweighted average = 1.25	

Additional Business Accomplishments

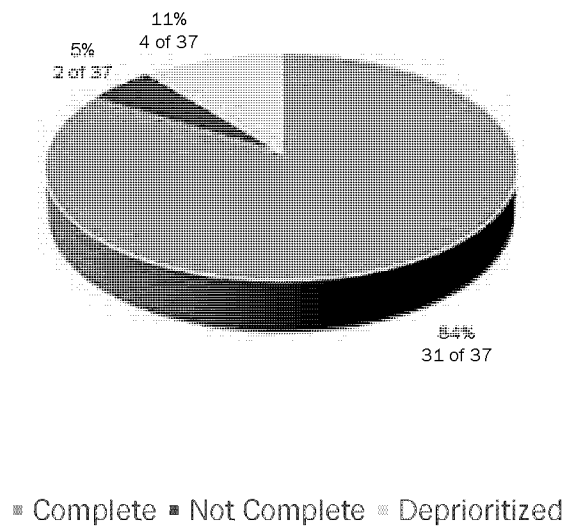
- Completed successful corporate bond offering, further strengthening corporate capital structure ($450 million in aggregate principal amount of 3.875% Senior Unsecured Notes due 2028)
- Achieved U.S. FDA approval of NARCAN® shelf-life extension from 24 months to 36 months
- Initiated $75M capital investment in Canton manufacturing facilities to support growth and diversification of CDMO business
- Completed restructuring and cost reduction program in Travel Health business to maintain franchise's long-term growth prospects, while managing impact of sharp demand declines
- Executed corporate reputation campaign including both paid and earned placements in national media organizations including CBS (60 Minutes), CNBC and NY Times
- Recruited, hired, onboarded and trained 800 total new employees, representing net workforce growth of approximately 25% from the start of the year
- Delivered special ownership award for employees

COVID Related Accomplishments

- Secured CDMO agreements with pharma & biotech innovators and BARDA / OWS for an initial contract value of ~ 1.5B for 2020 through 2022
- Recruited and on-boarded 250+ newly created roles in response to CDMO and Operation Warp Speed contract work
- Built technical manufacturing capability at Bayview to operate at OWS scale
- Enhanced cyber security programs to address heighted requirements from Operation Warp Speed
- Transitioned to hybrid work model (50% of employees working remotely; 25% FT on-site and 25% on-site part-time)
  - ✓ Accelerated roll-out of workplace collaboration tools (Microsoft Teams) to maintain operational continuity
  - ✓ Converted all non-manufacturing business activities to virtual (e.g. recruiting, on-boarding, training, audits)
- Adopted comprehensive workplace health, safety and wellbeing measures, including temp screening kiosks, COVID-19 testing, services, global health & safety operating procedures, contact tracing and case management for EEs experiencing symptoms and TalkSpace, a supplemental mental health service

2020 COP Performance Summary

- In addition to 6 Corporate Goals, there are 31 Corporate Operating Plan (COP) goals for 2020



On March 30th communicated that given the unexpected challenges associated with the COVID-19 pandemic, we made certain decisions to reprioritize certain activities tied to our Corporate Operating Plan (COP) goals and other key 2020 initiatives

Goal Performance Profile Comparison 2012-2020

Year	Complete	Not Complete	De-prioritized
2020[a]	**84%**	**5%**	**11%**
2019	75%	11%	14%
2018	70%	11%	20%
2017	87%	9%	4%
2016	82%	11%	7%
2015	81%	8%	11%
2014	82%	8%	10%
2013	83%	11%	6%
2012	90%	9%	1%
Average ('12'-'19)	**81%**	**10%**	**9%**

[a] 87% of reprioritized goals achieved

Recommendation for 2020 Corporate Factor

Considerations:

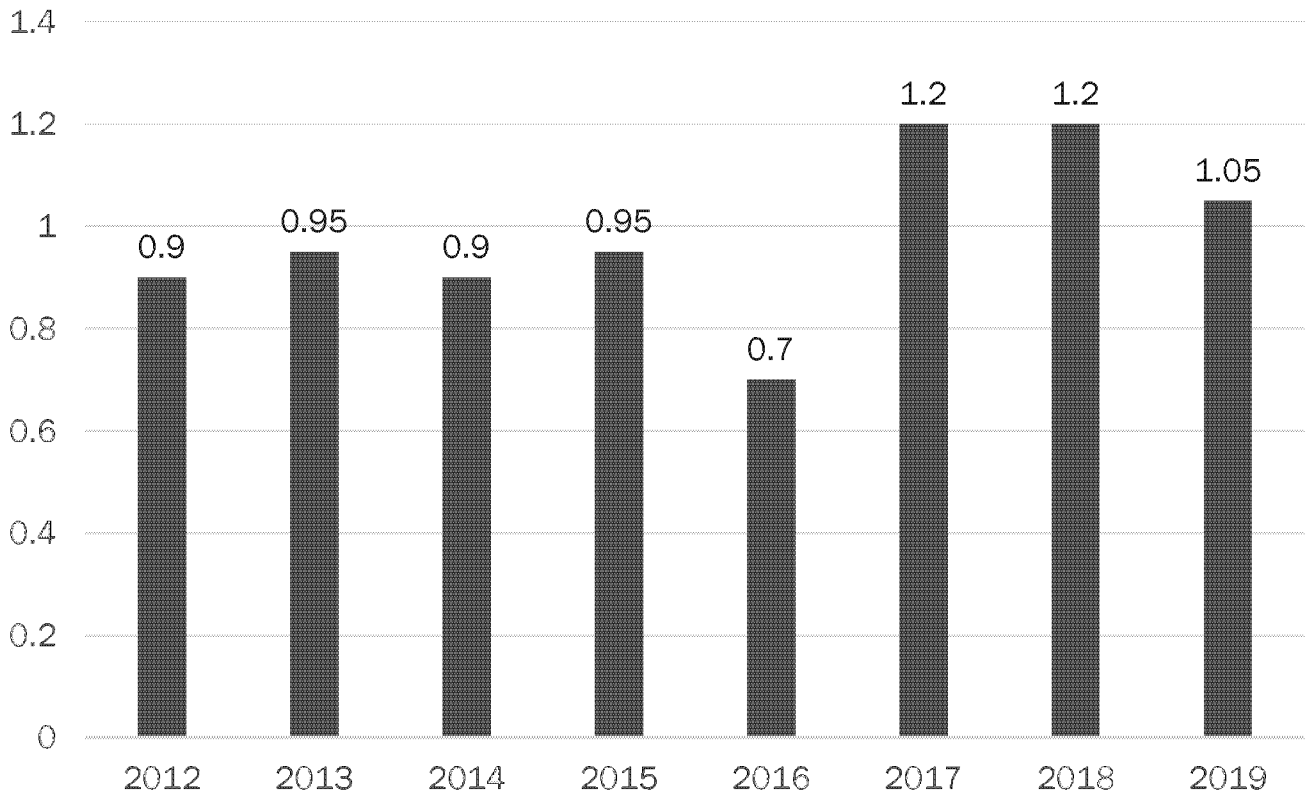
- Performance Against Corporate Goals
  - ✓ Mathematical average of performance on 6 corporate goals: 1.25
  - ✓ "Degree of difficulty" caused by circumstances of COVID19 did not compromise performance
  - ✓ Achieved 87% performance against Corporate Operating Plan
- Additional business achievements associated with the Company's core strategies
- Additional achievements related to our response to operational and people impact of COVID-19

Management recommends 2020 Corporate Factor of 1.4

(1.25 unweighted + 0.15 for incremental accomplishments)

Corporate Factor: Historical Trend

Average: 0.98



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emergent
BioSolutions
2021 Corporate Goals
Presentation to Compensation Committee
20 January 2021

Presenters and Guest Attendees

- **Presenter(s)**
  - Robert Kramer, President and Chief Executive Officer
  - Katy Strei, Executive Vice President, CHRO and Public Affairs
- **Guest Attendee(s)**
  - Dave Flaherty, Vice President Total Rewards

2021 Corporate Goals Recommendation

Area of Focus	Goal #	Goal
2021 Revenue Target	1	Execute budgeted plan to achieve revenue of [$2.110] billion
2021 Adjusted EBITDA Target	2	Execute budgeted plan to achieve adjusted EBITDA of [$834] million
M&A	3	Execute one transaction that aligns to our 2024 strategic objectives and expands our core product, pipeline and/or service offerings
Pipeline Maturity	4	Continue advancement of clinical pipeline programs in order to obtain approval of these products as planned and support growth from fiscal 2024 onward*
Engagement and Inclusion	5	Sustain improvements achieved in 2020 on Employee Engagement as measured by the 2021 Gallup Q12 Improve (statistically significant) 2020 baseline for the Gallup inclusion index
COVID-19 / CDMO Project Execution	6	Supply quality drug substance and drug product for COVID-19 vaccines and therapeutics meeting or exceeding customer expectations

*See next slide for details

2021 Opportunity Set for Corporate Goal #4

Target / Goal	Opportunities	Comments / Additional Details & Milestones
1 BLA/EUA Submission	▪ AV7909 ▪ COVID-HIG	▪ Advance AV7909 to BLA – Submit BLA to FDA (Q4) – Finalize Ph2 and Ph3 CSR (Q3) ▪ Submit COVID-HIG for EUA
1 Initiation of Phase 3 or Go/No Go	▪ CHIKV VLP ▪ FLU-IGIV	▪ Enter CHIKV VLP Ph3 Development – Initiate CHIKV Phase 3 (FSFV) (Q2) – Complete NHP passive study (Q4) ▪ Initiate pivotal program in hospitalized flu
Initiate at least 3 Phase 1	See Comments	▪ Representative Programs* – Shigella (Q1) – Lassa (Q3) – Uniflu (Q4) – SIAN (Q1) – Ketamine (Q2) – Nalmefene LAI (AP007) (Q4)
Advance other clinical candidates		▪ Representative Programs* – WEVEE (advance towards phase 2) – MMU – Auto injector platform (i.e., D4/2A)

* May include programs in-licensed or acquired

Emergent BioSolutions, Inc.

Individual Performance Factor for Section 16 Officers

January 20, 2021

Willis Towers Watson

Background

- As part of the annual incentive plan design framework implemented in early 2015, the Committee approved a construct for Emergent's Section 16 Officers consisting of a combination of both corporate and individual performance factors
  - At the time of adoption, the intended weighting was 90% corporate factor and 10% individual factor for the CEO and EVPs (i.e. Section 16 Officers)
  - During implementation, to ensure alignment and support collaboration among the executive team, management and the Committee opted to use corporate performance objectives in lieu of individual performance objectives for the CEO and EVPs – this practice has continued for each year since the program was implemented in 2015
- In our experience, the use of an individual performance component for top executives is often driven by company culture and/or philosophy
  - The framework provides an additional mechanism to align pay and performance and reward individual contributions, in addition to base salary and long-term incentives, and aligns with competitive practice (details on peer practice is provided in the Appendix)
- The following page outlines the individual performance factor design recommendation for the Committee's review and approval

From WTW's perspective, the adoption of individual performance differentiation (as appropriate) aligns with a majority of Emergent's compensation guiding principles[1]: 1) support a pay-for-performance philosophy, 2) focus on achieving well-articulated goals while demonstrating leadership values, 3) make compensation market-competitive to attract and retain top talent and 4) reward individual contributions

[1]The above listing only excludes Emergent's principle to "employ disciplined use of equity"

Recommendation

- Based on discussions with management, we recommend that Emergent adopt the following design framework:
  - **CEO** – formalize shift to 100% corporate performance only (no individual factor)
  - **Section 16 Officers** – utilize the individual performance component of the annual incentive plan as a formal mechanism to recognize individual performance/contribution for Section 16 Officers (in lieu of corporate performance) and differentiate payouts, as appropriate
    - Individual performance will comprise 10% of the target annual incentive opportunity, with corporate goals weighted 90%
    - Performance will be measured against the individual executive's highest priority business or leadership goal for the performance year
    - The individual component will be subject to the same performance assessment range as the corporate component (i.e., 50-150% of the target)

We provide an illustration of the recommended framework on the following page

Sample Illustration

Section 16 Officer (Non-CEO)

- Base salary: $525,000
- AIP Target: 60% of base salary ($315,000)

Appendix

Appendix

Summary of Peer Practice

- Based on the most recently available proxy disclosures for Emergent's 2021 peer group, we provide a summary of peer practice with respect to individual performance for Named Executive Officers below
  - Note that our observations are limited to the quality and/or level of detail provided in the CD&A; not all peer companies provide robust disclosure on specific mechanics underlying the annual incentive plan design

Plan Design

- The vast majority of peer companies (80%) have an additive plan design; the remaining companies use either a multiplicative plan design (Ionis), non-formulaic (Amphastar and PRA) or do not disclose details (OPKO Health)
  - The additive design provides for the ability to weight various performance components (e.g., company, BU, individual)

Individual Performance – 65% of peers recognize individual performance for NEOs as part of the annual incentive plan

- 35% of peer companies (7 of 20) disclose a formal plan component to recognize individual performance and differentiate awards
  - Five (5) peers disclose formal weightings on individual performance below the CEO level; the median individual performance weighting is 30% (ranges from 25% to 45%)
    - 3 of 6 (Akorn, Bruker and Catalent) use the same weighting for the CEO and other NEOs
    - The remaining two peers (Alkermes and Exelixis) use solely corporate performance for the CEO
  - One company (Amneal) uses individual performance as a modifier (0% to 150%) for corporate performance outcomes
  - One company (Ionis) has a multiplicative plan design that includes corporate and individual performance components
- An additional six (6) peers disclose that individual performance differentiation is informed by Committee/management discretion

Payout Differentiation

- 50% of peer companies (10 of 20) disclosed differentiated AIP payouts among the NEO population

Appendix

Peer Group Detail

Company	Plan Type	CEO				Other NEOs				Payout (% of Target)	
		Individual Component	Component Weighting		Individual Performance Measures	Individual Component	Component Weighting		Individual Performance Measures	CEO	Other NEOs
			Company	Individual			Company	Individual			
Alkermes plc	Additive	No	100%	--	--	Yes	75%	25%	Not disclosed	94%	100% - 125%
Amneal Pharmaceuticals	Additive	Yes	100%	Modifier (0-150%)	Not disclosed	Yes	100%	Modifier (0-150%)	Not disclosed	0%	0%
Amphastar Pharmaceuticals	Non-formulaic	N/D*	--	--	--	N/D*	--	--	--	131%	133% - 146%
Bio-Rad Laboratories, Inc.	Additive	No	100%	--	--	No	100%	--	--	105%	83%- 105%
Bio-Techne Corporation	Additive	N/D*	--	--	--	N/D*	--	--	--	159%	96% - 172%
Bruker Corporation	Additive	Yes	70%	30%	Various operational/strategic measures**	Yes	70%	30%	Various operational/strategic measures**	70%	40% to 104%
Catalent Inc	Additive	Yes	70%	30%	Various operational/strategic measures**	Yes	70%	30%	Various operational/strategic measures**	87%	87%
Exelixis, Inc.	Additive	No	100%	--	--	Yes	55%	45%	Not disclosed	110%	110% - 114%
Globus Medical, Inc.	Additive	No	100%	--	--	No	100%	--	--	112%	112%
Horizon Therapeutics plc	Additive	No	100%	--	--	No	100%	--	--	149%	149%
Incyte Corporation	Additive	No	100%	--	--	No	100%	--	--	132%	132%
Integra LifeSciences Holdings	Additive	No	100%	--	--	No	100%	--	--	100%	90% - 107%
Ionis Pharmaceuticals, Inc.	Multiplicative	Yes	n/a	n/a	Management by Objectives (MBOs)	Yes	n/a	n/a	Management by Objectives (MBOs)	156%	150%
Jazz Pharmaceuticals	Additive	No	100%	--	--	No	100%	--	--	129%	129% - 142%
Masimo Corporation	Additive	No	100%	--	--	No	100%	--	--	134%	134%
NuVasive, Inc.	Additive	No	100%	--	--	No	100%	--	--	150%	134%
OPKO Health	N/D*	N/D*	--	--	--	N/D*	--	--	--	ND	ND
PRA Health Sciences, Inc.	Non-formulaic	N/D*	--	--	--	N/D*	--	--	--	0%	ND
United Therapeutics Corp	Additive	No	100%	--	--	No	100%	--	--	125%	125%
Varian Medical Systems, Inc.	Additive	Yes	80%	20%	Various operational/strategic measures**	Yes	80%	20%	Various operational/strategic measures**	125%	125%
Emergent BioSolutions, Inc.	Additive	Yes	90%	10%	Corporate goals	Yes	90%	10%	Corporate goals	105%	105%

*N/D = not disclosed; peer group disclosure was insufficient to provide additional detail / insights into plan design

