

**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): December 12, 2025

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.)

**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 December 12, 2025, Emergent BioSolutions Inc. (the “Company”) issued a press release regarding the Company’s receipt of U.S. Food and Drug Administration approval for drug product manufacturing of raxibacumab at the Company’s Winnipeg manufacturing site, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Emergent BioSolutions Inc. on December 12, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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: December 12, 2025

By: /s/ RICHARD S. LINDAHL

Name: Richard S. Lindahl

Title: Executive Vice President, Chief Financial
Officer and Treasurer

Emergent BioSolutions Receives U.S. FDA Approval for Drug Product Manufacturing of raxibacumab at its Winnipeg, Canada Site

GAITHERSBURG, Md., December 12, 2025 (GLOBE NEWSWIRE) – Emergent BioSolutions (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) has approved its supplemental Biologics License Application (sBLA) for its Winnipeg, Canada facility to be added as the drug product manufacturing and testing site for raxibacumab, a monoclonal antibody for the treatment and prophylaxis of inhalational anthrax.

“We are pleased with the U.S. FDA approval of our sBLA for raxibacumab manufacturing at Emergent’s USMCA-compliant site in Winnipeg,” Joe Papa, president and CEO, Emergent. “This regulatory action further supports the advancement of our multi-year transformation strategy by building a flexible, streamlined and customer-focused manufacturing network. We will continue to take actions that progress our key turnaround priorities toward driving long-term and sustainable growth.”

This approval follows Emergent’s May 2024 [announcement](#) of a new operational plan to consolidate its manufacturing sites and concentrate operations in Winnipeg, Canada and Lansing, Michigan as part of its multi-year turnaround and transformation strategy. Emergent’s Winnipeg facility has over 45 years of experience developing and manufacturing preclinical to commercial therapeutics. Through this facility, Emergent maintains drug substance, fill/finish, and analytical testing capabilities to support the manufacturing of its medical countermeasures portfolio, as well as capacity for strategic manufacturing partnerships.

Indication and Select Important Safety Information for raxibacumab Injection

Indication raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.

Limitations of Use: The effectiveness of raxibacumab is based solely on efficacy studies in animal models of inhalational anthrax. There have been no studies of raxibacumab in the pediatric population; dosing in pediatric patients was derived using an extrapolation approach.

Important Safety Information

Warning: Hypersensitivity and Anaphylaxis

Hypersensitivity reactions, including anaphylaxis, have been reported during or after the administration of raxibacumab by intravenous infusion. Administer raxibacumab by intravenous infusion in monitored settings where appropriate equipment, medication (including epinephrine), and personnel trained in the management of hypersensitivity, anaphylaxis, and shock are available.

Adverse Reactions: Common adverse reactions in healthy adult subjects ($\geq 1.5\%$) were injection site reaction, erythema and pain, headache, rash, pain in extremity, pruritus, and somnolence.

To report Suspected Adverse Reactions, contact Emergent BioSolutions at 1-800-768-2304 or medicalinformation@ebsi.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full [Prescribing Information](#) for raxibacumab for additional safety information.

About Emergent BioSolutions At Emergent, our mission is to protect and save lives. For over 25 years, we've been at work preparing those entrusted with protecting public health. We deliver protective and life-saving solutions for health threats like smallpox, mpox, botulism, Ebola, anthrax and opioid overdose emergencies. To learn more about how we help prepare communities around the world for today's health challenges and tomorrow's threats, 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 raxibacumab manufacturing at our Winnipeg manufacturing site, capacity for strategic manufacturing partnerships, our multi-year transformation strategy, and actions to progress our key turnaround priorities 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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