

September 30, 2021

VIA EDGAR SUBMISSION

Securities and Exchange Commission  
Division of Corporation Finance Office of Healthcare & Insurance  
100 F Street, N.E.  
Washington, DC 20549-3561

Re: Emergent BioSolutions Inc.  
Form 10-K for the Fiscal Year Ended December 31, 2020  
Form 10-Q for the Fiscal Quarter Ended June 30, 2021  
File No. 001-33137

This letter sets forth the response of Emergent BioSolutions Inc. ("Emergent" or the "Company") to the comments contained in your letter, dated August 18, 2021, relating to Emergent's Form 10-K filed with the Commission on February 19, 2021 and Emergent's Form 10-Q filed with the Commission on April 30, 2021. The comments of the Staff of the Commission (the "Staff") are set forth in bold/italicized text below, and the Company's response is set forth in plain text immediately beneath such comment.

Form 10-K for the Fiscal Year Ended December 31, 2020  
Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations  
Contract Development and Manufacturing Services, page 58.

- 1. You disclosed here that the increase in the 2020 CDMO service revenue was due to the Covid-19 related contracts and arrangements. Considering the significance of this item in 2020 and for the six months ended June 30, 2021, tell us how you have considered compliance with the disclosure requirement under Item 303 of Regulation S-K, which requires the disclosure of any significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations, as well as any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. Please include revised disclosure to be included in future filings.***

The Company considered Item 303 of Regulation S-K in the preparation of its Form 10-K and Form 10-Q, concluding that nearly all of the increase in CDMO services revenue was related to the Company's COVID-19 related arrangements. Notwithstanding, in response to the Staff's comment, in the future the Company will provide quantification of the significant components of any material increase or decrease in revenues or expenses it believes necessary to understand the results of operations, as well as any known trends or uncertainties that have had or are reasonably expected to have a material favorable or unfavorable impact on net revenues, expenses or income from continuing operations. We have included below proposed disclosure based on the year ended December 31, 2020 compared to the year ended December 31, 2019:

"The increase in CDMO services revenue for the year ended December 31, 2020 of \$370.5 million is primarily due to the Company's public-private partnership with BARDA in support of the US Government's ("USG") efforts to address the COVID-19 pandemic, which resulted in an increase of \$253.3 million from BARDA as well as increases in aggregate sales from innovator manufacturers such as Johnson & Johnson ("JNJ") and AstraZeneca ("AZ"), which collectively resulted in an increase in revenue of \$96.7 million."

The Company has included below proposed disclosure based on its discussion for the three and six months ended June 30, 2021 compared to the three and six months ended June 30, 2020:

“The increase in CDMO service revenue for the three and six months ended June 30, 2021 of \$118.3 million and \$280.4 million, respectively, is due to the Company’s public-private partnership with BARDA and innovator manufacturers, including AZ and JNJ, to address the COVID-19 pandemic. The BARDA increase was \$25.8 million and \$123.3 million for the three and six months ended June 30, 2021 respectively. The arrangements with innovator manufacturers, including AZ and JNJ, resulted in increases in revenues of \$86.4 million and \$152.9 during the three and six months ended June 30, 2021, respectively. The arrangements with BARDA and innovators responding to COVID-19 were primarily entered into during the second and third quarters of 2020.”

Gross Profit Margin for Product Sales and CDMO services, page 59.

**2. Here you disclosed gross profit margin for product sales and CDMO services. Please respond to the following comments:**

- ***The gross profit margin balance you presented on page 59 showed a significant increase from 55.9% in 2019 to 63.6% in 2020. Explain to us, and revise all future filings to disclose the reason for the significant increase, including the underlying drivers and any trends.***
- ***During our prior review, you provided analysis and justifications for reporting a combined Cost of Product Sale and CDMO services as one line item in your statement of operations. Considering that now CDMO service increased to account for a significant share of your total revenue and costs, which also appears to have contributed to your margin improvement, please provide us with your analysis why it is appropriate to continue to report these costs as one line item.***

In response to the Staff’s comment, the Company will include narrative descriptions for changes in gross margin, to the extent material, in all future filings. The Company has included below the proposed disclosure based on its discussion for the year ended December 31, 2020 compared to the year ended December 31, 2019:

“The increase in gross margin percentage from 2019 to 2020 was primarily due to the operating leverage associated with both the Company’s public-private partnership with BARDA and new arrangements we entered into during 2020 with innovator manufacturers, such as AZ and JNJ, to address the COVID-19 pandemic.”

Management believes that the discussion of material changes in gross margin fluctuations will clarify the impact of product and CDMO sales on the Company’s operations.