** Includes the following: Quality and compliance; operational excellence; customer innovation/growth; organizational vitality/leadership; financial accountability

Emergent BioSolutions, Inc.
Executive Market Compensation Analysis
Section 16 Officers

January 20, 2021

Willis Towers Watson

Overview

- This document presents the results of Willis Towers Watson's competitive market review for Emergent's Section 16 Officers, as follows:

▪ President and CEO	▪ EVP, Corporate Development and General Counsel
▪ Executive Chairman*	▪ EVP, Chief Medical Officer
▪ EVP, CFO and Treasurer	▪ EVP, CHRO and Public Affairs
▪ EVP, Business Operations	▪ EVP, Manufacturing and Technical Operations

* Consistent with the approach taken historically, given the difficulty in finding relevant external benchmarks for the Executive Chairman role the Committee should consider factors such as internal parity within the executive team as well as the Executive Chairman's level of involvement and scope of responsibility when determining appropriate pay recommendations – given the nature of the position, it is our opinion that this continues to be the most appropriate method for evaluating compensation for the Executive Chairman

- Our review focuses on the following executive compensation elements:
  - Base salary
  - Target annual incentive opportunity (% of base)
  - Target total cash compensation (target TCC) – sum of base salary and target annual incentive opportunity
  - Target long-term incentive (LTI) value (i.e., expected values of LTI awards)
  - Target total direct compensation (target TDC) – sum of target TCC and target LTI values
- At this time, the competitive market data is presented to the Committee for reference purposes only – recommendations for 2021 pay adjustments, to include long-term incentive awards, will be presented to the Committee for approval in February 2021

Methodology

Competitive Data Sources

- Emergent's compensation levels for the Section 16 Officers, with the exception of the Executive Chairman, are compared to the competitive market data sources described below – a summary of position matches and definitions for pay elements under review can be found in Exhibit 1 of the Appendix

Peer Proxy Data	Radford Survey Data	Willis Towers Watson Survey Data[2]
• Long-standing source for competitive market data • Consists of 20 companies (approved by the Committee in November 2020) identified based on the following criteria: – Similar industry and commercial status[1] – Similar financial/size/business operations (e.g., revenue, net income, R&D expense, market cap and employee size – Consulting review to confirm appropriateness • Additional detail is provided in Exhibit 2 of the Appendix	• Long-standing source for competitive market data • Consists of a custom data sample of 19 companies reflecting the following criteria[1]: – Operating status – limited to publicly-traded companies only – Industry focus – includes Commercial Biopharma, Medical Devices and Diagnostics – Revenue size – includes companies with between $500M and $5B in revenue • We rely on tabular (i.e., as-reported) survey data for the custom cut ("Radford Custom Tabular"); Radford does not provide regression data • Participant detail is provided in Exhibit 3 of the Appendix	• Recent source for competitive market data in 2020 • Consists of a custom data sample of 16 companies reflecting the following criteria: – Operating status – limited to publicly-traded companies only – Industry focus – includes Pharmaceutical, Biotechnology and Medical Equipment and Supplies – Revenue size – includes companies from approximately $100M to $4.5B (intentionally wide range to ensure sufficiently robust data set) • Where available, we rely on regressed data reflecting FY 2020 projected revenues of $1.5B ("WTW Custom Regression"); supplemented with broader survey results data as needed ("WTW Total Sample Regression" and "WTW <$5B Tabular") • Participant detail is provided in Exhibit 3 of the Appendix

[1] Industries include biotechnology, life sciences tools and services, pharmaceuticals and health care equipment
[2] Broader market data was used as a supplemental data point for the EVP, Business Operations (<$5B Tabular), Chief Medical Officer (Total Sample Regression) and EVP, Manufacturing and Technical Operations (<$5B Tabular)

Competitive Market Data

Key Findings

Market Movement

- Given the adjustments to data sources to reflect Emergent's increased revenues of approximately $1.5B, we observe continued movement in the market data relative to last year
  - Movement in the market median range for the CEO varies by pay element from 12% to 19%; for other Section 16 officers, average movement varies from 5% to 10% – we provide a high level summary of aggregate market median movement in Exhibit 4 of the Appendix

Summary Findings

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target total cash (TCC) within +/- 15%; target total direct (TDC) within +/- 20%
- Emergent's Section 16 Officers generally fall within the competitive market median range for base salary, target TCC and target TDC, with limited exceptions
- In reviewing the detailed competitive market data, the Committee should consider the following:
  - In general, competitive market data tends to be relatively consistent across each data source, and in particular with respect to base salary and target TCC data
    - Long-term incentive ("LTI") and target TDC data have a tendency to be more volatile due to a number of factors:
      - Varying approaches to pay mix and LTI delivery (e.g., fixed shares, etc.) among the peer companies
      - Differing methodologies in data collection and reporting among data sources
  - Proxy data, which provides individual line-by-line data for each proxy peer company, can serve as a valuable resource to understanding of the full range of competitive market practice
  - Proxy data detail is provided in Exhibit 5 of the Appendix

Competitive Market Findings

Chief Executive Officer

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

President and CEO	Base Salary	Target STI (%)	Target TCC	Target LTI	Target TDC
EBS Current	$875	100%	$1,750	$4,100	$5,850

Competitive Market Data

Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - CEO	n =20	$1,000	$1,085	$1,195	100%	115%	125%	$1,930	$2,060	$2,250	$4,855	$7,310	$9,220	$6,875	$9,190	$11,460
Radford Custom Tabular	n=18	$865	$1,050	$1,150	100%	105%	120%	$1,735	$2,115	$2,515	$4,030	$6,145	$8,860	$5,765	$7,510	$10,100
WTW Custom Tabular	n=16	$850	$980	$1,050	100%	120%	125%	$1,880	$2,105	$2,300	$4,500	$5,765	$7,085	$6,355	$7,970	$9,450
WTW Custom Regression	n=16	$885	$945	$1,005	110%	115%	120%	$1,860	$2,025	$2,205	$4,865	$5,855	$7,035	$6,725	$7,880	$9,240
% Difference - EBS Current vs Market																
Peer Proxy Data - CEO		-12%	-19%	-27%	0%	-15%	-25%	-9%	-15%	-22%	-16%	-44%	-56%	-15%	-36%	-49%
Radford Custom Tabular		1%	-17%	-24%	0%	-5%	-20%	1%	-17%	-30%	2%	-33%	-54%	1%	-22%	-42%
WTW Custom Tabular		3%	-11%	-17%	0%	-20%	-25%	-7%	-17%	-24%	-9%	-29%	-42%	-8%	-27%	-38%
WTW Custom Regression		-1%	-7%	-13%	-10%	-15%	-20%	-6%	-14%	-21%	-16%	-30%	-42%	-13%	-26%	-37%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$850	$925	$1,000	100%	105%	110%	$1,735	$1,835	$1,930	$4,030	$4,450	$4,865	$5,765	$6,320	$6,875
50th Percentile		**$945**	**$1,015**	**$1,085**	**105%**	**115%**	**120%**	**$2,025**	**$2,070**	**$2,115**	**$5,765**	**$6,540**	**$7,310**	**$7,510**	**$8,350**	**$9,190**
75th Percentile		$1,005	$1,100	$1,195	120%	125%	125%	$2,205	$2,360	$2,515	$7,035	$8,130	$9,220	$9,240	$10,350	$11,460
Additional Peer Proxy Data																
		25th	50th	75th	25th	50th	75th	25th	50th	75th	25th	50th	75th	25th	50th	75th
CEO Roles Only	n=9	$900	$1,000	$1,015	100%	120%	125%	$1,975	$2,035	$2,200	$4,000	$6,115	$8,230	$5,955	$8,315	$10,230
Chairman and CEO Roles	n=11	$955	$1,035	$1,105	100%	100%	115%	$1,895	$2,075	$2,325	$5,870	$9,140	$11,000	$8,125	$11,440	$13,465

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile
Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, CFO and Treasurer

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, CFO and Treasurer	Base Salary	Target STI (%)	Target TCC	Target LTI	Target TDC
EBS Current	$550	60%	$880	$1,500	$2,380

Competitive Market Data

Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - CFO	n =20	$500	$560	$585	50%	60%	75%	$790	$875	$950	$1,165	$1,605	$2,345	$1,900	$2,525	$3,250
Radford Custom Tabular	n=18	$485	$560	$610	55%	70%	75%	$750	$925	$990	$880	$1,470	$2,190	$1,665	$2,285	$3,095
WTW Custom Tabular	n=16	$480	$525	$610	65%	70%	75%	$810	$920	$1,070	$1,155	$1,530	$2,030	$1,940	$2,405	$3,205
WTW Custom Regression	n=16	$490	$535	$580	60%	70%	80%	$845	$905	$965	$980	$1,395	$1,940	$1,825	$2,300	$2,905
% Difference - EBS Current vs Market																
Peer Proxy Data - CFO		10%	-2%	-6%	10%	0%	-15%	11%	1%	-7%	29%	-7%	-36%	25%	-6%	-27%
Radford Custom Tabular		13%	-2%	-10%	5%	-10%	-15%	17%	-5%	-11%	70%	2%	-32%	43%	4%	-23%
WTW Custom Tabular		15%	5%	-10%	-5%	-10%	-15%	9%	-4%	-18%	30%	-2%	-26%	23%	-1%	-26%
WTW Custom Regression		12%	3%	-5%	0%	-10%	-20%	4%	-3%	-9%	53%	8%	-23%	30%	3%	-18%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$480	$490	$500	50%	60%	65%	$750	$800	$845	$880	$1,025	$1,165	$1,665	$1,805	$1,940
50th Percentile		**$525**	**$545**	**$560**	**60%**	**65%**	**70%**	**$875**	**$900**	**$925**	**$1,395**	**$1,500**	**$1,605**	**$2,285**	**$2,405**	**$2,525**
75th Percentile		$580	$595	$610	75%	80%	80%	$950	$1,010	$1,070	$1,940	$2,145	$2,345	$2,905	$3,080	$3,250

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile
Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, Business Operations

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, Business Operations															
		Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
EBS Current		$530			60%			$848			$1,400			$2,248		
Competitive Market Data																
Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - Gen Mgmt	n =27	$480	$515	$565	55%	65%	80%	$730	$830	$985	$735	$1,250	$2,580	$1,520	$2,120	$3,650
Peer Proxy Data - 3HP	n =19	$485	$550	$620	50%	60%	75%	$760	$900	$1,010	$1,110	$1,580	$2,710	$1,865	$2,605	$3,610
Radford Custom Tabular	n=6	$435	$495	$540	50%	60%	60%	$690	$770	$880	$300	$580	$1,400	$980	$1,345	$2,120
WTW Custom Tabular	n=9	$385	$425	$470	55%	60%	75%	$580	$680	$820	$415	$650	$785	$1,085	$1,280	$1,550
WTW <$5B Tabular	n=18	$430	$595	$645	55%	75%	85%	$685	$1,035	$1,225	$405	$1,000	$1,820	$1,235	$1,950	$3,035
% Difference - EBS Current vs Market																
Peer Proxy Data - Gen Mgmt		10%	3%	-6%	5%	-5%	-20%	16%	2%	-14%	90%	12%	-46%	48%	6%	-38%
Peer Proxy Data - 3HP		9%	-4%	-15%	10%	0%	-15%	12%	-6%	-16%	26%	-11%	-48%	21%	-14%	-38%
Radford Custom Tabular		22%	7%	-2%	10%	0%	0%	23%	10%	-4%	367%	141%	0%	129%	67%	6%
WTW Custom Tabular		38%	25%	13%	5%	0%	-15%	46%	25%	3%	237%	115%	78%	107%	76%	45%
WTW <$5B Tabular		23%	-11%	-18%	5%	-15%	-25%	24%	-18%	-31%	246%	40%	-23%	82%	15%	-26%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$385	$435	$485	50%	55%	55%	$580	$670	$760	$300	$705	$1,110	$980	$1,425	$1,865
50th Percentile		**$425**	**$510**	**$595**	**60%**	**70%**	**75%**	**$680**	**$860**	**$1,035**	**$580**	**$1,080**	**$1,580**	**$1,280**	**$1,945**	**$2,605**
75th Percentile		$470	$560	$645	60%	75%	85%	$820	$1,025	$1,225	$785	$1,750	$2,710	$1,550	$2,600	$3,650

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile
Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, Corporate Development and General Counsel[1]

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, Corporate Development and General Counsel																
		Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
EBS Current		$530			60%			$848			$1,400			$2,248		
Competitive Market Data																
Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - GC	n =13	$495	$605	$660	50%	60%	60%	$775	$930	$1,060	$1,020	$1,550	$3,030	$2,035	$2,610	$3,825
Radford Custom Tabular	n=15	$530	$590	$665	50%	50%	65%	$800	$855	$1,105	$625	$1,125	$1,850	$1,405	$1,880	$2,490
WTW Custom Tabular	n=16	$450	$530	$660	50%	60%	65%	$670	$805	$1,095	$740	$1,150	$1,725	$1,500	$1,955	$2,705
WTW Custom Regression	n=16	$480	$540	$615	55%	60%	60%	$745	$860	$990	$690	$1,115	$1,725	$1,435	$1,975	$2,715
% Difference - EBS Current vs Market																
Peer Proxy Data - GC		7%	-12%	-20%	10%	0%	0%	9%	-9%	-20%	37%	-10%	-54%	10%	-14%	-41%
Radford Custom Tabular		0%	-10%	-20%	10%	10%	-5%	6%	-1%	-23%	124%	24%	-24%	60%	20%	-10%
WTW Custom Tabular		18%	0%	-20%	10%	0%	-5%	27%	5%	-23%	89%	22%	-19%	50%	15%	-17%
WTW Custom Regression		10%	-2%	-14%	5%	0%	0%	14%	-1%	-14%	103%	26%	-19%	57%	14%	-17%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$450	$490	$530	50%	55%	55%	$670	$735	$800	$625	$825	$1,020	$1,405	$1,720	$2,035
50th Percentile		**$530**	**$570**	**$605**	**50%**	**55%**	**60%**	**$805**	**$870**	**$930**	**$1,115**	**$1,335**	**$1,550**	**$1,880**	**$2,245**	**$2,610**
75th Percentile		$615	$640	$665	60%	65%	65%	$990	$1,050	$1,105	$1,725	$2,380	$3,030	$2,490	$3,160	$3,825

[1] Competitive market data reflects a 15% premium to account for additional responsibilities over the Corporate Development function

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile
Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, Chief Medical Officer

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, Chief Medical Officer

	Base Salary	Target STI (%)	Target TCC	Target LTI	Target TDC
EBS Current	$540	60%	$864	$1,000	$1,864

Target LTI reflects a pro-rated new hire award

Competitive Market Data

Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - CMO	n =3	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Peer Proxy Data - 4HP	n =18	$480	$540	$585	50%	60%	70%	$695	$845	$910	$850	$1,280	$2,575	$1,825	$2,190	$3,335
Radford Custom Tabular	n=8	$410	$565	$640	50%	55%	60%	$595	$880	$1,065	$800	$1,380	$3,870	$850	$2,195	$4,465
WTW Custom Tabular	n=6	$385	$480	$510	40%	50%	50%	$575	$675	$745	$580	$980	$1,460	$920	$1,580	$2,065
WTW Total Sample Regression	n=21	$420	$495	$585	55%	60%	65%	$645	$795	$975	$490	$910	$1,580	$1,135	$1,705	$2,555
% Difference - EBS Current vs Market																
Peer Proxy Data - CMO		--	--	--	--	--	--	--	--	--	--	--	--	--	--	--
Peer Proxy Data - 3HP		13%	0%	-8%	10%	0%	-10%	24%	2%	-5%	18%	-22%	-61%	2%	-15%	-44%
Radford Custom Tabular		32%	-4%	-16%	10%	5%	0%	45%	-2%	-19%	25%	-28%	-74%	119%	-15%	-58%
WTW Custom Tabular		40%	13%	6%	20%	10%	10%	50%	28%	16%	72%	2%	-32%	103%	18%	-10%
WTW Total Sample Regression		29%	9%	-8%	5%	0%	-5%	34%	9%	-11%	104%	10%	-37%	64%	9%	-27%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$385	$435	$480	40%	50%	55%	$575	$635	$695	$490	$670	$850	$850	$1,340	$1,825
50th Percentile		**$480**	**$525**	**$565**	**50%**	**55%**	**60%**	**$675**	**$780**	**$880**	**$910**	**$1,145**	**$1,380**	**$1,580**	**$1,890**	**$2,195**
75th Percentile		$510	$575	$640	50%	60%	70%	$745	$905	$1,065	$1,460	$2,665	$3,870	$2,065	$3,265	$4,465

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile
Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, CHRO and Public Affairs[1]

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, CHRO and Public Affairs	Base Salary	Target STI (%)	Target TCC	Target LTI	Target TDC
EBS Current	$437	50%	$656	$900	$1,556

