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FOIA Confidential Treatment Request

Confidential Treatment Requested by Emergent BioSolutions Inc. Pursuant to 17 C.F.R. §200.83. A version of this letter submitted via EDGAR omits confidential information. Brackets ([]) denote the omission of the confidential information from the EDGAR submission of this letter.

January 11, 2019

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, 2017 Filed February 23, 2018 Form 10-Q for the Quarterly Period Ended September 30, 2018 Filed November 2, 2018 Form 8-K Filed November 1, 2018 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 December 12, 2018, relating to Emergent's Form 10-K filed with the Commission on February 23, 2018, Emergent's Form 10-Q filed with the Commission on November 2, 2018, and Emergent's Form 8-K filed with the Commission on November 1, 2018. 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, 2017 Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations Year ended December 31, 2017 Compared to Year Ended December 31, 2016 Revenue

1. Please tell us the following regarding your discussion of the changes in revenue:

- How much of the increase in BioThrax product sales relates to volume versus price.
- What is meant by "timing of BioThrax deliveries to SNS" and how it explains the increase in BioThrax sales.
- The amount of other product sales by product for 2017 and 2016.
- The amount attributable to each bullet with regard to the increase in other product sales.
- The amount of expense incurred in 2017 and 2016 related to contracts and grants and where they are reflected in your financial statements.

Also address the above bullets, as applicable, to your MD&A revenue discussion for the nine months ended September 30, 2018 compared to nine months ended September 30, 2017 in your Form 10-Q for the quarterly period ended September 30, 2018.

In response to the Staff's comment, the Company respectfully advises the Staff that substantially all of the Company's sales of BioThrax[®] during the periods in question were made to the United States government ("USG") under two long-term procurement contracts between the Company and the Centers for Disease Control ("CDC") and Biomedical Advanced Research and Development Authority ("BARDA") at a fixed price per dose. The price per dose of BioThrax[®] in the two contracts is identical. Therefore, the fluctuations in BioThrax[®] revenue are related to changes in volume depending on the timing of when the USG requests delivery of doses to the Strategic National Stockpile ("SNS"). The SNS is a national repository of critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies maintained by the USG and it retains a threshold level of BioThrax[®] at any given time, as it deems necessary. The Company will clarify in future Exchange Act periodic reports that BioThrax[®] product sales fluctuations are substantially due to changes in volume and those changes in volume are driven by the timing of deliveries and acceptance of product by the USG.

For competitive and other reasons described herein, the Company has elected not to present revenue for each of its products on an individual basis. Additionally, certain of the Company's products are procured by the USG and other customers on an infrequent or periodic basis and therefore period to

period fluctuations in sales may not be meaningful to the long-term financial profile of a product. Furthermore, for fiscal years 2017, 2016, and 2015, no products other than BioThrax[®] had sales representing more than 10% of our total revenues. BioThrax[®] product sales represented 51%, 48%, and 60% of our total revenues for the fiscal years ended December 31, 2017, 2016, and 2015, respectively. For the nine months ended September 30, 2018, BioThrax[®] product sales represented 28% of our total revenues and ACAM2000[®] product sales represented 23% of our total revenues. For the nine months ended September 30, 2017, BioThrax[®] product sales represented 49% of our total revenues. The Company has presented the table below for the purpose of responding to the Staff's comment; however, the Company does not intend to present the below product sales revenue breakout in its future filings for the reasons mentioned above. The Company believes that presenting information in MD&A in a manner similar to the below could give investors a false impression, either favorably or unfavorably, about the Company's results of operations and the financial profile of its products on an individual basis, particularly given the fact that many of its products are purchased on an irregular basis and therefore fluctuations period over period are not necessarily indicative of a product's expected long-term performance.

[INFORMATION REDACTED]

In response to the Staff's comments requesting quantification of movement in other product sales, the Company has re-presented such text with quantification included below for the year ended December 31, 2017 compared to the year ended December 31, 2016:

"The increase in other product sales relates primarily to:

- the timing of BAT[®] deliveries to the SNS (\$28.4 million);
- international sales for VIGIV and Trobigard[™] (\$25.3 million); and
- sales of ACAM2000[®] and Raxibacumab, both acquired in October 2017 (\$20.5 million)."

Additionally, the Company has quantified the corresponding disclosure for the nine months ended September 30, 2018 and 2017:

"The increase in other product sales relates primarily to:

- sales of ACAM2000[®] (which was acquired in October 2017) to the CDC (\$116.7 million);
- sales of Raxibacumab (which was acquired in October 2017) to BARDA (\$39.6 million);
- sales of Trobigard[™] to the U.S. Department of State (\$17.5 million);
- sales of RSDL[®] to the DoD (\$7.4 million); and
- sales of Anthrasil[®] to the Canadian Defence Ministry (\$7.0 million).

These increases in other Products sales were partially offset by a decrease in BAT[®] sales (\$18.9 million) primarily due to the timing of deliveries to the SNS."

In future filings under the Exchange Act, the Company confirms that it will include quantification of changes in Results of Operations similar to the above presentation.

The revenues within our contracts and grants revenues primarily related to our cost-plus fixed fee contracts with the USG. The Company's expenses associated with contracts and grants are primarily recorded within research and development expenses and represented 43% and 67% of total research and development expenses for the years ended December 31, 2017 and 2016, respectively. Additionally, for the nine months ended September 30, 2018 and 2017 expenses associated with contracts and grants represented 34% and 46% of total research and development expenses, respectively.