The Company respectfully refers the Staff to its response No. 3 in its letter, dated January 11, 2019, responding to the SEC comment letter dated December 12, 2018, from the Staff’s prior review for the reasons why we present our cost of product sales and CDMO services as one line item in our statement of operations. The inputs and outputs in the manufacturing process are similar regardless of whether the Company is producing material for itself or external customers. The Company’s contract manufacturing business includes production of bulk drug substances and drug products. When producing bulk drug substances for customers, the Company procures raw materials and produces the contract manufacturing customer’s product from scratch and retains title and risk of loss to the product until it is delivered to the customer upon completion of the manufacturing process and the product has been approved by the Company’s quality

control review process. For drug product customers, the Company receives work in process inventory from its clients and brings the product to a filled and finished state. The Company performs similar production activities for its own products and therefore does not view the costs associated with performing these activities for third-party customers as separate from the costs incurred to produce its own products. Often the Company uses excess capacity at facilities primarily used for its own products to perform contract manufacturing services. As a result, management views expenses associated with its manufacturing operations on an aggregate basis when analyzing the financial performance of its manufacturing facilities. The financial reports provided to the chief operating decision maker ("CODM") also present the expenses associated with product sales and CDMO services on a combined basis, further supporting the external presentation of these expenses on a combined basis. Furthermore, the Company communicates its gross margin goals to its investors on an aggregated basis believing this is the most useful measure of profitability of its manufacturing facilities.

Note 2. Summary of Significant Accounting Policies  
Revenue Recognition - CDMO Services, page 81

- 3. Here you disclosed that you have determined that the technology transfer, stand-ready and suite-reservation performance obligations are satisfied over time, but only provided the method used to recognize revenue for the suite-reservation performance obligation. Please provide revised disclosure to be included in future filings of the method used to recognize the technology transfer and stand-ready performance obligations, and why the methods used provide a faithful depiction of the transfer of goods and services. Refer to ASC 606-10-50-18.**

In response to the Staff's comments, the Company will enhance its disclosure of the accounting policy for CDMO service revenue recognition in future filings as documented below:

"The Company performs CDMO services for third parties. Under these contracts, activities can include pharmaceutical product process development, drug substance manufacturing, drug product manufacturing services for injectable and other sterile products, process design, technology transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging, stability studies, and suite-reservations. These contracts vary in duration, activities, and number of performance obligations. Performance obligations identified under these arrangements may include drug substance and/or drug product manufacturing, technology transfer activities, and suite-reservations.

Drug substance and drug product manufacturing performance obligations are recognized as revenue over-time because the Company's performance does not create an asset with an alternative use and the Company has an enforceable right to payment for performance completed as work is performed. In drug product arrangements, the customer typically owns and supplies the active pharmaceutical ingredient, or API, that is used in the manufacturing process; in drug substance arrangements, the customer provides certain seed material that is used in the manufacturing process. The transaction price is stated in the agreement as a fixed price per unit, with no contractual provision for a refund or price concession. We use an input method to measure progress toward the satisfaction of the related performance obligations based on costs incurred as a percentage of total costs to complete which we believe best depicts the transfer of control of goods or services promised to our customers.

For arrangements where we have identified technology transfer activities to be a separate performance obligation, revenues are recognized over-time as the service is provided as there is no alternative future use to the Company for the asset created and the Company has an

enforceable right to payment for performance completed as of that date. The Company measures progress toward completion based on an input method using costs incurred to date as a percentage of total costs to complete the technology transfer activities.

Suite reservations are classified as leases because not only does the customer direct the use of the identified suite, but also obtains substantially all the economic benefits from the manufacturing capacity. If a customer reserves more than one suite, the allocation of contract value is based on relative selling price which varies due to size, location, capacity, production capability for drug product or drug substance, and the time of planned use. The associated revenue is recognized on a straight-line basis over the period of performance. For arrangements that contain both lease and non-lease components, consideration in the contract is allocated on a relative standalone selling price basis."

Note 3. Revenue Recognition, page 85

**4. Considering their significance, please expand to provide, here or where appropriate, information of your CDMO contracts in sufficient detail to enable investors to understand the nature, amount, timing and uncertainty of revenue, cash flows arising from these contracts, including both qualitative and quantitative information, as required under ASC 606-10-50-1. At a minimum, please clarify to us, including proposed disclosure for future filings, the following:**

- **how you accounted for each component of each significant contract, including the BARDA contract entered into on May 24, 2020, and included in Exhibit 10.62, which consists of \$542.7 million allocated to the reservation of manufacturing capacity and \$85.5 million for accelerating the planned expansion of viral and non-viral drug product fill/finish capacity.**
  - **Tell us your consideration of accounting for the reservation of the manufacturing capacity performance obligation in Task 1 of the May 2020 BARDA agreement as a lease. Tell us which contract(s) had a suite-reservation performance obligation referred to on page 86 and why. If the suite-reservation performance obligation relates to the BARDA agreement, please reconcile the amount allocated to the reservation of manufacturing capacity in Task 1 of the Task order ending in 007 to the amounts disclosed on page 86 for operating leases.**
  - **Clarify if the reservation of manufacturing capacity, for which \$542.7 million was valued as disclosed on page 13, includes the manufacturing activities performance obligation discussed in Task 1 in section C.3.1 of the BARDA agreement and, if so, why the \$542.7 million is not allocated between the reservation of manufacturing capacity and manufacturing activities performance obligations. Refer to Section C.3.1 of the BARDA agreement.**
  - **Clarify if you expensed the costs of the capacity expansion in Task 2 of section C.3.2 of the BARDA agreement as research and development or capitalized the amounts pursuant to ASC 730-10-25-2a. If you capitalized the costs, please tell us why you believe the costs have alternative future use. In this regard, we note the reference on page 13 to capital investment projects which appears to include the costs under the BARDA agreement.**
- **how you accounted for modifications of your original task orders, including modifications to the BARDA agreements to date.**

