

ATTORNEY GENERAL OF THE STATE OF NEW YORK
INVESTOR PROTECTION BUREAU

In the Matter of
Investigation by LETITIA JAMES,
Attorney General of the State of New York
- of -
Emergent BioSolutions, Inc.,
Respondent

Assurance No. 26-001

ASSURANCE OF DISCONTINUANCE

The Office of the Attorney General of the State of New York (“OAG”) commenced an investigation pursuant to the Martin Act (N.Y. General Business Law § 352 et seq.) and N.Y. Executive Law § 63(12) into allegations of insider trading by Robert G. Kramer, the then-Chief Executive Officer (“CEO”) of Emergent BioSolutions, Inc. (“Emergent”, “Respondent Emergent” or “the Company”), and Respondent Emergent’s approval of the CEO’s trading. This Assurance of Discontinuance (“Assurance”) contains the findings of OAG’s investigation as to Emergent, and the relief agreed to by OAG and Emergent.

OAG FINDINGS

1. In the midst of the COVID-19 crisis, the CEO submitted, and Emergent subsequently approved, a request for its then-CEO to enter into a 10b5-1 trading plan for Emergent stock while in possession of material non-public information regarding manufacturing issues at Emergent involving the contamination and delayed production of COVID-19 vaccine

drug substance for AstraZeneca PLC (“AstraZeneca”). Emergent was aware of these manufacturing issues at the time it approved the CEO’s plan.

2. Emergent is a Delaware corporation, publicly traded on the New York Stock Exchange, with headquarters in Gaithersburg, Maryland. Emergent describes itself as a global life sciences company focused on providing a portfolio of innovative preparedness and response products and solutions to civilian and military populations that address accidental, deliberate, and naturally occurring public health threats.

3. On May 15, 2020, the federal government announced the Operation Warp Speed program (“Operation Warp Speed”), to coordinate efforts in the public and private sectors to manufacture vaccines for the coronavirus as quickly as possible.

4. Emergent’s involvement with COVID-19 vaccine drug substance manufacturing began on June 1, 2020, when Emergent entered into an agreement with the U.S. government to support the rapid development and distribution of COVID-19 vaccines at Emergent’s Bayview, Maryland plant.

5. On June 11, 2020, Emergent publicly announced a contract to provide development and manufacturing services for AstraZeneca’s COVID-19 vaccine candidate, AZD1222. The announcement valued the contract at \$87 million.

6. On July 27, 2020, Emergent announced a second contract with AstraZeneca, which Emergent valued at \$174 million. That contract supplemented the previous contract and provided for contract development and manufacturing (“CDMO”) services for vaccine drug substance production by Emergent between July 2020 and June 2021 at a large scale for commercial supply. Emergent’s announcement stated that the two contracts with AstraZeneca were worth a combined value of \$261 million.

7. In the week following Emergent's announcement of its CDMO contract with AstraZeneca, Emergent's stock price rose 43.6% from \$94.99 on July 27, 2020 to \$136.39 on August 5, 2020.

8. As the manufacturing process changed and evolved over the fall of 2020, Emergent experienced manufacturing difficulties and contamination of the AstraZeneca vaccine drug substance. Emergent noticed indices of contamination in Emergent's AZD1222 vaccine drug substance, including elevated endotoxin and excess bioburden in multiple drug substance batches, as early as September 26, 2020.

9. Production of multiple batches of Emergent's AZD1222 vaccine drug substance was paused and investigated, and multiple batches were ultimately aborted, rejected or destroyed. These manufacturing and contamination issues led to an inability of Emergent to meet the expected production schedule included in its contracts with AstraZeneca.

10. The CEO was aware of and continuously updated on the contamination situation throughout the relevant period.

11. On or about October 1, 2020, Emergent began an investigation into "initial indications of microbial contamination" in the early batches of the vaccine drug substance Emergent manufactured for AstraZeneca.

12. On or about October 6, 2020, an executive vice president responsible for manufacturing operations provided the CEO with a copy of a PowerPoint presentation, including slides about the aborted, contaminated batches, from a joint meeting held the previous day with management from AstraZeneca and the federal government.