Competitive Market Data

Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - 5HP	n =17	$430	$485	$530	50%	55%	60%	$675	$760	$835	$600	$1,200	$2,235	$1,320	$1,840	$3,070
Radford Custom Tabular	n=14	$385	$450	$485	45%	50%	60%	$605	$695	$755	$385	$835	$1,115	$880	$1,200	$2,105
WTW Custom Tabular	n=15	$385	$450	$485	50%	60%	65%	$590	$680	$775	$495	$745	$935	$1,085	$1,410	$1,680
WTW Custom Regression	n=15	$400	$445	$495	55%	55%	60%	$620	$695	$780	$580	$770	$920	$1,200	$1,465	$1,700
% Difference - EBS Current vs Market																
Peer Proxy Data - 5HP		2%	-10%	-18%	0%	-5%	-10%	-3%	-14%	-21%	50%	-25%	-60%	18%	-15%	-49%
Radford Custom Tabular		14%	-3%	-10%	5%	0%	-10%	8%	-6%	-13%	134%	8%	-19%	77%	30%	-26%
WTW Custom Tabular		14%	-3%	-10%	0%	-10%	-15%	11%	-4%	-15%	82%	21%	-4%	43%	10%	-7%
WTW Custom Regression		9%	-2%	-12%	-5%	-5%	-10%	6%	-6%	-16%	55%	17%	-2%	30%	6%	-8%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$385	$410	$430	45%	50%	55%	$590	$635	$675	$385	$495	$600	$880	$1,100	$1,320
50th Percentile		**$445**	**$465**	**$485**	**50%**	**55%**	**60%**	**$680**	**$720**	**$760**	**$745**	**$975**	**$1,200**	**$1,200**	**$1,520**	**$1,840**
75th Percentile		$485	$510	$530	60%	65%	65%	$755	$795	$835	$920	$1,580	$2,235	$1,680	$2,375	$3,070

[1] Published survey data (WTW and Radford) reflects a 10% premium to account for additional responsibilities related to Public Affairs and Communications functions

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile

Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Competitive Market Findings

EVP, Manufacturing and Technical Operations[1]

- In general, Willis Towers Watson considers the following to be competitive ranges when assessing competitiveness against market – base salary within +/- 10%; target TCC within +/- 15%; target TDC within +/- 20%

EVP, Manufacturing and Technical Operations	Base Salary	Target STI (%)	Target TCC	Target LTI	Target TDC
EBS Current	$458	50%	$687	$900	$1,587

Competitive Market Data

Data Source	Sample Size	Base Salary			Target STI (%)			Target TCC			Target LTI			Target TDC		
		25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile	25th %ile	50th %ile	75th %ile
Peer Proxy Data - Gen Mgmt	n =27	$480	$515	$565	55%	65%	80%	$730	$830	$985	$735	$1,250	$2,580	$1,520	$2,120	$3,650
Peer Proxy Data - 5HP	n =17	$430	$485	$530	50%	55%	60%	$675	$760	$835	$600	$1,200	$2,235	$1,320	$1,840	$3,070
Radford Custom Tabular	n=5	$465	$510	$535	40%	65%	65%	$630	$685	$845	$450	$550	$1,435	$1,140	$1,290	$2,350
WTW Custom Tabular	n=5	$460	$475	$700	50%	60%	70%	$680	$760	$1,170	$870	$975	$2,290	$1,625	$1,795	$3,360
WTW <$5B Tabular	n=7	$425	$465	$640	40%	60%	65%	$595	$745	$1,055	$255	$885	$1,185	$850	$1,630	$2,035
% Difference - EBS Current vs Market																
Peer Proxy Data - Gen Mgmt		-5%	-11%	-19%	-5%	-15%	-30%	-6%	-17%	-30%	22%	-28%	-65%	4%	-25%	-57%
Peer Proxy Data - 5HP		7%	-6%	-14%	0%	-5%	-10%	2%	-10%	-18%	50%	-25%	-60%	20%	-14%	-48%
Radford Custom Tabular		-2%	-10%	-14%	10%	-15%	-15%	9%	0%	-19%	100%	64%	-37%	39%	23%	-32%
WTW Custom Tabular		0%	-4%	-35%	0%	-10%	-20%	1%	-10%	-41%	3%	-8%	-61%	-2%	-12%	-53%
WTW <$5B Tabular		8%	-2%	-28%	10%	-10%	-15%	15%	-8%	-35%	253%	2%	-24%	87%	-3%	-22%
Competitive Market Ranges																
		Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High	Low	Mid*	High
25th Percentile		$425	$455	$480	40%	50%	55%	$595	$665	$730	$255	$565	$870	$850	$1,240	$1,625
50th Percentile		**$465**	**$490**	**$515**	**55%**	**60%**	**65%**	**$685**	**$760**	**$830**	**$550**	**$900**	**$1,250**	**$1,290**	**$1,705**	**$2,120**
75th Percentile		$530	$615	$700	60%	70%	80%	$835	$1,005	$1,170	$1,185	$1,885	$2,580	$2,035	$2,845	$3,650

[1] Published survey data (Radford and WTW) reflects a 15% premium to account for additional responsibilities related to the CDMO Business Unit

* Represents a calculated value reflecting the midpoint between the "low" and "high" of the competitive market percentile

Note: Peer proxy data, Radford data and WTW tabular data represent independently arrayed data for all pay elements. For regressed data, target STI and LTI has been derived based on independently arrayed base salary, target TCC and target TDC data

Appendix

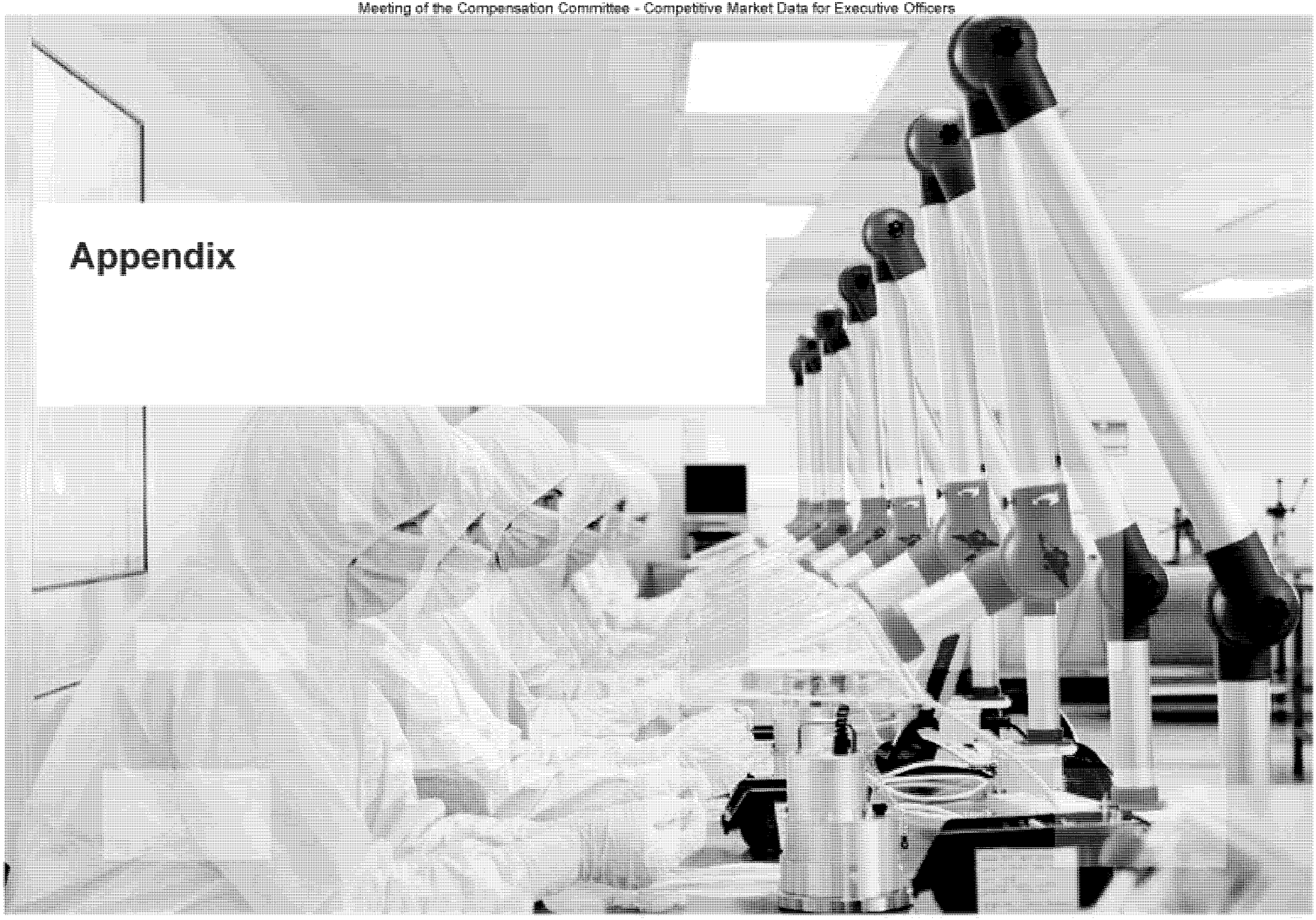

Exhibit 1

Market Benchmark Detail

Emergent Position	Proxy Comparator Group Match		Radford Match	WTW Match
	Positional	Ordinal		
President & CEO	Chief Executive Officer (n=20)	n/a	CEO – Corporate - Global (n=18)	Chief Executive Officer (n=16)
EVP, CFO and Treasurer	Chief Financial Officer (n=20)	n/a	CFO/Top Financial Executive - Global (n=18)	Chief Financial Officer (n=16)
EVP, Business Operations	General Business Management (n=29)	3rd Highest Paid Executive (n=19)	Top Division Executive w/ 20% premium (n=6)	Segment Head (n=9)
EVP, Corporate Development and General Counsel[1]	General Counsel / Top Legal Executive (n=13)	n/a	Top Legal Counsel – Global (n=15)	Top Legal Executive (n=16)
EVP, Chief Medical Officer	n/a Insufficient CMO data (n=3)	4th Highest Paid Executive (n=18)	Chief Medical Officer – Global (n=8)	Chief Medical Officer (n=6)
EVP, CHRO and Public Affairs[2]	n/a	5th Highest Paid Executive (n=17)	Top Human Resources Executive – Global (n=14)	Top Human Resources Executive (n=15)
EVP, Manufacturing and Technical Operations[3]	General Business Management (n=29)	5th Highest Paid Executive (n=17)	Top Operations Executive – Global (n=5)	Top Pharmaceutical Technical Operations Executive (n=5)

[1] Competitive market data reflects a 15% premium to account for additional responsibilities over the Corporate Development function
[2] Published survey data reflects a 10% premium to account for additional responsibilities over the Public Affairs and Communications functions
[3] Published survey data reflects a 15% premium to account for additional responsibilities related to the CDMO business unit

Exhibit 1

Radford and WTW Job Descriptions

Emergent Title	Radford Description	WTW Description
President and CEO	Top executive in an independent corporation accountable for the global operations of the company. Responsible for overseeing all aspects of the business, including directing the organization to ensure the attainment of financial and strategic goals and maximizing return on invested capital. Responsible for the formulation of current and long-range strategic plans and objectives. Represents the organization in relations with its customers, investors, financial community and employees.	Manages the profitability and growth of the organization | Accountable to the Board of Directors for all activities of the organization | Directs the organization in establishing long-range plans, strategy and policy
EVP, CFO and Treasurer	Top executive responsible for overseeing the global financial strategy and organization of an independent corporation. Works with senior executives and the Board of Directors to establish financial and strategic goals for the company, and financial and investing strategies to meet specific business objectives, legal, regulatory and securities reporting requirements. Responsibilities include long-range financial planning and policies, accounting practices and procedures and the company's relationship with the financial and shareholder communities. Oversees all aspects of financial planning and reporting including; the controller function, accounting, treasury, and tax on a global basis to ensure compliance with financial reporting standards, shareholder requirements and regulatory requirements. May also direct the functions of business planning, legal, human resources, and/or information systems.	Establishes, implements, and maintains the financial plans and policies of the organization, including fiscal controls, preparation and interpretation of financial reports, and safeguarding of the organization's assets | Develops and maintains overall accounting policies and controls | Establishes and maintains good corporate relations with the investment and banking communities | Assists in long-range planning and advises management on financial affairs | May manage one or more significant staff functions, but primary focus is the management of the organization's finances
EVP, Business Operations	Top executive responsible for overseeing all operations in a group (a collection of two or more divisions). Responsible for multiple profit and loss centers and for directing a full complement of multiple division senior management to ensure the attainment of financial and strategic business goals. Responsible for establishing objectives, plans and budgets, typically relying on corporate senior management for setting strategic direction, guidance and company-wide policies that are implemented within the group. Sales support is typically provided to the group at the corporate level offering business leverage across the company's product/service portfolio. Accountable for financial contribution (e.g., profit/loss) and the attainment of short and long-range objectives, and for management of the full complement of functional managers, including research and development, clinical, marketing, process development/operations/manufacturing, planning, and finance/administration functions.	Has primary responsibility for a major segment of the organization's operations, which may consist of multiple divisions and typically represents a significant portion (15% or more) of corporate revenues | Sets the overall strategic direction for the segment | Typically reports to the CEO or COO

Exhibit 1

Radford and WTW Job Descriptions

Emergent Title	Radford Description	WTW Description
EVP, Corporate Development and General Counsel	Top executive responsible for overseeing the legal function in an independent corporation on a global basis. As top in-house legal executive: responsible for setting global legal strategies and functional plans for the company. Responsible for overseeing all legal matters pertaining to the organization, including patent, copyright, intellectual property and employment law matters and the coordination of any legal matters handled by outside counsel. Develops functional plans for managing legal matters, including activities to be performed in-house or through third-party relationships to best manage the company's legal activities and minimize risk for the business.	Serves as chief legal adviser and counsels management on the legal implications of all organization activities and problems | Provides legal services as required in legal proceedings | Keeps abreast of legislative and administrative regulatory developments | Obtains the services of outside counsel as required to complement available internal legal resources
EVP, Chief Medical Officer	Top executive in an independent corporation responsible for overseeing the development of the company's global product portfolio strategy to bring products, services and programs to market in compliance with global regulatory, legislative and medical/health requirements. The position typically has functional responsibility for all clinical development activities, which may run from pre-clinical through Phase III programs and may have responsibility for on-market products. Responsible for developing strategic plans for the company's product portfolio to ensure development programs meet quality and safety standards required by medical and regulatory agencies. Typically has responsibility for all clinical development, including providing leadership to regulatory affairs, medical affairs, biometrics and data management to ensure a successful product approval and launch. Oversees the portfolio management activities for the company to ensure appropriate objectives and resources are deployed to meet strategic portfolio plans delivering on key milestones to advance all the company's products in development. Responsible for representing the company with regulatory and legislative agencies, globally addressing the scientific and medical/health aspects of the company's product portfolio. The position may also provide consultative guidance on health-related matters to leaders across the company and with outside health/medical and regulatory organizations. Oversees the company's product portfolio investments to meet fiscal year goals, providing strategic input to the annual and long-range budgetary process.	Provides oversight and advice on all medical issues relevant to the organization, including adverse events, product quality, product withdrawal and perceived ethical problems

Exhibit 1

Radford and WTW Job Descriptions

Emergent Title	Radford Description	WTW Description
EVP, CHRO and Public Affairs	Top executive responsible for overseeing the overall human resources function in an independent corporation on a global basis. Responsible for overseeing the planning, development, implementation and administration of the company's human resources strategies and programs, including succession planning, compensation and benefits, recruitment, training, leadership development, talent management, performance management and employee relations programs. Responsible for establishing long-range human resource strategies and practices for the organization to meet specific business objectives. Ensures business processes comply with regulatory and legal requirements globally to minimize risk to the organization. May provide internal leadership coaching to members of the CEO's executive staff and interacts with executive-level management on a peer basis. May have responsibility for facilities/real estate management.	Has primary responsibility for designing, developing and implementing all human resource policies and programs, including labor relations, if applicable | For noncorporate positions, this position is typically responsible for the execution and administration of policies within a segment of the organization | In highly-decentralized organizations, responsibilities could also include policy design at the segment level
EVP, Manufacturing and Technical Operations	Top executive responsible for overseeing the overall global operations and manufacturing functions in an independent corporation. Sets operations and manufacturing strategy to ensure attainment of financial and strategic goals, translating strategy into tactics, priorities and resource requirements. Oversees the execution of manufacturing, quality assurance, quality control, materials, procurement, logistics, production control and/or manufacturing-related engineering for the company's full product portfolio which may include; early stage product development to full on-market manufacturing, insourcing versus outsourcing strategies, partnership management and execution. The position has responsibility for the company's logistics strategy and oversight of supply chain management activities to deliver products to clinical trials and/or market within defined regulatory, legal, quality and cost standards.	Has primary responsibility for all aspects of production operations for the global ethical pharmaceutical business | Responsibilities include manufacturing/engineering operations and logistics, may include supply chain | May also be responsible for manufacturing and engineering for non-pharmaceutical business unit(s)