- ***the basis for your accounting for the BARDA contract and each significant contract, including the Johnson & Johnson and AstraZeneca contracts, referencing the appropriate accounting literature.***
- ***where you disclosed in your filing new tasks such as the BARDA agreement included in Exhibit 10.66 or any significant modifications to your agreements, other than in the Exhibits.***
  - ***If no additional disclosure is considered necessary in the body of the filing, please tell us why.***
  - ***Tell us if the reduction in price for your May 2020 task order ending in 007, discussed in Exhibit 10.10 of the June 30, 2021 10-Q, is material to your financial statements and, if so, why the terms of the modification are not disclosed.***
- ***the nature of each performance obligation for each significant contract and when your performance obligations are satisfied. Refer to ASC 606-10-50-12.***
- ***the amount of the transaction price allocated to performance obligations for each contract that are unsatisfied as of the end of the reporting period pursuant to ASC 606-10-50-13 and an explanation of when you expect to recognize the revenue.***
- ***your consideration of providing disaggregated revenue by significant contract, contract-type, and prime vs subcontractor pursuant to ASC 606-10-50-5.***
- ***why disclosure of the terms of the significant contracts is not required to be included in the filing.***
- ***your consideration of including the reservation fee for the BARDA contract in your description of CDMO services throughout the filing, including pages 5 and 12. In this regard, the description appears inconsistent with the description on page 81 in the financial statements.***

The Company has summarized below the accounting analysis of the arrangements for BARDA, JNJ and AZ which have had the most material impact to CDMO revenue in 2020 and 2021. Although these arrangements have different customers and provide for varying services, they are complementary to result in a coordinated response to the COVID-19 pandemic. On a quantitative basis, the Company generally considers arrangements which are expected to provide a contribution of 10% or more of total revenues for consideration of additional disclosure. During the year ended December 31, 2020, the arrangement with BARDA contributed \$253.3 million or more than 10% of total revenues of \$1,555 million, while the arrangements with JNJ and AZ aggregated to \$96.7 million or less than 10% of total revenues. The nature, timing, and uncertainty of revenue from these arrangements are consistent with services that the Company has provided in prior periods. The Company has performed technology transfer services and batch manufacturing activities for other clients. The AZ and JNJ arrangements were unusual due to the nature of the manufacturing processes, developing vaccines to fight COVID-19 being high profile, and because they included lease components. In future filings, we will clarify that the BARDA Task Order 007 represents a lease and we will update the disclosure on page 86 accordingly. Other than the disclosure of the BARDA TOR as a lease, the Company does not believe that providing additional disclosure related to those arrangements would be material to the users of the financial statements. These proposed disclosures are detailed in the responses below.

**BARDA Task Order 007** (“the TOR”)

Background - The Company received the TOR issued by BARDA under prime contract HHS010020120004I on May 24, 2020 and classified it as a separate contract that was in the scope of ASC 842.

The items promised in the TOR include the right to use manufacturing suites at various locations over differing time periods, construction activities to enhance manufacturing capabilities, and manufacturing planning and reporting. BARDA entered into the contract to ensure that manufacturing capacity was available for products that responded to the COVID-19 pandemic as the Company had other commercial opportunities for the manufacturing suites at the same time. This manufacturing capacity is in addition to the scope of service in the original agreement and the price of the TOR is reflective of standalone selling prices for the additional service provided. Therefore, the Company concluded that BARDA benefits from the separately identifiable rights to use suite space under the new agreement. The Company anticipated additional task orders under the original prime contract would be required for BARDA to take full advantage of the arrangement.

Lease accounting considerations – The Company acknowledges the Staff’s comment regarding our consideration of accounting for the reservation of the manufacturing capacity as a lease. The Company initially determined that the reservation of the manufacturing capacity was representative of a stand-ready performance obligation, rather than a lease. The Company’s original evaluation of the TOR concluded that it was not a lease as the Company did not believe that BARDA was receiving the economic benefits (i.e. the assets’ primary outputs) of the space. In preparing the response to the Staff’s comments and performing further review, the Company has now concluded that the correct classification of the arrangement is as a lease. BARDA has the right to direct the use of the manufacturing capacity in the space, and thus the right to obtain substantially all of the economic benefits from the suites. The revenue recognition pattern for a stand-ready obligation however is consistent with an operating lease in that the Company generally uses a straight-line revenue recognition pattern.

Lease Components - The Company evaluated the other services promised in the TOR and determined that the only components in the arrangements are represented by the leases to reserve manufacturing capacity at the individual suites.

