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): October 5, 2023

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.)

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 8.01. Other Events

On October 5, 2023, Emergent BioSolutions Inc. (the "Company") issued a statement announcing recent communications it received from the U.S. Food and Drug Administration (the "FDA") related to the Company's Camden manufacturing facility in Baltimore, Maryland.

The FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, the FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Based on the FDA's determination that the Camden facility is VAI, the facility is considered to be in a minimally acceptable state of compliance with regard to current good manufacturing practice (CGMP). Furthermore, the FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3).

The FDA also sent Emergent a "Warning Letter close-out letter" which states that "it appears that [Emergent has] adequately addressed the violations contained in [the] Warning Letter" that was originally issued to Emergent on August 10, 2022 regarding the Camden facility.

A copy of the Company statement is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) *Exhibits.*

Exhibit No.	Description
99.1	Company statement issued on October 5, 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: October 5, 2023 By: /s/ RICHARD S. LINDAHL

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

A Statement on Emergent's Camden Manufacturing Facility Regulatory Status

GAITHERSBURG, Md., October 5, 2023 – Emergent (NYSE: EBS) received important communications from the U.S. Food and Drug Administration (FDA) regarding its Camden drug product manufacturing facility in Baltimore, Maryland.

This week, FDA sent Emergent a "Warning Letter close-out letter," regarding its Camden facility, stating that "it appears that [Emergent has] adequately addressed the violations contained in the Warning Letter" originally issued in August 2022. FDA has also communicated to Emergent that the inspection classification for its Camden facility is "Voluntary Action Indicated" and that the inspection is considered "closed." This is regarding an FDA inspection from February 2022, which classified the Camden facility as "Official Action Indicated."

Emergent is committed to ensuring continued compliance with Current Good Manufacturing Practices requirements and remains steadfast in manufacturing and delivering high-quality products across its global network of manufacturing facilities.

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, 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 forward-looking statements.