

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
SOUTHERN DIVISION

STEPHEN M. WEISS, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

v.

EMERGENT BIOSOLUTIONS INC., ROBERT
G. KRAMER, RICHARD S. LINDAHL and
SYED HUSAIN,

Defendants.

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Plaintiff Stephen M. Weiss brings this class action (the “Action”) for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) on behalf of a class (the “Class”) consisting of all persons or entities that purchased or otherwise acquired Emergent BioSolutions Inc. (“Emergent” or the “Company”) common stock from April 24, 2020 through April 16, 2021, inclusive (“Class Period”), and were damaged thereby, against Emergent, its Chief Executive Officer (“CEO”) Robert G. Kramer (“Kramer”), the Company’s Executive Vice President, Chief Financial Officer (“CFO”) and Treasurer Richard S. Lindahl (“Lindahl”) and its former Senior Vice President and Head of Contract Development and Manufacturing (“CDMO”) Syed T. Husain (“Husain”) (together, the “Defendants”).

Plaintiff’s allegations are based upon personal knowledge as to himself and his own acts and upon information and belief as to all other matters. Plaintiff’s information and belief is based on an investigation conducted by and through Plaintiff’s counsel, which included, among other things, consultation with experts and a review of public filings with the U.S. Securities and Exchange Commission (“SEC”), press releases, investor presentations, earnings calls, analyst research and media reports concerning Emergent.

Counsel’s investigation into the facts supporting the claims alleged herein continues, and many of the relevant facts are known only to Defendants, or are exclusively within Defendants’ custody or control. Plaintiff believes that substantial additional evidentiary support for the allegations set forth herein will be uncovered after a reasonable opportunity for further investigation and discovery of Defendants.

I. INTRODUCTION

1. This action arises from Defendants’ numerous misrepresentations and omissions concerning the business and operations of vaccine manufacturer Emergent as well as pervasive quality control problems at the Company’s primary Bayview facility in Baltimore, Maryland that

culminated in *the destruction of up to 100 million COVID-19 Johnson & Johnson (“J&J”) and AstraZeneca vaccine doses.*

2. Beginning in the Spring of 2020, the Company claimed it had secured production deals with J&J, AstraZeneca and the U.S. federal government to manufacture COVID-19 vaccine candidates in transactions worth more than \$1.5 billion. In announcing the deals, Emergent touted its supposed manufacturing expertise and emphasis on quality control, claiming Emergent was “*uniquely prepared*” to scale up production due to its “*proven manufacturing capabilities*” that were purportedly already in place and that it was selected due to its history of “*high-quality manufacturing.*”

3. None of Defendants’ statements concerning the Company’s manufacturing processes, capabilities, quality control procedures and status as a purported leader in the biopharmaceutical manufacturing industry were true.

- First, an internal audit conducted in June of 2020 by J&J subsidiary Janssen Pharmaceuticals found two “*Major*” quality control deficiencies, including “*deficient*” contamination control and that the Company failed to conform to basic industry standards;
- Second, U.S. Food and Drug Administration (“FDA”) inspections of Emergent’s Baltimore facility conducted both prior to and following the Company’s award of COVID-19 vaccine manufacturing contracts notified the Company of a “*series of quality control shortcomings*” including “*fail[ure] to ensure that electronic data*” was “protected from deletion or manipulation,” “*carelessness in the handling of rejected materials*” and failure to “follow proper testing and lab procedures;” and
- Third, Dr. Carlo de Notaristefani, an Operation Warp Speed Manufacturing & Supply Chain adviser charged with overseeing the production of COVID-19 vaccines on behalf of the federal government, issued a draft report in June 2020 stated that Emergent’s key manufacturing risk was the “*remediation of the compliance gaps identified by the FDA inspection held in April 2020.*” Dr. Notaristefani further noted that the Company’s staffing was “*inadequate to enable the Company to manufacture at the required rate*” and Emergent would need to expend “significant resources” and “strengthen” quality controls to meet manufacturing scale-up and roll-out deadlines.

4. Defendants have *admitted* to the FDA in response to a Form 483 notification issued on April 20, 2021 that the Company was plagued by serious manufacturing problems that precipitated the destruction of vaccines. In response to the April 2021 FDA Form 483, Emergent conceded that the “*sudden scale-up to full-scale manufacturing activities*” contributed to “a dramatic increase in storage and staging demands” and “*strained the capacity*” as the facility “operated at full capacity for the first time.”

5. Emergent further acknowledged its employees were not adequately trained, claiming in its Form 483 response that the Company was “using the pause in new manufacturing to provide comprehensive training to facility personnel, to ensure that, upon resumption of operation, site personnel will be prepared to execute their roles in a consistently [Good Manufacturing Practice]-compliant manner.” In spite of these admissions to the FDA, *the Company failed to disclose any of these manufacturing quality control problems to investors.*

6. On March 31, 2021, *The New York Times* published an article reporting on the accidental contamination of COVID-19 vaccines developed by J&J and AstraZeneca at the Emergent manufacturing plant in Baltimore. The article stated that in late February 2021, employees at Emergent’s Baltimore manufacturing plant “mixed up” ingredients of the two different COVID-19 vaccines, contaminating up to 15 million doses of J&J’s vaccine and forcing regulators to delay authorization of the plant’s production lines. The March 31, 2021 *New York Times* article further revealed that Emergent’s massive vaccine lot contamination went *undiscovered for days* until J&J’s quality control checks uncovered it.

7. On April 1, 2021, the *Associated Press* reported on Emergent’s “history of violations,” noting that the FDA has repeatedly cited Emergent for problems such as poorly trained employees, cracked vials and problems managing mold and other contamination in its facilities.

8. Two days later, on April 3, *The New York Times* reported that the Biden administration took the extraordinary action of putting J&J in charge of Emergent's Baltimore plant and prohibiting Emergent from producing the AstraZeneca vaccine, an incredible blow for a Company that had touted its "unique" preparedness and "proven manufacturing capabilities" only months prior. The article called the "ingredient mix-up" and stripping of Emergent's control over its own plant "a significant setback and a public relations debacle."

9. As a result of these disclosures, Emergent's stock price declined \$12.45 per share, from \$92.91 per share on March 31, 2021 to \$80.46 per share at market close on April 1, 2021. As additional facts were released, the Company's stock price continued to decline, from \$80.46 per share on April 1, 2021 to \$78.62 per share as of market close on April 5, 2021.

10. On April 6, 2021, *The New York Times* published another report, citing undisclosed internal documents and interviews with current and former federal officials, as well as Company employees. This article found Emergent to be ill-equipped to take on the important manufacturing task of producing COVID-19 vaccines, despite having received a \$163 million federal contract to improve its facility and prepare for high-volume production. Audits and investigations – including ones conducted in 2020 by J&J, AstraZeneca, two federal agencies and Emergent's own quality evaluators – found that Emergent had not followed basic industry standards at its Baltimore facility, and identified repeated shortcomings in efforts to disinfect and prevent contamination. Specifically, an audit conducted for AstraZeneca highlighted the risks of viral cross-contamination, which experts believe was responsible for tainting the millions of J&J doses.