Cost of Product Sales and Contract Manufacturing

2. Please tell us the amount attributable to each bullet with regard to the increase in cost of product sales and manufacturing.

In response to the Staff's comments requesting quantification of the increase in cost of product sales and manufacturing, the Company has re-presented such text with quantification included below for the year ended December 31, 2017 compared to the year ended December 31, 2016:

"Cost of product sales and contract manufacturing increased by \$64.4 million, or 49%, to \$195.7 million for 2017 from \$131.3 million for 2016. The increase was primarily attributable to:

- the timing of non-cash fair value adjustments to the contingent consideration liability (year over year increase of \$8.2 million);
- timing of BAT[®] sales to the SNS (\$7.2 million);
- timing of international sales for VIGIV and Trobigard[™] (\$13.7 million);
- sales of the newly acquired ACAM2000[®] and Raxibacumab products (\$18.5 million) (both acquired October 2017); and
- increased costs associated with the expansion of our contract manufacturing business (\$18.8 million)."

In future filings under the Exchange Act, the Company confirms that it will include quantification of changes in Results of Operations similar to the above presentation.

Consolidated Financial Statements

Consolidated Statements of Operations

3. Regarding the line item cost of product sales and contract manufacturing, please provide us the amounts included for fiscal years December 31, 2016 and 2017 and the nine months ended September 30, 2018 for cost of product sales versus cost of contract manufacturing. Tell us how your current presentation that combines those items into one line item complies with rule 5-03(b)2 of Regulation S-X.

The Company respectfully advises the Staff that it uses the same manufacturing facilities and methods of production for its own products as well as for fulfillment of its contract manufacturing contracts. Prior to completing two recent acquisitions in October 2018, the Company operated seven manufacturing facilities, five of which are multi-purpose as they perform manufacturing activities for its own marketed products as well as contract manufacturing customers. The inputs and outputs in the manufacturing process are similar regardless of whether the Company is producing material for itself or external customers. 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 Company's contract manufacturing business includes performing "fill-finish" work for biologics products as well as producing bulk material for certain customers. For "fill-finish" customers, the Company receives work in process inventory from its client and brings the product to filled and finished state and incurs costs to complete the manufacturing process. Additionally, when producing bulk material 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 being approved by the Company's quality control review process. 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 should be viewed separately from the costs incurred to produce its own products. Furthermore, the Company has historically communicated its gross margin goals to its investors on an aggregated basis as it believes viewing overall gross margin is most useful to investors as the Company looks to optimize the profitability of its manufacturing facilities by producing its own products and utilizing excess capacity for contract manufacturing customers where possible. As the Company expands its product portfolio, particularly with the recent acquisition of three marketed products during the fourth quarter of 2018, the Company expects that the contract manufacturing business will be less than 10% of total revenues in future periods and it is forecasted to be less than 10% of total revenues in fiscal year 2019. As a result of these facts, the Company does not believe that expenses related to its contract manufacturing business represent "cost of services" per Rule 5-03(b)2 of Regulation S-X and believes its presentation of expenses to be in compliance with Regulation S-X as well as the most useful presentation of this expense to users of the financial statements.

Notes to Consolidated Financial Statements 2. Summary of Significant Accounting Policies Revenue Recognition

4. Please provide us an accounting analysis that describes your accounting treatment (i.e. separation, measurement, recognition and classification) for the March 16, 2017 contract and modification that you entered with BARDA. Provide reference to authoritative literature supporting your treatment.

On September 30, 2016, the Company and BARDA entered into an agreement for the advanced development and delivery of NuThraxTM ("BARDA NuThraxTM Contract"). The BARDA NuThraxTM Contract consisted of a five-year base period of performance to develop NuThraxTM (contract value of []) and to manufacture and deliver an initial 2.0 million NuThraxTM doses into the SNS after receiving Emergency Use Authorization ("EUA") preauthorization approval by US Food and Drug Administration ("FDA") (contract value of []). The BARDA NuThraxTM Contract also included procurement options (exercisable by BARDA) for the delivery of an additional 7.5 million to 50 million doses of NuThraxTM to the SNS, with a contract value of approximately \$255 million up to approximately \$1.3 billion, and options (also exercisable by BARDA) for an additional clinical study and postmarketing commitments with a contract value of \$48 million.

On March 16, 2017, the Company and BARDA entered into a new agreement for the delivery of BioThrax[®] to the SNS in exchange for \$99.9 million ("BARDA BioThrax[®] Contract"). In connection with the signing of this agreement, the Company and BARDA also entered into a modification of the BARDA NuThraxTM Contract ("Modification to the BARDA NuThraxTM Contract"). The Modification to the BARDA NuThraxTM Contract (increased the number of doses of NuThraxTM to be delivered under the base period from 2.0 million to 3.0 million, with no additional consideration to be provided to the Company, resulting in an implied discount on the initial doses to be delivered. Additionally, the Modification to the BARDA NuThraxTM Contract included a discount on the sales price for doses to be procured during the option period of up to \$100 million.

Accounting Standards Codification ("ASC") 605-25-25-3 states "...separate contracts with the same entity or related parties that are entered into at or near the same time are presumed to have been negotiated as a package and shall, therefore, be evaluated as a single arrangement in considering whether there are one or more units of accounting." As the BARDA BioThrax[®] Contract and the Modification to the BARDA NuThraxTM Contract were entered into at the same time and the related terms of the agreements were negotiated as a package, the Company concluded that these concurrent agreements represent a single arrangement and the related timing and measurement of revenue recognition must be evaluated in accordance with ASC 605-25, *Revenue Recognition — Multiple-Element Arrangements*.

