

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11371 / April 7, 2025

ADMINISTRATIVE PROCEEDING
File No. 3-22472

In the Matter of

Emergent BioSolutions, Inc.

Respondent.

**ORDER INSTITUTING CEASE-AND-
DESIST PROCEEDINGS PURSUANT TO
SECTION 8A OF THE SECURITIES ACT
OF 1933, MAKING FINDINGS, AND
IMPOSING A CEASE-AND-DESIST
ORDER**

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 (“Securities Act”), against Emergent BioSolutions, Inc. (“Emergent” or “Respondent”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933, Making Findings, and Imposing A Cease-and-Desist Order (“Order”), as set forth below.

III.

On the basis of this Order and Respondent’s Offer, the Commission finds¹ that:

¹ The findings herein are made pursuant to Respondent’s Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Summary

1. This proceeding arises out of violations of Section 17(a)(2) of the Securities Act by Emergent. From at least April 2020 to April 2021 (“relevant period”), Emergent made a series of materially misleading public statements touting Emergent’s ability and readiness to manufacture COVID-19 vaccine doses at its Bayview facility (“Bayview”) in Baltimore, Maryland, while omitting information about issues in the state of readiness of its facilities, personnel training, and quality control protocols to implement its contracted manufacturers’ COVID-19 vaccine manufacturing processes.

Respondent

2. Emergent is a Delaware corporation with its principal executive offices in Gaithersburg, Maryland. Emergent is a global life sciences company focused on providing products that address accidental, deliberate, and naturally occurring public health threats (such as the opioid crisis and COVID-19). Emergent’s shares trade on the New York Stock Exchange under the ticker symbol “EBS” and its common stock is registered pursuant to Section 12(b) of the Securities Exchange Act of 1934 (“Exchange Act”).

Facts

Emergent’s Background and Agreements to Manufacture COVID-19 Vaccines

3. During the relevant period, Emergent’s business focused on distinct public health threat categories, including a contract development and manufacturing organization (“CDMO”) business line that provides services including vaccine drug substance manufacturing to biopharmaceutical companies, government agencies, and non-governmental organizations.

4. As of 2021, Emergent had seven manufacturing and development facilities in the United States including Bayview, which Emergent acquired in 2009 and operated until its closure in May 2024. Bayview was comprised of four independent manufacturing suites supported by a number of facilities and functions, including quality control labs. These independent suites were designed to give Emergent the ability to manufacture different vaccines at Bayview simultaneously. Bayview was one of only three facilities in the United States federally designated as a Center for Innovation in Advanced Development and Manufacturing, the purpose of which is to support public health emergency needs.

5. In 2020, in response to the COVID-19 pandemic, Emergent entered into agreements with two pharmaceutical companies (separately, “Pharmaceutical Company A” and “Pharmaceutical Company B” and collectively, the “Pharmaceutical Companies”) to manufacture the Pharmaceutical Companies’ COVID-19 vaccines at Bayview, and the U.S. government awarded Emergent a \$628 million task order to reserve space to support the manufacturing of these

vaccines as part of Operation Warp Speed² (collectively, the “COVID-19 Agreements”). The U.S. government task order required Emergent to maintain the cleanliness and readiness of its facilities, equipment, and personnel in order to manufacture the COVID-19 vaccines safely and reliably for commercial use.

Emergent Publicly Projects Confidence in Bayview’s Manufacturing Capabilities

6. Following the execution of the COVID-19 Agreements, Emergent made a series of statements publicly projecting confidence in Emergent’s manufacturing capabilities. Among other things, during an April 30, 2020 earnings call, Emergent executives declared that the company had “proven manufacturing capabilities” and was ready to “rapidly deploy” its CDMO services to meet the substantial demand for a vaccine.

7. However, during the relevant period, Emergent was repeatedly warned about issues in the readiness of processes at Bayview to support commercial-scale manufacturing. These readiness issues were revealed by inspections performed by two federal agencies, the Pharmaceutical Companies, and Emergent’s internal personnel. One Food and Drug Administration (“FDA”) inspection of Bayview’s quality control laboratory in April 2020 found issues with quality control and employee training relating to current good manufacturing practices and preventing contamination in the laboratory. Further, the FDA found Emergent’s response to the April 2020 FDA inspection report to be deficient stating it “does not consider [the Bayview] facility ready to support commercial operations.” Two inspections in June 2020 performed respectively by the Pharmaceutical Companies, found additional quality control issues, including mold issues and deficiencies in cross-contamination control measures.

8. Internal communications reveal that Emergent executives were aware of, and concerned about, the readiness issues at Bayview. For instance, emails on June 24, 2020 from Emergent’s then-Senior Vice President of Manufacturing indicated that the FDA rejection of Emergent’s response to the April 2020 FDA Inspection report was “deeply concerning.” In another email discussing Emergent’s quality control systems, the same executive noted, “Room to improve is a huge understatement.”