13. On October 13, 2020, key managers and employees working for both Emergent and AstraZeneca concluded that five out of the first seven batches of vaccine drug substance

produced by Emergent using AstraZeneca's manufacturing process were likely to be lost to contamination, due to alarm level tests for endotoxin and bioburden (tests that indicated the presence of unacceptably high levels of toxic bacteria), and discussed the possible need to stop manufacturing in order to further investigate the cause of the contamination.

14. On October 14, 2020, the CEO asked his investment advisor to implement a stock trading plan ("the Trading Plan"), which would, at or above a pre-arranged strike price, result in his exercise of Emergent stock options and the immediate sale of the acquired Emergent shares, in a series of trades starting 63 days after the effective date of the Plan.

15. New York State and federal securities laws forbid the trading of stock by company insiders in possession of material non-public information. The federal securities rules include SEC Rule 10b5-1* which allows company insiders to establish a trading plan for the purchase or sale of company stock on a pre-arranged schedule. Under federal law, if an insider enters into an SEC Rule 10b5-1 trading plan in good faith (i.e. while not in possession of material nonpublic information) and that insider subsequently trades pursuant to that plan, the insider may have an affirmative defense to a charge of insider trading. However, neither federal law, nor New York state law, permits SEC Rule 10b5-1 trading plans to be used as a way of evading insider trading laws.

16. On October 23, 2020, an AstraZeneca's Senior Vice President emailed Emergent's Executive Vice President of Manufacturing ("EVP-M") that: "The situation is clearly deeply concerning as [also] the most recent batch has endotoxin/Bio hits and my understanding is that we now have found it in the buffer solution. This really makes me concerned that we may have a bigger and more systematic issue at the Site"

* 17 CFR 240.10b5-1.

17. The same day, AstraZeneca's EVP emailed Emergent's EVP-M that "We remain very concerned and sincerely hope that EBS can turn this around rapidly While I understand your point on the speed of what we are doing, I must share that others in our partner network have performed more reliably to date. We are simply nervous that the US supply chain is falling behind."

18. On Saturday November 7, 2020, AstraZeneca executives, including the EVP and SVP, spoke with members of the Emergent Executive Management Team regarding their concerns and the lack of progress in resolving the bioburden contamination problem, and requested increased involvement from Emergent senior level leadership. AstraZeneca told Emergent that the situation at that time was urgent and serious.

19. Over the course of the weekend, AstraZeneca management suggested to Emergent's EVP-M and others at Emergent that production be paused and the schedule slowed down while Emergent continued to investigate the source of the contamination, so as not to lose additional batches of vaccine.

20. Over November 11 and 12, 2020, Emergent's Senior Counsel reviewed the CEO's Rule 10b5-1 Trading Plan and coordinated with the investment advisor for the CEO to sign. The Trading Plan became effective on November 13, 2020.

21. On November 13, 2020, while Emergent was in an all-hands-on-deck manufacturing crisis and internal investigation of the undisclosed and unresolved contamination and manufacturing problems, Emergent approved the CEO's finalized Trading Plan, which the CEO then executed.

22. The contamination problem continued and remained unresolved through November despite substantial efforts to locate the root cause of the problem. Unresolved, these

issues threatened the ability of Emergent to manufacture AstraZeneca vaccine drug substance in accordance with the expected production schedule included in its contracts with AstraZeneca.

These problems were not disclosed to the public.

23. Emergent reviewed and approved the CEO's Rule 10b5-1 Trading Plan.

24. Emergent was aware of the unresolved manufacturing and contamination problems and of the CEO's awareness of those problems.

25. The Trading Plan provided for the CEO's exercise of Emergent stock options, and for the CEO's sale of the shares he acquired under the Plan, starting 63 days after approval of the Plan. Emergent received \$2,526,688.94 from the CEO upon his exercise of the Emergent stock options, and the CEO received proceeds of \$10,121,079.50 on the sale of Emergent stock that he acquired under the Trading Plan.

26. On April 4, 2021, the United States Food and Drug Administration ordered a permanent halt to Emergent's production of the AstraZeneca vaccine. At that time, Emergent had successfully completed only 28 commercially viable batches and had 13 batches in progress. These numbers were far below the numbers in the expected production schedule included in Emergent's contracts with AstraZeneca.