Identification of deliverables

The Company identified the following deliverables related to the multiple-element arrangement:

- Development services for the NuThrax[™] product candidate
- Delivery of BioThrax[®]

The Company concluded these deliverables have standalone value and therefore, represent separate units of accounting under ASC 605-25-25-5. In addition, the Company concluded that the incremental doses of NuThraxTM to be provided as part of the base period procurement and the reduction in price per dose in the optional procurement are significant and incremental discounts that need to be valued as elements of the arrangement.

The Company concluded that other elements identified within the multiple-element arrangement (i.e., initial and additional delivery of NuThraxTM doses, NuThraxTM post marketing commitment, and NuThraxTM clinical potency study) were substantive options or contingent deliverables and should be excluded from the initial measurement and allocation of the arrangement consideration.

The Company generally used the following criteria to determine whether an item should be presumed to be a deliverable:

- It is explicitly referred to as an obligation of the vendor in a contractual agreement.
- It requires a distinct action by the vendor.
- The vendor's failure to complete an action would result in significant contractual penalty.
- The inclusion or exclusion of the item in the arrangement reasonably would be expected to cause the arrangement consideration to vary by more than an insignificant amount.

<u>Development services for the NuThraxTM product candidate</u> – The Company concluded that the NuThraxTM development activities represented a deliverable. The Company is required to perform development activities as outlined in the executed contract and such activities require distinct action by the Company. Additionally, the consideration to be received for development activities is a substantial portion of the contractual consideration. If the Company fails to perform the development activities, it would not receive the consideration for that deliverable as stated in the contract, which would be a significant reduction in the total arrangement consideration. The consideration is received as the Company performs the development activities and invoices BARDA for its services.

<u>Delivery of BioThrax</u>[®] – The Company has identified the delivery of BioThrax[®] doses as a deliverable. The Company is obligated to provide BARDA with the BioThrax[®] doses per the executed contract. The manufacturing and delivery of the BioThrax[®] doses requires distinct action by the Company. Additionally, the consideration to be received for supplying the BioThrax[®] doses is approximately \$99.9 million. If the Company fails to provide the doses, there would be a significant reduction in the total arrangement consideration.

Initial delivery of NuThraxTM doses (base period) – The Company concluded that the initial delivery of NuThraxTM doses (base period) represented a contingent deliverable and that it should be excluded from the initial measurement and allocation. The Company believes it is appropriate to exclude a contingent deliverable from the initial measurement and allocation of the arrangement consideration if (1) considerable uncertainty exists about the outcome of the contingency and (2) the additional fee the customer would have to pay upon delivery of the contingent good or service is consistent with its estimated selling price. When these attributes are present, the contingent deliverable generally may be accounted for separately when the good or service is

delivered. In contrast, when considerable uncertainty exists about the outcome, but the additional fee is below the estimated selling price of the contingent good or service (or there is no additional fee), a significant and incremental discount may be present.

At inception of the modified arrangement, the NuThraxTM product candidate was undergoing phase II trials and had not yet been fully developed or received any regulatory approval (EUA pre-approval or FDA licensure). As NuThraxTM is not a licensed or EUA pre-approved product, there is development risk to the Company and uncertainty related to EUA pre-approval or FDA licensure of the product candidate. The initial delivery of NuThraxTM doses will only occur if NuThraxTM EUA pre-approval is obtained and there is considerable uncertainty regarding the outcome of this contingency. This uncertainty exists, in part, because to issue EUA pre-approval, a determination must be made that there is no adequate, approved, and available alternative to the product candidate for preventing, or treating the disease and the perceived benefits of the candidate must outweigh its potential risks. The standards for achieving FDA licensure are more difficult to meet. Therefore, the initial delivery of NuThraxTM doses is considered a contingent deliverable.

Although the initial delivery of NuThraxTM doses is considered to be a contingent deliverable, the Company determined that the discount attributed to the initial delivery of NuThraxTM doses (base period) is significant and incremental and should be considered as an element of the total arrangement. As part of the Modification to the BARDA NuThraxTM contract, the Company agreed to provide an additional 1 million doses for no incremental consideration (the total number of doses to be delivered increased from 2.0 million to 3.0 million but the total consideration remained the same, i.e., an additional 1 million doses with a selling price of [_] being provided for no additional consideration). The overall selling price associated with the free doses being provided indicates the discount is significant. As the Company did not have a history of selling NuThraxTM doses on a standalone basis, the Company used the price per dose from the BARDA NuThraxTM Contract as a proxy for a standalone selling price. The Company does not have a history of providing discounts to the USG on similar contracts with elements of development and/or product sales. Based on the aforementioned factors, the Company concluded this discount is significant and incremental.

Based on the above considerations, the Company concluded that the discount attributed to the initial delivery of NuThraxTM doses was an element of the arrangement to be evaluated at modification of the arrangement.

Additional delivery of NuThraxTM doses (option period), NuThraxTM post marketing commitment, and NuThraxTM potency study – The Company concluded that these were substantive options for additional deliverables in the future (also subject to the contingent deliverable considerations above in the case of additional delivery of NuThraxTM doses), i.e. the USG is not required to purchase additional products or services and the Company is not obligated under the option to deliver goods and services unless and until such time as the USG elects to exercise the option.

Similar to the conclusion reached above regarding the initial delivery of NuThraxTM doses, the Company concluded that the discount attributed to the additional delivery of NuThraxTM doses (option period) was also significant and incremental and should be considered as an element of the total arrangement.

