

November 12, 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 October 29, 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. Refer to your response to comment 6 and the proposed disclosure in response to comment 4 with respect to the status of the AZ contract. You state that you are in negotiations with AZ to settle your contract and have not included revenue associated with the performance of any future services for AZ in the unsatisfied performance obligation disclosure. Please address the following:
  - a. As previously requested, please clarify in your proposed disclosure how your results of operations have been and are expected to be affected in the future for the renegotiation of the AstraZeneca contract. In this regard, we note the increase in selling, general and administrative expenses in the six months ended June 30, 2021 compared to the prior period of \$15.2 million and the \$12 million spent to remediate and strengthen the manufacturing process at the Bayview site referred to in your earnings call. In addition, it is unclear if there was any lost revenue and related cost of sales relating to the AZ contract.
  - b. Clarify in the filing the nature of the renegotiation, which appears to be a termination of the contract, and the status thereof. Specifically state that AZ's period of performance was from July 2020-September 2020 and you will not be recording any future revenues for the AZ contract.
  - c. Tell us why additional disclosure is not required in the notes to the financial statements.

We acknowledge the Staff's comments and have revised our disclosures in our Form 10-Q for the quarter ended September 30, 2021 filed on November 5, 2021 to include our accounting policy for CDMO arrangements that end in early termination as follows: "The Company's CDMO customer contracts generally include provisions entitling the Company to a termination penalty when the contract is terminated prior to the contract's nominal end date. The termination penalties in the customer contracts vary but are generally considered substantive for accounting purposes and create enforceable rights and obligations throughout the stated duration of the contract. The Company accounts for a contract cancellation as a contract modification. The determination of the contract termination penalty is based on the terms stated in the related customer agreement. As of the modification date, the Company updates its estimate of the transaction price, subject to constraints, and recognizes the amount over the remaining performance period or measure of progress under the arrangement."

We then further explain in the revenue footnote (Note 10) the status of the AstraZeneca ("AZ") arrangement as follows: "During the three months ended June 30, 2021, AZ instructed the Company to cease performing new manufacturing services. At that time the Company updated its estimated transaction price subject to constraints and measure of progress under the arrangement. The Company has completed the release of all previously manufactured batches for AZ and there are no remaining unsatisfied performance obligations included in the Company's unsatisfied performance obligation disclosure."

The period of performance for the AZ contract referenced in the Staff's comment of July 2020 through September 2020 relates to the suite reservation and associated lease revenues. The AZ contract's total period of performance was from the second quarter 2020 through third quarter 2021.

To clarify the impact of AZ being removed from the Bayview facility we added the following disclosure in the inventory footnote (Note 3). "Inventories, net is stated at the lower of cost or net realizable value. During the nine months ended September 30, 2021, the Company recorded inventory write-offs at its Bayview facility of \$41.5 million, which were directly or indirectly the result of the cross-contamination event at the Bayview facility identified during the three months ended June 30, 2021. The inventory write-off resulted from the Company's plan to discard raw materials and in-process batches that were deemed unusable. The charge was reflected as a component of cost of contract development and manufacturing."

The disclosure above aggregated both AZ and Johnson and Johnson ("JNJ") manufacturing materials, because neither customer exceeds 10% of revenues. Disclosures for AZ and JNJ are aggregated in our discussion of the results of operations as well. The discussion of CDMO revenues is as follows: "The increase in CDMO services revenue for the three months ended September 30, 2021 of \$59.5 million is largely due to out-of-period adjustments (see Note 2) of \$49.3 million along with incremental manufacturing activities. The increase for the nine months ended September 30, 2021 is due to the Company's partnerships with innovators, including JNJ and AZ, to address the COVID-19 pandemic. The AZ and JNJ arrangements were entered into during the second and third quarters of 2020 and the Company began servicing other innovator companies in 2021. Additionally, during the nine months ended September 30, 2021 at 600 increased for the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020 due to an increase in CDMO service activities, increases in costs due to out-of-period adjustments (see Note 2) of \$28.8 million." Additionally, the Company included the following disclosure for CDMO expenses, "Cost of CDMO increased for the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020 due to an increase in CDMO service activities, increases in costs due to out-of-period adjustments (see Note 2) and additional costs to support remediation efforts for our COVID-19 manufacturing activities. Additionally, during the nine months ended September 30, 2021, the Company recorded inventory write-offs at its Bayview facility of \$41.5 million, which were directly or indirectly the result of the cross-contamination event at the Bayview facility identified during the three months ended June 30, 2021."