OAG's CONCLUSIONS

27. Emergent's serious contamination problems and its loss of multiple batches of vaccine drug substance, along with ongoing difficulties in implementing various manufacturing process changes, and the impact of these circumstances on Emergent's drug substance manufacturing capability and production schedule, were material non-public information.

28. The CEO entered into the Rule 10b5-1 Trading Plan while in possession of material nonpublic information and thus did not enact the Trading Plan in good faith.

29. Emergent approved the CEO's Trading Plan despite the CEO's possession of material non-public information, and that Emergent had not disclosed the information at the time of the Plan or sales.

30. Emergent's actions, as stated above, violated the Martin Act, General Business Law § 352-c and 353, and Executive Law § 63(12).

31. Respondent Emergent neither admits nor denies the OAG's findings in paragraphs 1-__, *supra*.

32. OAG finds the relief and agreements contained in this Assurance appropriate and in the public interest. THEREFORE, the OAG is willing to accept this Assurance pursuant to Executive Law § 63(15), in lieu of commencing a statutory proceeding for violations of the Martin Act and Executive Law § 63(12) based on the conduct described above during the period October 2020 through April 2021.

RELIEF

33. General Injunction: Respondent Emergent shall not engage, or attempt to engage, in conduct in violation of any applicable laws, including but not limited to the Martin Act, and Executive Law § 63(12), and expressly agrees and acknowledges that any such conduct is a violation of the Assurance, and that the OAG thereafter may commence the civil action or proceeding contemplated in paragraph 41, in addition to any other appropriate investigation, action, or proceeding.

34. Monetary Relief: Within 10 days of the Effective Date of this Assurance, Respondent Emergent shall pay \$900,000 to the State of New York, either by wire transfer to the account provided by the OAG, or by certified or bank check payable to the State of New York.

35. If paid by wire transfer, the payment shall reference this Assurance No, 26-001. If paid by certified or bank check, the check shall be delivered to: Office of the Attorney General of the State of New York, 28 Liberty Street, 21st Floor, New York, New York, 10005, Attn: Shamiso Maswoswe, Chief, Investor Protection Bureau.

36. Respondent Emergent will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state or local tax, directly or indirectly, for any portion of the payment it shall make pursuant to this Assurance.

37. Respondent Emergent will not claim, assert, or apply insurance coverage for any portion of the payment it shall make pursuant to this Assurance.

38. Insider Trading Policy and Pre-Clearance Form: Respondent Emergent shall amend its current Insider Trading Policy to include at least the following:

- a. An enhanced and revised Trading Pre-Clearance Form, attached hereto as Exhibit A, certifying that any Board Member or officer at the level of Senior Vice President and above seeking to trade : 1) is aware of the Respondent's insider trading policy, 2) is aware that it is unlawful to trade in the securities of the Respondent, or to enter into or modify a Rule 10b5-1 trading plan, while in possession of material non-public information concerning the Respondent, 3) is aware that both civil and criminal penalties, as well as damages could be imposed if they trade or enter into or modify a Rule 10b5-1 trading plan while in possession of material non- public information concerning the Respondent, 4) is not in possession of or aware of any material information regarding the Respondent that has not been publicly disclosed by the Respondent in a widely disseminated press release or in a public filing with the SEC, and 5) in connection

with evaluating their foregoing certification in the preceding sub-paragraph, they have considered whether they are aware of any material incident as defined in Exhibit A, that has not been publicly disclosed, and they are not in possession or aware of any such information; and

- b. A requirement that any Board Member or officer at the level of Senior Vice President and above who seeks approval for a Rule 10b5-1 Plan or modification of such a Plan complete a Trading Pre-Clearance Form, attached hereto as Exhibit A as described above.

39. Reporting: For a period of three (3) years from the Effective Date of this Assurance, Respondent Emergent shall provide to the OAG, within 20 business days of the end of each quarter, (a) a report listing the names, addresses and positions of all Board Members and Officers holding the position of Senior Vice President and above who have adopted, modified, or terminated a written trading arrangement under SEC Rule 10b5-1, and (b) copies of all such trading arrangements under SEC Rule 10b5-1, modifications or terminations, and copies of all Pre-Clearance Forms signed by such Board Members and Officers of Emergent.