For the post marketing commitment and the clinical potency study, with a contract value of approximately \$48 million, the Company concluded there were no significant and incremental discounts (the amount was determined based on the Company's history and experience with similar contracts with the USG) and therefore, the Company concluded these should not be accounted for as elements of the arrangement at inception.

Identification of units of accounting

After identifying the deliverables, the next step in applying the multiple-element arrangements guidance is to determine whether the deliverables should be accounted for as separate units of accounting. ASC 605-25-25-5 states:

"In an arrangement with multiple deliverables, the delivered item or items shall be considered a separate unit of accounting if both of the following criteria are met:

- The delivered item or items have value to the customer on a standalone basis. The item or items have value on a standalone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s).
- If the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in the control of the vendor."

<u>Development services for the NuThraxTM product candidate</u> – In regards to the first criterion of ASC 605-25-25-5, the Company concluded that the research and development services have standalone value. BARDA has the rights to all data created under the BARDA NuThraxTM Contract that could be used to direct the development of other anthrax products or biological products with similar characteristics to anthrax. The Company provides research and development under several contracts with the USG (whether or not related to NuThraxTM), which is also reflective of the fact that there is standalone value associated with the performance of development activities. The second criterion is not applicable as there is no general right of return associated with these services. Based on these factors, the Company concluded that the separability criteria have been met and the NuThraxTM development should be accounted for as a separate of unit of accounting.

<u>Delivery of BioThrax</u>[®] – BioThrax[®] is the only FDA approved active immunization for the prevention of anthrax disease. The Company has been manufacturing and supplying BioThrax[®] to the USG over several years. The Company believes that BARDA's ability to use the BioThrax[®] doses for its intended purpose without the receipt of the remaining deliverables (all related to NuThraxTM) indicate that the item has standalone value. BARDA is able to obtain the value intended from the BioThrax[®] doses when delivered and BARDA could have purchased BioThrax[®] doses on a standalone basis. The second criterion is not applicable as there is no general right of return associated with the BioThrax[®] doses. Based on these factors, the Company concluded that the separability criteria have been met and the delivery of BioThrax[®] doses should be accounted for as a separate of accounting.

As discussed above, the two discounts attributed to the initial and additional deliveries of NuThrax[™] are also considered elements of the arrangement to be accounted for at the inception of the arrangement.

Measurement and allocation of arrangement consideration, recognition, and classification

The next step is to measure the arrangement consideration and to allocate it to the units of accounting. The amount of allocable arrangement consideration is limited to amounts for noncontingent elements that are fixed or determinable. Accordingly, the allocable arrangement consideration includes \$99.9 million in consideration related to BioThrax[®] doses and [] for NuThraxTM development, which reflects the undelivered portion of NuThraxTM development at the time of the amendment (the nature of the development services was not modified, i.e., same services performed prior and subsequent to the modification). The Company determined the total consideration to be allocated to the elements of the arrangement to be [].

Management allocated the total consideration to each of the elements identified based on their relative selling price as follows:

[INFORMATION REDACTED]

The Company determined the selling price of the NuThraxTM development (using a cost build-up for internal and external costs, plus a specified mark-up) and the BioThrax[®] doses based on comparable deliverables offered in similar contracts the Company has with the USG. The Company determined the selling price of the discounts using an undiscounted probability adjusted model, which factored in the expected timing of regulatory approval for the NuThraxTM product candidate, expected levels of procurement of the NuThraxTM product candidate upon regulatory approval and the market conditions for these types of medical countermeasures.

For the NuThraxTM development, the Company recognizes as revenue the proportion of the arrangement consideration allocated to the development services as the development services are performed (akin to a proportional performance). For the delivery of BioThrax[®] doses, the Company recognizes as revenue the proportion of the arrangement consideration allocated to the delivery of BioThrax[®] doses as the deliveries occur. This results in differences between revenue recognized and the related invoiced amounts for both the NuThraxTM development services and the delivery of BioThrax[®] doses. This difference represents the proportion of the arrangement consideration allocated to the two discounts related to future deliveries of NuThraxTM doses and are deferred as the NuThraxTM development and the delivery of BioThrax[®] doses are performed. The deferred revenue balances will be recognized as revenue upon delivery of the NuThraxTM doses subject to the discounts or upon the future extinguishment of the Company's obligation to deliver NuThraxTM doses to which the discount applies.

Revenues related to the development services for the NuThraxTM product candidate and the delivery of BioThrax[®] are included in revenues - contracts and grants and revenues – product sales, respectively, in the Company's consolidated statements of operations.

Form 8-K Dated November 1, 2018

Exhibit 99

5. Please refer to Compliance and Disclosure Interpretations: Non-GAAP Financial Measures and specifically to the answers to questions 103.02 and 102.05. Tell us how your presentation of EBITDA and adjusted EBITDA on a per share basis complies with those answers.

In response to the Staff's comment, the Company respectfully confirms that in future presentations of EBITDA and adjusted EBITDA the Company will not present such metrics on a per share basis and will ensure it is adhering to *Compliance and Disclosure Interpretations: Non-GAAP Financial Measures*.