11. The April 6, 2021 *New York Times* article also noted that the most recent loss of the J&J doses had not been the first time Emergent had to discard its manufactured coronavirus vaccines for fear of contamination, as between October 2020 and January 2021, Emergent

discarded five lots of AstraZeneca vaccine – each the equivalent of two million to three million doses – because of contamination or suspected contamination. In November 2020, production of a batch of J&J vaccine was also discarded after workers “hooked up” the wrong gas line and accidentally “suffocated” the cells where the virus for the vaccine is grown. The next month, workers making AstraZeneca’s vaccine deviated from manufacturing standards on average more than three times a day, and about one-fifth of the deviations were classified as major.

12. On April 19, 2021, Emergent revealed that “at the request of the FDA, Emergent agreed not to initiate the manufacturing of any new material at its Bayview facility and to quarantine existing material manufactured at the Bayview facility pending completion of the [FDA] inspection and remediation of any resulting findings.”

13. As a result of these disclosures, the price of Emergent’s common stock declined \$9.77 per share, or more than 12%, from \$77.64 per share on April 16, 2021 to close at \$67.87 per share on April 19, 2021.

14. All told, Defendants’ misrepresentations and subsequent disclosures concerning Emergent’s quality control problems and related issues cost Emergent investors more than *\$1.5 billion* in value. As of the market close on May 28, 2021, the Company’s stock was trading at \$59.89 per share.

II. PARTIES

A. Plaintiff

15. Plaintiff Stephen M. Weiss purchased shares of Emergent common stock during the Class Period, as reflected in his Certification attached hereto as Exhibit 1, and was damaged thereby.

B. Corporate Defendant

16. Defendant Emergent is a Maryland corporation with its headquarters located at 400 Professional Drive, Suite 400, Gaithersburg, Montgomery County, Maryland, 20879. Emergent's common stock is traded on the New York Stock Exchange ("NYSE") under the symbol "EBS."

C. Individual Defendants

17. Defendant Robert G. Kramer Sr., at all relevant times, has served as the Chief Executive Officer and President of Emergent, and is a member of the Company's Board of Directors. Defendant Kramer's address is 400 Professional Drive, Suite 400, Gaithersburg, Montgomery County, Maryland, 20879.

18. Defendant Richard S. Lindahl, at all relevant times, has served as the Chief Financial Officer of Emergent. Defendant Lindahl's address is 400 Professional Drive, Suite 400, Gaithersburg, Montgomery County, Maryland, 20879.

19. Defendant Syed T. Husain, at all relevant times, has served as a Senior Vice President and Head of the Company's CDMO business unit. Defendant Husain's address is 400 Professional Drive, Suite 400, Gaithersburg, Montgomery County, Maryland, 20879.

20. Defendants Kramer, Lindahl and Husain are collectively referred to hereinafter as the "Individual Defendants." Because of their positions with the Company, the Individual Defendants possessed the power and authority to control the contents of Emergent's reports to the SEC, as well as its press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each Individual Defendant, while serving as a senior executive of Emergent, was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Defendants knew

that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each “group-published” information and were the result of the collective actions of the Individual Defendants.

III. SUBSTANTIVE ALLEGATIONS

A. Emergent Employs an Aggressive Lobbying and Acquisition Strategy to Become the Largest Strategic National Stockpile Supplier

21. Emergent was formed in 1998 as BioPort Corporation, a private company created by a group of investors led by Lebanese businessman Fuad El-Hibri for the purpose of acquiring the United States’ sole anthrax vaccine manufacturing facility and related operating licenses in a bidding process conducted by the State of Michigan, the then-owner/operator of that facility. The Company purchased the license and manufacturing facility from Michigan for \$25 million and began manufacturing its anthrax vaccine for one customer – the U.S. Department of Defense.

22. In the wake of 9/11, Congress passed the BioShield Act which authorized the expenditure of \$5.6 billion for the stockpiling of vaccines and other medical equipment in the event of another terrorist attack. The massive expenditure prompted the creation of new vaccine start-up companies which developed alternative anthrax vaccines to BioPort’s decades-old product. To thwart competition from vaccine manufacturer upstarts and secure its position as the nation’s sole anthrax vaccine supplier, BioPort rebranded itself as Emergent, moved the Company to Maryland and engaged in an aggressive lobbying campaign to convince lawmakers to award the Company lucrative contracts to manufacture its anthrax vaccine.

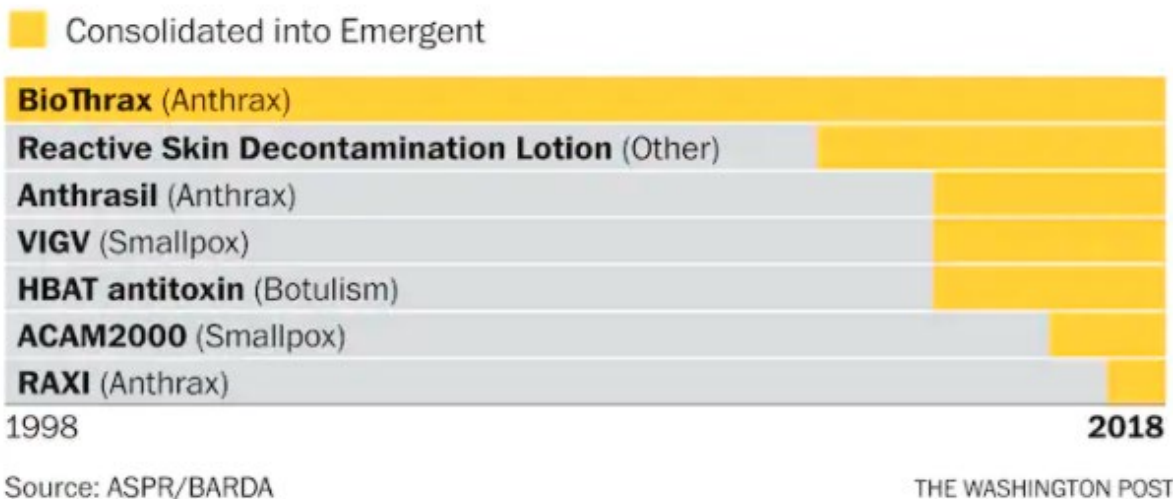
23. Emergent’s lobbying campaign worked. By 2010, the Company had annual revenue exceeding \$250 million derived from one product – the anthrax vaccine – for the U.S.

government. In 2017, Emergent entered into a new agreement with the U.S. government in which it charged the government \$30 per dose of its updated BioThrax vaccine – approximately five times what the Company was paid under its original contract.