40. Subsequent Proceedings: Respondent expressly agrees and acknowledges that the OAG may initiate a subsequent investigation, civil action, or proceeding to enforce this Assurance, for violations of the Assurance, or if the Assurance any portion thereof is voided pursuant to paragraph 53, and agree and acknowledge that in such event:

1. any statute of limitations or other time-related defenses are tolled from and after the effective date of this Assurance;
2. the OAG may use statements, documents or other materials produced or provided by the Respondent prior to or after the effective date of this Assurance;

3. any such civil action or proceeding must be adjudicated by the courts of the State of New York, and that Respondent irrevocably and unconditionally waives any objection based upon personal jurisdiction, inconvenient forum, or venue; and
4. evidence of a violation of this Assurance shall constitute prima facie proof of a violation of the applicable law pursuant to Executive Law § 63(15).

41. In the event that the OAG brings an action against any other party relating to the substance of this Assurance, Emergent shall fully cooperate in the acceptance of any subpoena and in the production and authentication of any statements, documents or other materials in its possession or control. Respondent Emergent agrees to use its best efforts to cause its current and former employees, officers and directors to be interviewed by the OAG or to testify in connection with any such action.

42. In the event that the OAG believes that Respondent has defaulted in the performance of any obligation set forth in this Assurance, the OAG will provide written notice of such default to the designated representative of Respondent. Respondent shall then have seven (7) days to respond and/or certify that any default has been cured.

43. Unless a term limit for compliance is otherwise specified within this Assurance, Respondent's obligations under this Assurance shall be enduring.

44. If a court of competent jurisdiction determines that Respondent has violated this Assurance, Respondent shall pay to the OAG the reasonable cost, if any, of obtaining such determination and of enforcing this Assurance, including without limitation legal fees, expenses, and court costs.

Effects of Assurance

45. All terms and conditions of this Assurance shall continue in full force and effect on any successor, assignee, or transferee of the Respondent. Respondent shall include any such successor, assignment, or transfer agreement a provision that binds the successor, assignee or transferee to the terms of the Assurance. No party may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without the prior written consent of the OAG.

46. Nothing contained herein shall be construed as to deprive any person of any private right under the law.

47. Any failure by the OAG to insist upon the strict performance by Respondent of any of the provisions of this Assurance shall not be deemed a waiver of any of the provisions hereof, and the OAG, notwithstanding that failure, shall have the right thereafter to insist upon the strict performance of any and all of the provisions of this Assurance to be performed by the Respondent.

Communications

48. All notices, reports, requests, and other communications pursuant to this Assurance must reference this Assurance No. 26-001, and shall be in writing and shall, unless expressly provided otherwise herein, be given by hand delivery; express courier; or electronic mail at an address designated in writing by the recipient, followed by postage prepaid mail, and shall be addressed as follows:

If to Respondent Emergent, to:

General Counsel
Emergent BioSolutions Inc.
300 Professional Drive
Gaithersburg, MD 20879

With a copy of any notice or correspondence to LegalNotices@ebsi.com

If to OAG, to:

Office of the Attorney General of the State of New York,
28 Liberty Street, 21st Floor, New York, New York, 10005
Attn: Shamiso Maswoswe,
Chief, Investor Protection Bureau, or such other member of OAG's staff as designated by the
Attorney General.

Representations and Warranties

49. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by Respondent in agreeing to this Assurance.

50. Respondent Emergent represents and warrants, through the signatures below, that the terms and conditions of this Assurance are duly approved. Respondent further represents and warrants that Respondent, through the undersigned as signatory to this Assurance, is a duly authorized officer of the Company with full power and authority to execute this Assurance.

51. Respondent agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any finding in the Assurance or creating the impression that the Assurance is without legal or factual basis. Provided, however, that nothing in this paragraph shall affect Respondent's ability to advance factual or legal defenses in litigation, regulatory proceedings, or in response to potential claims regarding the same or similar conduct.

52. This Assurance may not be amended except by an instrument in writing signed on behalf of Respondent Emergent and the OAG.