To elaborate further, the Company determined that the capital expenditures included in the arrangement are not separate performance obligations but a component of the lease. While the Company is required to put the assets in place for the reserved space, the government does not take ownership at the end of the arrangement and the Company retains title to the assets. In accordance with ASC 360-10-30-1, the Company reflected the cost of these capital expenditures as a component of property, plant, and equipment on the Company’s balance sheet. These tangible fixed assets have a long-term useful life beyond the term of the TOR.

The manufacturing planning and reporting consists of reporting that is required at various intervals (i.e., monthly/quarterly) that the Company provides to keep BARDA informed on the status of the capital projects or manufacturing activities within the suites. BARDA does not benefit directly from the planning and reporting deliverables without the access to the manufacturing capacity.

In conclusion, although various services are provided in the arrangement, the Company has only lease components under the BARDA arrangement. As a result, the total transaction price of

\$628.2 million has been allocated to each manufacturing suite's identified lease component based on a relative stand-alone selling price with consideration to size, location, capacity, production capability for drug product or drug substance manufacturing, and term. The allocated transaction price has been recognized as revenue over the respective reservation periods as an operating lease on a straight-line basis based on each manufacturing suites' lease commencement date for the manufacturing capacity.

Modifications - The Company and BARDA intended to have future price adjustments based on foreseeable, but unfinalized plans to use the manufacturing capacity for third party innovator company manufacturing. The purpose of the arrangement was to assure BARDA that the products most needed to respond to COVID-19 had manufacturing capacity. While BARDA approved the products that would use the space, BARDA had no specific production plans at the beginning of the arrangement. Depending on the nature of the third-party arrangement, the Company may reduce the price a third-party pays for manufacturing activities or BARDA may receive a credit once another party begins to use the manufacturing capacity. Any reduction to the overall future consideration that BARDA pays as a result of a third-party manufacturing contract will result in a contract modification between BARDA and the Company. For each modification the Company determined whether the lease modification should be accounted for as a separate contract in accordance with ASC 842-10-25-8. For modifications determined to be a separate contract, we accounted for the modification as a new lease. For modifications determined not to represent a separate contract, we recognized the change in the lease payments prospectively on a straight-line basis over the remaining lease term.

As noted in Section C.3.1 of the BARDA arrangement, the pricing structure is based on batch production manufacturing capacity at a facility, since batches are produced during an allocated time slot in a suite. The prospective adjustments in BARDA pricing are also calculated with reference to batch production.

Modifications to the TOR include the following:

Modification	Accounting Impact	Disclosure
BARDA also issued Task Order No. 75A50120F33008 (task order #3008) under the TOR which was disclosed as exhibit 10.66 as part of the Company's 10-K). This task order was amended as part of exhibit 10.68 as part of the Company's 10-K. It is valued at \$20 million for additional capacity reservation.	The Company determined the task order was a new contract as new capacity was provided at stand-alone selling price. The Company evaluated whether the reservation of capacity was a lease under ASC 842 which resulted in the same considerations and conclusion as noted above for the BARDA TOR.	Not material for disclosure.

The Company and BARDA entered an amendment of contract P0007 which is further referenced as exhibit 10.10 in our June 30, 2021, Form 10-Q filing. It reduced the contract value of TOR 7 by \$13 million.	The Company determined this was not a new contract. The reduction in price associated with this amendment is recognized prospectively over the lease term.	Not material for disclosure.
The Company and BARDA entered an amendment P00005 included as exhibit 10.2 as part of the March 31, 2021, 10Q to reduce the contract value by \$0.3 million.	The reduction in price associated with the amendment is not material to the financial statements but reduced the overall transaction price.	Not material for disclosure
The Company and BARDA entered an amendment P00006 included in exhibit 10.3 as part of the March 31, 2021, 10Q to add up to an additional \$23 million to increase operational capabilities of one of the Company's manufacturing suites.	The Company determined this was not a new contract. The increase in price associated with this amendment is recognized prospectively over the lease term.	Not material for disclosure

In response to the Staff's comment, in the future the Company will provide enhanced disclosure to clarify that the TOR lease obligation is the only identified component associated with the contract and that it is recorded as a component of CDMO revenue. This will require an update to the business discussion and financial statements, and the Company has its discussion on pages 5, 13, 81, 86, 87 and 92 of the December 31, 2020 Form 10-K as follows:

Page 5 - CDMO services

"Our portfolio of CDMO services consists of distinct but interrelated service groups: development services (process and analytical development); drug substance manufacturing; drug product manufacturing (fill/finish) and packaging; and, when necessary, suite reservation obligations. These services, which we refer to as "molecule-to-market" offerings, employ five technology platforms (mammalian, microbial, viral, plasma and gene therapy) across a network of nine geographically distinct development and manufacturing sites operated by us for our internal products and pipeline and CDMO services, for both clinical-stage and commercial-stage projects. We direct these CDMO services for a variety of third-party customers, including government agencies, innovative pharmaceutical companies, and non-government organizations."

Page 13 - BARDA COVID-19 Public-Private Partnership.