24. With the anthrax vaccine monopoly secured, Emergent actively worked to consolidate its power over the U.S. national stockpile through the strategic acquisition of at least seven treatments considered critical for the stockpile, as reflected in the chart below:¹

Consolidation of key biodefense treatments by Emergent

In 2010, Emergent told investors that it planned to accelerate its growth through "strategic acquisitions" of other biodefense companies and their products. Over the next decade, the company scooped up treatments for anthrax, botulism, smallpox and other threats.



25. Each time Emergent acquired an essential medicine, it massively increased the prices charged to the U.S. government (and therefore taxpayers). For example, in 2017, Emergent acquired the rights to a smallpox vaccine known as ACAM2000 from the government's previous

¹ See Jon Swaine, Robert O'Harrow Jr., and Aaron C. Davis, "Before the pandemic, top contractor received billions from government to help prepare the nation for biowarfare," *Washington Post*, accessible at https://www.washingtonpost.com/investigations/before-the-pandemic-top-contractor-received-billions-from-government-to-help-prepare-the-nation-for-biowarfare/2020/06/17/38d9ad3a-a41b-11ea-8681-7d471bf20207_story.html

supplier. Under the prior contract, the vaccine supplier Sanofi Pasteur charged the federal government \$4.27 per dose by the end of the contract's life. Emergent's Vice President for Investor Relations Robert Burrows stated that, pursuant to the terms of the new contract entered into with the federal government, Emergent was charging \$9.44 per dose for the exact same vaccine – an increase of more than 50%.

26. The price increases were enabled by Emergent's successful lobbying efforts. Since becoming publicly traded in 2006, Emergent has spent more than \$43 million on lobbying and more than \$4 million in 2019 alone – figures which vastly exceed those expended by similarly sized companies.

27. Emergent's lobbying clout enabled the Company to continue manufacturing excess anthrax vaccines at the expense of other pandemic preparedness initiatives. For example, in 2015, the U.S. federal government approved a plan to purchase tens of millions of N95 respirators – equipment necessary to stop the spread of airborne infectious diseases like COVID-19 – but the plan was ultimately scrapped and instead the government spent over \$1 billion on anthrax vaccines from Emergent. And between 2010 and 2018, Emergent's anthrax vaccine drained an average of \$560 million per year from the strategic stockpile budget – approximately 40%.

28. Emergent profited massively from the arrangement. In 1998, the anthrax vaccine cost the U.S. federal government just \$3.35 per dose. By 2010, the price of a single dose of the same anthrax vaccine had risen to \$28. Emergent's senior executives have described the arrangement as a “monopoly” and recorded a profit margin of approximately 75% on the vaccine sales.

B. Emergent’s Vaccine Manufacturing Facilities Were Plagued with Quality Control Problems Predating the COVID-19 Pandemic

29. Unknown to investors and despite Emergent’s apparent success and profitability, the Company had a history of serious data integrity and quality control deficiencies.

30. As early as December 2017, during an FDA inspection of an Emergent plant in Canton, Massachusetts, the FDA noted the Company had not corrected “continued low level mold and yeast isolates” previously found in the facility.

31. In September 2018, FDA investigators questioned why Emergent had “*an unwritten policy of not conducting routine compliance audits*” at the Baltimore Camden plant. In the same report, the FDA noted that “*Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not adequately established and followed.*”

32. In 2019, the U.S. Office of the Assistant Secretary for Preparedness and Response (“ASPR”) commissioned a review of Emergent’s progress under a \$163 million contract awarded in 2012 to retrofit and expand Emergent’s Baltimore production facility. The commission determined Emergent’s ability to deliver in a pandemic remained largely unproven.

C. Despite Emergent’s Pervasive Quality Control Lapses, the Company Procures Contracts Worth \$1.5 Billion to Manufacture COVID-19 Vaccine Candidates

33. In April 2020, Emergent announced that the Company had entered into an agreement with J&J to provide its manufacturing facilities to support J&J’s goal of supplying one billion doses of a COVID-19 vaccine. Under the deal, valued at \$135 million, Emergent would provide drug substance manufacturing services and reserve large-scale manufacturing capacity for J&J.

34. On June 1, 2020, as part of Operation Warp Speed, the national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures), the U.S. government awarded Emergent an approximately \$628 million contract to reserve manufacturing space and upgrade its facilities. The government's press release stated that "[b]efore a vaccine is even approved, Emergent's manufacturing capabilities will pave the way for drug companies with candidates approaching approval to begin turning out doses." The \$628 million no-bid contract was one of the largest such awards at the time, leading Bloomberg to call Emergent "the ultimate Operation Warp Speed company."

35. On June 11, 2020, Emergent announced that it had signed yet another agreement to manufacture COVID-19 vaccines. Under this agreement, valued at \$87 million, Emergent agreed to provide contract development and manufacturing services and secure large-scale manufacturing capacity through 2020 to support AstraZeneca's COVID-19 vaccine candidate. In announcing this deal, Emergent's President and CEO Kramer stated, "[w]ith this agreement, we bring to our facilities two of the five leading candidates being developed with U.S. government funding."

D. Emergent Receives Early Warnings about Quality Control Problems at Its Baltimore COVID-19 Manufacturing Facility

36. Between June 9 and June 18, 2020, as Emergent was preparing for the rapid production and deployment of the COVID-19 vaccine, J&J's main United States subsidiary, Janssen Pharmaceuticals, conducted an External Audit of Emergent's Baltimore facility. The audit observed two Major observations and required Emergent to implement a corrective action plan by August 21, 2020.

37. Also in mid-June of 2020, the Operation Warp Speed Manufacturing & Supply Chain adviser, Dr. Carlo de Notaristefani, issued a draft report concluding Emergent's Baltimore

facility lacked enough trained staff and had a record of problems with quality control. The report identified key scale-up, personnel and compliance risks as follows:

Risks identified for Bayview

- Scale up risk – limited: the scale up ratios are small, and the organization has the necessary experience/competence. Main risk here is process drifting, to be assessed with strong change control.
- Facilities readiness risk – medium: Most of the critical equipment for the Janssen vaccine has not been received yet, and will have to be installed and qualified. Warehousing must be expanded, and so QC and Utilities. Might require government support for expediting.
- Personnel risk – significant: The staffing plans presented seem inadequate to the level of concurrent activities required for full scale production of 3 programs. In addition, recent FDA and customer audits has highlighted the need for extensive training of personnel, and strengthening of the quality function.
- Compliance risk – significant: Emergent Bayview has been focused on R&D activities for the last 8+ years, and will have to strengthen the change control process, systems audit trails, and quality oversight to address audit observations and ensure products licensure. This will require significant resources and commitment.

