## News Release



## FOR IMMEDIATE RELEASE

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Emergent BioSolutions Submits sBLA for FDA Approval of Large-Scale Manufacturing of BioThrax in Building 55

**GAITHERSBURG**, **Md.**—**April 18**, **2016**—Emergent BioSolutions Inc. (NYSE:EBS) today announced that it has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of the manufacture of BioThrax<sup>®</sup> (Anthrax Vaccine Adsorbed) in Building 55, the company's large-scale manufacturing facility. The sBLA is supported by data that demonstrate that BioThrax manufactured at large scale in Building 55 is comparable to BioThrax manufactured in the currently-licensed facility. This submission follows the company's successful completion of the re-analysis of data from one of more than 30 comparability assays for BioThrax manufactured in the new facility as requested by FDA.

"Emergent is pleased to have reached this significant milestone in our BioThrax comparability program. Anticipating that a typical FDA review of such a submission is four months, we expect the review process to be completed in the fall of this year," said Adam Havey, executive vice president and president, biodefense division at Emergent BioSolutions. "We believe that our submission conveys the robustness of our large-scale manufacturing process, the comparable product attributes, and the efficacy and consistency of the product from our new facility, supported by a variety of developmental and pivotal nonclinical studies. This milestone reflects many years of steadfast dedication from our project team and their effective collaboration with the U.S. government."

BioThrax is the only FDA-licensed vaccine indicated for both pre-exposure and post-exposure prophylaxis of anthrax disease. Since 2001, the company has been supplying BioThrax to the Strategic National Stockpile to support the U.S. government's biosecurity and preparedness efforts. Building 55 has the potential to expand manufacturing capacity of BioThrax to an estimated 20 to 25 million doses annually from the seven to nine million doses produced annually out of the currently-licensed facility. The capability to manufacture BioThrax at large scale positions the company to meet the government's desire of stockpiling 75 million doses of a licensed anthrax vaccine.

This program is fully funded at \$104 million under contract number HHSO100201000034C by the Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

## **About Emergent BioSolutions**

Emergent BioSolutions is a global specialty biopharmaceutical company dedicated to one simple mission—to protect and enhance life. We develop, manufacture, and deliver a portfolio of medical





countermeasures for biological and chemical threats as well as emerging infectious diseases. We also develop and commercialize therapeutics and other specialty products for hospitals and clinics in the areas of hematology/oncology, transplantation, infectious diseases and autoimmune disorders. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025. Additional information about the company may be found at <a href="https://www.emergentbiosolutions.com">www.emergentbiosolutions.com</a>. Follow us @emergentbiosolu.

## **Safe Harbor Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our strategy, future operations, prospects, plans, objectives, and any other statements containing the words "believes," "expects," "anticipates," "intends," "plans," "estimates" and similar expressions, are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the timing of and our ability to obtain and maintain approval for Building 55; appropriations for BioThrax procurement; our ability to obtain new BioThrax sales contracts or modifications to existing contracts; and our manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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