Exhibit 2

2021 Proxy Peer Group

- Below is a summary of the 20-company proxy peer group approved by the Committee at the November meeting

Note: Highlighting reflects peer additions for 2021

Company Name	Revenue ($M)	Net Income ($M)	R&D Expense ($M)	R&D as % of Revenue	Spot Market Cap[1] ($M)	12-Month Avg Market Cap[1] ($M)	# of Ees	GICS Industry	Scope (US vs Int'l)[2]
Varian Medical Systems, Inc.	$3,225	$282	$288	8%	$15,747	$11,978	10,052	Health Care Equipment	Int'l
Catalent, Inc.	$3,094	$221	$64	2%	$14,074	$9,890	13,900	Pharmaceuticals	Int'l
PRA Health Sciences, Inc.	$3,066	$243	$0	0%	$6,395	$6,282	17,500	Life Sciences Tools and Services	Int'l
Bio-Rad Laboratories, Inc.	$2,312	$1,759	$203	9%	$15,320	$12,284	8,120	Life Sciences Tools and Services	Int'l
Jazz Pharmaceuticals plc	$2,162	$523	$653	30%	$7,708	$6,990	1,620	Pharmaceuticals	Int'l
Incyte Corporation	$2,159	$447	$1,169	54%	$18,675	$19,119	1,456	Biotechnology	US
Bruker Corporation	$2,073	$197	$189	9%	$5,871	$6,759	7,230	Life Sciences Tools and Services	Int'l
Amneal Pharmaceuticals, Inc.	$1,626	-$362	$235	14%	$626	$567	5,500	Pharmaceuticals	Int'l
Integra LifeSciences Holdings Corp	$1,518	$50	$190	13%	$3,797	$4,476	4,000	Health Care Equipment	Int'l
United Therapeutics Corporation	$1,449	-$105	$1,183	82%	$4,486	$4,440	920	Biotechnology	Int'l
Horizon Therapeutics plc	$1,300	$573	$334	26%	$17,372	$8,392	1,225	Pharmaceuticals	Int'l
Alkermes plc	$1,171	-$197	$513	44%	$2,736	$2,866	2,235	Biotechnology	Int'l
NuVasive, Inc.	$1,168	$65	$72	6%	$2,537	$3,249	2,800	Health Care Equipment	Int'l
Ionis Pharmaceuticals, Inc.	$1,123	$294	$414	37%	$7,013	$7,968	817	Biotechnology	US
Exelixis, Inc.	$968	$321	$337	35%	$7,975	$6,204	617	Biotechnology	Int'l
Masimo Corporation	$938	$196	$93	10%	$12,077	$10,222	1,600	Health Care Equipment	Int'l
OPKO Health, Inc.	$902	-$315	$163	18%	$2,177	$1,596	6,096	Biotechnology	Int'l
Globus Medical, Inc.	$785	$155	$60	8%	$4,822	$5,026	2,000	Health Care Equipment	Int'l
Bio-Techne Corporation	$739	$229	$100	13%	$9,165	$8,659	2,300	Life Sciences Tools and Services	Int'l
Amphastar Pharmaceuticals, Inc.	$322	$49	$69	21%	$892	$880	2,027	Pharmaceuticals	Int'l
n=20									
Summary Statistics									
25th Percentile	**$960**	**$50**	**$88**	**9%**	**$3,532**	**$4,142**	**1,564**		
50th Percentile	**$1,374**	**$209**	**$196**	**14%**	**$6,704**	**$6,521**	**2,268**		
75th Percentile	**$2,160**	**$301**	**$356**	**31%**	**$12,576**	**$8,967**	**6,380**		
Emergent BioSolutions Inc.[3]	**$1,500**	**$365**	**$226**	**15%**	**$5,292**	**$3,779**	**2,200**	**Biotechnology**	**Int'l**
Percentile Rank	57%	81%	57%	54%	39%	23%	46%		

Note: Peer financials were extracted from Standard and Poor's Capital IQ (CapIQ) financial database and reflect most recent fiscal year unless noted otherwise.
1. Spot market capitalization as of September 21, 2020. 12-month average is based on the period between September 21, 2019 and September 21, 2020.
2. Reflects US versus international operations based on CapitalIQ business description
3. Emergent revenue and net income reflect guidance as of 7/30/20; R&D expense and employees reflect FYE results per Emergent's FY19 10-K filing

Exhibit 3

Radford Custom Cut Detail (n=19)

Note: Not all participating organizations report data for all positions under review

Company Name	Revenue ($M)	Net Income ($M)	R&D Expense ($M)	R&D as % of Revenue	Spot Market Cap[1] ($M)	12-Month Avg Market Cap[1] ($M)	# of Ees	GICS Industry
Amneal Pharmaceuticals, Inc.	$1,626	-$362	$235	14%	$626	$567	5,500	Pharmaceuticals
Alexion Pharmaceuticals, Inc.	$4,991	$2,404	$886	18%	$24,490	$23,111	3,082	Biotechnology
Vertex Pharmaceuticals Incorporated	$4,163	$1,177	$1,755	42%	$68,763	$62,714	3,000	Biotechnology
BioMarin Pharmaceutical Inc.	$1,704	-$24	$715	42%	$14,015	$16,309	3,001	Biotechnology
Bio-Techne Corporation	$739	$229	$100	13%	$9,165	$8,659	2,300	Life Sciences Tools and Services
Catalent, Inc.	$3,094	$221	$64	2%	$14,074	$9,890	13,900	Pharmaceuticals
Charles River Laboratories International, Inc.	$2,621	$252	$0	0%	$10,826	$7,967	17,100	Life Sciences Tools and Services
CONMED Corporation	$955	$29	$45	5%	$2,094	$2,505	3,300	Health Care Equipment
Exelixis, Inc.	$968	$321	$337	35%	$7,975	$6,204	617	Biotechnology
Horizon Therapeutics Public Limited Company	$1,300	$573	$334	26%	$17,372	$8,392	1,225	Pharmaceuticals
IDEXX Laboratories, Inc.	$2,407	$428	$133	6%	$31,019	$25,049	9,200	Health Care Equipment
Incyte Corporation	$2,159	$447	$1,169	54%	$18,675	$19,119	1,456	Biotechnology
Indivior PLC	$785	$134	$53	7%	$844	$454	796	Pharmaceuticals
Ionis Pharmaceuticals, Inc.	$1,123	$294	$414	37%	$7,013	$7,968	817	Biotechnology
Myriad Genetics, Inc.	$639	-$200	$95	15%	$940	$1,436	2,700	Biotechnology
PRA Health Sciences, Inc.	$3,066	$243	$0	0%	$6,395	$6,282	17,500	Life Sciences Tools and Services
Quidel Corporation	$535	$73	$53	10%	$8,390	$5,362	1,250	Health Care Supplies
Seagen Inc.	$917	-$159	$719	78%	$31,116	$22,532	1,605	Biotechnology
United Therapeutics Corporation	$1,449	-$105	$1,183	82%	$4,486	$4,440	920	Biotechnology
n=19								
Summary Statistics								
25th Percentile	**$936**	**$2**	**$59**	**6%**	**$5,441**	**$4,901**	**1,238**	
50th Percentile	**$1,449**	**$229**	**$235**	**15%**	**$9,165**	**$7,968**	**2,700**	
75th Percentile	**$2,514**	**$374**	**$717**	**39%**	**$18,023**	**$17,714**	**4,400**	
Emergent BioSolutions Inc.[2]	**$1,500**	**$365**	**$226**	**15%**	**$5,292**	**$3,779**	**2,200**	**Biotechnology**
Percentile Rank	52%	75%	50%	50%	25%	20%	44%	

Note: Peer financials were extracted from Standard and Poor's Capital IQ (CapIQ) financial database and reflect most recent fiscal year unless noted otherwise.

1. Spot market capitalization as of September 21, 2020. 12-month average is based on the period between September 21, 2019 and September 21, 2020.
2. Emergent revenue and net income reflect guidance as of 7/30/20; R&D expense and employees reflect FYE results per Emergent's FY19 10-K filing

Exhibit 3

WTW Custom Cut Detail (n=16)

Note: Not all participating organizations report data for all positions under review

Company Name	Revenue ($M)	Net Income ($M)	R&D Expense ($M)	R&D as % of Revenue	Spot Market Cap[1] ($M)	12-Month Avg Market Cap[1] ($M)	# of Ees	GICS Industry
Abiomed, Inc.	$841	$203	$99	12%	$11,976	$9,386	1,536	Health Care Equipment
AtriCure, Inc.	$231	-$35	$41	18%	$1,737	$1,555	730	Health Care Equipment
Catalent, Inc.	$3,094	$221	$64	2%	$14,074	$9,890	13,900	Pharmaceuticals
CONMED Corporation	$955	$29	$45	5%	$2,094	$2,505	3,300	Health Care Equipment
DENTSPLY SIRONA Inc.	$4,029	$263	$131	3%	$9,769	$10,738	15,200	Health Care Supplies
Edwards Lifesciences Corporation	$4,348	$1,047	$793	18%	$50,641	$46,589	13,900	Health Care Equipment
Elanco Animal Health Incorporated	$3,071	$68	$270	9%	$12,526	$10,199	6,080	Pharmaceuticals
Endo International plc	$2,914	-$423	$1,010	35%	$722	$942	3,172	Pharmaceuticals
Establishment Labs Holdings Inc.	$90	-$38	$15	17%	$436	$438	487	Health Care Supplies
Haemonetics Corporation	$988	$77	$31	3%	$4,236	$5,329	3,004	Health Care Supplies
ICON Public Limited Company	$2,806	$374	$0	0%	$9,320	$8,682	15,250	Life Sciences Tools and Services
IDEXX Laboratories, Inc.	$2,407	$428	$133	6%	$31,019	$25,049	9,200	Health Care Equipment
Integer Holdings Corporation	$1,258	$96	$47	4%	$1,874	$2,450	8,250	Health Care Equipment
Integra LifeSciences Holdings Corporation	$1,518	$50	$190	13%	$3,797	$4,476	4,000	Health Care Equipment
STERIS plc	$3,031	$408	$66	2%	$14,633	$12,848	13,000	Health Care Equipment
West Pharmaceutical Services, Inc.	$1,840	$242	$39	2%	$20,442	$13,804	8,200	Health Care Supplies
n=16								
Summary Statistics								
25th Percentile	**$980**	**$45**	**$41**	**3%**	**$2,039**	**$2,491**	**3,130**	
50th Percentile	**$2,123**	**$150**	**$65**	**5%**	**$9,544**	**$9,034**	**7,140**	
75th Percentile	**$3,041**	**$291**	**$147**	**14%**	**$14,214**	**$11,266**	**13,225**	
Emergent BioSolutions Inc.[2]	**$1,500**	**$365**	**$226**	**15%**	**$5,292**	**$3,779**	**2,200**	**Biotechnology**
Percentile Rank	40%	79%	83%	77%	41%	31%	16%	

Note: Peer financials were extracted from Standard and Poor's Capital IQ (CapIQ) financial database and reflect most recent fiscal year unless noted otherwise.

1. Spot market capitalization as of September 21, 2020. 12-month average is based on the period between September 21, 2019 and September 21, 2020.
2. Emergent revenue and net income reflect guidance as of 7/30/20; R&D expense and employees reflect FYE results per Emergent's FY19 10-K filing

Exhibit 4

Year-to-Year Market Movement

- We provide a high level summary of year-over-year market movement for the Section 16 Officer population below
  - Year-to-year volatility in the underlying market data tends to be more pronounced for roles with relatively small sample sizes, and in some instances, reflect decreases from the prior year
- Consistent with prior years, we find that all data sources remain reasonably well-aligned with respect to base salary and total cash compensation, despite the variation in market movement by data source

Pay Element	Market Movement – Market Median Range	
	CEO	Other Section 16 Officers (Avg)
Base Salary	12%	8%
Target Total Cash Compensation	19%	10%
Target Total Direct Compensation	16%	5%

Exhibit 5

Positional Proxy Data Detail – Chief Executive Officer

Gray shading reflects peer additions for 2021

Company	Executive	Position	Total Compensation Opportunity					
			Base Salary[1]	Target Annual Bonus $	Target Annual Bonus % Base	Target Total Cash[2]	Actual LTI Value[3]	Target Total Direct Comp[4]
Alkermes plc	Richard F. Pops	Chairman and CEO	$1,037	$1,037	100%	$2,075	$12,606	**$14,681**
Amneal Pharmaceuticals, Inc.	Robert A. Stewart	Former President and CEO	$1,000	$1,000	100%	$2,000	$8,231	**$10,231**
Amphastar Pharmaceuticals, Inc.	Jack Yongfeng Zhang	CEO and Chief Scientific Officer	$898	$1,075	120%	$1,973	$3,980	**$5,953**
Bio-Rad Laboratories, Inc.	Norman D. Schwartz	Chairman, President and CEO	$950	$1,093	115%	$2,043	$5,143	**$7,185**
Bio-Techne Corporation	Charles R. Kummeth	President and CEO	$1,053	$1,448	138%	$2,501	$8,669	**$11,170**
Bruker Corporation	Frank H. Laukien	Chairman, President and CEO	$759	$1,062	140%	$1,821	$3,413	**$5,234**
Catalent, Inc.	John R. Chiminski	Chairman and CEO	$1,075	$1,387	129%	$2,462	$6,600	**$9,062**
Exelixis, Inc.	Michael M. Morrissey	President and CEO	$1,017	$1,017	100%	$2,034	$8,774	**$10,808**
Globus Medical, Inc.	David M. Demski	President and CEO	$470	$863	184%	$1,333	$1,977	**$3,309**
Horizon Therapeutics plc	Timothy P. Walbert	Chairman, President and CEO	$1,114	$1,281	115%	$2,395	$9,139	**$11,534**
Incyte Corporation	Hervé Hoppenot	Chairman, President and CEO	$1,099	$1,099	100%	$2,199	$12,678	**$14,877**
Integra LifeSciences Holdings	Peter J. Arduini	President and CEO	$980	$1,176	120%	$2,156	$5,700	**$7,856**
Ionis Pharmaceuticals, Inc.	Stanley T. Crooke	Chairman, President and CEO	$912	$592	65%	$1,504	$7,624	**$9,128**
Jazz Pharmaceuticals plc	Bruce C. Cozadd	Chairman and CEO	$984	$984	100%	$1,967	$9,470	**$11,438**
Masimo Corporation	Joe E. Kiani	Chairman and CEO	$1,126	$1,126	100%	$2,251	$12,000	**$14,251**
NuVasive, Inc.	J. Christopher Barry	CEO	$800	$1,000	125%	$1,800	$4,000	**$5,800**
OPKO Health, Inc.	Phillip Frost	Chairman and CEO	$960	$0	0%	$960	$1,065	**$2,025**
PRA Health Sciences, Inc.	Colin Shannon	President and CEO	$1,100	$1,100	100%	$2,200	$6,116	**$8,316**
United Therapeutics Corporation	Martine A. Rothblatt	Chairman and CEO	$1,275	$1,403	110%	$2,678	$10,003	**$12,680**
Varian Medical Systems, Inc.	Dow R. Wilson	President and CEO	$1,000	$1,250	125%	$2,250	$7,000	**$9,250**

n =20

75th Percentile	**$1,080**	**$1,195**	**125%**	**$2,250**	**$9,220**	**$11,460**
Median	**$1,000**	**$1,085**	**115%**	**$2,060**	**$7,310**	**$9,190**
25th Percentile	**$940**	**$1,000**	**100%**	**$1,930**	**$4,855**	**$6,875**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Positional Proxy Data Detail – Chief Executive Officer (CEO)

