
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 20, 2023

EMERGENT BIOSOLUTIONS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33137
(Commission File Number)

14-1902018
(IRS Employer
Identification No.)

**400 Professional Drive, Suite 400,
Gaithersburg, Maryland 20879**

(Address of principal executive offices, including zip code)

(240) 631-3200

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.001 per share	EBS	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On July 20, 2023, Emergent BioSolutions Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration approved CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. A copy of the Company’s press release is attached hereto as Exhibit 99.1.

The information contained in this Item 7.01 shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing, under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Emergent BioSolutions Inc. on July 20, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EMERGENT BIOSOLUTIONS INC.

Dated: July 21, 2023 By: _____ /s/ RICHARD S. LINDAHL

Name: Richard S. Lindahl
Title: Executive Vice President, Chief Financial
Officer and Treasurer

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Emergent BioSolutions Receives U.S. FDA Approval of CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, a Two-Dose Anthrax Vaccine for Post-Exposure Prophylaxis Use

- Emergent has been delivering CYFENDUS™ vaccine to the U.S. Department of Health and Human Services since 2019, under pre-Emergency Use Authorization status, and will continue to work with the U.S. government to transition to post-approval procurement

GAITHERSBURG, Md.—July 20, 2023—Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) has approved CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, for post-exposure prophylaxis of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. The efficacy of CYFENDUS™ vaccine for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax.

“The approval of CYFENDUS™ vaccine is symbolic of Emergent’s longstanding partnership with the U.S. government and our shared commitment to helping protect public health,” said Dr. Kelly Warfield, Emergent’s senior vice president, science and development. “The 20-year journey from early development to approval is a major milestone that attests to Emergent’s scientific and technical prowess and partnering capabilities. We are grateful for the yearslong collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and early support from the Defense Advanced Research Projects Agency (DARPA) and the National Institute of Allergy and Infectious Diseases (NIAID). Congratulations to the Emergent team and all our partners for advancing this product to approval.”

“CYFENDUS™ vaccine is a component of the U.S. government’s preparedness efforts against anthrax, which remains a high-priority national security threat due to its ability to be easily disseminated, lethality, and potential for major public health impact,” said Paul Williams, Emergent’s senior vice president, products business. “The approval of the CYFENDUS™ vaccine demonstrates what effective public-private partnerships can achieve for national security. Emergent will continue to work closely with the U.S. government to transition this product to post-approval procurement while ensuring an uninterrupted supply of this important vaccine.”

CYFENDUS™ vaccine is comprised of Anthrax Vaccine Adsorbed (AVA) and an additional adjuvant. It has been demonstrated that by using an additional adjuvant, two doses administered over 14 days elicit protective levels of immune response, which can be especially important in response to a large-scale public health emergency involving anthrax. In December 2018, CYFENDUS™ vaccine was the subject of a pre-emergency use authorization package submitted to the FDA. The following year, the U.S. government began procuring this product for national preparedness efforts.

In addition to the CYFENDUS™ vaccine, Emergent’s anthrax franchise includes the BioThrax® vaccine, which will continue to serve a critical purpose, as well as two treatments, Anthrasil® [Anthrax Immune Globulin Intravenous (human)], a polyclonal antibody therapeutic, and raxibacumab, a monoclonal antibody therapeutic.

The FDA approval of CYFENDUS™ vaccine is based on data from a series of studies supported by the U.S. government and conducted by Emergent, including:

- a pivotal Phase 3 clinical study that evaluated the lot consistency, immunogenicity, and safety of the vaccine following a two-dose schedule administered intramuscularly in healthy adults,
- a Phase 2 study that evaluated non-interference between the vaccine and antibacterial drugs approved for post-exposure prophylaxis of anthrax disease, and
- non-clinical studies that assessed protective efficacy of the vaccine against lethal challenge with anthrax spores and helped identify neutralizing antibody levels associated with protection against disease.

The Biologics License Application submission and attainment of product licensure were completed under contract number HHSO100201600030C for the advanced development and delivery of CYFENDUS™ vaccine, funded by BARDA, within the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services. Early-stage development funding was also provided by NIAID, part of the National Institutes of Health, and DARPA of the U.S. Department of Defense.

About CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted)

Indication

CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted) is a vaccine indicated for post-exposure prophylaxis of anthrax disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when given with recommended antibacterial drugs.

The efficacy of CYFENDUS™ vaccine for post-exposure prophylaxis (PEP) is based solely on studies in animal models of inhalational anthrax.

Important Safety Information

Contraindication: Do not take CYFENDUS™ vaccine if you are allergic to CYFENDUS™ vaccine, BioThrax® (Anthrax Vaccine Adsorbed) or any ingredient of the vaccine.

Allergic reactions: Appropriate medical treatment and supervision must be available after receiving CYFENDUS™ vaccine to manage possible serious allergic reactions. Get medical help right away if you have any symptoms of a serious allergic reaction.

Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to CYFENDUS™ vaccine.

Pregnancy: CYFENDUS™ vaccine can cause fetal harm when administered to a pregnant individual. Before getting CYFENDUS™ vaccine, tell your healthcare provider if you may be pregnant, plan to get pregnant soon, or are nursing a baby.

Adverse reactions: The most common adverse reactions reported were tenderness, pain, warmth, itching, swelling, redness, bruising, arm motion limitations, muscle aches, tiredness, headache, and fever.

U.S. Prescribing Information

The full Prescribing Information for CYFENDUS™ vaccine can be found [here](#). If it is not currently available via this link, it will be visible as soon as possible as the company works to finalize the document. Please check back for the full information shortly.

About Emergent BioSolutions

At Emergent, our mission is to protect and enhance life. For over 20 years, we've been at work defending people from things we hope will never happen—so we are prepared, just in case they ever do. We provide solutions for complex and urgent public health threats through a portfolio of vaccines and therapeutics that we develop and manufacture for governments and consumers. We also offer a range of integrated contract development and manufacturing services for pharmaceutical and biotechnology customers. To learn more about how we plan to protect or enhance 1 billion lives by 2030, visit our [website](#) and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

Safe Harbor Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the development, availability, and government procurement of CYFENDUS™ vaccine and the continued development of Emergent's anthrax franchise, are forward-looking statements. We generally identify forward-looking statements by using words like “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “should,” “will,” “would,” and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. 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. Readers should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Readers 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. Readers should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the U.S. Securities and Exchange Commission, when evaluating our forward-looking statements.

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