Emergent Continues Publicly Projecting Confidence in Manufacturing COVID-19 Vaccines and Conducts Securities Offerings

9. Despite private acknowledgement of readiness issues at Bayview, Emergent continued making public statements during industry conferences, nationally televised shows, and earnings calls that projected confidence in Emergent’s ability to manufacture the COVID-19 vaccine drug substance, while omitting information about the readiness issues identified through the various inspections of Bayview. In doing so, Emergent failed to exercise reasonable care, resulting in public statements that were materially misleading to investors.

² Operation Warp Speed was a partnership between the Departments of Health and Human Services and Defense formed with the purpose of helping accelerate the development, manufacture, and distribution of COVID-19 vaccines.

10. Throughout the relevant period, Emergent offered and sold securities when it issued to its employees approximately 807,181 performance stock units and restricted stock units pursuant to an existing stock incentive plan for which Emergent filed a registration statement on Form S-8. Emergent obtained money when employees exercised stock options for approximately 614,158 shares. Emergent also sold approximately \$450 million of unsecured notes. On August 5, 2020, Emergent filed a Form 8-K with the Commission disclosing the notes offering to investors. The note offering was completed on August 7, 2020.

Cross-Contamination Between the Pharmaceutical Companies' Vaccines Occurs at Bayview and News of the Cross-Contamination Causes Emergent's Stock Price to Drop

11. On March 5, 2021, routine quality testing detected an "out of specification" batch of Pharmaceutical Company A's vaccine drug substance manufactured at Bayview between January 19 and February 21, 2021, due to the presence of an alternate viral drug substance in the batch (the "Cross-Contamination Event"). By March 25, 2021, investigational testing confirmed that the out of specification batch was cross-contaminated with viral drug substance belonging to Pharmaceutical Company B's vaccine.

12. The investing public was unaware of the readiness issues at Bayview and the Cross-Contamination Event until the evening of March 31, 2021 (after market close), when the press reported that Emergent had contaminated millions of Pharmaceutical Company A's COVID-19 vaccine doses after workers "mix[ed]-up" ingredients from the Pharmaceutical Companies' vaccines. Then, on April 1, 2021, Emergent published a statement acknowledging that it identified and disposed of a single batch of drug substance, which had not been released to the public, that did not meet specifications.

13. Following this news, Emergent's stock price dropped from a \$92.91 closing price on March 31, 2021, to a \$80.46 closing price on April 1, 2021.

14. On the same day, Emergent's then-Chief Executive Officer appeared in a nationally televised interview on CNBC and stated, "just to be clear, it isn't the case or wasn't the case where an ingredient from one vaccine contaminated or impacted the other." During the CNBC interview, the executive touted Emergent's "dedicated durable manufacturing process" and "durable quality systems" and said Emergent "remain[s] confident" about the FDA's eventual approval of Bayview to manufacture Pharmaceutical Company A's vaccine for commercial use.

15. Following the Cross-Contamination Event, the FDA initiated an inspection of Bayview on April 12, 2021 to assess Emergent's quality control protocols. While the April 2021 FDA inspection was ongoing, a second press article published on April 14, 2021, listing Emergent's then-CEO as the author, declared that Emergent's Bayview facility was "now ready to produce 1 billion vaccines a year to fight COVID-19."

16. On April 19, 2021, Emergent filed an 8-K publicly disclosing its agreement with the FDA to halt COVID-19 vaccine manufacturing at Bayview. After the release of the 8-K filing, Emergent's stock price dropped from a \$77.64 closing price on April 16, 2021, to a \$67.87 closing

price on April 19, 2021. Subsequently, the U.S. government and Emergent mutually agreed to terminate the Bayview task order.

Violations

17. As a result of the conduct described above, Emergent violated Section 17(a)(2) of the Securities Act, which prohibits any person, in the offer or sale of a security, from obtaining money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent Emergent's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 8A of the Securities Act, Respondent Emergent cease and desist from committing or causing any violations and any future violations of Section 17(a)(2) of the Securities Act.

B. Respondents shall, within 14 days of the entry of this Order, pay a civil money penalty in the amount of \$1,500,000 to the Securities and Exchange Commission. The Commission may distribute civil money penalties collected in this proceeding if, in its discretion, the Commission orders the establishment of a Fair Fund pursuant to 15 U.S.C. § 7246, Section 308(a) of the Sarbanes-Oxley Act of 2002. The Commission will hold funds paid pursuant to this paragraph in an account at the United States Treasury pending a decision whether the Commission, in its discretion, will seek to distribute funds or, subject to Exchange Act Section 21F(g)(3), transfer them to the general fund of the United States Treasury. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. §3717.

Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Emergent as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Glenn Gordon, Associate Regional Director, Division of Enforcement, Securities and Exchange Commission, 801 Brickell Avenue, Suite 1950, Miami, FL 33131.

C. Regardless of whether the Commission in its discretion orders the creation of a Fair Fund for the penalties ordered in this proceeding, amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

By the Commission.

Vanessa A. Countryman
Secretary