Gray shading reflects peer additions for 2021

Company	Executive	Position	Total Compensation Opportunity: Base Salary[1]	Target Annual Bonus $	Target Annual Bonus % Base	Target Total Cash[2]	Actual LTI Value[3]	Target Total Direct Comp[4]
CEO Only								
Amneal Pharmaceuticals, Inc.	Robert A. Stewart	Former President and CEO	$1,000	$1,000	100%	$2,000	$8,231	**$10,231**
Amphastar Pharmaceuticals, Inc.	Jack Yongfeng Zhang	CEO and Chief Scientific Officer	$898	$1,075	120%	$1,973	$3,980	**$5,953**
Bio-Techne Corporation	Charles R. Kummeth	President and CEO	$1,053	$1,448	138%	$2,501	$8,669	**$11,170**
Exelixis, Inc.	Michael M. Morrissey	President and CEO	$1,017	$1,017	100%	$2,034	$8,774	**$10,808**
Globus Medical, Inc.	David M. Demski	President and CEO	$470	$863	184%	$1,333	$1,977	**$3,309**
Integra LifeSciences Holdings	Peter J. Arduini	President and CEO	$980	$1,176	120%	$2,156	$5,700	**$7,856**
NuVasive, Inc.	J. Christopher Barry	CEO	$800	$1,000	125%	$1,800	$4,000	**$5,800**
PRA Health Sciences, Inc.	Colin Shannon	President and CEO	$1,100	$1,100	100%	$2,200	$6,116	**$8,316**
Varian Medical Systems, Inc.	Dow R. Wilson	President and CEO	$1,000	$1,250	125%	$2,250	$7,000	**$9,250**
Chairman and CEO								
Alkermes plc	Richard F. Pops	Chairman and CEO	$1,037	$1,037	100%	$2,075	$12,606	**$14,681**
Bio-Rad Laboratories, Inc.	Norman D. Schwartz	Chairman, President and CEO	$950	$1,093	115%	$2,043	$5,143	**$7,185**
Bruker Corporation	Frank H. Laukien	Chairman, President and CEO	$759	$1,062	140%	$1,821	$3,413	**$5,234**
Catalent, Inc.	John R. Chiminski	Chairman and CEO	$1,075	$1,387	129%	$2,462	$6,600	**$9,062**
Horizon Therapeutics plc	Timothy P. Walbert	Chairman, President and CEO	$1,114	$1,281	115%	$2,395	$9,139	**$11,534**
Incyte Corporation	Hervé Hoppenot	Chairman, President and CEO	$1,099	$1,099	100%	$2,199	$12,678	**$14,877**
Ionis Pharmaceuticals, Inc.	Stanley T. Crooke	Chairman, President and CEO	$912	$592	65%	$1,504	$7,624	**$9,128**
Jazz Pharmaceuticals plc	Bruce C. Cozadd	Chairman and CEO	$984	$984	100%	$1,967	$9,470	**$11,438**
Masimo Corporation	Joe E. Kiani	Chairman and CEO	$1,126	$1,126	100%	$2,251	$12,000	**$14,251**
OPKO Health, Inc.	Phillip Frost	Chairman and CEO	$960	$0	0%	$960	$1,065	**$2,025**
United Therapeutics Corporation	Martine A. Rothblatt	Chairman and CEO	$1,275	$1,403	110%	$2,678	$10,003	**$12,680**
n =20								
Summary Statistics - CEO Only; n=9								
		75th Percentile	**$1,015**	**$1,175**	**125%**	**$2,200**	**$8,230**	**$10,230**
		Median	**$1,000**	**$1,075**	**120%**	**$2,035**	**$6,115**	**$8,315**
		25th Percentile	**$900**	**$1,000**	**100%**	**$1,975**	**$4,000**	**$5,955**
Summary Statistics - Chairman and CEO; n=11								
		75th Percentile	**$1,105**	**$1,205**	**115%**	**$2,325**	**$11,000**	**$13,465**
		Median	**$1,035**	**$1,095**	**100%**	**$2,075**	**$9,140**	**$11,440**
		25th Percentile	**$955**	**$1,010**	**100%**	**$1,895**	**$5,870**	**$8,125**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Positional Proxy Data Detail – Chief Financial Officer (CFO)

Gray shading reflects peer additions for 2021

			Total Compensation Opportunity					
				Target Annual Bonus		Target Total	Actual	Target Total Direct
Company	Executive	Position	Base Salary[1]	$	% Base	Cash[2]	LTI Value[3]	Comp[4]
Alkermes plc	James M. Frates	SVP and CFO	$556	$278	50%	$834	$2,234	**$3,068**
Amneal Pharmaceuticals, Inc.	Todd P. Branning	SVP and CFO	$530	$265	50%	$795	$2,154	**$2,949**
Amphastar Pharmaceuticals, Inc.	William J. Peters	SVP, CFO and Treasurer	$529	$338	64%	$867	$1,050	**$1,917**
Bio-Rad Laboratories, Inc.	Ilan Daskal	EVP and CFO	$500	$325	65%	$825	$1,384	**$2,209**
Bio-Techne Corporation	James T. Hippel	EVP, Finance and CFO	$566	$481	85%	$1,047	$2,016	**$3,063**
Bruker Corporation	Gerald N. Herman	CFO	$452	$271	60%	$722	$548	**$1,270**
Catalent, Inc.	Wetteny Joseph	SVP and CFO	$580	$442	76%	$1,022	$820	**$1,842**
Exelixis, Inc.	Christopher J. Senner	EVP and CFO	$628	$283	45%	$911	$2,324	**$3,235**
Globus Medical, Inc.	Daniel T. Scavilla	EVP, Chief Commercial Officer and Former CFO	$366	$400	109%	$766	$1,054	**$1,820**
Horizon Therapeutics plc	Paul W. Hoelscher	EVP and CFO	$583	$350	60%	$934	$2,774	**$3,707**
Incyte Corporation	Christiana Stamoulis	EVP and CFO	$588	$294	50%	$882	$3,300	**$4,182**
Integra LifeSciences Holdings	Glenn G. Coleman	Corporate VP, Chief Operating Officer and Former CFO	$600	$480	80%	$1,080	$1,292	**$2,372**
Ionis Pharmaceuticals, Inc.	Elizabeth L. Hougen	SVP, Finance and CFO	$500	$200	40%	$699	$2,648	**$3,347**
Jazz Pharmaceuticals plc	Matthew P. Young	EVP and CFO	$580	$319	55%	$899	$2,406	**$3,305**
Masimo Corporation	Micah Young	EVP and CFO	$430	$215	50%	$644	$1,200	**$1,844**
NuVasive, Inc.	Rajesh J. Asarpota	EVP and CFO	$482	$434	90%	$916	$1,450	**$2,366**
OPKO Health, Inc.	Adam E. Logal	SVP and CFO	$600	$0	0%	$600	$639	**$1,239**
PRA Health Sciences, Inc.	Michael J. Bonello	EVP and CFO	$500	$350	70%	$850	$1,656	**$2,506**
United Therapeutics Corporation	James C. Edgemond	CFO and Treasurer	$675	$506	75%	$1,181	$3,251	**$4,432**
Varian Medical Systems, Inc.	Gary E. Bischoping, Jr.	SVP, Finance and CFO	$567	$425	75%	$991	$1,550	**$2,541**
n =20								
		75th Percentile	**$585**	**$425**	**75%**	**$950**	**$2,345**	**$3,250**
		Median	**$560**	**$330**	**60%**	**$875**	**$1,605**	**$2,525**
		25th Percentile	**$500**	**$275**	**50%**	**$790**	**$1,165**	**$1,900**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Positional Proxy Data Detail – General Business Management (Gen Mgmt)

Gray shading reflects peer additions for 2021

Company	Position	Total Compensation Opportunity					
		Base Salary[1]	Target Annual Bonus $	Target Annual Bonus % Base	Target Total Cash[2]	Actual LTI Value[3]	Target Total Direct Comp[4]
Alkermes plc	Former President and Chief Operating Officer	$700	$525	75%	$1,225	$3,872	**$5,097**
Amneal Pharmaceuticals, Inc.	EVP, Commercial Operations	$662	$530	80%	$1,191	$2,438	**$3,629**
Amphastar Pharmaceuticals, Inc.	EVP, Production Center and President, Armstrong Pharmaceuticals, Inc.	$405	$287	71%	$692	$410	**$1,102**
Bio-Rad Laboratories, Inc.	EVP and Chief Operating Officer	$575	$460	80%	$1,035	$382	**$1,417**
Bio-Rad Laboratories, Inc.	EVP and President, Life Science Group	$445	$245	55%	$690	$1,163	**$1,853**
Bio-Rad Laboratories, Inc.	EVP, Global Commercial Operations	$484	$266	55%	$750	$1,163	**$1,914**
Bio-Techne Corporation	President, Protein Sciences	$552	$442	80%	$994	$1,613	**$2,606**
Bio-Techne Corporation	President, Diagnostics and Genomics	$500	$400	80%	$900	$1,208	**$2,108**
Bruker Corporation	EVP, President, Bruker Nano Group and Bruker Nano Surfaces Division	$579	$376	65%	$955	$962	**$1,917**
Bruker Corporation	President, Bruker CALID Group and Bruker Daltonics Division	$374	$224	60%	$599	$628	**$1,226**
Bruker Corporation	President, Bruker BioSpin Group	$356	$185	52%	$541	$224	**$765**
Catalent, Inc.	President, Biologics and Chief Commercial Officer	$540	$191	35%	$731	$2,020	**$2,752**
Catalent, Inc.	President and Chief Operating Officer	$483	$391	81%	$874	$718	**$1,592**
Horizon Therapeutics plc	EVP and Chief Commercial Officer	$530	$720	136%	$1,250	$2,723	**$3,973**
Incyte Corporation	EVP and Head, Discovery Chemistry	$511	$321	63%	$832	$6,104	**$6,936**
Incyte Corporation	EVP and General Manager, US	$483	$241	50%	$724	$2,949	**$3,672**
Integra LifeSciences Holdings	Corporate VP and President, Orthopedics and Tissue Technologies	$477	$286	60%	$763	$648	**$1,411**
Integra LifeSciences Holdings	Corporate VP and President, Codman Specialty Surgical Solutions	$452	$271	60%	$723	$595	**$1,318**
Ionis Pharmaceuticals, Inc.	SVP and Chief Operating Officer	$528	$264	50%	$792	$5,471	**$6,263**
Jazz Pharmaceuticals plc	President and Chief Operating Officer	$625	$344	55%	$969	$4,607	**$5,576**
Jazz Pharmaceuticals plc	EVP, U.S. Commercial	$525	$289	55%	$814	$2,048	**$2,861**
Masimo Corporation	Chief Operating Officer	$550	$275	50%	$825	$1,200	**$2,025**
NuVasive, Inc.	President	$515	$464	90%	$979	$1,500	**$2,479**
NuVasive, Inc.	President, U.S. Commercial	$398	$299	75%	$697	$750	**$1,447**
United Therapeutics Corporation	President and Chief Operating Officer	$885	$752	85%	$1,637	$3,751	**$5,388**
Varian Medical Systems, Inc.	President, Proton Solutions and Chief Growth Officer	$722	$650	90%	$1,372	$2,100	**$3,472**
Varian Medical Systems, Inc.	President, Oncology Systems	$499	$374	75%	$872	$1,250	**$2,122**

n =27

75th Percentile	**$565**	**$450**	**80%**	**$985**	**$2,580**	**$3,650**
Median	**$515**	**$320**	**65%**	**$830**	**$1,250**	**$2,120**
25th Percentile	**$480**	**$270**	**55%**	**$730**	**$735**	**$1,520**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Exhibit 5

Positional Proxy Data Detail – General Counsel (GC)

Gray shading reflects peer additions for 2021

			Total Compensation Opportunity					
			Base	Target Annual Bonus		Target Total	Actual	Target Total Direct
Company	Executive	Position	Salary[1]	$	% Base	Cash[2]	LTI Value[3]	Comp[4]
Alkermes plc	David J. Gaffin	SVP, Chief Legal Officer, Chief Compliance Officer and Secretary	$550	$275	50%	$825	$2,633	**$3,458**
Amneal Pharmaceuticals, Inc.	David A. Buchen	SVP, Chief Legal Officer and Corporate Secretary	$575	$345	60%	$920	$3,000	**$3,920**
Bio-Techne Corporation	Brenda S. Furlow	SVP, General Counsel and Secretary	$475	$285	60%	$760	$1,009	**$1,769**
Catalent, Inc.	Steven L. Fasman	SVP, General Counsel and Corporate Secretary	$600	$440	73%	$1,040	$780	**$1,820**
Exelixis, Inc.	Jeffrey J. Hessekiel	EVP and General Counsel	$558	$251	45%	$809	$2,324	**$3,133**
Globus Medical, Inc.	Kelly G. Huller	SVP, General Counsel and Corporate Secretary	$300	$100	33%	$400	$679	**$1,079**
Integra LifeSciences Holdings	Eric I. Schwartz	Corporate VP, General Counsel and Secretary	$425	$255	60%	$680	$886	**$1,566**
Ionis Pharmaceuticals, Inc.	Patrick R. O'Neil	SVP, Legal, General Counsel, Chief Compliance Officer and Corporate Secretary	$483	$193	40%	$676	$2,648	**$3,324**
Jazz Pharmaceuticals plc	Suzanne Sawochka Hooper	Former EVP and General Counsel	$580	$319	55%	$899	$2,406	**$3,305**
Masimo Corporation	Tom McClenahan	EVP, General Counsel and Corporate Secretary	$428	$214	50%	$642	$1,200	**$1,841**
NuVasive, Inc.	Nathaniel B. Sisitsky	SVP, General Counsel and Corporate Secretary	$375	$225	60%	$600	$600	**$1,200**
United Therapeutics Corporation	Paul A. Mahon	EVP, General Counsel and Corporate Secretary	$850	$553	65%	$1,403	$3,001	**$4,403**
Varian Medical Systems, Inc.	John W. Kuo	SVP, General Counsel and Corporate Secretary	$525	$394	75%	$919	$1,350	**$2,269**
n =13								
		75th Percentile	**$575**	**$345**	**60%**	**$920**	**$2,635**	**$3,325**
		Median	**$525**	**$275**	**60%**	**$810**	**$1,350**	**$2,270**
		25th Percentile	**$430**	**$225**	**50%**	**$675**	**$885**	**$1,770**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Exhibit 5

Positional Proxy Data Detail – Chief Medical Officer

Gray shading reflects peer additions for 2021

			Total Compensation Opportunity					
				Target Annual Bonus		Target Total	Actual	Target Total Direct
Company	Executive	Position	Base Salary[1]	$	% Base	Cash[2]	LTI Value[3]	Comp[4]
Alkermes plc	Craig C. Hopkinson	SVP, Medicines Development and Medical Affairs, and Chief Medical Officer	$621	$311	50%	$932	$2,633	**$3,565**
Exelixis, Inc.	Gisela M. Schwab	President, Product Development and Medical Affairs and Chief Medical Officer	$718	$359	50%	$1,077	$2,789	**$3,866**
Incyte Corporation	Steven H. Stein	EVP and Chief Medical Officer	$579	$289	50%	$868	$6,104	**$6,972**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Provided for reference only

Exhibit 5

Ordinal Proxy Data Detail – 2nd Highest Paid Executive (2HP) (provided for reference only)

Gray shading reflects peer additions for 2021

Company	Position	Total Compensation Opportunity: Base Salary[1]	Target Annual Bonus $	Target Annual Bonus % Base	Target Total Cash[2]	Actual LTI Value[3]	Target Total Direct Comp[4]
Alkermes plc	Former President and Chief Operating Officer	$700	$525	75%	$1,225	$3,872	**$5,097**
Amneal Pharmaceuticals, Inc.	SVP, Chief Legal Officer and Corporate Secretary	$575	$345	60%	$920	$3,000	**$3,920**
Amphastar Pharmaceuticals, Inc.	Chairman, Chief Operating Officer and Chief Scientist	$732	$544	74%	$1,276	$1,680	**$2,956**
Bio-Rad Laboratories, Inc.	EVP and CFO	$500	$325	65%	$825	$1,384	**$2,209**
Bio-Techne Corporation	EVP, Finance and CFO	$566	$481	85%	$1,047	$2,016	**$3,063**
Bruker Corporation	EVP, President, Bruker Nano Group and Bruker Nano Surfaces Division	$579	$376	65%	$955	$962	**$1,917**
Catalent, Inc.	President, Biologics and Chief Commercial Officer	$540	$191	35%	$731	$2,020	**$2,752**
Exelixis, Inc.	President, Product Development and Medical Affairs and Chief Medical Officer	$718	$359	50%	$1,077	$2,789	**$3,866**
Globus Medical, Inc.	Executive Chairman	$392	$476	122%	$868	$1,318	**$2,185**
Horizon Therapeutics plc	EVP and Chief Administrative Officer	$611	$367	60%	$978	$3,202	**$4,180**
Incyte Corporation	EVP and Chief Medical Officer	$579	$289	50%	$868	$6,104	**$6,972**
Integra LifeSciences Holdings	Corporate VP, Chief Operating Officer and Former CFO	$600	$480	80%	$1,080	$1,292	**$2,372**
Ionis Pharmaceuticals, Inc.	SVP and Chief Operating Officer	$528	$264	50%	$792	$5,471	**$6,263**
Jazz Pharmaceuticals plc	President and Chief Operating Officer	$625	$344	55%	$969	$4,607	**$5,576**
Masimo Corporation	Chief Operating Officer	$550	$275	50%	$825	$1,200	**$2,025**
NuVasive, Inc.	President	$515	$464	90%	$979	$1,500	**$2,479**
OPKO Health, Inc.	Vice Chairman and Chief Technical Officer	$900	$0	0%	$900	$1,065	**$1,965**
PRA Health Sciences, Inc.	EVP and CFO	$500	$350	70%	$850	$1,656	**$2,506**
United Therapeutics Corporation	President and Chief Operating Officer	$885	$752	85%	$1,637	$3,751	**$5,388**
Varian Medical Systems, Inc.	President, Proton Solutions and Chief Growth Officer	$722	$650	90%	$1,372	$2,100	**$3,472**
n =20							
	75th Percentile	**$705**	**$480**	**80%**	**$1,080**	**$3,340**	**$4,410**
	Median	**$580**	**$365**	**65%**	**$960**	**$2,020**	**$3,010**
	25th Percentile	**$535**	**$315**	**50%**	**$865**	**$1,365**	**$2,330**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Ordinal Proxy Data Detail – 3rd Highest Paid Executive (3HP)