Form 10-Q for the Quarterly Period Ended September 30, 2018

<u>Notes to Condensed Consolidated Financial Statements</u> 2. Revenue Recognition

6. Regarding your adoption of ASU 2014-09, please:

- Tell us why the adoption of ASC 606 resulted in a \$42.4 million increase in deferred revenue liability.
- Tell us whether you applied the guidance to all contracts at the date of initial application or only to contracts that were not completed at the date of initial application. Refer to ASC 606-10-65-1.h.
- Tell us whether you applied the practical expedient for contract modifications referred to in ASC 606-10-65-1f(4) and, if so, whether you applied the guidance in ASC 606-10-65-1.g.
- Provide us the disclosures required by ASC 606-10-65-1.i. and tell us why you did not make these disclosures.

The Company advises the Staff that its adoption of ASC 606 resulted in a \$42.4 million increase in deferred revenue liability based on the application of the new accounting standard solely to its Centers for Innovation in Advanced Development and Manufacturing ("CIADM") contract with the USG. The difference in revenue recognized to date under ASC 605 vs. ASC 606 as of the adoption date was primarily attributable to the difference in the overall consideration or transaction price, resulting from different accounting treatment related to options within the contract and the inclusion of a significant financing component under ASC 606.

The CIADM contract was originally a 25-year arrangement entered into in 2012 to provide the USG with 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 diseases in response to public health emergencies. The contract consisted of an eight-year base period starting in June 2012. The contract also included 24 one-year options that commenced in June 2013 and allow the contract to ultimately be extended through June 2037 at the USG's discretion.

During the option years that began in June 2013, the arrangement included potential services under separate options which could be exercised by the USG (additional options). Such optional services included workforce development, maintenance of the manufacturing facility and equipment for that specific facility, performance of activities necessary to maintain the license for the pandemic influenza vaccine manufacturing capability, and other services as requested under separate task orders to be negotiated separately. In addition, in order to extend the contract the USG would also have to exercise an annual renewal option (annual option).

Beginning in June 2013, the Company was expected to be able to stand ready and be available to respond to the USG and importantly, to respond to any task orders that may be issued during the base period and additional option periods. Being able to stand ready to perform in the event of an outbreak is of importance to the USG and by entering into this arrangement with the Company, the USG expected to receive the benefit of having access to Company's readiness and its capability to immediately respond to public health threats. Prior to June 2013, the Company was performing fulfillment and set-up activities to be able to perform under the contract.

Subsequent to the end of the contractual base period in June 2020, in order to extend the contract, the USG would be required to exercise an annual option as the USG's failure to do so would terminate the contract.

The Company expected that the USG would exercise the annual options in order to extend the contract beyond 2020, as the exercises may take place for no incremental consideration. For example, the USG may exercise an annual option period from 2020-2021 to extend the contract and require the Company to stand ready, but not exercise individual additional options for services (e.g., workforce development). Therefore, the annual option period may be exercised for no additional consideration and although the Company may not perform any incremental services during that period, the Company would be still be expected to stand ready to respond to requests for any incremental services through other option exercises.

When analyzing the CIADM contract under ASC 606, the Company identified performance obligations as follows:

- one seven-year stand-ready performance obligation over the base period of the arrangement from June 2013 to June 2020.
- 17 individual annual option periods that include material rights from June 2020 to June 2037.

The Company concluded there was a promise by the Company to the USG to provide access to utilize the Company's development and production capabilities from June 2013 to June 2020, representing a performance obligation by the Company to stand ready to provide such services. The stand-ready obligation has provided the USG with the capacity and ability to produce medical countermeasures in a tight timeframe, which previously was not available to the USG. The Company is required to respond to options for additional services the USG can exercise in order to make use of the Company's production and research capabilities.

Due to the existence of the substantive penalty in the base period, the Company identified one 7 year stand-ready performance obligation during the base period. As discussed previously, the annual option period exercise is required to extend the contract subsequent to the end of the base period in June 2020 for no incremental consideration, which is indicative of a material right associated with each of the remaining 17 annual option periods. Therefore, the Company has also identified the 17 annual option period renewals, each with a material right, as separate performance obligations.

For the additional options to provide services, the Company concluded these options are not performance obligations as they are USG options and do not represent an enforceable right until the options are exercised by the USG. The Company also evaluated whether there was a material right associated with these options and concluded that no material right exists. The consideration the Company is entitled to receive by the customer exercising these options is consistent with the stand-alone selling price ("SSP") of the optional goods and services. Therefore, the Company concluded these options did not represent a performance obligation at inception of the contract.

Series considerations

ASC 606-10-25-14(b) defines as a second type of performance obligation — a promise to transfer to the customer a series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer under ASC 606-10-25-15:

"A series of distinct goods or services has the same pattern of transfer to the customer if both of the following criteria are met:

- Each distinct good or service in the series that the entity promises to transfer to the customer would meet the criteria in paragraph 606-10-25-27 to be a performance obligation satisfied over time.
- In accordance with paragraphs 606-10-25-31 through 25-32, the same method would be used to measure the entity's progress toward complete satisfaction of the performance obligation to transfer each distinct good or service in the series to the customer."

The Company determined that (a) the stand-ready obligation is satisfied over time as the USG simultaneously receives and consumes the benefits of the stand-ready service and (b) the same method would be used in measuring progress toward satisfaction. The Company concluded the identified stand-ready performance obligations represent a series of distinct services that are substantially the same and have the same pattern of transfer to the customer. Consistent with the FASB/IASB Joint Transition Resource Group for Revenue Recognition Memo No. 39, "If the nature of the entity's promise is the act of standing ready or providing a single service for a period of time (that is, because there is an unspecified quantity to be delivered), the evaluation would likely focus on whether each time increment, rather than the underlying activities, are distinct and substantially the same.....the Boards intended that a series could consist of distinct time increments (an hour of cleaning) or the good or service delivered (each unit of electricity), depending on the nature of the promise." With respect to the stand-ready promise in the contract, the Company is required to stand ready for a specified period of time to deliver an unspecified quantity of items. Although the products and services which may be purchased vary, the Company's actions to fulfill the stand ready performance obligation are substantially identical each day.