Risks identified for Camden

38. Dr. Notaristefani’s report specifically noted as a key risk the “remediation of the compliance gaps identified by the FDA inspection held in April 2020.” Dr. Notaristefani’s report further stated, among other things, Emergent failed to provide a T&E plan by June 17, 2020 and the current hiring plan to support the required production was “inadequate to enable the company to manufacture at the required rate”:

Operation Warp Speed

CdN

The two key risks to the plan are linked to the hiring of people and their training, and the remediation of the compliance gaps identified by the FDA inspection held in April 2020. A more detailed T&E plan was requested and solicited several times from Emergent, and as of 6/17 was not provided yet.

The following slide shows the current hiring plan to support the required production plan. I believe this plan to be inadequate to enable the company to manufacture at the required rate, but I recognize the limits in the plant's ability to grow, and the time required to train new employees. This increases the risk to the schedule obviously, and will have to be monitored closely. Offloading the Novavax program to a different facility will also help reduce the load on Emergent Bayview

The plant will have to operate on a 24/7 schedule, which means 5 teams will be required in manufacturing, QC and some of the other support functions. Keeping into account an attrition rate of the order of 10%-15%/year, we will have to extend the hiring plan and the company has accepted to review it and discuss it with BARDA. Reinforced quality oversight and training to strengthen compliance will also absorb resources.

Crisis Pushed to Oversight Request, Health and Human Services

39. Finally, the report noted compliance risks that “will require significant effort to be addressed to the agency’s satisfaction”:

Compliance risk

The Bayview plant received a pre-approval inspection by the FDA resulting in 5 observations, mostly focused on data integrity in the QC lab, training of operators, and general QA practices. The plant also received a customer audit for cause triggered by some data integrity issues identified in the QC testing of the customer product.

Produced to House Do Not Disclose

6/17/2020

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Operation Warp Speed

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While these observations are not unusual in a startup mostly dedicated so far to development activities, they will require significant effort to be addressed to the agency’s satisfaction. The resources and time required should be built into the plan

Request

E. Emergent’s Quality and Data Control Problems Cause the Spoilation of Millions of COVID-19 Vaccine Doses

40. On March 31, 2021, after the close of markets, *The New York Times* published an article reporting on the accidental contamination of COVID-19 vaccines developed by J&J and AstraZeneca at the Emergent manufacturing plant in Baltimore. The *New York Times* article stated that in late February 2021, employees at Emergent’s Baltimore manufacturing plant inconceivably “mixed up” ingredients of the two different COVID-19 vaccines, contaminating up to 15 million doses of J&J’s vaccine and forcing regulators to delay authorization of the plant’s production lines.

41. On April 3, *The New York Times* reported that the Biden administration took the extraordinary action of putting J&J in charge of Emergent’s Baltimore plant and prohibiting it from producing the AstraZeneca vaccine, an incredible blow for a company that had touted its “unique” preparedness and “proven manufacturing capabilities” only months prior. The article described the “ingredient mix-up” and stripping of Emergent’s control over its own plant “a significant setback and a public relations debacle.”

42. An April 6, 2021 *New York Times* article also noted that the loss of the J&J doses was not the first time Emergent had to throw out coronavirus vaccine for fear of contamination, as between October 2020 and January 2021, Emergent discarded five lots of AstraZeneca vaccine – each the equivalent of two million to three million doses – because of contamination or suspected contamination. In November 2020, production of a batch of J&J vaccine was also discarded after workers “hooked up” the wrong gas line and accidentally “suffocated” the cells where the virus for the vaccine is grown.

F. Government Investigations Follow

43. On April 19, 2021, the Oversight Committee and the Select Subcommittee on the Coronavirus Crisis sent a letter to Emergent’s President and CEO, Defendant Kramer, and well as

the Company's Executive Chairman, Fuad El-Hibri, announcing that it was investigating whether Emergent leveraged its relationship with a Trump Administration official to secure and profit from federal contracts despite a track record of increasing prices without justification and failing to deliver on contractual requirements.

44. The letter noted that "Dr. Robert Kadlec, who served as Assistant Secretary for Preparedness and Response under President Trump and previously worked as a consultant for Emergent, appears to have pushed for this award despite indications that Emergent did not have the ability to reliably fulfill the contract."

45. The letter further noted that:

We are also investigating Emergent's actions to unduly influence the assets currently stockpiled in the Strategic National Stockpile (SNS), which is critical to providing for the emergency health security of the United States in the event of a public health emergency or bioterrorist attack.⁷ Emergent is the sole supplier of the SNS's stockpile of anthrax vaccine. Emergent has raised the government purchasing price of the anthrax vaccine by 800% since acquiring the drug in 1998. As a result, through most of the last decade, nearly half of the SNS's budget has been spent purchasing Emergent's anthrax vaccine. These spiraling costs contributed to shortages of critical supplies, including ventilators, reusable respirator masks, and other personal protective equipment, which severely impacted the government's ability to respond to the coronavirus crisis.

46. On May 19, 2021, the Majority Staff of the Select Subcommittee on the Coronavirus Crisis published its Preliminary Findings from its Investigation into Emergent. The report contained numerous details documenting Emergent's systemic failure to address deficiencies at the Baltimore manufacturing facility. Among other things, the report found:

- "New documents from two separate inspections performed in June 2020 show that Emergent was warned that it needed "extensive training of personnel" and "strengthening of the quality function," and that it had a "deficient" virus contamination control strategy. Despite the serious nature of these findings and similar concerns raised during four other inspections

in 2020, Emergent failed to promptly and fully remediate the problems at the facility.”

- “Emergent has privately admitted to serious manufacturing problems. In its response to an April 2021 Food and Drug Administration (FDA) inspection report, Emergent admitted that the “sudden scale-up to full-scale manufacturing activities for two different Covid-19 vaccine drug substances” contributed to “a dramatic increase in storage and staging demands” and “strained the capacity” of Emergent’s equipment as the facility “operated at full capacity for the first time.” This report provides new detail on the failures that led to the contamination of up to 15 million Johnson & Johnson vaccines at its facility in January and February 2021, as well as the events leading up to the discovery and investigation of the contamination.”

IV. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

47. The Class Period begins on April 24, 2020, the day after Emergent announced that it had entered into an agreement with J&J to manufacture J&J’s COVID-19 vaccine candidate at the Company’s Baltimore facility. Days later, during Emergent’s First Quarter 2020 earnings call held on April 30, 2020, Defendant Kramer stated:

First, we’re taking our history of working hand-in-hand with the U.S. government to be able to develop and manufacture critical vaccines and therapeutics, and applying those skills to help our fellow innovators, such as J&J, Novavax, and Vaxart, to accelerate the development of their COVID-19 candidates and be in a position to manufacture them in significant quantities. Secondly, *we’re leveraging our long history of manufacturing our own therapeutics and vaccines to develop 2 COVID-19 product candidates*, which we’ll discuss in more detail later on the call.

Simply put, Emergent is built for this challenge.

Emergent is uniquely prepared to answer the call for medical solutions to the COVID pandemic. We have proven manufacturing capabilities in place and, in concert with the U.S. government, have built the ability to quickly advance early-stage candidates through development to commercial-scale manufacturing. We’re working with leading innovators in support of their efforts to develop vaccines, while at the same time advancing 2 potential therapy of our own.