Gray shading reflects peer additions for 2021

		Total Compensation Opportunity					
			Target Annual Bonus		Target Total		Target Total Direct
Company	Position	Base Salary[1]	$	% Base	Cash[2]	Actual LTI Value[3]	Comp[4]
Alkermes plc	SVP, Medicines Development and Medical Affairs, and Chief Medical Officer	$621	$311	50%	$932	$2,633	**$3,565**
Amneal Pharmaceuticals, Inc.	EVP, Commercial Operations	$662	$530	80%	$1,191	$2,438	**$3,629**
Amphastar Pharmaceuticals, Inc.	President and General Counsel	$618	$429	69%	$1,047	$1,580	**$2,627**
Bio-Rad Laboratories, Inc.	EVP, Global Commercial Operations	$484	$266	55%	$750	$1,163	**$1,914**
Bio-Techne Corporation	President, Protein Sciences	$552	$442	80%	$994	$1,613	**$2,606**
Bruker Corporation	CFO	$452	$271	60%	$722	$548	**$1,270**
Catalent, Inc.	SVP and CFO	$580	$442	76%	$1,022	$820	**$1,842**
Exelixis, Inc.	EVP, Scientific Strategy and Chief Scientific Officer	$552	$249	45%	$801	$2,789	**$3,590**
Globus Medical, Inc.	EVP, Chief Commercial Officer and Former CFO	$366	$400	109%	$766	$1,054	**$1,820**
Horizon Therapeutics plc	EVP, Head, Research and Development and Chief Scientific Officer	$644	$386	60%	$1,030	$2,819	**$3,849**
Incyte Corporation	EVP and Head, Discovery Chemistry	$511	$256	50%	$767	$6,104	**$6,870**
Integra LifeSciences Holdings	Corporate VP, General Counsel and Secretary	$425	$255	60%	$680	$886	**$1,566**
Ionis Pharmaceuticals, Inc.	SVP, Development	$491	$196	40%	$688	$3,078	**$3,766**
Jazz Pharmaceuticals plc	EVP and CFO	$580	$319	55%	$899	$2,406	**$3,305**
Masimo Corporation	EVP, Operations and Clinical Research	$459	$229	50%	$688	$1,200	**$1,888**
NuVasive, Inc.	EVP and CFO	$482	$434	90%	$916	$1,450	**$2,366**
OPKO Health, Inc.	EVP, Administration	$810	$0	0%	$810	$639	**$1,449**
United Therapeutics Corporation	CFO and Treasurer	$675	$506	75%	$1,181	$3,251	**$4,432**
Varian Medical Systems, Inc.	SVP, Finance and CFO	$567	$425	75%	$991	$1,550	**$2,541**
n =19							
	75th Percentile	**$620**	**$430**	**75%**	**$1,010**	**$2,710**	**$3,610**
	Median	**$550**	**$320**	**60%**	**$900**	**$1,580**	**$2,605**
	25th Percentile	**$485**	**$255**	**50%**	**$760**	**$1,110**	**$1,865**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Ordinal Proxy Data Detail – 4th Highest Paid Executive (4HP)

Gray shading reflects peer additions for 2021

		Total Compensation Opportunity					
			Target Annual Bonus		Target Total		Target Total Direct
Company	Position	Base Salary[1]	$	% Base	Cash[2]	Actual LTI Value[3]	Comp[4]
Alkermes plc	SVP, Chief Legal Officer, Chief Compliance Officer and Secretary	$550	$275	50%	$825	$2,633	**$3,458**
Amneal Pharmaceuticals, Inc.	SVP and Chief Scientific Officer	$550	$275	50%	$825	$2,151	**$2,976**
Amphastar Pharmaceuticals, Inc.	SVP, CFO and Treasurer	$529	$338	64%	$867	$1,050	**$1,917**
Bio-Rad Laboratories, Inc.	EVP and President, Life Science Group	$445	$245	55%	$690	$1,163	**$1,853**
Bio-Techne Corporation	President, Diagnostics and Genomics	$500	$400	80%	$900	$1,208	**$2,108**
Bruker Corporation	President, Bruker CALID Group and Bruker Daltonics Division	$374	$224	60%	$599	$628	**$1,226**
Catalent, Inc.	SVP, General Counsel and Corporate Secretary	$600	$440	73%	$1,040	$780	**$1,820**
Exelixis, Inc.	EVP and CFO	$628	$283	45%	$911	$2,324	**$3,235**
Horizon Therapeutics plc	EVP and CFO	$583	$350	60%	$934	$2,774	**$3,707**
Incyte Corporation	EVP and CFO	$588	$294	50%	$882	$3,300	**$4,182**
Integra LifeSciences Holdings	Corporate VP and President, Orthopedics and Tissue Technologies	$477	$286	60%	$763	$648	**$1,411**
Ionis Pharmaceuticals, Inc.	SVP, Finance and CFO	$500	$200	40%	$699	$2,648	**$3,347**
Jazz Pharmaceuticals plc	Former EVP and General Counsel	$580	$319	55%	$899	$2,406	**$3,305**
Masimo Corporation	EVP and CFO	$430	$215	50%	$644	$1,200	**$1,844**
NuVasive, Inc.	President, U.S. Commercial	$398	$299	75%	$697	$750	**$1,447**
OPKO Health, Inc.	SVP and CFO	$600	$0	0%	$600	$639	**$1,239**
United Therapeutics Corporation	EVP, General Counsel and Corporate Secretary	$850	$691	81%	$1,541	$3,001	**$4,541**
Varian Medical Systems, Inc.	SVP, General Counsel and Corporate Secretary	$525	$394	75%	$919	$1,350	**$2,269**
n =18							
	75th Percentile	**$585**	**$345**	**70%**	**$910**	**$2,575**	**$3,335**
	Median	**$540**	**$290**	**60%**	**$845**	**$1,280**	**$2,190**
	25th Percentile	**$480**	**$250**	**50%**	**$695**	**$850**	**$1,825**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

Notes:
OPKO Health - did not disclose target incentive opportunities or actual incentive payouts. OPKO Health has a discretionary bonus plan and has not paid out since 2015.

Exhibit 5

Ordinal Proxy Data Detail – 5th Highest Paid Executive (5HP)

Gray shading reflects peer additions for 2021

		Total Compensation Opportunity					
			Target Annual Bonus		Target Total	Actual	Target Total Direct
Company	Position	Base Salary[1]	$	% Base	Cash[2]	LTI Value[3]	Comp[4]
Alkermes plc	SVP and CFO	$556	$278	50%	$834	$2,234	**$3,068**
Amneal Pharmaceuticals, Inc.	SVP and CFO	$530	$265	50%	$795	$2,154	**$2,949**
Amphastar Pharmaceuticals, Inc.	EVP, Production Center and President, Armstrong Pharmaceuticals, Inc.	$405	$287	71%	$692	$410	**$1,102**
Bio-Rad Laboratories, Inc.	EVP and Chief Operating Officer	$575	$460	80%	$1,035	$382	**$1,417**
Bio-Techne Corporation	SVP, General Counsel and Secretary	$475	$285	60%	$760	$1,009	**$1,769**
Bruker Corporation	President, Bruker BioSpin Group	$356	$185	52%	$541	$224	**$765**
Catalent, Inc.	President and Chief Operating Officer	$483	$391	81%	$874	$718	**$1,592**
Exelixis, Inc.	EVP and General Counsel	$558	$251	45%	$809	$2,324	**$3,133**
Globus Medical, Inc.	SVP, General Counsel and Corporate Secretary	$300	$100	33%	$400	$679	**$1,079**
Horizon Therapeutics plc	Former EVP and Chief Business Officer	$562	$337	60%	$900	$2,758	**$3,658**
Incyte Corporation	EVP and General Manager, US	$483	$241	50%	$724	$2,949	**$3,672**
Integra LifeSciences Holdings	Corporate VP and President, Codman Specialty Surgical Solutions	$452	$271	60%	$723	$595	**$1,318**
Ionis Pharmaceuticals, Inc.	SVP, Legal, General Counsel, Chief Compliance Officer and Corporate Secretary	$483	$193	40%	$676	$2,648	**$3,324**
Jazz Pharmaceuticals plc	EVP, U.S. Commercial	$525	$289	55%	$814	$2,048	**$2,861**
Masimo Corporation	EVP, General Counsel and Corporate Secretary	$428	$214	50%	$642	$1,200	**$1,841**
NuVasive, Inc.	SVP, General Counsel and Corporate Secretary	$375	$225	60%	$600	$600	**$1,200**
Varian Medical Systems, Inc.	President, Oncology Systems	$499	$374	75%	$872	$1,250	**$2,122**

n =17

75th Percentile	**$530**	**$290**	**60%**	**$835**	**$2,235**	**$3,070**
Median	**$485**	**$270**	**55%**	**$760**	**$1,200**	**$1,840**
25th Percentile	**$430**	**$225**	**50%**	**$675**	**$600**	**$1,320**

1. Salary is annualized if partial year for executive
2. Target total cash includes base salary and target bonus, if disclosed; otherwise reflects actual bonus paid
3. LTI Grant Value represents FAS ASC-718 grant value for all equity awards plus target award for long-term cash plans
4. Target TDC (Total Direct Compensation) = target total cash + long-term incentives

EMERGENT BIOSOLUTIONS INC.

Draft Resolutions of Compensation Committee of the Board of Directors

January 20, 2021

Approve Minutes

RESOLVED, that the minutes of the meetings of the Committee held on November 11, 2020, are hereby approved.

Approve 2020 Corporate Performance Factor

FURTHER RESOLVED, that in making bonus determinations for employees of the Corporation for 2020, management shall take into account corporate performance and individual performance, and that the adjustment factor to be applied in making such determinations for corporate performance shall be [___].

Approve 2021 Goals for Executive Officers

FURTHER RESOLVED, that the Corporate Goals and Executive Officer Goals for 2021 set forth on Exhibit A are hereby approved.

EXHIBIT A

2021 Corporate Goals and Named Executive Officer Goals

1. Execute budgeted plan to achieve revenue of [$2.110] billion.
2. Execute budgeted plan to achieve adjusted EBITDA of [$834] million.
3. Execute one transaction that aligns to our 2024 strategic objectives and expands our core product, pipeline and/or service offerings.
4. Continue advancement of clinical pipeline programs in order to obtain approval of these products as planned and support growth from fiscal 2024 onward.
5. Sustain improvements achieved in 2020 on Employee Engagement as measured by the 2021 Gallup Q12 Improve (statistically significant) 2020 baseline for the Gallup inclusion index.
6. Supply quality drug substance and drug product for COVID-19 vaccines and therapeutics meeting or exceeding customer expectations.

Presenters & Guest Attendees

Presenters:

- Rich Lindahl, EVP & Chief Financial Officer
- Brian Millard, SVP Finance & Corporate Controller
- Laima Bashir, VP Financial Planning & Analysis

Questions/Issues for the Audit Committee

- Does the Committee require clarification on any of the materials presented?
- Does the Committee have any concerns about the FY 2021 Budget and/or Guidance presented?

Agenda

- FY 2020 Preliminary Results
  - FY 2020 Financial Results
  - Comparison versus Analyst Guidance
- FY 2021 Budget Overview
  - Executive Summary
  - Key Assumptions & Budget Drivers
  - Financial Details
  - Cash Sources & Uses
  - Trends & Comparison versus Analyst Guidance
  - Risks & Opportunities
  - Key Takeaways
- Appendix

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FY 2020 Preliminary Results

EBS
NYSE

2020 Preliminary vs 2019 - Non-GAAP

Strong Revenue & Profitability growth YoY setting stage for 2021

$M *Favorable /(Unfavorable)*	2020 Prelim	2019 Actual	YoY $	YoY %
Product Sales	986	903	83	9%
CDMO	450	80	370	462%
C&G	115	123	(8)	(6%)
Revenue	**1,551**	**1,106**	**445**	**40%**
Gross Profit	**976**	**581**	**395**	**68%**
Gross Margin	68%	59%	890 bps	
R&D	213	214	1	0%
SG&A	303	261	(42)	(16%)
Operating Expenses	**516**	**475**	**(41)**	**(9%)**
Adjusted Net Income	**421**	**152**	**268**	**176%**
% of Revs	*27%*	*14%*	*1330 bps*	
Adjusted EBITDA	**631**	**280**	**351**	**126%**
% of Revs	*41%*	*25%*	*1540 bps*	
Net R&D/Adjusted Revs	*7%*	9%	*250 bps*	
SG&A/Revs	*20%*	*24%*	*410 bps*	

Commentary YoY

- **Revenue**: $1.6B, +40% YoY, driven mostly by CDMO and Anthrax revenues
- **Gross Margin:** 68%, +890bps YoY mostly due to CDMO margin and mix
- **Operating Expenses:** $516M, +$41M & +9% YoY
  - **Net R&D 7% of Revenue**, +250 bps YoY driven by higher adjusted revenues
  - **SG&A 20% of Revenue**, +410 bps, with key investments in IT and additional compensation
- **Adj. EBITDA:** $631M, +$351M YoY;
  - +126%, Margin +1540 bps YoY

Income Statement – 2020 Preliminary vs Analyst Estimates

$M	2020 Preliminary	2020 Preliminary Proposed Guidance	2020 Current Guidance 11/05/2020	First Call Consensus	Analyst Estimates (Range)
Revenue					
Product Sales	$986				
Contract manufacturing	450				
Contracts and Grants	115				
Total Revenue	**1,551**	**$1,545 - $1,555**	**$1,520 - $1,580**	**$1,529**	**$1,492 - $1,561**
Cost of product sales and contract manufacturing	507				
Gross profit on product sales and contract manufacturing	929				
Gross Profit Margin	65%				
Research and development expense	242				
Selling, General and Administrative expense	306				
Intangible asset amortization	60				
Total Operating Expense	608				
Income from operations	436				
Other Expense	(29)				
Income before provision for income tax expense	406				
Provision for income taxes	(106)				
Net Income	**$301**	**n/a**	**n/a**	**$275**	**$258 - $300**
Adjusted Net Income	$421	$415 - $430	$375 - $405	$379	$354 - $406
EBITDA	$552	n/a	n/a	n/a	n/a
Adjusted EBITDA	$631	$625 - $645	$575 - $615	$560	$509 - $593

