## News Release



#### FOR IMMEDIATE RELEASE

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# EMERGENT BIOSOLUTIONS AND FDA FINALIZE COMPARABILITY PROTOCOLS ENABLING MANUFACTURING OF BIOTHRAX CONSISTENCY LOTS IN BUILDING 55

**ROCKVILLE, MD—April 22, 2014**—Emergent BioSolutions Inc. (NYSE: EBS) today announced that it has initiated manufacturing of BioThrax® (Anthrax Vaccine Adsorbed) consistency lots in Building 55, following review by the U.S. Food and Drug Administration (FDA) of the Manufacturing and Non-Clinical Study Protocols submitted by the company supporting the Building 55 comparability program. The goal of the comparability program is to generate data that will show BioThrax manufactured at large scale in Building 55 is comparable to the BioThrax currently manufactured in the approved facility, Building 12. BioThrax is the only FDA-licensed vaccine for the prevention of anthrax disease.

"Emergent is pleased to have reached an agreement with FDA that now enables the final steps towards securing approval of Building 55 for large scale manufacturing of BioThrax. This progress could not have been achieved without the successful collaboration between the company, FDA, and BARDA," said Adam Havey, executive vice president and president, biodefense division at Emergent BioSolutions. "This multi-year effort to expand our manufacturing capability is intended to address the U.S. Government's stated need for this critical medical countermeasure in the Strategic National Stockpile. We look forward to our continued partnership with the government to bring this program to completion."

The Manufacturing and Non-Clinical Study Protocols reviewed with FDA specify the criteria by which product manufactured in Building 55 will be determined as comparable to BioThrax currently produced in Building 12. The company has initiated manufacturing consistency lots of BioThrax in Building 55 to demonstrate comparability and for use in the pivotal non-clinical study, which is scheduled to begin this year. Data from this non-clinical study, together with the comparability data from these consistency lots, will be used to support a Prior Approval Supplement to the BioThrax licensed BLA for the approval of Building 55.

Building 12 produces 7 to 9 million doses of BioThrax annually. Building 55 has the potential to triple manufacturing capacity to an estimated 20 to 25 million doses annually. Both facilities are located on Emergent's Lansing, Michigan campus.

This program is fully funded under contract number HHSO100201000034C, in the amount of up to \$107 million, provided by the Biomedical Advanced Research and Development Authority (BARDA)

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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 specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at <a href="https://www.emergentbiosolutions.com">www.emergentbiosolutions.com</a>. Follow us @emergentbiosolu.

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#### **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 and objectives of management, 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 appropriations for BioThrax® procurement; our ability to obtain new BioThrax sales contracts or modifications to existing contracts; our plans to pursue label expansions and improvements for BioThrax; availability of funding for our U.S. government grants and contracts; the timing of and our ability to obtain and maintain approval for Building 55; 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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