"On June 1, 2020, we announced that we had been issued a task order under our existing Center for Innovation in Advanced Development and Manufacturing (CIADM) agreement with BARDA for COVID-19 vaccine development and manufacturing. The task order has a contract value of up



to \$628.2 million and includes the reservation of manufacturing capacity and accelerated expansion of fill/finish capacity valued at \$542.7 million and \$85.5 million, respectively. These activities enable the Company to meet its operating lease obligations to BARDA.”

Page 81 - CDMO Services – See updates to item #3 above.

Page 86 – Revenue Recognition footnote

“During the year-ended December 31, 2020, the Company entered into lease arrangements with BARDA to reserve drug substance and drug product manufacturing capacity at various manufacturing sites that are recognized on a straight-line basis over the applicable reservation period. The arrangements had a total transaction price of \$648.2 million, and the Company recognized revenue of \$253.3 million associated with the BARDA arrangements during the year ended December 31, 2020. There were no similar arrangements with BARDA during the years ended December 31, 2019 and 2018. The remaining unrecognized lease payments under these arrangements is expected to be recognized in 2021 and totals \$394.9 million as of December 31, 2020. Additionally, during the year ended December 31, 2020, the Company entered into CDMO service arrangements with biotech innovators in support of the COVID-19 pandemic resulting in most of the increase in non-government revenues during the year-ended December 31, 2020 compared to the years ended December 31, 2019 and 2018.”

Page 87 – Transaction price allocated to remaining performance obligations

“The Company’s multi-year CDMO service arrangements that were entered into during 2020 include operating leases whereby the customer has the right to direct the use of and obtain substantially all of the economic benefits of manufacturing suites. The associated revenue is recognized on a straight-line basis over the term of the lease. The remaining term on the Company’s operating lease components approximates 1.2 years. The Company utilizes a cost-plus model to determine the stand-alone selling price of the lease to allocate contract consideration between the lease and non-lease components. During the year ended December 31, 2020, the Company’s lease revenues were \$283.8 million, which is included within CDMO services in the consolidated statement of operations. The Company did not recognize lease revenue during the years ended December 31, 2019 and 2018. The Company has allocated contracted operating lease revenues due under our long-term CDMO service arrangements as follows:

	Year ended December 31,
2021	\$ 469.7
2022	74.8
2023	15.7
	\$ 560.2

Page 92 – Property, plant, and equipment footnote

“For the years ended December 31, 2020 and 2019, construction-in-progress primarily includes costs incurred related to construction to advance the Company’s CDMO capabilities. These costs include capital expenditures related to our BARDA COVID-19 Public-Private Partnership.”

***Johnson & Johnson (“JNJ”) / AstraZeneca (“AZ”) Arrangements***

The Company entered multiple contracts with both JNJ and AZ during the year ended December 31, 2020, which have similar characteristics and were disclosed in press releases. The first was a technology transfer letter agreement entered into on April 20, 2020 and then a manufacturing

services agreement entered into on July 2, 2020 with JNJ. These contracts were evaluated and resulted in a combining of contracts under ASC 606. The Company also entered into an initial master services agreement, on June 10, 2020 and a definitive master services agreement, on July 24, 2020, with AZ. These contracts were also evaluated and resulted in a combining of contracts under ASC 606.

The Company evaluated the promised services under ASC 606-10-25-14 and determined that each contract had three performance obligations: suite reservation, technology transfer and drug substance manufacturing. Under ASC 606-10-32-2, the Company then allocated the transaction price to each performance obligation on a relative standalone selling price basis using the Company's best estimate. The contract values represented the total consideration the Company expected to be entitled to for providing services.

The JNJ and AZ suite reservation performance obligations conveyed the right to control the use of identified property, plant and equipment and receive all the economic benefits of the assets within specific suites to JNJ and AZ in accordance with the definition of a lease under ASC 842-10-15-3. The suite reservation component in these arrangements are separate from the suite reservations under the BARDA arrangement. The disclosure on page 86 of Form 10-K for the impact of suite reservation components pertains to the contract with JNJ as the suite reservation component of the AZ contract's period of performance was from July 2020 – September 2020, and therefore did not include any future revenues to be reported in the Form 10-K for the year ended December 31, 2020. As discussed above, we will update our disclosures to include the BARDA lease in the disclosure. The Company recognizes contract value allocated to suite reservation straight-line over the reservation period.

The technology transfer performance obligations in the JNJ and AZ arrangements enabled them to establish the manufacturing process for their unlicensed vaccines and obtain valuable know how. The technology transfer process included multiple process validation points and reporting which allowed the customers to improve their manufacturing processes in real-time and utilize the reporting and information to benefit their manufacturing process more broadly at other manufacturing sites across the globe. The Company concluded that over-time recognition using an input method faithfully depicts the Company's performance toward satisfaction of its performance obligation in accordance with ASC 606-10-55-17. The Company measures progress toward completion using costs incurred to date as a percentage of total estimated costs to complete the technology transfer activities.