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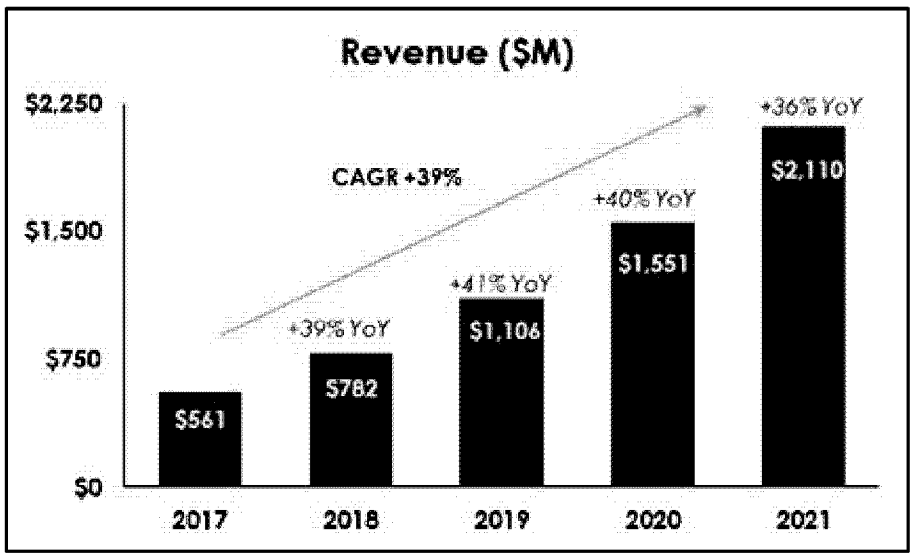
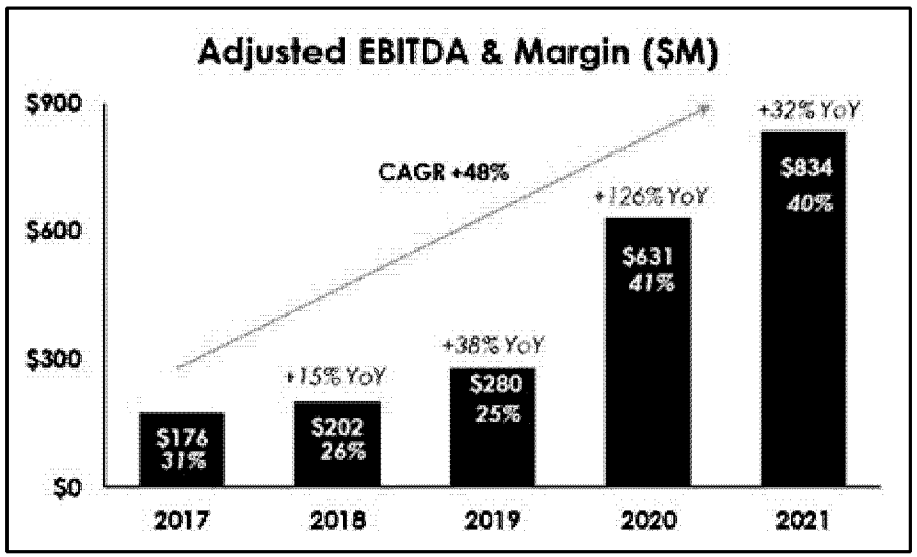
FY 2021 Budget Update

Executive Summary

Continued top line growth & strong profitability

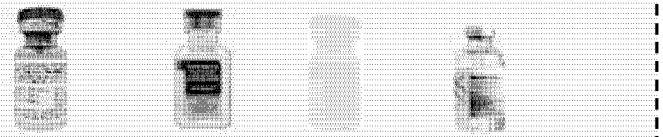




- **Total Revenue: $2,110M, +559M & +36% YOY**
  - 4 year CAGR +39% with continued momentum since 2017
  - Main driver CDMO and maintained strength in MCM & NARCAN
- **Adjusted EBITDA $834M, 40% Margin, +$203M & +32% YoY**
  - 4 year CAGR +48% driven by increased gross margin and scaling operating expenses
  - Gross Margin 65%, (330) bps versus 2020 driven by CDMO mix and rate

FY 2021 Budget - Continued strategic momentum

MCM

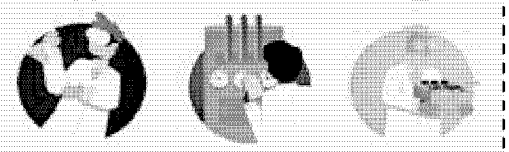


- **Biothrax & AV7909 $315M**
  - Continued USG procurement with normalized annual volumes
- **ACAM2000 $206M**
  - Slight increase YoY driven by pricing increases, volume in-line with historical levels
- **Raxibacumab $50M**
  - Assumes contract execution in 2021 by USG

Commercial

- **NARCAN $327M**
  - Authorized Generic ('AG') / Generic ('Gx') launch in H2 2021
  - Opioid Label change – U.S. Commercial Rx Market Expansion
- **Travel Health $0**
  - Continued headwinds from COVID-19 travel with no assumed revenue in 2021

CDMO



- **CDMO $976M**
  - Development Services: $13M
  - Drug Substance: $705M
  - Drug Product: $258M
  - 97% of 2021 budgeted secured
- **Customer Segment Diversity**
  - Pharma & Biotech: $581M
  - Govt / NGOs: $395M
- **Pipeline / Portfolio Progression:**
  - Customers: 57, Molecules: 73, Projects: 86

FY 2021 focused on continued investments to drive long-term sustainable growth

- **Research & Development:** Investments in Chikungunya, Seasonal Flu, & functions with a focus on commercialization of the portfolio
- **SG&A:** Scalable investments across functional groups, with primary focus on resources, IT, & product marketing

2021 Budget Key Assumptions – Organic Business Only

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Revenue

- **CDMO $976M,** +$527M YoY, +$142M BARDA, +$121M AZ, +$253M Janssen
- **AV7909 $282M,** ($66M) YoY, 10.4M doses @ avg price $28
- **BioThrax $33M,** +$7M YoY, USG 0.9M doses @ avg price $33
- **ACAM2000 $206M,** +$6M YoY, USG 18.2M doses @ $10; Singapore 0.8M doses @ $30
- **NARCAN $327M,** +$18M YoY, assumes AG launch in H2 2021 $36M
- **Therapeutics $187M**, +$80M YoY, mostly driven by +$50M Raxi, +$62M VIG offset by lower ($22M) BAT
- **Travel Health $0**, due to COVID impact

OpEx

- **Budget New Hires:** 302, YE Headcount 2,866
- Merit Increase 3.25%; Bonus assumed at 100%
- Vacancy assumed at 4% of Total Compensation
- **R&D Reserve:** $23M inclusive of $12.5M of CEO reserve
- **SG&A Reserve:** $23M inclusive of $12.5M of CEO reserve

Other

- **CapEx:** $258M increasing $97M YoY focused on investments in R&D and SG&A; includes USG funding of $79M
- **Preliminary Tax Rate:** 25%
- Constant Fx versus 2020

2021 Budget vs 2020 Preliminary - Non-GAAP

Adjusted EBITDA Growth of 32%

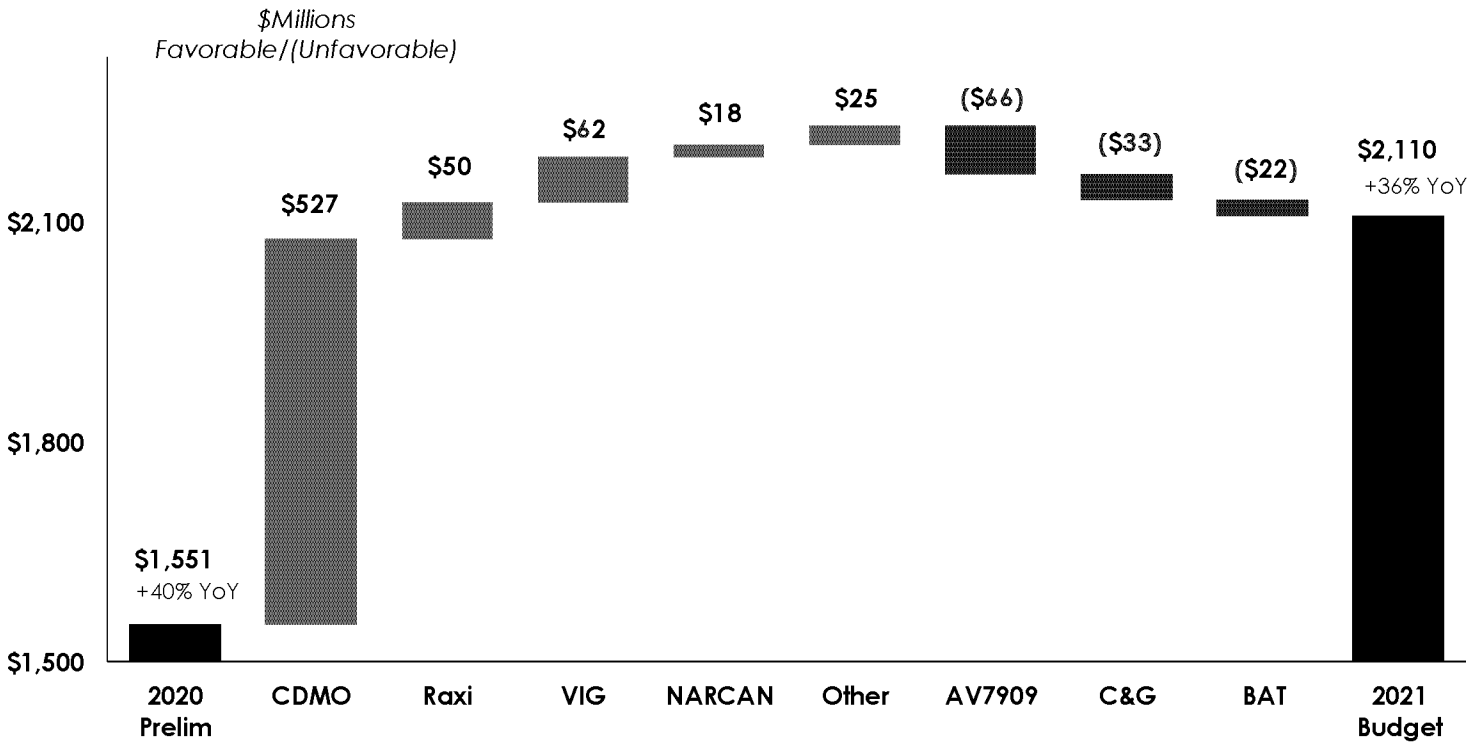
$M *Favorable /(Unfavorable)*	2021 Budget	2020 Prelim	YoY $	YoY %
Product Sales	1,052	986	66	7%
CDMO	976	450	527	117%
C&G	82	115	(33)	(29%)
Revenue	**2,110**	**1,551**	**559**	**36%**
Gross Profit	**1,318**	**976**	**342**	**35%**
Gross Margin	65%	68%	(300) bps	
R&D	264	213	(51)	(24%)
SG&A	369	303	(66)	(22%)
Operating Expenses	**633**	**516**	**(117)**	**(23%)**
Adjusted Net Income	**553**	**421**	**133**	**32%**
% of Revs	*26%*	*27%*	*(90) bps*	
Adjusted EBITDA	**834**	**631**	**203**	**32%**
% of Revs	*40%*	*41%*	*(110) bps*	
Net R&D/Adjusted Revs	*9%*	*7%*	*(220) bps*	
SG&A/Revs	*17%*	*20%*	*200 bps*	

Commentary YoY

- **Revenue**: $2.1B, +36% YoY, driven mostly by CDMO, Raxi and VIG revenues
- **Gross Margin:** 65%, (300)bps YoY mostly due to CDMO margin and mix
- **Operating Expenses:** $633M, +117M & +23% YoY
  - **Net R&D 9% of Revenue**, (220) bps YoY driven by Chikungunya, Seasonal Flu, & Reserve
  - **SG&A 17% of Revenue**, +200 bps, with key investments in IT SG&A, & Reserve
- **Adj. EBITDA:** $834M, +$203M YoY;
  - +32%, Margin (110) bps YoY

2021 Budget Revenue Bridge YoY

Primary driver of growth in 2021 driven by CDMO, +$527M

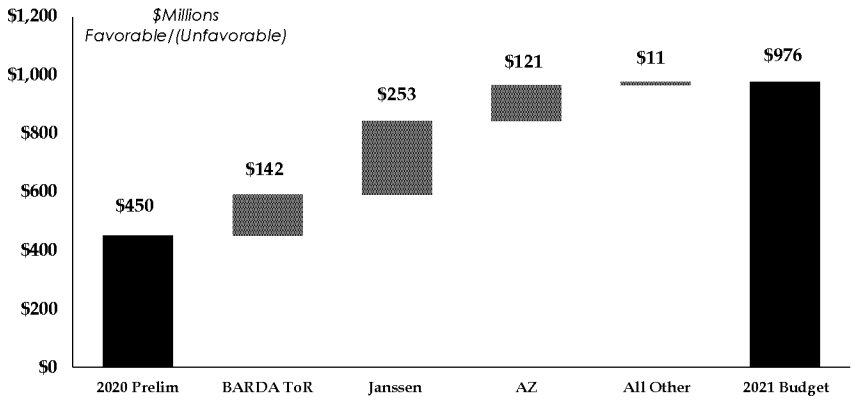


$M	2021 Budget	YoY
NARCAN	327	6%
AV7909	282	(19%)
ACAM2000	206	3%
VIG	85	**
Raxibacumab	50	**
BioThrax	33	29%
RSDL	30	12%
BAT	27	(45%)
Trobigard	10	**
Anthrasil	1	(51%)
Total Product Sales	**1,052**	**7%**
CDMO	976	117%
C&G	82	(29%)
Total Revenue	**2,110**	**36%**

*** In excess of +/- 150%*

2021 NARCAN & CDMO Detail

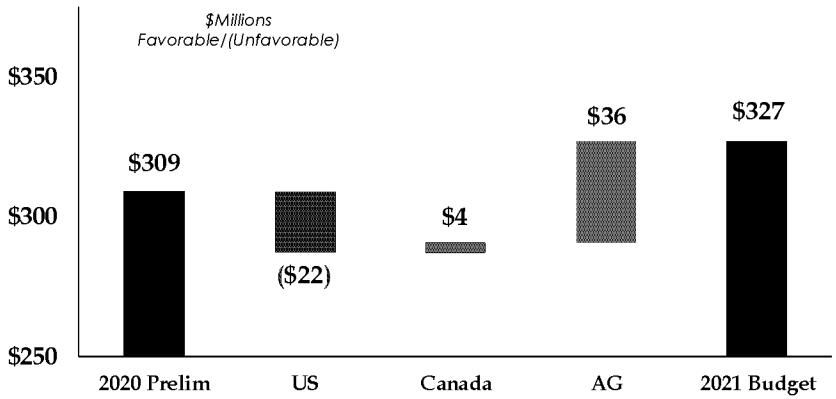
CDMO



CDMO Rev	2021 Budget	2020 Prelim	YoY	
BARDA	395	253	142	56%
Janssen	313	60	253	426%
AZ	158	38	121	320%
Other	110	99	11	11%
Total	**976**	**450**	**527**	**117%**

- **Revenue $976M, +$527M YoY**
  - BARDA $395M, +$142M YoY
  - Janssen "J&J" $313M, +$253M YoY
  - AZ $158M, +$121M YoY
- **Other**: +$11M, +11% YoY due to Bayview and Rockville capacity consumed by COVID contracts
  - **Development Services:** $13M, +327% YoY
  - **Camden:** $81M, +13% YoY

NARCAN



- **NARCAN $327M, +$18M YoY**
  - Authorized Generic ('AG') launch in H2 2021, $36M
  - No OTC switch or Competitor in 2021
  - No Price Increase assumed for NARCAN Brand
  - Branded Competition assumed in 2021
  - Opioid Label change – U.S. Commercial Rx Market Expansion

2021 Budget Quarterly P&L

56% of Revenue in H2 driven by Product Sales timing

$M	Q1	Q2	Q3	Q4	2021 Budget
Revenue	**413**	**511**	**573**	**614**	2,110
% Total	*20%*	*24%*	*27%*	*29%*	*100%*
Gross Margin	*68%*	*63%*	*64%*	*65%*	*65%*
R&D	69	68	65	62	264
SG&A	93	92	92	93	369
Operating Expenses	**162**	**160**	**157**	**154**	**633**
% Total	*26%*	*25%*	*25%*	*24%*	*100%*
Adjusted Net Income	**91**	**123**	**156**	**183**	**553**
% Total	*16%*	*22%*	*28%*	*33%*	*100%*
Adjusted EBITDA	**143**	**187**	**233**	**272**	834
% Total	*17%*	*22%*	*28%*	*33%*	*100%*
% of Revs	*35%*	*37%*	*41%*	*44%*	*40%*
Net R&D/Adjusted Revs	*10%*	*9%*	*9%*	*8%*	*9%*
SG&A/Revs	*23%*	*18%*	*16%*	*15%*	*17%*

Commentary YoY

- **Revenue**
  - H1 44% of FY driven by timing of product sales & CDMO
  - H2 56% of FY primarily due to product sales
- **OpEx consistent quarterly phasing**
  - R&D H1 driven by funded R&D
  - R&D H2 driven by unfunded R&D (Chikungunya)
  - SG&A timing of marketing spend, headcount, & professional services
- **Adjusted EBITDA phasing due to Revenue timing**
  - H1 Margin 36%
  - H2 Margin 43%

2021 Budget Revenues by Quarter

Q1 +115% YoY driven by CDMO offset by Product Sales timing

$M	Q1	Q2	Q3	Q4	2021 Budget	YoY
NARCAN	80	90	90	67	327	6%
AV7909	57	65	78	82	282	(19%)
ACAM2000	0	54	70	82	206	3%
VIG	1	0	31	53	85	**
Raxibacumab	0	0	17	33	50	**
BioThrax	0	1	0	31	33	29%
RSDL	4	10	11	5	30	12%
BAT	10	1	7	9	27	(45%)
Trobigard	0	6	0	4	10	**
Anthrasil	1	0	0	0	1	(51%)
Total Product Sales	**153**	**228**	**304**	**367**	**1,052**	**7%**
% of Total Product Sales	*15%*	*22%*	*29%*	*35%*	*100%*	
CDMO	229	261	252	235	976	117%
C&G	31	22	17	12	82	(29%)
Total Revenue	**413**	**511**	**573**	**614**	**2,110**	**36%**
YoY	*115%*	*29%*	*49%*	*6%*	*36%*	