48. Also on the call, Defendant Husain stated:

Emergent's state-of-the-art infrastructure, proven track record, and expertise in development and manufacturing as well as commercialization of solutions that address public health threats, provide the foundation for a differentiated CDMO that allows us the ability to work with 5 technology platforms and deploy our network of 9 development and manufacturing sites. We leverage these strengths to pave the way for fellow innovators to progress their clinical candidates to benefit patients. We have been, and continue to be, built for this.

49. The above statements were materially false and misleading and failed to disclose:

(i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

50. On May 12, 2020, Defendant Lindahl presented at the 2020 Bank of America Virtual Healthcare conference. The slide presentation published to Emergent's website in advance of the conference contained the following slide:

Our services



Molecule-to-market CDMO offerings



Development services
[DVS]



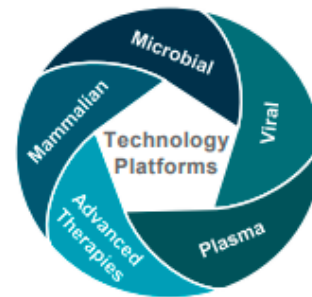
Drug substance
[DS]



Drug product &
packaging
[DP]

Sustainable competitive advantages

- Foundational market approach
- Science and technology
- Industry-leading track record
- Speed and flexibility to market
- Tailored, individualized and integrated offerings
- 9 Global development & manufacturing sites
- Center for Innovation in Advanced Development and Manufacturing (CIADM)



\$20B Market Opportunity

7

WHO WE ARE / WHAT WE DO

51. The above statements concerning Emergent’s “industry-leading track record” and “speed and flexibility to market” were materially false and misleading when made and failed to disclose: (i) Emergent’s Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent’s Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants’ public statements about Emergent’s ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

52. On May 12, 2020, during the Bank of America Virtual Healthcare Conference, Defendant Lindahl stated: “just note that Emergent has always been a unique company with distinctive capabilities, particularly in high-quality manufacturing” and that “this is a set of

services to address the whole spectrum of molecule-to-market offerings, leveraging our capabilities that we've developed over time in our state-of-the-art manufacturing facilities.”

53. Defendant Lindahl further stated:

We have a number of competitive advantages on this front as you can see in the middle of the page. We offer these services out of our 9 global development and manufacturing sites. And in particular, we have one of those sites has been designated as a center for innovation and advanced development and manufacturing. That's what we refer to as our Bayview site in Baltimore. And that has been the locus of a number of the contracts that we've announced in recent weeks. And again, I'll dive a little more deeply into those in a little bit.

54. The above statements were materially false and misleading and failed to disclose:

(i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

55. On June 1, 2020 Emergent issued a press release announcing that it had joined the U.S. Government's Operation Warp Speed program for development and manufacturing of the COVID-19 vaccine. The press release quoted Defendant Kramer as stating: ***“Emergent is proud of this expanded BARDA partnership that symbolizes confidence in our development and manufacturing capabilities that have served the U.S. government's needs for more than two decades”*** and that ***“[o]ur longstanding record of delivering safe and effective medical***

countermeasures for public health positions us to continue to help at this critical moment by advancing COVID-19 vaccine programs of our fellow innovators in the industry.”

56. Also in the June 1, 2020 press release, Defendant Husain was quoted as saying: *“Emergent’s landmark partnership with BARDA puts us at the forefront of CDMO collaborations, elevating us to respond to these unprecedented times,”* and that “[t]his innovative solution paves the way for pharmaceutical and biotechnology innovators with leading COVID-19 vaccine candidates to have an established U.S. development and manufacturing supply chain. This investment in increased capacity and capabilities will serve the industry’s expanding clinical and commercial pipelines more broadly, ultimately benefiting more patients globally.”

57. The above statements were materially false and misleading and failed to disclose: (i) Emergent’s Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent’s Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants’ public statements about Emergent’s ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

58. On June 24, 2020, Defendant Lindahl presented at the 2020 IDEAS Northeast Investor Conference. The presentation published to Emergent’s website in advance of the conference contained the same slide reference in paragraph 50 above. The presentation also contained a slide dedicated to Emergent’s COVID-19 CDMO partnerships as follows:

CDMO COVID-19 partnerships



		SERVICE OFFERINGS		
		Development Services	Drug Substance	Drug Product
		SITES		
		Gaithersburg, Maryland	Baltimore, Maryland (Boyview)	Baltimore, Maryland (Camden)
		PARTNERSHIP ACTIVITIES		
NOVAVAX	NVX-CoV2373	●	●	●
VAXART	COVID-19	●	●	
Johnson & Johnson	COVID-19		●	
AstraZeneca	COVID-19	●	●	

Novavax

- Agreement provides clinical supply to support Phase I trial in May 2020

Vaxart

- Agreement provides clinical supply to support Phase I trial in H2 2020

Johnson & Johnson

- Agreement to be US manufacturer of drug substance, enables readiness and reservation of certain capacity to provide large-scale manufacturing in 2021
- Capacity up to 300M doses annually
- Long term commercial supply agreement under negotiation

AstraZeneca

- Agreement to be US supplier of drug substance, enables development services, tech transfer, PPQ, large-scale capacity reservation through 2020
- Supply agreement under negotiation

59. The above statements concerning Emergent’s supposed “Capacity [of] up to 300M doses annually” were materially false and misleading when made because, in truth, Emergent’s manufacturing facilities lacked the capacity to scale up production of the J&J vaccine and the Company’s Baltimore facility suffered from myriad undisclosed quality control problems.

60. The presentation contained an additional slide concerning its involvement in the U.S. government’s Operation Warp Speed Program as follows:

Emergent and US Government Warp Speed Program



- **\$628M** Task Order under existing **CIADM** contract for rapid production of **leading COVID-19 vaccine candidates**
- Emergent provides **molecule-to-market CDMO** services and commits manufacturing capacity **[\$543M]**
- Expands **viral and non-viral CDMO** drug product fill/finish capacity **[\$85M]**

"Emergent's manufacturing capabilities will pave the way for drug companies with candidates approaching approval to begin turning out doses. Securing more manufacturing capacity here in America for candidates that make it to the final stages of Operation Warp Speed will help get a vaccine to American patients without a day wasted."

- Alex Azar, US HHS Secretary

EMERGENT

25 COVID-19 RESPONSE

61. The above statements were materially false and misleading and failed to disclose: (i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

62. On July 6, 2020, Emergent issued a press release announcing that it had officially signed a five-year agreement for large-scale drug substance manufacturing for J&J's lead COVID-19 vaccine candidate. Under the agreement, valued at \$480 million for the first two years,

Emergent would begin manufacturing J&J's COVID-19 vaccine in 2021 at the Company's manufacturing facility in Baltimore. In announcing the agreement, Defendant Kramer highlighted the Company's "manufacturing strength to address the COVID-19 pandemic." Defendant Husain added that Emergent had "the expertise and capabilities to meet the long-term needs of [its] customers and provide ongoing commercial manufacturing to benefit patients."