Drug substance batch production is a separate performance obligation in both the JNJ and AZ arrangements. The completed batches, once released after quality assurance standards have been met, are made available to our customer who is then responsible for fill/finish activities and further distribution to patients. The Company historically has recognized revenue for batch production when the Company makes a batch available to the customer upon completion of the required quality assurance procedures and documentation. The use of an output measure resulted in a revenue recognition pattern comparable to a point in time measure. In preparing our response to the Staff's comments, we have now concluded that the correct accounting would have been the use of an input measure resulting in an over-time revenue recognition pattern. In accordance with ASC 606-10-25-27(c), there is no alternative use for CDMO manufacturing batch production to the Company and the Company has an enforceable right to payment for performance completed to date. The Company will recognize revenue from batch production using an input method based on costs incurred to measure progress toward the transfer of control of batch production to our customers. Further, in accordance with ASC

606-10-25-14(b), we have concluded that our batch production services represent a series of distinct services that are substantially the same and that have the same pattern of transfer, and as such that they would be considered a single performance obligation. This revenue recognition methodology will also result in the Company recognizing substantially all of the costs associated with its contract manufacturing and development services as an expense when incurred, and generally not having any work-in-process inventory for its CDMO contracts.

***Materiality Assessment***

The Company has calculated the impact of the changes to our accounting policies described above compared to our historical revenue and cost recognition patterns, concluding that for all quarterly and annual periods previously reported, the impact is not material. The following tables outline the impact of all uncorrected adjustments identified by the Company to key financial metrics for historical periods:

<b>Total Revenues</b>				
<b>Period</b>	<b>As Reported</b>	<b>Adjustment</b>	<b>As Adjusted</b>	<b>% Change</b>
Year Ended December 31, 2018	\$ 782.4	\$ 7.0	\$ 789.4	0.9%
Year Ended December 31, 2019	1,106.0	(5.4)	1,100.6	(0.5%)
Year Ended December 31, 2020	1,555.4	21.9	1,577.3	1.4%
Quarter Ended March 31, 2020	192.5	0.3	192.8	0.2%
Quarter Ended June 30, 2020	394.7	12.6	407.3	3.2%
Quarter Ended September 30, 2020	385.2	1.0	386.2	0.3%
Quarter Ended December 31, 2020	583.0	8.0	591.0	1.4%
Quarter Ended March 31, 2021	343.0	33.7	376.7	9.8%
Quarter Ended June 30, 2021	397.5	(18.7)	378.8	(4.7%)
<b>Cost of Product Sales and CDMO Services</b>				
<b>Period</b>	<b>As Reported</b>	<b>Adjustment</b>	<b>As Adjusted</b>	<b>% Change</b>
Year Ended December 31, 2018	\$ 322.3	\$ 5.8	\$ 328.1	1.8%
Year Ended December 31, 2019	433.5	(4.4)	429.1	(1.0%)
Year Ended December 31, 2020	524.0	12.4	536.4	2.4%
Quarter Ended March 31, 2020	76.9	-	76.9	0.0%
Quarter Ended June 30, 2020	129.8	5.8	135.6	4.5%
Quarter Ended September 30, 2020	149.0	6.9	155.9	4.6%
Quarter Ended December 31, 2020	168.3	(0.3)	168.0	(0.2%)
Quarter Ended March 31, 2021	99.3	37.6	136.9	37.9%
Quarter Ended June 30, 2021	227.8	(12.9)	214.9	(5.7%)
<b>Income Before Income Taxes</b>				
<b>Period</b>	<b>As Reported</b>	<b>Adjustment</b>	<b>As Adjusted</b>	<b>% Change</b>
Year Ended December 31, 2018	\$ 81.5	\$ 2.3	\$ 83.8	2.8%
Year Ended December 31, 2019	77.4	1.8	79.2	2.3%
Year Ended December 31, 2020	407.2	6.7	413.9	1.6%
Quarter Ended March 31, 2020	(21.3)	(0.1)	(21.4)	0.5%
Quarter Ended June 30, 2020	120.7	4.4	125.1	3.6%
Quarter Ended September 30, 2020	55.0	(5.9)	49.1	(10.7%)

Quarter Ended December 31, 2020	252.8	8.3	261.1	3.3%
Quarter Ended March 31, 2021	85.2	(3.9)	81.3	(4.6%)
Quarter Ended June 30, 2021	7.2	(5.8)	1.4	(80.6%)
<b>Net Income</b>				
<b>Period</b>	<b>As Reported</b>	<b>Adjustment</b>	<b>As Adjusted</b>	<b>% Change</b>
Year Ended December 31, 2018	\$ 62.7	\$ (0.3)	\$ 62.4	(0.5%)
Year Ended December 31, 2019	54.5	1.8	56.3	3.2%
Year Ended December 31, 2020	305.1	5.0	310.1	1.6%
Quarter Ended March 31, 2020	(12.5)	(0.1)	(12.6)	0.6%
Quarter Ended June 30, 2020	92.7	3.3	96.0	3.6%
2020 Quarter Ended September 30,	39.5	(4.4)	35.1	(11.2%)
2020 Quarter Ended December 31,	185.4	6.2	191.6	3.4%
Quarter Ended March 31, 2021	69.7	(2.9)	66.8	(4.1%)
Quarter Ended June 30, 2021	4.6	(4.3)	0.3	(93.3%)

The Company also considered the impact of the above adjustments to current and total assets and liabilities for the historical periods presented above, concluding that such adjustments were not material.