Determination of the transaction price

The Company determined the transaction price in accordance with ASC 606-10-32-1 through 3. As of the adoption date, the Company concluded the transaction price for the arrangement should be [] as of the adoption date comprised of the following:

- Consideration of \$163.2 million
- Significant financing component of []

The Company identified consideration of \$163.2 million comprised of all consideration it expects to receive associated with the base period activities.

In regards to the significant financing component, ASC 606-10-32-15 states:

"In determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract."

The Company evaluated and concluded the consideration to be received by the Company during the base period reflected a significant financing component. The Basis for Conclusions of ASU 2014-09 included the following paragraph related to the significant financing component:

"BC238. The Boards decided not to exempt an entity from accounting for the effects of a significant financing component for advance payments. This is because ignoring the effects of advance payments could substantially skew the amount and pattern of profit recognition if the advance payment is significant and the primary purpose of that payment is to provide financing to the entity. Consider the example in which an entity requires a customer to pay in advance for a long-term construction contract because the entity requires financing to obtain materials for the contract. If the entity did not require the customer to pay in advance, the entity would need to obtain the financing from a third party and, consequently, would charge the customer a relatively higher amount to cover the finance costs incurred. However, in either scenario the goods or services transferred to the customer are the same; it is only the party providing the financing to the entity that changes. Consequently, the entity's revenue should be consistent regardless of whether it receives the significant financing benefit from the customer or from a third party."

The Company evaluated the fact that there was a significant delay in the timing of the cash flows (up to \$163.2 million between 2013 and 2020 from the USG) and the period over which the USG expects to receive benefits from the stand ready performance obligation in return for that consideration (a 24 year period between 2013 and 2037) and concluded that this difference in timing implicitly provided the Company with a significant benefit of financing. Therefore, in accordance with ASC 606-10-32-16, the Company concluded that there is a significant financing component of the contract.

Based on the above considerations, the Company determined the transaction price to be [] as of the adoption date under ASC 606.

Allocation of the transaction price

ASC 606 generally requires the identified transaction to be allocated to the different performance obligations identified based on their relative SSP. However, ASC 606-10-55-45 provides an alternative to estimating the standalone selling price of an option:

"If a customer has a material right to acquire future goods or services and those goods or services are similar to the original goods or services in the contract and are provided in accordance with the terms of the original contract, then an entity may, as a practical alternative to estimating the standalone selling price of the option, allocate the transaction price to the optional goods or services by reference to the goods or services expected to be provided and the corresponding expected consideration. Typically, those types of options are for contract renewals."

The Company evaluated and concluded that the nature of the stand-ready services that are provided during the initial 7 year period and the subsequent 17 annual option periods are the same, and these services are in accordance with the terms of the original contract. Therefore, the Company determined the "renewal option approach" or the "look-through model" described above is an appropriate the Company concluded that total consideration should be allocated proportionately to each of the performance obligations based on the number of years.

Revenue recognition

ASC 606-10-25-27 states:

"An entity transfers control of a good or service over time and, therefore, satisfies a performance obligation and recognizes revenue over time, if one of the following criteria is met:

- a. The customer simultaneously receives and consumes the benefits provided by the entity's performance as the entity performs (see paragraphs 606-10-55-5 through 55-6).
- b. The entity's performance creates or enhances an asset (for example, work in process) that the customer controls as the asset is created or enhanced (see paragraph 606-10-55-7).
- c. The entity's performance does not create an asset with an alternative use to the entity (see paragraph 606-10-25-28), and the entity has an enforceable right to payment for performance completed to date (see paragraph 606-10-25-29)."

The Company evaluated the criteria above, concluding that it met the first criterion as it stands ready and maintains the capability to produce for the USG when and if needed. The Company performs its stand ready obligation to respond to requests made by the USG throughout the contract period, including the option years.

The Company considered the nature of the promised services to be transferred to the USG when determining the method to measure progress in accordance with ASC 606-10-25-33, which states:

"Appropriate methods of measuring progress include output methods and input methods. Paragraphs 606-10-55-16 through 55-21 provide guidance for using output methods and input methods to measure an entity's progress toward complete satisfaction of a performance obligation. In determining the appropriate method for measuring progress, an entity shall consider the nature of the good or service that the entity promised to transfer to the customer."

The Company evaluated the above guidance and concluded time elapsed would be the most appropriate measure of progress for the stand-ready performance obligation. As the Company's performance obligation is to provide access to its production capabilities continuously throughout the duration of the contract, a time-based measure resulting in straight-line revenue recognition would be proportionate to the Company's progress in satisfying the performance obligation over time.

Comparison to ASC 605

The exclusion of the separate additional options from the identified performance obligations at the inception of the arrangement under ASC 606 is different from the historical accounting treatment under ASC 605. Under ASC 605, the deliverables and the unit of accounting identified included all options throughout the 25 year term as the options were not deemed to be substantive due to several factors, one of which is the likelihood the USG would exercise the options as it would be economically compelled to do so. Under ASC 605, the Company had concluded the options were not substantive as the USG would incur a substantial economic penalty for its failure to exercise the options. Specifically, the USG was obligated to pay the Company \$163 million during the base period. After the eight year base period and the payment of \$163 million to the Company, it was concluded as unlikely that the USG would not exercise successive options to extend the contract through June 2037 for relatively minor consideration of [] per year (represents consideration related to additional optional goods and services identified in the contract).