63. Shortly thereafter, on July 27, 2020, Emergent issued a press release announcing another deal with AstraZeneca to provide services to support production of its COVID-19 vaccine candidate. This deal, valued at approximately \$174 million, also contracted Emergent to produce drug substance manufacturing services at its Baltimore facility, beginning in 2020, at a large scale for commercial supply. In the press release, Defendant Husain stated, "Emergent stands ready alongside leading innovators to rapidly deploy our [CDMO] services to help meet the substantial demand for a vaccine – anchored on our foundational expertise in development and manufacturing and propelled by our commitment to our mission – to protect and enhance life."

64. The above statements were materially false and misleading and failed to disclose: (i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

65. On July 30, 2020, the Company issued a press release reporting financial results for its second quarter and six months ended June 30, 2020 and conducted an investor conference call.

During the July 30, 2020 Second Quarter 2020 earnings call, Defendant Kramer stated:

In June, in an award valued at approximately \$628 million, Emergent joined the U.S. government in a landmark public-private CDMO partnership as part of Operation Warp Speed, committing our development and manufacturing services for production of COVID-19 vaccine candidates for commercial innovators through 2021 at a minimum. This agreement secures capacity for drug substance manufacturing and drug product manufacturing at our 3 Maryland-based facilities. It also includes an incremental investment of \$85 million for the rapid expansion of our viral and nonviral CDMO drug product fill/finish capacity at our Baltimore, Camden and Rockville facilities.

Also in June, we announced a partnership to manufacture AstraZeneca's leading vaccine candidate. Under that agreement, valued at approximately \$87 million, Emergent will provide development services, technology transfer, analytical testing, drug substance process and performance qualification and will reserve certain large-scale manufacturing capacity through 2020. Earlier this week, we announced an additional agreement with AstraZeneca to manufacture drug substance at large scale for commercial supply. The contract is valued at approximately \$174 million through 2021, and it brings the total AstraZeneca commitment to just over \$260 million. The agreement leaves open the option to enter into additional commercial manufacturing commitments as the candidate progresses over the next 3 years.

Given the scale and the ongoing nature of the threat as well as our diverse offering across development services, drug substance, drug product and our leading development and manufacturing expertise, we anticipate significant demand for our CDMO business for the next several years across small, mid and large pharma and biotech as well as the U.S. government and NGOs.

66. On August 12, 2020, Emergent's Vice President of Investor Relations Robert G. Burrows presented at the 2020 Intellisight Conference. The presentation published to Emergent's website in advance of the conference contained the below slide:

New COVID-19 CDMO partnerships



New CDMO Partnerships with Government & Non-Government Customers for COVID-19 Vaccine Candidates

- Announced collaborations with Johnson & Johnson, AstraZeneca, Novavax and Vaxart to develop and manufacture COVID-19 vaccine candidates
- Expanded existing partnership with the USG under "Operation Warp Speed" to accelerate efforts for COVID-19 investigational vaccines, including:
 - **\$543MM** to provide CDMO services and commit manufacturing capacity
 - **\$85MM** to expand viral and non-viral CDMO drug product fill/finish capacity

Announced COVID-19 Related CDMO Contracts				
Contract Party	Announced	Value	Start Date	Duration
BARDA	6/1	\$628MM	2020	1+ year
Johnson & Johnson	7/6	\$480MM ¹	2021	5 years
	4/23	\$135MM	2020	1+ year
AstraZeneca	7/27	\$174MM ²	2020	3 years
	6/11	\$87MM	2020	1 year
Novavax	3/10	Not Disclosed	2020	Not Disclosed
Vaxart	3/18	Not Disclosed	2020	Not Disclosed

¹ Reflects value in year 1 and 2, combined

² Reflects value in year 1

>\$1.5B of contracted CDMO revenue signed since March

23 COVID-19 RESPONSE

Intelligence Conference 2020

67. The above statements were materially false and misleading and failed to disclose: (i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

68. On September 14, 2020, the Company presented at the Morgan Stanley Annual Global Healthcare Conference, where Defendant Lindahl boasted that J&J and AstraZeneca chose Emergent due to the Company's "high-quality manufacturing...primarily in the Bayview facility

that we have, which was designed expressly for the purpose in partnership with the government of dealing with an emergency just like COVID.” Lindahl added that Emergent’s manufacturing sites can “handle a different set of applications and be set up to move very rapidly, and that’s exactly what we’re doing right now.”

69. The above statements were materially false and misleading and failed to disclose: (i) Emergent’s Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent’s Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants’ public statements about Emergent’s ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

70. On November 5, 2020, Emergent reported financial results for the third quarter and nine-month period ending September 30, 2020 and conducted an investor conference call. On the call, Defendant Husain stated:

I’m incredibly pleased to be here today to provide a deep dive into the CDMO business. As Bob noted earlier, we have demonstrated significant revenue and portfolio growth by deploying our expertise across development services, drug substance manufacturing and drug product manufacturing with both industry and government customers. While much of the recent growth has been driven by collaborations on COVID-19 programs, I want to emphasize the durability and sustainability of our CDMO business. Our ongoing investment in both capacity and new capabilities will increase our ability to meet the expected long-term demand, leading to significant long-term growth.

Our confidence is based on several factors. First, we have an extremely successful track record of development and manufacturing abilities. Bob alluded to the history of Emergent in his comments, and that legacy continues to benefit us to this day. We also have an enterprise team of more than 1,400 technical and quality compliance professionals, a vital key to our success. Another advantage is the location of our facilities and capabilities that are in close proximity to pharma and biotech hubs. Finally, we possess a unique biologics platform of technologies with customizable offerings across the entire drug development life cycle.

In the next couple of slides, I'll give a brief overview of the CDMO business. For those interested in more detail, the slides and transcript from our 2019 Analyst and Investor Day are available on our IR website. This slide shows the broad and varied offerings we provide to our customers, allowing for end-to-end integrated services. With 3 molecules to market service offerings, 5 technology platforms and 9 development and manufacturing sites, we have the foundation to meet the individual needs of our customers now and into the future. Given time constraints, I'm not going into detail on our service offerings, but do want to note 3 main buckets: development services; drug substance manufacturing; and drug product manufacturing and packaging. Again, offering 1, 2 and or all 3 services allows us to rapidly partner and collaborate with customers from concept to commercialization, which we describe as molecule-to-market.