53. In the event that any one or more of the provisions of this Assurance is for any reason held by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any

respect, then in the sole discretion of the OAG such invalidity, illegality or unenforceability shall not affect any other provision of this Assurance.

54. Respondent Emergent acknowledges that it has entered into this Assurance freely and voluntarily and upon due deliberation with the advice of counsel.

55. This Assurance shall be governed by the laws of the State of New York without regard to any conflict of laws principles.

56. This Assurance may be executed in multiple counterparts by the parties hereto.

57. The effective date of this Assurance shall be January 15, 2026 ("Effective Date").

Dated: New York, New York

January 15, 2026

LETITIA JAMES
Attorney General of the State of New York

By: 

T. Austin Brown
Assistant Attorney General
Investor Protection Bureau

Steven J. Glassman
Special Counsel in Economic Justice
Economic Justice Division

Kenneth Haim
Deputy Bureau Chief
Investor Protection Bureau

Shamiso Maswoswe
Chief of the Investor Protection Bureau
28 Liberty Street
New York, New York 10005
Counsel for the People of the State of New York

EMERGENT BIOSOLUTIONS, INC.

By:

Joseph Papa
President and Chief Executive Officer
Emergent BioSolutions, Inc.
300 Professional Drive
Gaithersburg, MD 20879

ACKNOWLEDGEMENT

State of Florida) ss.:

County of Collier .)

On the 9 day of January in the year 2020 before me personally came Joseph Papa, who being by me duly sworn, did depose and say that he resides in Naples, FL; that he is the officer duly appointed of Emergent BioSolutions Inc., the corporation described in the above executed instrument, and that he signed his name thereto by delegated authority of the board of directors of said corporation. *by means of physical presence. TK*

Tiffany E. Kosow
NOTARY PUBLIC

Tiffany E. Kosow

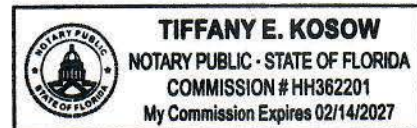


Exhibit A: Trading Pre-Clearance Form

EMERGENT BIOSOLUTIONS INC. TRADING PRE-CLEARANCE FORM

DESCRIPTION OF PROPOSED TRANSACTION

Name: _____

Today's Date: _____

Title: _____

Department: _____

Proposed Number of Shares: _____

Type of Transaction:

(Option Exercise, Purchase, Sale or Gift *(describe)*)

CERTIFICATION: By my signature below, I certify to Emergent BioSolutions Inc. (the "Company") that

- (1) I have read and am familiar with the Company's Insider Trading Policy;
- (2) I am aware that it is unlawful to trade in the securities of the Company, or to enter into or modify a Rule 10b5-1 trading plan ("Trading Plan"), while in possession of material non-public information concerning the Company;
- (3) I am aware that civil and criminal penalties as well as damages could be imposed if I trade or enter into or modify a Trading Plan while in possession of material non- public information concerning the Company;
- (4) I am not in possession of or aware of any material information regarding the Company that has not been publicly disclosed by the Company in a widely disseminated press release or in a public filing with the SEC; and
- (5) In connection with evaluating my certification that I am not in possession of or aware of any material information regarding the Company that has not been publicly disclosed by the Company, I have considered whether I am aware of any Material Incident, as defined below, that has not been publicly disclosed, and certify that I am not in possession or aware of such information.

"Material Incident is defined as a:

- (i) significant development in the Company's relationships with key regulators, including, without limitation, any inspection with findings requiring changes, improvements, or reforms, inspection observations reported on a FDA Form 483, or material violations issued by the FDA or any other governmental or regulatory body;
- (ii) whistleblower or ethics complaint and the results of any investigations into such complaints that concern the facility, its operations, or a material contract the facility is responsible for;
- (iii) material and notable production issues, including, but not limited to: significant production delays, contamination issues, quality control, regulatory compliance, destruction of large quantities of products, major personnel issues; or
- (iv) Contract disputes and significant developments in the Company's relationships with key contractual partners, or production of their own vaccines or medications.

Exhibit A: Trading Pre-Clearance Form

Signature: _____ Dated: _____

FOR INTERNAL USE

Approved? ☐ Yes ☐

No

Date of Expiration of
Clearance