In contrast, under ASC 606, an option is only identified as a performance obligation based on whether the option represents a material right. The new standard disregards the likelihood of the options being exercised arising from economic compulsion. Per the FASB/IASB Joint Transition Resource Group for Revenue Recognition ("TRG") Memo No. 48, if there are no contractual penalties (e.g., termination fees, monetary penalties for not meeting contractual minimums), TRG members generally agreed that, even if an entity may think that it is virtually certain (e.g., the customer is economically compelled) that a customer will exercise its option for additional goods and services, the entity should not identify the additional goods and services underlying the option as promised goods or services (or performance obligations) at contract inception. Only the option should be assessed to determine whether it represents a material right to be accounted for as a performance obligation. As a result, consideration that would be received for optional goods or services should not be included in the transaction price at contract inception.

Based on the above guidance, the Company concluded as the options identified above do not represent a material right, and the options should not be identified as performance obligations at contract inception under ASC 606 (note the distinction between annual option periods vs additional options for goods and services during the term of the contract). Therefore, under ASC 605, the Company had identified, as one unit of accounting, the overall service of being stand-ready for the duration of the contract including all annual option periods as well as the additional options for goods and services as promises within the contract. This resulted in different performance obligations/promised goods and services being identified as well as different overall transaction price under ASC 606 vs. ASC 605.

As the Company had identified one unit of accounting that included all additional options for goods and services within the contract, the Company determined the total consideration to be approximately [] under the contract at inception under ASC 605. This consideration is significantly higher than the transaction price of [] determined under ASC 606.

Under ASC 605, the Company had determined the related revenue should be recognized on a straight-line basis over the expected service period through June 2037 (up to the amount to be billed to the USG to date) as there was not a more discernible pattern of performance. This is consistent with the guidance provided in the Staff Accounting Bulletin Topic 13, which states "provided all other revenue recognition criteria are met, service revenue should be recognized on a straight-line basis, unless evidence suggests that the revenue is earned or obligations are fulfilled in a different pattern, over the contractual term of the arrangement or the expected period during which those specified services will be performed, whichever is longer."

The overall difference between revenue recognized since inception under ASC 606 and ASC 605 arises from the estimate of the total payments to be received. Under ASC 606, the total transaction price of [] is being recognized on a straight-line basis over the 24 year period, resulting in total revenue of [] recognized since inception as of the adoption date. Under ASC 605, the total revenue recognized to date was [] determined on total amount billed to date (which is less than the maximum revenue recognition of approximately [] based on a straight-line calculation). The aforementioned differences in performance obligations/promised goods and services being identified as well as differences in the overall transaction price under ASC 606 vs. ASC 605 resulted in a [] increase in deferred revenue liability as of the adoption date of January 1, 2018. The remaining difference of [] relates to the interest expense incurred to date related to the significant financing component under ASC 606 with a corresponding increase to deferred revenue liability.

In response to the Staff's question regarding the disclosure requirements per ASC 606-10-65-1.h, the Company adopted ASC 606 using the modified retrospective method and applied ASC 606 to contracts that were not completed as of January 1, 2018. The Company respectfully advises the Staff that it included the following language in its Form 10-Q for the three and nine months ended September 31, 2018: "The Company finalized the review of its portfolio of revenue contracts that were not complete as of the adoption date and made its determination of its revenue streams as well as completed extensive contract specific reviews to determine the impact of the new standard on its historical and prospective revenue recognition." The Company will include similar language in its Form 10-K filing for the year ended December 31, 2018.

The Company respectfully advises the Staff that it did not adopt ASC 606 using the full retrospective method and therefore it does not believe the literature in ASC 606-10-65-1.f is applicable to its adoption under the modified retrospective method.

The Company respectfully advises the Staff that its revenue recognition under ASC 606 in the nine months ended September 30, 2018 was not materially different than its revenue recognition under prior guidance during this period given the revenue recognition under ASC 605 for the CIADM contract was recognized on a straight-line basis up to cost incurred and the cost incurred in the nine months ended September 30, 2018 would have resulted in similar revenue recognition as compared to revenue recognized under ASC 606. Additionally, the Company had included the following text in Note 2 to its Form 10-Q for the nine months ended September 30, 2018 to comply with ASC 606-10-65-1.i: "For the three and nine months ended September 30, 2018, there was a nominal difference between revenues recognized under ASC 606 and revenues recognized based on the prior revenue recognition guidance for the same period." The Company advises the Staff that revenue recognized under the CIADM contract during the nine months ended September 30, 2018 was approximately \$6 million under ASC 606 compared to approximately \$9 million that would have been recognized under ASC 605, which is a difference of less than 1% of the Company's total revenues during the period.