The next slide shows a high-level overview of our facilities, which are spread across 9 locations in the United States, Canada and Switzerland. While this slide reinforces the substantial expertise and infrastructure already in place, importantly, it also shows the significant opportunity for expected further investments as evident with our active investments at 3 of our facilities: viral vector and gene therapy drug substance manufacturing at our Canton, Massachusetts facility; nonviral drug product manufacturing at our Baltimore, Maryland Camden facility; and viral drug product manufacturing at our Rockville, Maryland facility. This will allow us to increase our capacity to deliver on future business opportunities in the coming years. As a reminder, presently, we are only in – only 1 year into the relaunching of this business to realize the full potential of our broad network of sites as well as growing capabilities and capacities.

71. In response to an analyst inquiry regarding Emergent's ability to handle multiple COVID-19 vaccine clients, Defendant Husain assured during the call that the Company's facilities

are “designed to handle multiple products... [the] facility in Baltimore, which is known as our Bayview facility, so right now, that is predicated on multiple products being in there.”

72. Defendant Kramer further stated in response to an analyst question:

First of all, as Syed has articulated, we have a fairly broad and diverse network of 9 different CDMO development and manufacturing sites. And as you know, just from following us for quite some time, all of those manufacturing sites are a bit different. If you talk about capacity for COVID-19 vaccine development manufacturing in Bayview, which is where the majority of that work is being done, I think we've said out loud that we're pretty much capacity maxed out right now with the work that we're doing with J&J, with AZ, with Novavax and as well as with Vaxart.

73. During the JPMorgan Healthcare conference held on January 11, 2021, Defendant Kramer stated:

I think in terms of the relationships with our collaborators, just – they continue to be exceptionally strong. As you know, we're working with firms like J&J as well as AstraZeneca. We've done work for Novavax, for Vaxart and some other firms. It continues to evolve. It continues to get stronger. Our focus clearly during 2020 was to initially ensure that we're standing up the manufacturing muscle, if you will, to be able to support the large-scale vaccine manufacturing capability for a number of candidates. I think the relationship also with BARDA and OWS and HHS continues to be very strong.

74. On February 18, 2021, the Company reported financial results for the fourth quarter and year ended December 31, 2020. During Emergent's conference call with investors, Defendant Kramer stated that Emergent was “playing a critical role in the fight against COVID-19 with the development and manufacturing of clinical and commercial materials across our 3 CDMO service pillars for a variety of customers, most notably Johnson & Johnson, AstraZeneca...” In response to analyst inquiry, Defendant Kramer stated, “Specific to J&J, you know what they said in terms of their short-term goal is to provide as many as 100 million doses to the U.S. government in the first half of 2021. And we're right on schedule to support that.”

75. The above statements were materially false and misleading and failed to disclose: (i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

76. Emergent's annual report filed on Form 10-K on February 19, 2021 contained the following Risk Factors with respect to Emergent's business and operations:

Problems may arise during the production of our marketed products and product candidates, as well as those we produce for our CDMO customers, due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development and our ability to ramp up production to meet the needs of our customers could cause delays in recognizing revenues, which would harm our business, financial condition, operating results and cash flows.

* * *

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture anthrax vaccines, ACAM2000 or our other products, as well as deliver our CDMO services, which would harm our business, financial condition, operating results and cash flows.

* * *

An interruption in our manufacturing operations could result in our inability to produce our products and product candidates for delivery to satisfy the demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flows.

* * *

In addition, we may not be able to ramp up our manufacturing processes to meet the rapidly changing demand or specifications of our customers on the desired timeframe, if at all. For example, we have not previously had to ramp our organization for a commercial launch of any product at the current pace required to address treatments related to COVID-19 and doing so in a pandemic environment with an urgent, critical global need creates unique manufacturing challenges, challenges related to distribution channels, and the need to establish teams of people with the relevant skills. Our inability to ramp up manufacturing to meet the demand or specifications of our customers could also harm our business, financial condition, operating results and cash flows.

77. The above statements were materially false and misleading and failed to disclose:

- (i) Emergent’s Baltimore plant had a documented history of serious quality control and manufacturing issues;
- (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues;
- (iii) Emergent’s Baltimore plant had heightened risk of manufacturing problems, including contamination risks;
- (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and
- (v) as a result of the foregoing, Defendants’ public statements about Emergent’s ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

78. On March 1, 2021, Defendant Lindahl presented at the J.P. Morgan Global Leveraged Finance and High Yield Conference. The slide presentation published to Emergent’s website in advance of the conference claimed Emergent had a “Proven 22-year track record in preparedness and response,” was a “trusted partner to governments” and had a “scalable and sustainable business model”:

Company snapshot



A life sciences company with a diversified portfolio of **products + pipeline** plus **CDMO services** focused on addressing **public health threats**.

- Proven **22-year track record in preparedness and response**
- **Leadership positions** in key public health threat markets
- **Trusted partner** to governments, NGOs and pharma/biotech innovators
- Organized as **four distinct business units** with shared services
- **Scalable and sustainable** business model

4

WHO WE ARE

JPMorgan Leveraged Finance/High Yield Conference 2021

79. The above statements were materially false and misleading and failed to disclose: (i) Emergent's Baltimore plant had a documented history of serious quality control and manufacturing issues; (ii) Emergent was the recipient of multiple citations by the FDA in connection with quality control and data integrity issues; (iii) Emergent's Baltimore plant had heightened risk of manufacturing problems, including contamination risks; (iv) the Company previously had to discard the equivalent of millions of doses of COVID-19 vaccines after workers at the Baltimore plant deviated from manufacturing standards; and (v) as a result of the foregoing, Defendants' public statements about Emergent's ability and capacity to mass manufacture multiple COVID-19 vaccines at its Baltimore manufacturing site were materially false and/or misleading and/or lacked a reasonable basis.

V. THE TRUTH IS DISCLOSED

80. On March 31, 2021, after the close of markets, *The New York Times* published an article reporting on the accidental contamination of COVID-19 vaccines developed by J&J and

AstraZeneca at the Emergent manufacturing plant in Baltimore. The *New York Times* article stated that in late February 2021, employees at Emergent's Baltimore manufacturing plant inconceivably "mixed up" ingredients of the two different COVID-19 vaccines, contaminating up to 15 million doses of J&J's vaccine and forcing regulators to delay authorization of the plant's production lines.

81. Further, the March 31, 2021 *New York Times* article noted that Emergent's massive vaccine lot contamination went undiscovered for days until J&J's quality control checks uncovered it, raising questions about Emergent's failed training and supervision of its employees during the production process.

82. On April 1, 2021, the *Associated Press* reported on Emergent's "history of violations," noting that the FDA has repeatedly cited Emergent for problems such as poorly trained employees, cracked vials and problems managing mold and other contamination in its facilities. The April 1, 2021 article highlighted that the FDA's inspection of Emergent's Baltimore plant had faulted the Company for a series of quality control shortcomings.