The Company believes the above disclosures provide sufficient information for users of the financial statements about the status of the AZ arrangement.

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

2. We note your response to our prior comment 2 and your proposed disclosures. Your arguments, including your references to your prior response, focused on the manufacturing of bulk drug substances and drug products. Your recent revision of your revenue recognition policy for the drug substance batch production indicated a different pattern for control transfer under ASC 606. Furthermore, your business has also evolved to include a large portion of suite reservation operation, which appears to be bearing a significantly higher margin. Please tell us how you determined that disclosure of your costs related to the CDMO service was not required by Article 5 of Regulation S-X which requires separate disclosure of cost of tangible goods sold, cost of services, and expenses applicable to rental income if their related revenue is over 10% net sales and gross revenues. In addition, please clarify that you will separately present your leasing income on the face of the income statement.

We acknowledge the Staff's comments and have revised the presentation of the face of our statements of operations in our Form 10-Q for the quarter ended September 30, 2021 filed on November 5, 2021 to include the following presentation of:

- a) CDMO lease revenues and CDMO services revenues subtotaled for total CDMO revenues, and
- b) Cost of goods sold for products and cost of CDMO.

The Company has presented CDMO services and lease costs in aggregate given we operate an integrated manufacturing network, our leasing activities are not core to our business strategy, our current material lease revenues are temporary in nature, and the cost structure associated with our manufacturing facilities will remain with the Company even after the material lease revenues expire. We anticipate that in 2022 our lease revenues will comprise 3-4% of total revenues, and as such we believe the disclosure of CDMO costs in aggregate is most useful.

## Consolidated Financial Statements 17. Segment Information, page 105

- 3. We note your response to our prior comment 5. Please respond to the following comments relating to your segment presentation under ASC 280: Tell us how often the CODM meets with his/her direct reports, the financial information the CODM reviews to prepare for those meetings, the financial information discussed in those meetings, and who else attends those meetings.
  - a. If not already covered by your response to bullet 1, describe the information regularly provided to the CODM and how frequently it is prepared. More specifically, clarify if any business units performance results are presented, or discussed, as part of, or outside of the consolidated company-wide performance presentation that the CODM reviews.
  - b. Explain how budgets are prepared, who approves the budget at each step of the process, the level of detail
  - discussed at each step, and the level at which the CODM makes changes to the budget. Also describe the level of detail communicated to the CODM when actual results differ from budgets and who is C. involved in meetings with the CODM to discuss budget-to-actual variances.

Our chief operating decision maker ("CODM"), our President and Chief Executive Officer ('CEO"), has weekly or bi-weekly scheduled one-on-one meetings with each of his direct reports. During those one-on-one meetings the CODM and his direct reports will discuss operational performance including new and potential business, manufacturing and quality performance, customer relations, human resource matters, communications, and other items. These one-on-one meetings do not routinely involve the review of financial information and generally do not involve the review of specific materials, but rather are meant to be a forum for the open exchange of information between the CODM and his direct reports on a variety of topics. The following roles report directly to the CODM:

- Executive Vice President, Chief Operating Officer ("COO")
- Executive Vice President, Chief Financial Officer & Treasurer ("CFO")
- Executive Vice President, Corporate Development, External Affairs, and General Counsel
- Executive Vice President, Chief Medical Officer
- Executive Vice President, Chief Human Resources Officer
- Senior Vice President, Global Quality