In addition to the quantitative analysis above, the Company considered qualitative factors when assessing materiality. The Company concluded that the adjustments are not qualitatively material as they did not affect any of the qualitative criteria outlined in SEC Staff Accounting Bulletin No. 99 – Materiality, such as whether the misstatements masked a change in earnings or trends, changes a loss into income or vice versa, or the Company's compliance with loan covenants or other contractual requirements as well as other qualitative factors. While the quarterly impact of the adjustments is a significant percentage of net income for the three month period ended June 30, 2021, the quarterly performance of the Company in any given period is generally not indicative of annual performance due to variability in timing of product deliveries and services rendered. To assess the impact from an investor's perspective in addition to the qualitative factors above, the Company considered the quantitative impact of the adjustments to the fiscal years' 2020 and forecasted 2021 net income and determined that the changes were not material.

The Company will correct for these adjustments in the quarter ending September 30, 2021. The cumulative impact of these adjustments to net income is approximately a \$0.7 million net decrease to net income and is not expected to be material.

#### **Consideration of disclosures related to revenue arrangements**

Based on the discussion above along with the planned prospective changes in disclosures:

- The Company believes it has complied with the disclosure requirements outlined in ASC 606-10-50-1 which requires the Company to disclose qualitative and quantitative information about all of the following:
  - a. Its contracts with customers (see paragraphs 606-10-50-4 through 50-16)
  - b. The significant judgements, and changes in the judgements, made in applying the guidance
  - c. Any assets recognized from the costs to obtain or fulfill a contract with a customer

Further, in accordance with ASC 606-10-50-2 the Company believes it has disclosed the appropriate “level of detail necessary to satisfy the disclosure objective and how much emphasis to place on the various requirements. An entity shall aggregate or disaggregate disclosures so that useful information is not obscured by either the inclusion of a large amount of insignificant detail or the aggregation of items that have substantially distinct characteristics.”

- These new agreements include performance obligations that have revenue classifications consistent with prior periods and no changes in the description of performance obligations are needed to present revenue in accordance with ASC 606-10-50-5.
- The nature of each performance obligation included in these contracts and when performance obligations are satisfied are disclosed in Note 2 of our Form 10-K consistent with ASC 606-10-50-12. The Company has provided updated disclosure information about its performance obligations in contracts with customers, including a description of when the Company satisfies its performance obligations as well as the nature of the goods or services that the entity has promised to transfer. See updates to disclosure in our response to Comment #2.
- The Company's contracts do not require further disclosure as it relates to the following:
  - unusual significant payment terms,
  - complex variable consideration,
  - significant financing components,
  - obligations for returns, refunds, and other similar obligations, or
  - warranties.
- The Company has considered its disclosure of disaggregated revenue in accordance with ASC 606-10-55-89 thru 91 as presented on page 85 of the Company's Form 10-K. The Company is required to disaggregate revenue from contracts with customers into categories that depict how the nature, amount, timing, and uncertainty of revenue and cash flows are affected by economic factors. The presentation of the Company's US GAAP financial statements are consistent with external earnings releases, annual reports, and investor presentations. Additionally, our CEO, who is also our CODM, reviews monthly consolidated statements with the same revenue presentation as our US GAAP financial statements. He also reviews separate product revenue information, but these products are aggregated for presentation on our consolidated financial statements because they are all similar types of life enhancing products, such as a vaccine, therapeutic or medical device. CDMO is a manufacturing service, and contract and grant revenue relates to research and development services with a customer base that differs from CDMO services. We have also disaggregated revenue between US Government and Non- U.S. government arrangements as discussed in ASC 606-10-55-91 in the revenue footnote. As such, the Company believes that revenue disaggregated for products, CDMO and contracts and grants on the income statement, and then further between US and Non- US government arrangements in the revenue footnote continues to be appropriate.
- The Company has considered the following requirements related to disclosures about its unsatisfied performance obligations:
  - The aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied (or partially unsatisfied) as of the end of the reporting period, or

- An explanation of when the entity expects to recognize as revenue the amount disclosed in accordance with paragraph 606-10-50-13(a), which the entity shall disclose in either of the following ways:
  - On a quantitative basis using the time bands that would be most appropriate for the duration of the remaining performance obligations
  - By using qualitative information.