** In excess of +/- 150%

Commentary YoY

- **Product Sales $1B, +7% YoY**
  - Back half weighted at 64% of Full Year
  - AV7909 (19%) YoY due to normalized annual volume & 2020 base being higher
    - Shift from 2019 & maximizing volume under 2020 contract (Q2)
  - Biothrax weighted to Q4 driven by contract and funding timing
  - Raxibacumab contract expect in 2021 with majority of volume in Q4
- **CDMO $1B, +117% YoY**
  - Quarterly volumes $230M - $260M based on manufacturing across contracts

2021 Cashflow Forecast

$1B ending cash balance with ample cashflow throughout the year

2021 Cashflow Forecast					
($M)	Q1	Q2	Q3	Q4	FY
Beginning Balance	$626	$698	$728	$895	$626
Net Sources	$501	$405	$545	$596	$2,047
Net Uses	($429)	($375)	($378)	($353)	($1,535)
Ending Balance	**$698**	**$728**	**$895**	**$1,138**	**$1,138**

Balance Sheet ($M)	2020	2021
Net Debt	**332**	**(199)**
Net Leverage*	**0.5x**	**-0.2x**
Debt Service Coverage Ratio*	**16.7x**	**11.8x**

**Max Net Leverage 4.5x; Minimum Debt Service Coverage Ratio 2.5x*

Commentary

Emergent maintaining strong cash position and cashflow throughout 2021

- **2020 Ending Balance $626M**
- **2021 Ending balance $1.1B**
  - Generating $512M across the year with adequate quarterly cashflow
  - Domestic Balance $960M by year end
- **Total Debt $905M** by end of 2021
  - Down $39M from $944M in 2020
- Net Debt ($199M) & Net Leverage -0.2x

Guidance and Key Financial Metrics

$M	2019 Actual	2020 Prelim	2020 Proposed Guidance	2020 Consensus	2021 Budget	2021 Proposed Guidance	2021 Consensus
Revenue	**1,106**	**1,551**	**1,545 - 1,555**	**1,529**	**2,110**	**1,950 - 2,050**	**1,872**
YoY Growth	*41%*	*40%*			*35%*		
Adjusted Net Income	152	421	415 - 430	379	553	475 - 525	476
Adjusted EBITDA	**280**	**631**	**625 - 645**	**560**	**834**	**750 - 810**	**746**
Margin	*25%*	*41%*	*40% - 41%*		*40%*	*38% - 40%*	
Anthrax	173	374			315	280 - 310	
ACAM 2000	243	200			206	185 - 205	
NARCAN	280	309			327	305 - 325	
CDMO	80	450			976	925 - 965	
Implied Other Revenues	330	218			286	220 - 240	
Total Revenues	**1,106**	**1,551**			**2,110**		

2021 Budget Risks & Opportunities

Net Revenue Impact ~ ($47M)

$M	FY Upside				Revenue Upside			
Drivers	Revenue	Expense	Operating Income	Comments	Q1	Q2	Q3	Q4
CDMO BU	40	20	20	DS & DP opportunities in Winnipeg; additional revenue in Camden			20	20
Devices	25	11	14	Opioid Label Expansion $4M; Promo impact $6M; Co-Rx Upside $7M; Trobigard Int'l sales $8M	5	7	9	4
Therapeutics	84	52	32	Int'l sales $21M; COVID HIG $39M; EIG $14M; EBOLA project $10M , Flu cost saving $6M	17	10	19	37
Opex		(14)	14	Project Timing; Professional Services; Unused reserve				
Total	**149**	**69**	**80**		**22**	**17**	**48**	**61**

$M	FY Downside				Revenue Downside			
Drivers	Revenue	Expense	Operating Income	Comments	Q1	Q2	Q3	Q4
CDMO BU	(15)	3	(18)	Business acquisition timing and customer project delays; DS lot failures ($11M)			(8)	(8)
Devices	(59)	(13)	(46)	NARCAN Q1 Gx entry ($46M); Opiod Label expansion ($6M); Co-Rx risk ($7M); G2N Returns	(30)	(25)	(3)	(2)
Therapeutics	(73)	(25)	(48)	Raxi contract ($50M); VIG Plasma collection risk ($21M); COVID OH ($8M); MMU ($1.5M)	(1)	(0)	(25)	(46)
Vaccines	(50)	(14)	(36)	Quality challenges ($40M); 300K lesser BioThrax doses delivered than planned ($10M)			(20)	(30)
Total	**(196)**	**(49)**	**(147)**		**(30)**	**(25)**	**(56)**	**(85)**
Net Impact	**(47)**	**20**	**(67)**		**(8)**	**(8)**	**(7)**	**(24)**

2021 Budget Key Takeaways

1. 2021 Budget delivers strong top line growth and maintains profitability in-line with 2020
2. Investments align to our Strategic Plan objectives while maintaining adequate flexibility to remain dynamic throughout the year (reserves)
3. Budget is achievable with fairly balanced risks and opportunities across the organization
4. 2021 continues to deliver strong free cash flow building on 2020 performance

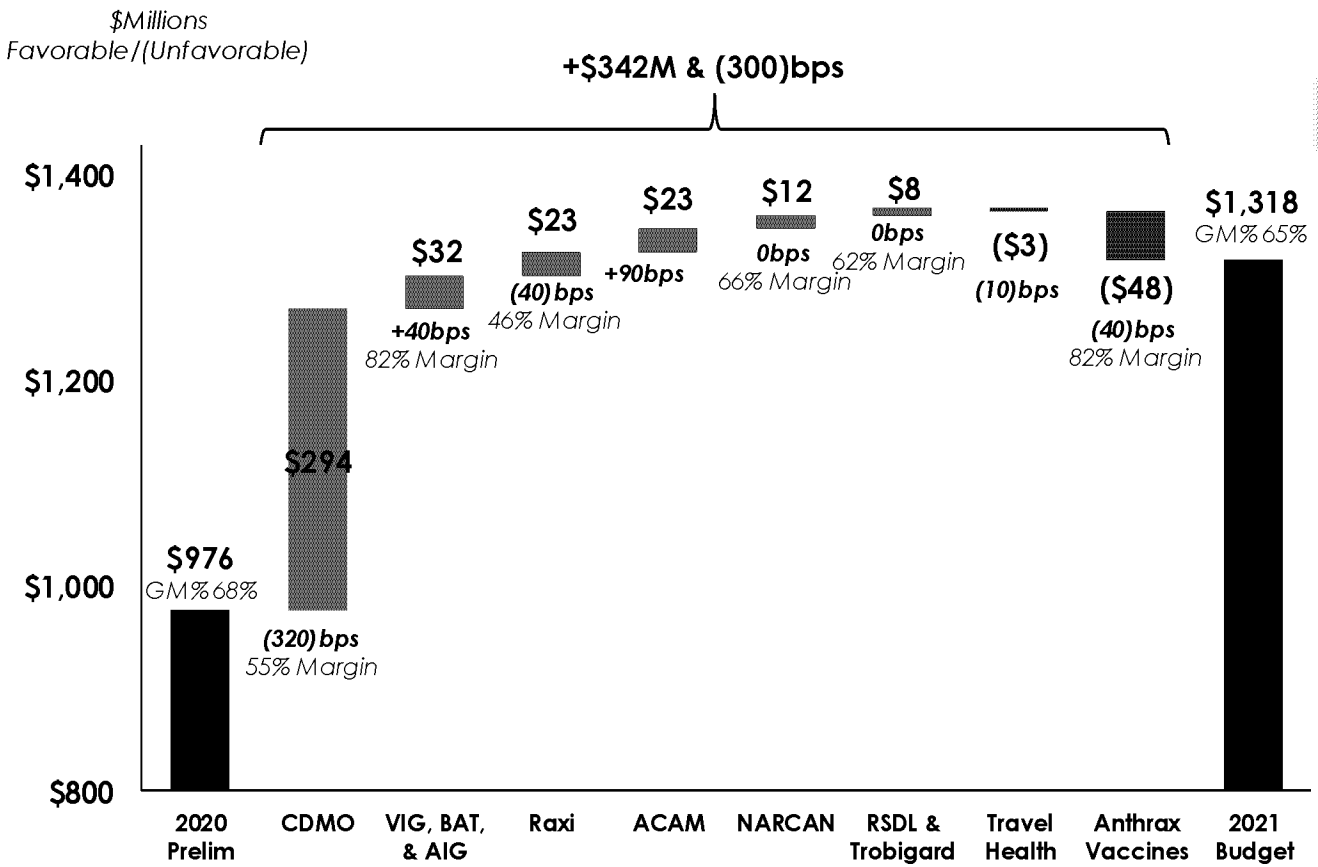
emergent

Appendix

Trend Summary
Non-GAAP

$M *Favorable/(Unfavorable)*	2021 Budget	2020 Prelim	2019 Actual	2018 Actual	2017 Actual
Revenue	**2,110**	**1,551**	**1,106**	**782**	**561**
YoY	*36%*	*40%*	*41%*	*39%*	
Gross Margin	**65%**	**68%**	**59%**	**57%**	**62%**
YoY	*(300) bps*	*890 bps*	*200 bps*	*(500) bps*	
Operating Expenses	**633**	**516**	**475**	**317**	**232**
YoY	*23%*	*9%*	*50%*	*37%*	
Adjusted Net Income	**553**	**421**	**152**	**123**	**96**
YoY	*32%*	*177%*	*24%*	*28%*	
Adjusted EBITDA	**834**	**631**	**280**	**202**	**176**
YoY	*32%*	*126%*	*38%*	*15%*	
% Revenue	*40%*	*41%*	*25%*	*26%*	*31%*
Net R&D/Adjusted Revs	*9%*	*7%*	*9%*	*9%*	*5%*
SG&A/Revs	*17%*	*20%*	*24%*	*24%*	*24%*

2021 Gross Margin Walk vs 2020 Preliminary



Commentary YoY

- **Gross Margin $1.3B, +$342M & (300) bps YoY driven by CDMO**
  - Margin decrease YoY primarily driven CDMO mix & rate offset by ACAM & Raxi rate improvements
  - CDMO:+$294M & (320)bps impact driven:
    - BARDA ToR: $130M, 92% margin
    - AZ & Janssen: $164M, 42% margin due to increased batches (raw materials)
  - Product Gross Margin: +$48M with Revenue +$66M driven by Therapeutics, Raxi, ACAM, and offset by Vaccines

2021Budget Capex

($M)	Q1	Q2	Q3	Q4	2021	Comments
Bayview	$ 11	$ 4	$ -	$ -	$ 15	Equipment & Bioreactors (Janssen & BARDA)
Bern	0	2	8	7	17	Chik expansion
Camden	3	1	2	-	6	New fill line
Canton	1	7	13	13	34	Expansion
Central Warehouse	7	10	1	-	19	New facility
Devices BU	1	6	5	5	17	D4/PCIA
IT	2	2	2	2	8	LIMS & MES Pilot Rollout
Rockville	26	30	19	-	74	New fill line (BARDA)
S/T Strategic/Expansion	**52**	**62**	**50**	**27**	**190**	
All Other Items	18	21	17	13	68	
Total Budget	**$ 70**	**$ 82**	**$ 66**	**$ 40**	**$ 258**	

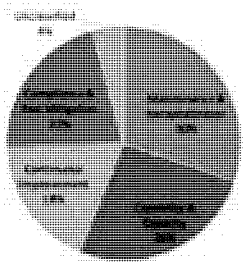
***Net CapEx Investment for EBS: $179M**
(after reimbursement of $79M)

All Other Items ($M)	Q1	Q2	Q3	Q4	2021
Global Engineering	$ 0.3	$ 0.3	$ 0.3	$ 0.3	$ 1.0
Bayview	2.1	2.0	0.9	0.9	6.1
Bern	1.9	2.1	0.7	1.9	6.6
Camden	1.9	3.5	2.3	1.4	9.1
Canton	1.7	1.7	3.2	0.9	7.5
Gaithersburg (300P)	0.4	2.5	0.3	0.4	3.6
Head Office	-	0.1	0.1	0.1	0.2
Lansing	2.1	1.6	3.0	2.2	8.9
Rockville	0.1	0.7	0.7	0.9	2.3
Winnipeg	1.1	1.6	0.8	0.9	4.4
SubTotal Mfg Sites	**11.5**	**16.1**	**12.3**	**9.7**	**49.6**
Devices BU	1.5	0.5	0.4	0.1	2.6
IT	0.8	0.6	0.5	0.8	2.6
TX BU	0.9	0.9	1.4	1.4	4.5
Vaccines BU	2.8	2.7	2.1	1.1	8.7
Total All Other Items	**$ 17.6**	**$20.8**	**$ 16.6**	**$ 13.1**	**$ 68.0**

Commentary

- Total budget $258M, +$97M over 2020 forecast $162M
  - Funding: Emergent $179M; external $79M
  - Type: strategic/expansion $190M; all other $68M
- Majority of spend, $174M, is related to carryover projects; including $166M on strategic/expansion projects
- Budget is ~12% of budgeted 2021 revenue (8% excluding externally funded items)

Breakout of All Other Items by Category



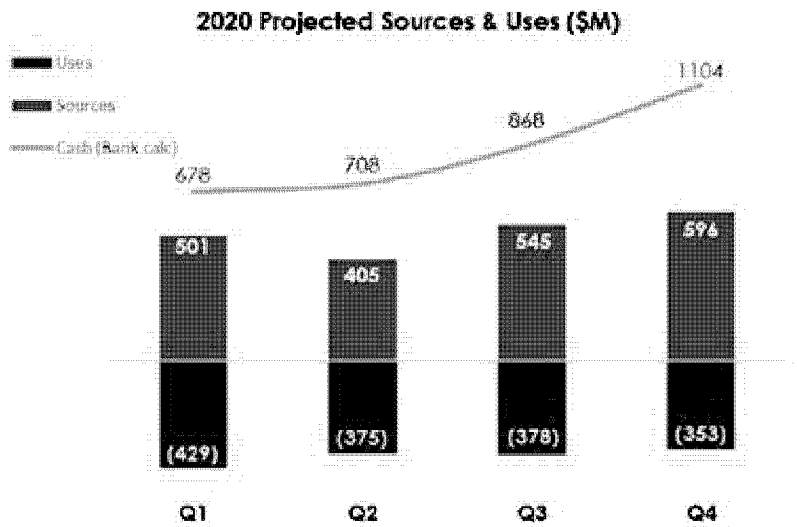
Financial Position (Bank calculation)

Balance Sheet ($M)	2020	2021
Total Debt	944	905
Cash	612	1104
Net Debt	**332**	**(199)**
Net Leverage*	**0.5x**	**-0.2x**
Debt Service Coverage Ratio*	**16.7x**	**11.8x**
Additional Borrowing Capacity**	2,711	4,131
Undrawn Revolver	$597	$600

*Max Net Leverage 4.5x; Minimum Debt Service Coverage Ratio 2.5x
**Incremental debt capacity while maintaining compliance with debt covenants

FY 2021	Q1	Q2	Q3	Q4
Net Debt	**250**	**213**	**46**	**(199)**
Net Leverage Ratio	**0.3x**	**0.3x**	**0.1x**	**-0.2x**
Debt Service Coverage Ratio	**13.4x**	**13.3x**	**12.7x**	**11.8x**

Note: Forecasted Interest rate for total debt is ~3.4%
(includes $350M of fixed rate swaps)



Note: Cash balance excludes A/R

U.S. 2021 Salary Range (for MD, PA, CA*)

2021	US - 100		
	Maryland, DC, Radnor, San Diego, Field Sales		
	Minimum	**Midpoint**	**Maximum**
A01	$33,500	$ 39,500	$45,500
A02	$39,000	$ 46,000	$53,000
A03	$44,000	$ 52,000	$60,000
A04	$49,500	$ 58,000	$66,500
A05	$60,500	$ 71,000	$81,500
A06	$72,500	$ 85,000	$97,500
A07	$83,500	$ 98,500	$113,500
A08	$95,000	$ 112,000	$129,000
A09	$110,500	$ 130,000	$149,500
A10	$128,500	$ 151,000	$173,500
A11	$146,500	$ 172,500	$198,500
A12	$168,000	$ 197,500	$227,000
A13	$181,000	$ 213,000	$245,000
A14	$194,500	$ 229,000	$263,500
A15	$221,000	$ 260,000	$299,000
A16	$252,000	$ 296,500	$341,000
A17	$274,000	$ 322,500	$371,000
A18	$316,000	$ 395,000	$474,000

* in certain other locations, EBS applies a premium of 10% (MA) or discount of between 5 (MI) and 20% (MS) to the above range

1