The CODM is also the leader of the Executive Management Team ("EMT") which meets weekly and is comprised of the CODM and the direct reports listed above. The EMT oversees general management of the business, advising the CODM on key matters, and providing strategic direction. The routine weekly EMT meetings do not generally include discussion of financial performance; however, the EMT, including the CODM, receives a monthly financial report which contains historical and forecasted financial performance metrics, such as actual and forecasted revenues by product/service, as well as consolidated measures of profitability. This monthly financial report is prepared using consolidated financial information and does not contain any grouping or totaling of revenues, expenses, or profitability by business line, and does not contain information that would enable the calculation of profitability by business line. This monthly financial report is the primary information used by the CODM to allocate resources and assess performance. The monthly financial reporting includes a consolidated enterprise level analysis of the drivers for fluctuations compared to the most recent forecast. The fluctuation analysis references significant drivers of changes in consolidated performance, including products, functional departments, and unique transactions.

In addition to the monthly financial reporting reviewed by the CODM; on a quarterly basis, the Company conducts a Quarterly Business Review ("QBR") which is a series of meetings to review commercial, operational, and financial performance by business line. Attendees at the QBR include the EMT (including the CODM), all senior vice presidents, and select other members of management as appropriate. The content in the OBR materials includes discussion of recent business accomplishments and challenges, commercial opportunities, research and development updates, as well as a review of select financial metrics for each business line. The financial metrics reviewed at the QBR include revenues by product/service, research and development expense ("R&D expense"), and selling, general and administrative expense ("SG&A expense") by business line. The financial metrics do not include cost of goods or services or any metric of profitability or information such that profitability can be independently calculated.

Prior to commencing the annual budgeting process, the CODM and the EMT determine parameters and metrics at the consolidated level that serve as guiding principles to prepare the budget. The finance organization, with leadership from the CFO, set financial targets for each business line and functional department to achieve based on recent performance and known trends. Each husiness

line and functional department then creates their budget, which is then further revised based on a resource allocation exercise which is performed at the consolidated enterprise level to determine how to allocate investments and potential opportunities. The CODM participates in that resource allocation exercise at the enterprise level. The resource allocation exercise is a cross-business line exercise and resources are allocated to specific initiatives or projects rather than business lines. For example, while the business line leaders have autonomy for day-to-day decisions, major or strategic decisions and allocation of resources are made at the enterprise level by the CODM. Following CODM review, the budget is then finalized and a review is provided to the Board of Directors.

Additionally, we would like to clarify for the Staff that the Company implemented a new organizational structure in early October 2021 as disclosed in our Form 10-Q filing on November 5, 2021. The key components of the new business structure include a Government (MCM) line of products, Commercial line of products, and contract development and manufacturing offerings as well as the centralization of research and development ("R&D") functions and capabilities at the enterprise level. The centralization of R&D at the enterprise level further illustrates the allocation of resources at the enterprise level with respect to our potential future growth through our R&D pipeline. The Company does not anticipate changes to the level of detail or metrics in the financial information to be provided to the CODM as part of this reorganization.

We respectfully remind the Staff of the following points referenced in our prior response letter dated September 30, 2021:

- a. The business line leaders all report to the Company's Executive Vice President and COO. The COO is responsible for evaluating the performance of the business line leaders and reviewing more detailed financial information, but he does not have the authority to make major resource allocation decisions.
- b. All employees of the Company, including the business line leaders, have annual bonus and compensation plans that are based on the Company's consolidated performance against corporate goals, including financial goals. The business line leaders are not compensated based on the financial performance of their respective businesses.

The Company believes its organizational structure and the format of the financial information presented to the CODM support the conclusion that the Company operates as one operating and reportable segment in accordance with ASC 280.

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.