83. Two days later, on April 3, 2021, *The New York Times* reported that the Biden administration took the extraordinary action of putting J&J in charge of Emergent's Baltimore plant and prohibiting it from producing the AstraZeneca vaccine, an incredible blow for a Company that had touted its "unique" preparedness and "proven manufacturing capabilities" only months prior. The article called the "ingredient mix-up" and stripping of Emergent's control over its own plant "a significant setback and a public relations debacle."

84. On this news, Emergent's stock price declined precipitously from \$92.91 at close on March 31, 2021 down to \$80.46 at the close of trading on April 1, 2021— a \$12.45 drop equating to over a 13% decline in share price. As more facts unfolded in the media, the Company's stock price continued to decline, closing at \$78.62 on April 5, 2021. Additionally, on April 6, 2021, *The*

New York Times published another report, citing undisclosed internal documents and interviews with current and former federal officials, as well as Company employees. The April 6, 2021 *New York Times* article found Emergent to be ill-equipped to take on the important manufacturing task of producing COVID-19 vaccines, despite having received a \$163 million federal contract to improve its facility and prepare for high-volume production. Audits and investigations – including ones conducted in 2020 by J&J, AstraZeneca, two federal agencies and Emergent’s own quality evaluators – found that Emergent had not followed basic industry standards at its Baltimore facility, and identified repeated shortcomings in efforts to disinfect and prevent contamination. Specifically, an audit conducted for AstraZeneca highlighted the risks of viral cross-contamination, which experts believe was responsible for tainting the millions of J&J doses.

85. The April 6, 2021 *New York Times* article also noted that the loss of the J&J doses was not the first time Emergent had to throw out coronavirus vaccine for fear of contamination, as between October 2020 and January 2021, Emergent discarded five lots of AstraZeneca vaccine – each the equivalent of two million to three million doses – because of contamination or suspected contamination. In November 2020, production of a batch of J&J vaccine was also discarded after workers “hooked up” the wrong gas line and accidentally “suffocated” the cells where the virus for the vaccine is grown. The next month, workers making AstraZeneca’s vaccine deviated from manufacturing standards on average more than three times a day, and about one-fifth of the deviations were classified as major.

VI. DEFENDANTS ACTED WITH SCIENTER WHEN THEY MADE OR CAUSED TO BE MADE MATERIAL MISSTATEMENTS OR OMISSIONS IN VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT

86. Defendants were active and culpable participants in the fraud alleged herein, as evidenced by their knowing or reckless issuance and/or ultimate authority over the materially false or misleading statements alleged herein. Each of the Individual Defendants acted with scienter in

that each knew or recklessly disregarded that each of his respective public statements alleged above was materially false or misleading when made, and knowingly or recklessly participated or acquiesced in the issuance or dissemination of each such statement as a primary violator of Section 10(b) of the Exchange Act.

VII. PRESUMPTION OF RELIANCE

87. At all relevant times, the market for Emergent's common stock was efficient for the following reasons, among others:

(a) Emergent common stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Emergent filed periodic reports with the SEC;

(c) Emergent regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Emergent was followed by numerous securities analysts employed by major brokerage firms. Each of these reports was publicly available and entered the public marketplace.

88. As a result of the foregoing, the market for Emergent's common stock promptly digested current information regarding Emergent from all publicly available sources and reflected such information in the price of Emergent's common stock. All purchasers of Emergent common stock during the Class Period suffered similar injury through their purchase of Emergent common stock at artificially inflated prices, and a presumption of reliance applies.

89. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S.

128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose.

VIII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

90. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this complaint. The specific statements alleged herein to be false and misleading were not identified as “forward looking statements” when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements.

91. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Emergent who knew that those statements were false when made.

IX. CLASS ACTION ALLEGATIONS

92. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf individuals or entities, excluding Defendants and their affiliates, that purchased or otherwise acquired common stock of Emergent from April 24, 2020 through April 16, 2021.

93. There are questions of law and fact that are common to the Class, which predominate over any individual issues, including:

- (a) whether Defendants misrepresented material facts;

- (b) whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;
- (c) whether the price of Emergent's common stock was artificially inflated;
- (d) whether the Individual Defendants are liable as "controlling persons" under §20(a) of the Exchange Act; and
- (e) whether Plaintiff and the other members of the Class were injured as a result of Defendants' misconduct.

94. Plaintiff's claims are typical of the claims of the other members of the Class because Plaintiff and the Class sustained damage from Defendants' wrongful conduct.

95. Plaintiff is committed to prosecuting this action and has retained competent counsel experienced in litigation of this nature. Plaintiff has the same interests as the other members of the Class. Accordingly, Plaintiff is an adequate representative of the Class and will fairly and adequately protect the interests of the Class.

96. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

X. CLAIMS FOR RELIEF

COUNT I For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

97. Plaintiff repeats, incorporates and realleges each and every allegation contained above as if fully set forth herein.

98. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) caused Plaintiff and other members of the Class to purchase Emergent common stock at artificially inflated prices.

99. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Emergent's common stock in violation of Section 10(b) of the Exchange Act, 15 U.S.C. §§ 78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

100. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operation and prospects.

101. During the Class Period, Defendants made the false statements specified above, which they knew, or recklessly disregarded, to be false or misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

102. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or recklessly disregarded the true facts that were available to them. Defendants engaged in this misconduct to conceal Emergent's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

103. As described above, Defendants acted with scienter in committing the wrongful acts and omissions alleged herein in that they either had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard

for the truth in that they failed to ascertain and disclose the true facts, even though such facts were available to them.

104. Defendants engaged in this scheme in order to maintain and/or inflate the prices of Emergent's common stock.

105. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Emergent's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the prices they paid, or at all, had they been aware that the market prices for Emergent's common stock had been artificially inflated by Defendants' fraudulent course of conduct.

106. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered damages in connection with its purchases of Emergent common stock during the Class Period.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against Defendants Kramer, Lindahl and Husain

107. Plaintiff repeats, incorporates and realleges each and every allegation set forth above as if fully set forth herein.

108. This Count is asserted against Defendants Kramer, Lindahl and Husain for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

109. During his tenure as CEO of Emergent, Defendant Kramer was a controlling person of Emergent within the meaning of Section 20(a) of the Exchange Act. By reason of his position of control and authority as Emergent's CEO, Defendant Kramer had the power and authority to cause Emergent to engage in the wrongful conduct complained of herein. Defendant Kramer was able to and did control, directly and indirectly, the content of the public statements made by Emergent, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein during the Class Period.

110. As set forth above, Emergent violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Emergent and, as a result of their own conduct, Defendants Kramer, Lindahl and Husain are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as, Emergent is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiff and other members of the Class who purchased Emergent common stock during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

D. Awarding such equitable/injunctive or other further relief (including, but not limited to, rescission) as the Court may deem just and proper.

XII. JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: June 2, 2021

/s/

Andrew Radding, Esq. (Bar No. 00195)

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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Emergent BioSolutions Facing Securities Class Action Over Vaccine Manufacturing Woes, Stock Drops](#)
