



## **Emergent BioSolutions Receives FDA Approval Extending Shelf Life of BioThrax (Anthrax Vaccine Adsorbed) to 4 Years**

June 10, 2009

**Emergent entitled to approximately \$30 million from HHS for prior deliveries to the Strategic National Stockpile; amount expected to be recognized as revenue in 2Q 2009 FDA approval triggers BioThrax price increase for future deliveries under HHS procurement contracts HHS follow-on procurement contract for the delivery of 14.5 million doses now based on an increased price per dose and valued at \$405 million**

ROCKVILLE, Md.--(BUSINESS WIRE)--Jun. 10, 2009-- Emergent BioSolutions Inc. (NYSE:EBS) announced today that its flagship product, BioThrax® (Anthrax Vaccine Adsorbed), has been granted a shelf life extension from 3 to 4 years by the U.S. Food and Drug Administration (FDA). Based on this approval, Emergent has achieved a contract milestone warranting a payment of approximately \$30 million for doses previously delivered to the Strategic National Stockpile (SNS) under the terms of the company's existing BioThrax procurement contracts with the Department of Health and Human Services (HHS). This amount is expected to be recognized as revenue in the second quarter of 2009. In addition, FDA approval of 4-year expiry dating results in an immediate price increase for the future delivery of BioThrax doses under the current contract as well as under the follow-on multi-year contract, valued at \$405 million, for the delivery of 14.5 million doses of BioThrax.

"We are pleased that the FDA has approved the 4-year expiry dating of BioThrax as this extends the ability of the U.S. government to store our product in the nation's Strategic National Stockpile," said Fuad El-Hibri, chairman and chief executive officer of Emergent BioSolutions. "This is a critically important product feature that we believe will increase the attractiveness of BioThrax to the U.S. government as it increases BioThrax's lifecycle value. We are continuing our efforts to further enhance the attributes of BioThrax, including research towards a further reduction in the vaccination schedule and an expanded label indication for post-exposure prophylaxis. We believe these enhancements, if approved, will advance the U.S. government's preparedness efforts in response to anthrax as a potential weapon of bioterrorism."

Emergent has been pursuing a number of BioThrax product enhancements over the past several years. In addition to FDA approval of 4-year dating for BioThrax, in December 2008, Emergent received FDA approval of a reduced vaccination regimen to a five-dose schedule and a change to an intramuscular route of administration. Emergent continues to research additional enhancements to BioThrax such as a possible further reduction in the vaccination regimen and a potential label expansion to include use as a post-exposure prophylaxis.

To date, Emergent has supplied over 33 million doses of BioThrax to the U.S. government, with additional deliveries to the SNS scheduled through the third quarter of 2011.

### **About BioThrax**

BioThrax is the only FDA-licensed vaccine for the prevention of anthrax infection. It is indicated for the active immunization of adults who are at high risk of exposure to anthrax. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis*. Since 1998, the U.S. government has procured nearly 33.5 million doses of BioThrax. During that time period, more than 8.7 million doses have been administered to more than 2.2 million military personnel. For full FDA-approved prescribing information, please visit [www.biothrax.com/prescribinginformation\\_biothrax\\_us.pdf](http://www.biothrax.com/prescribinginformation_biothrax_us.pdf).

### **Important Information About BioThrax®**

The most common (>10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema and arm motion limitation. The most common (>5%) systemic adverse reactions were muscle aches, fatigue and headache. Serious allergic reactions, including anaphylactic shock, have been observed during post-marketing surveillance in individuals receiving BioThrax.

Pregnant women should not be vaccinated unless the potential benefits of vaccination have been determined to outweigh the potential risk to the fetus. If BioThrax is used during pregnancy, or if the patient becomes pregnant during the immunization series, the patient should be apprised of the potential hazard to the fetus. This product should be administered with caution to persons with a possible history of latex sensitivity since the vial stopper contains dry natural rubber.

Vaccination with BioThrax should be avoided by individuals with a history of anaphylactic or anaphylactic-like reaction following a previous dose of BioThrax.

BioThrax is not licensed for use in a post-exposure setting. The safety and efficacy of BioThrax have not been established in pregnant women, nursing mothers, pediatric populations or geriatric populations.

BioThrax may not protect all individuals vaccinated, particularly patients with impaired immune responses due to congenital or acquired immunodeficiency, or immunosuppressive therapy. Individuals are not considered protected until they have completed the full vaccination series.

### **About Emergent BioSolutions Inc.**

Emergent BioSolutions Inc. is a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and

therapeutics that assist the body's immune system to prevent or treat disease. Emergent's marketed product, BioThrax (Anthrax Vaccine Adsorbed), is the only vaccine licensed by the U.S. Food and Drug Administration for the prevention of anthrax. Emergent's development pipeline includes programs focused on anthrax, botulism, tuberculosis, typhoid, hepatitis B and chlamydia. Additional information may be found at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com).

#### **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, future financial position, future revenues, projected costs, prospects, plans and objectives of management, including any potential future securities offering, our expected revenue growth and net earnings for 2009, and any other statements containing the words "believes", "expects", "anticipates", "plans", "estimates" and similar expressions, are forward-looking statements. 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; our plans to pursue label expansions and improvements for BioThrax®; our plans to expand our manufacturing facilities and capabilities; our ongoing and planned development programs, preclinical studies and clinical trials; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 and subsequent reports filed with the SEC. The company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

BioThrax is a registered trademark of Emergent Biodefense Operations Lansing Inc.

Source: Emergent BioSolutions Inc.

#### **Emergent BioSolutions Inc.**

##### **Investors Contact:**

Robert G. Burrows  
Vice President, Investor Relations  
**301-795-1877**

[BurrowsR@ebsi.com](mailto:BurrowsR@ebsi.com)

or

##### **Media Contact:**

Tracey Schmitt  
Vice President, Corporate Communications  
**301-795-1800**

[SchmittT@ebsi.com](mailto:SchmittT@ebsi.com)