

**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 12, 2022

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 8.01. Other Events

On August 12, 2022, Emergent BioSolutions Inc. (the “Company”) issued a statement announcing that it received a communication from the U.S. Food and Drug Administration (the “FDA”) on August 10, 2022. That communication from the FDA included the issuance of a warning letter with respect to the Company’s Camden manufacturing facility in Baltimore, Maryland. The warning letter cites two areas of deficiencies as follows:

- systems for cleaning and maintenance of equipment to prevent contamination of drug product, specifically related to particulates from the metal trays, and
- processes and practices surrounding aseptic processing.

In addition, the FDA recommended the Company review and assess its Quality Management System and engage a consultant with respect to Current Good Manufacturing Practices.

While waiting for FDA’s response related to a February 2022 inspection of the facility, the Company retained a third party for additional review of the facility and to provide additional oversight of processes for product release. The Company remains committed to upgrading its physical capabilities and strengthening its culture of quality and compliance.

A copy of the Company statement is attached hereto as Exhibit 99.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99	Company statement issued on August 12, 2022.
101	Emergent BioSolutions Inc. Current Report on Form 8-K, dated August 12, 2022 formatted in XBRL (Extensible Business Reporting Language): Cover Page. The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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: August 12, 2022

By: /s/ RICHARD S. LINDAHL
Name: Richard S. Lindahl
Title: Executive Vice President, Chief Financial Officer and Treasurer



Emergent BioSolution's Statement on the Status of its Camden Manufacturing Facility

GAITHERSBURG, Md., August 12, 2022 – Emergent (NYSE: EBS) received a communication from the FDA on August 10, 2022. That communication included the issuance of a warning letter. We share the FDA's focus on protecting public health. Quality and compliance are critical to our operations at Emergent.

As we discussed on our August 1, 2022 earnings call, while waiting for FDA's response related to the February 2022 inspection of the facility, we retained a third party for additional review of the facility and to provide additional oversight of our processes for product release. As the FDA states in the warning letter, this step is critical to ensuring medically necessary products get to the patients who need them.

Biopharmaceutical manufacturing is complex, and the stakes are high. That is why we have made significant investments to upgrade our physical capabilities and are focused on strengthening our culture of quality and compliance. This is a process that doesn't happen overnight, but one to which we are committed.

Safe Harbor Statement

This communication may include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact are forward-looking statements. You should not unduly rely on any forward-looking statements, which speak only as of the date of this communication. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the Securities and Exchange Commission, when evaluating forward-looking statements.

Media Contact:

Matt Hartwig
Director, Media Relations
240-760-0551
hartwigm@ebsi.com

Investor Contact:

Robert G. Burrows
Vice President, Investor Relations
240-631-3280
burrowsr@ebsi.com