7. Regarding your application of ASC 606, please address the following:

- For each type of performance obligation you have, tell us whether it is recognized over time or at a point in time and specifically how it is satisfied as well as the payment terms. For those recognized over time, tell us the method you use to recognize revenue and why it represents a faithful depiction of the transfer of the goods or services.
- In the third paragraph, you indicate that the Company's variable consideration primarily includes consideration transferred under its development contracts with the U.S. government as consideration received can vary based on developmental progression of the product candidate(s). Please tell us more specifically about why this consideration can vary and why you have not constrained it.
- In the fourth paragraph you indicate that revenue for long-term development contracts is generally recognized based upon the cost-to-cost measure of progress, provided that the Company meets the criteria associated with transferring control of the good or service over time. Please tell us about any exceptions to your general recognition policy.
- Regarding your disclosure in the eighth paragraph, tell us why with reference to authoritative literature it is appropriate to recognize revenue for the CIADM contract with Barda on a straight- line basis.
- Regarding your disclosure in the ninth paragraph, provide us an analysis with reference to authoritative literature that supports your accounting for the modification of the CIADM contract that reduced the optional periods to seven as a termination and creation of a new contract to be accounted for prospectively.

The Company respectfully advises the Staff that the performance obligations within its contracts and related revenues are generally recognized as follows:

Performance obligations recognized at a point in time:

The Company recognizes performance obligations for its product sales and contract manufacturing contracts at a point in time when the title and risk of loss transfers to the customer and the customer has the significant risks and rewards of ownership. This transfer generally occurs once the product has been shipped to the customer and in many cases once the product has passed the customer's quality control process to ensure the product meets the required specifications.

The Company evaluates its product sales contracts and contract manufacturing contracts by analyzing the criteria under ASC 606-10-25-27.

The Company determined that its product sales do not meet any of the criteria defined under ASC 606-10-25-27 to recognize revenue over time as the customer:

- Does not receive or consume the benefits provided by the Company's performance as the Company performs, rather only receives benefit from the product once title and risk of loss is transferred to the customer.
- The Company's performance does not create or enhances an asset that the customer controls as the asset is created or enhanced.
- The Company does not have an enforceable right to payment for its product sales until the title and risk of loss is transferred to the customer.

The Company has determined its contract manufacturing contracts do not meet the criteria under ASC 606-10-25-27 as:

- the customer does not simultaneously receive and consume the benefits provided by the Company's performance. The customer begins to benefit when the product has passed the Company's quality control process to validate that the activities performed by the Company has met the customer's specifications;
- the Company's performance does not create or enhance an asset that the customer controls as the Company owns and controls all activities it is performing for the customer until the quality control process is completed; and
- the Company's performance does not create an asset with alternative use to the customer as the Company's performance occurs using the

precise specifications provided by the customer and the Company does not have an enforceable right to payment until it completes its performance under the contract based on the specifications provided by the customer. Additionally, partial performance by the Company would not result in useful product to the customer given the methods of production and regulated environment of the products.

As a result, the Company recognizes revenue on its product sales and contract manufacturing contracts, based on ASC 606-10-25-30, at the point the customer benefits from the Company's performance and the Company has an enforceable right to payment.

Performance obligations recognized over time:

The Company's development contracts generally are cost plus fixed fee arrangements, which the Company treats as a single performance obligation with variable consideration. The Company has determined that its development contracts meet criteria in ASC 606-10-25-27(a) as the customer does simultaneously receive and consume the benefits provided by the Company's performance. The Company's customers have real-time access to the data and results produced via monthly, quarterly and annual reports. In addition, the Company does have an enforceable right to payment under the Federal Acquisition Regulation ("FAR") for services provided to the USG. The Company recognizes revenue on its development contracts as it performs services for the customer under those contracts by measuring the progress toward complete satisfaction of the related performance obligation (with the exception of the CIADM contract as explained in response #6 above.) The Company uses the input method using costs incurred to measure such progress as the customer has the benefit of access to the development research under these projects and therefore benefits from the Company's performance incrementally as research and development activities occur under each project.

On a quarterly basis, the Company evaluates its contracts that have variable consideration to determine if any constraint on the variable consideration is necessary per ASC 606-10-32-12. Consideration received under the Company's development contracts, which are primarily cost plus fixed fee contracts, with the USG is variable depending on the level of cost required to complete the development activities for the customer. As of September 30, 2018, the Company evaluated and concluded no constraint would be necessary on the variable consideration. There was low uncertainty about the amount of variable consideration as the consideration reflected a cost build-up for internal and external costs, plus a specified mark-up. The Company has extensive history with performing services for the USG by preparing a cost-based budget to determine the total consideration for its USG contracts. The Company's experience with other cost-plus arrangements is that it has historically used all available and approved funding. Based on the current status of the development projects and the expectation that the Company will perform the required development services and collect the consideration in full, the Company concluded it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and no constraint was necessary on the variable consideration as of September 30, 2018. The Company performs similar analysis on variable consideration and the related constraint (or lack thereof) at each reporting period.

The Company respectfully refers to the Staff to its response to question #6 above for an explanation of its straight-line revenue recognition under the CIADM contract.

In September 2018, the Company and the USG modified the CIADM contract which cancelled option periods 15 to 24 thereby shortening the total life of the contract to 15 years from its original 25-year length. As mentioned in response #6 above, the CIADM contract is a series of distinct services provided to the customer over the option periods in the contract, i.e., the services to be provided before and after the modification are distinct. The modification is a reduction of services and therefore the modification was not accounted for as a separate contract in accordance with ASC 606-10-25-12. As such, per ASC 606-10-25-13(a), the Company accounted for the modification as if it were a termination of the existing contract, and the creation of a new contract, as the remaining services were distinct from the services transferred on or before the date of the modification. The modification resulted in the same revenue recognition analysis as the analysis for the initial arrangement discussed in response #6 above, but with a revised transaction price to reflect the remaining services as of the modification date, with different straight-line revenue amount being recognized prospectively.

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.

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