In response to ASC 606-10-50-13(a) disclosure requirements, the Company will update future filings as noted in the paragraph below from the Company's June 30, 2021 Form 10-Q:

"As of June 30, 2021, the Company expects future revenues on unsatisfied performance obligations of approximately \$1.4 billion associated with all arrangements entered into by the Company. The unsatisfied performance obligations declined by \$0.3 million during the three months ended June 30, 2021, due to revenue recognized and net contract modifications. While the Company generated new business during the period, it is also in negotiations with AZ to settle its contract and has not included revenue associated with the performance of any future services for AZ in the unsatisfied performance obligation disclosure. The Company expects to recognize a majority of the \$1.4 billion of unsatisfied performance obligations within the next 24 months. The amount and timing of revenue recognition for unsatisfied performance obligations can change. The future revenues associated with unsatisfied performance obligations exclude the value of unexercised option periods in the Company's revenue arrangements. Often the timing of manufacturing activities changes based on customer needs and resource availability. Regulatory compliance may also impact the status of the Company's COVID related CDMO arrangements. Government funding appropriations can impact the timing of product deliveries. The success of the Company's development activities that receive development funding support from the USG under development contracts can also impact the timing of revenue recognition."

Consolidated Financial Statements

17. Segment Information, page 105

- 5. You state on page 7 that you are organized into four business units, however you have only presented one reportable segment. Please provide us an analysis of why you believe additional segment disclosure is not required pursuant to ASC 280.**

The Company respectfully advises the Staff that the Company determined it operates in one operating and one reportable segment as prescribed by ASC 280-10-50-1. An operating segment is a component of an enterprise that has all of the following characteristics:

- a. It engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same public entity).

The Company is organized into four business units, Vaccines, Therapeutics, Devices, and CDMO. Each has a business leader required to sell and distribute product, manage product costs, and develop complimentary products and services for its customers. The Company's business units are primarily responsible for managing their product and customer base.

- b. Its operating results are regularly reviewed by the public entity's chief operating decision maker (CODM) to make decisions about resources to be allocated to the segment and assess its performance.

The business unit leaders all report to the Company's Executive Vice President and Chief Operating Officer ("COO"). The COO reports to the President and Chief Executive Officer ("CEO") who is the chief operating decision maker ("CODM") as defined in ASC 280. The CEO is the chairperson of the Executive Management Team, with responsibility for the direct oversight of the following functions: legal, human resources, quality and operational excellence, finance, and medical and regulatory affairs. The CEO is responsible for determining the allocation of resources within the Company. The CEO reviews consolidated companywide performance, including a consolidated income statement, key consolidated balance sheet metrics, and consolidated Adjusted EBITDA in the routine reporting received to assess performance and allocate resources.

- c. Its discrete financial information is available.

Discrete financial information related to the Company's business units as well as products are available monthly to business unit leaders and the COO. The financial metrics include revenue and gross margin. The business unit information also includes SG&A costs and operating income.

Although the Company is organized into four business units with each having a business leader as well as discrete financial information, the Company concluded its business units did not meet the criteria of operating segments. The CODM does not regularly review business unit financial operating results to make resource allocation decisions. Furthermore, the Company's compensation programs are based on companywide consolidated performance for all employees. Additionally, information regularly presented to the Board of Directors includes a consolidated US GAAP income statement, key consolidated balance sheet metrics, and consolidated Adjusted EBITDA. As such, the Company has one operating and one reportable segment to present in accordance with ASC 280.

Form 10-Q for the Fiscal Quarter Ended June 30, 2021

Item 1. Risk Factors

Product Development and Commercialization Risks, page 39

- 6. You disclose in Risk Factors the FDA inspection on April 21, 2021 which discovered cross-contamination of a single drug substance lot intended for further drug product manufacturing and use in the Johnson & Johnson's COVID-19 vaccine. Please provide revised disclosure to be included in future filings for the following:**
- **Disclose in Management's Discussion and Analysis the effect the cross contamination had on your results of operations.**
  - **Clarify on page 29 that the \$41.5 million inventory write-off relates to the cross-contamination issue.**
  - **Provide additional disclosure relating to the status of the AstraZeneca contract as a result of the cross-contamination issue and how your results of operations have been and will be affected in the future.**

In response to the Staff's comments, the Company has included proposed disclosure based on the paragraph describing the cost of product sales and CDMO services within the management discussion and analysis as it will appear in future filings:



“Cost of product sales and CDMO services increased for the three and six months ended June 30, 2021, due to a higher volume of CDMO services, largely related to the Company's public-private partnership to address the COVID-19 pandemic. In addition, the Company recorded inventory write-offs of \$41.5 million which were directly or indirectly the result of the cross-contamination event at the Bayview facility during three and six months ended June 30, 2021. The inventory write-off was due to raw materials and in-process batches that the Company plans to discard as they were deemed unusable. These increases were partially offset by decreases in the cost of product sales due to less volume.”

In response to the Staff's comments regarding disclosure of the status of the AZ contract, the Company will update future filings as noted in the proposed disclosure drafted in item #4 above for 606-10-50-13(a).

Please do not hesitate to call me at (240) 631-3200 with any questions or further comments you may have regarding these filings or if you wish to discuss the above responses.

/s/Richard S. Lindahl  
Richard S. Lindahl  
Executive Vice President, Chief Financial Officer and Treasurer  
Emergent BioSolutions Inc.