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): August 29, 2024

EMERGENT BIOSOLUTIONS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33137**	**14-1902018**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

300 Professional Drive,
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, $0.001 par value 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 August 29, 2024, Emergent BioSolutions Inc. ("Emergent") issued a press release containing the announcement described below. A copy of this press release is attached as Exhibit 99.1 to this Current Report and incorporated herein by reference.

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 8.01. Other Events.

On August 29, 2024, Emergent announced U.S. Food and Drug Administration approval of Emergent's supplemental Biologics License Application for the expansion of the indication for ACAM2000® (Smallpox and Mpox (Vaccinia) Vaccine, Live), to include immunization for the prevention of mpox disease in individuals determined to be at high risk for mpox infection. This approval follows Emergent's announcement that it filed an Expression of Interest with the World Health Organization ("WHO") for the WHO's assessment of ACAM2000® vaccine to be added as an Emergency Use Listing in connection with the mpox outbreak.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press release issued by Emergent BioSolutions Inc. on August 29, 2024.
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: August 29, 2024 By: /s/ RICHARD S. LINDAHL

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

Emergent BioSolutions' ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live) Receives U.S. FDA Approval for Mpox Indication; Public Health Mpox Outbreak Continues Across Africa & Other Regions

GAITHERSBURG, Md., August 29, 2024 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for the expansion of the indication for ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live) to include prevention of mpox disease in individuals determined to be at high risk for mpox infection. The approval is based on previously available human safety data and data from a well-controlled animal study in which ACAM2000® vaccine was shown to be effective in protecting against mpox virus exposure.

ACAM2000® is a single-dose vaccine administered percutaneously via a bifurcated needle that is dipped into the vaccine solution and the skin is pricked several times in the upper arm with a droplet of the vaccine.

The vaccine was first approved by the FDA in 2007 for active immunization for the prevention of smallpox disease in individuals determined to be at high risk for smallpox infection. Mpox, previously called monkeypox, is an infectious disease endemic to central and west Africa caused by the double-stranded DNA mpox virus. The virus is a member of the Orthopoxvirus genus in the Poxviridae family, related to the virus which caused smallpox, which was eradicated in 1980.

"The FDA approval of ACAM2000® for immunization against mpox in high-risk individuals further strengthens and broadens our industry-leading smallpox portfolio, which includes VIGIV® and TEMBEXA®, said Joe Papa, president and CEO of Emergent. "This expanded indication for ACAM2000® comes at a critical time as the global health community comes together to ensure an effective and cohesive response to the recent upsurge in mpox cases. Emergent is poised to support the global response needed by actively engaging with world health leaders, as well as deploying product currently available in inventory based on the needs, as well as the ability to increase supply."

This approval follows Emergent's announcement that it filed an Expression of Interest (EOI) with the World Health Organization (WHO) for the WHO's assessment of ACAM2000® vaccine to be added as an Emergency Use Listing in connection with the mpox outbreak. Emergent also is in discussions with other global public health leaders to help address the current mpox outbreak in response to the WHO's Director-General's August 14 statement declaring that the upsurge of mpox is a public health emergency of international concern under the International Health Regulations. As part of its support to the response, Emergent announced that it will donate 50,000 doses of ACAM2000® for potential deployment across impacted countries in Central Africa.

"Mpox has progressed to become an uncontrolled epidemic in Africa — prompting the WHO to declare a second public health emergency of international concern — creating an enormous need to use all effective tools to extinguish it as a threat," said Dr. Amesh A. Adalja, FIDSA FACP FACEP & health security and emerging infectious diseases expert, Johns Hopkins Center for Health Security. "ACAM2000®, a direct descendant of the Jenner vaccine (humanity's first) which was used to eradicate smallpox, and now with the broadened indication, will be an invaluable tool in this endeavor."

In 2022, the world experienced a global outbreak of clade II mpox, which led to more than 95,000 cases across 115 non-endemic countries.

The clade I variant of mpox is characterized by more severe clinical outcomes and a higher case fatality rate. The recently identified clade Ib variant, exhibiting enhanced transmissibility through close contact, has led to an increase in cases, particularly in Central Africa, and a sizable impact on children and families. According to the WHO, clade I mpox tends to cause a higher number of severe infections and have a higher mortality rate than clade II mpox.

About ACAM2000®, (Smallpox and Mpox (Vaccinia) Vaccine, Live)

ACAM2000® is the primary smallpox vaccine designated for use in a bioterrorism emergency, with doses having been supplied to the U.S. Strategic National Stockpile. ACAM2000® is also licensed in Canada, Australia and Singapore and is currently stockpiled both in the U.S. and internationally.

ACAM2000® is indicated in the U.S. for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox and mpox infection.

The labeling for ACAM2000® contains a contraindication for individuals with severe immunodeficiency. Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur in persons with weakened immune systems. Individuals with severe immunodeficiency who are not expected to benefit from the vaccine should not receive ACAM2000®. The risk for experiencing severe vaccination complications must be weighed against the risk for experiencing a potentially severe or fatal smallpox or mpox infection.

Additionally, there are warnings and precautions for myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinial skin infections, erythema multiforme major (including Stevens-Johnson Syndrome), eczema vaccinatum resulting in permanent sequelae or death, accidental eye infection (ocular vaccinia), which can cause ocular complications that may lead to blindness, and fetal death. These have occurred following either primary vaccination or revaccination with live vaccinia virus vaccines, including ACAM2000®. These risks are increased in certain individuals and may result in severe disability, permanent neurological sequalae and/or death.

Please see the Prescribing Information for ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live) Vaccine for full Boxed Warning and additional safety information.

The full U.S. Prescribing Information for ACAM2000® (Smallpox and Mpox (Vaccinia) Vaccine, Live) 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 25 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 help protect public health, visit our website and follow us on LinkedIn, X, Instagram, Apple Podcasts and Spotify.

Safe Harbor Statement

This communication 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 expected timing for delivery of the ACAM2000® vaccine and Emergent's ability to increase inventories of ACAM2000® vaccine to meet requested levels within specified time frames, if needed, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future," "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target," "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 based on information that is currently available. 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 statements. Any forward-looking statement speaks only as of the date of this communication and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by any forward-looking statements. Readers should consider this cautionary statement, as well as the risk factors and other disclosures included in our periodic reports filed with the Securities and Exchange Commission, when evaluating our forward-looking statements.

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