IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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IN RE EMERGENT BIOSOLUTIONS INC. SECURITIES LITIGATION	*	**Civ. No. DLB-21-955**
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MEMORANDUM OPINION

Nova Scotia Health Employees' Pension Plan and City of Fort Lauderdale Police & Firefighter's Retirement System, as lead plaintiffs, bring this securities class action against Emergent BioSolutions Inc. ("Emergent") and three Emergent officers (collectively, "the Individual Defendants," and collectively with Emergent, "the Defendants"). Emergent is a biopharmaceutical company that was tasked by the federal government in the early days of the pandemic to develop and manufacture drug substances for COVID-19 vaccines. The lead plaintiffs, on behalf of a class of shareholders who acquired Emergent stock between March 10, 2020 and November 4, 2021 (collectively, "the Plaintiffs"), assert violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a) (2018) ("the Exchange Act"), and a regulation promulgated thereunder, 17 C.F.R. § 240.10b-5 (2022) ("Rule 10b-5"). Generally, they allege the Defendants defrauded them by misrepresenting Emergent's drug substance manufacturing capabilities at a facility located in Baltimore, Maryland and, after news broke of a contamination incident at the facility, by misrepresenting the magnitude of the contamination and its causes. The disclosures of the alleged misrepresentations caused the prices of Emergent stock to drop sharply, resulting in shareholder losses.

The Defendants move to dismiss the amended complaint under Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995

("PSLRA"). ECF 72. The motion is fully briefed. ECF 80 & 115. A hearing was held on April 19, 2023. For the following reasons, the motion to dismiss is granted in part and denied in part.

I. Factual Background[1]

A. Emergent and the Bayview facility

Emergent is a Maryland-based biopharmaceutical company that provides preparedness and response products to address public health threats. Emergent is comprised of six segments focusing on different public health threat categories, including a Contract Development and Manufacturing Organization ("CDMO") segment that provides "molecule-to-market" offerings such as drug substance manufacturing for vaccines. Emergent provides CDMO services to biopharmaceutical companies, government agencies, and non-governmental organizations. The company is led by Defendant Robert G. Kramer, who has served as President since March 2018 and Chief Executive Officer and Director since April 2019. Defendant Richard S. Lindahl has been Emergent's Executive Vice President, Chief Financial Officer, and Treasurer since March 2018. Defendant Syed T. Husain was Emergent's Senior Vice President and Head of the CDMO segment until his resignation, announced on April 29, 2021.

Emergent has seven manufacturing and development facilities in the United States, including a facility in Baltimore, Maryland ("the Bayview facility" or "Bayview") that Emergent acquired in 2009. Originally a contract testing laboratory, the Bayview facility underwent renovations in 2011 and 2018 to add manufacturing and pilot plant capabilities, resulting in four separate suites (also referred to as "Areas"). It is one of just three facilities in the United States

[1] This section summarizes the allegations in the Plaintiffs' amended complaint, ECF 54. The Court also considers the 51 exhibits attached to the Defendants' motion to dismiss, which are referenced in the amended complaint and whose authenticity the Plaintiffs do not challenge. *See Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 607 (4th Cir. 2015). The Court also has taken judicial notice of a Congressional report dated May 10, 2022 and its exhibits. ECF 113.

that is federally designated as a Center for Innovation in Advanced Development and Manufacturing ("CIADM"), the purpose of which is to support public health emergency needs. In June 2012, the U.S. Department of Health and Human Services ("HHS") awarded Emergent a $163 million contract to prepare the Bayview facility for mass production of vaccines in a pandemic.

B. Emergent and COVID-19 vaccines

In early 2020, soon after the COVID-19 pandemic began, the United States government funded Operation Warp Speed ("OWS") to support rapid development, manufacturing, and distribution of vaccines. As part of OWS, on April 23, Emergent entered into an agreement with Johnson & Johnson ("J&J"), valued at $135 million, to provide drug substance manufacturing services for J&J's COVID-19 vaccine as well as to reserve large-scale manufacturing capacity for J&J. The parties entered into another agreement on July 6 that expanded the arrangement to a five-year deal, valued at an additional $480 million for the first two years. During those years, Emergent would provide drug substance manufacturing services for J&J at the Bayview facility. For the remaining three years, it would provide a "flexible capacity deployment model to support annual dose requirements." ECF 54, ¶ 52.

On May 30, HHS's Biomedical Advanced Research and Development Authority ("BARDA") issued a task order to Emergent to ensure capacity reservation and expansion to facilitate the manufacture of third-party COVID-19 vaccines. The contract, valued at approximately $628 million, required Emergent to "maintain the reserved capacities in a state of readiness to perform current good manufacturing practices (cGMP) manufacturing activities . . . for the entirety of the period of performance." *Id.* ¶ 53.

On June 11, Emergent contracted with AstraZeneca ("AZ") to provide CDMO services and reserve large-scale manufacturing capacity at the Bayview facility for AZ's COVID-19 vaccine. That agreement was valued at approximately $87 million. On July 27, Emergent entered another deal with AZ, valued at approximately $174 million through 2021, to produce large-scale drug substance manufacturing at the Bayview facility under a flexible capacity deployment model.

In August, Emergent began manufacturing the AZ bulk drug substance in Area 3 of the Bayview facility. Each "batch" of AZ bulk drug substance translated to roughly 2.5 – 3 million AZ COVID-19 vaccine doses. Several months later, in November, Emergent began manufacturing the J&J bulk drug substance in Areas 1 and 2 of the Bayview facility. Each "batch" of J&J bulk drug substance translated to roughly 10 – 15 million J&J COVID-19 vaccine doses. J&J vaccines, once manufactured, were sent to a J&J laboratory for quality control testing before distribution.

In total, Emergent was awarded approximately $628 million in government funding and a combined $876 million from its J&J and AZ agreements to provide large-scale manufacturing facilities that would support the rapid supply of vaccine doses to the public once the vaccines were developed and approved. When each of these deals was announced, analysts raised the price target on Emergent's stock.

C. Contamination and quality control concerns

The Plaintiffs allege that between March 10, 2020 and November 4, 2021 ("the Class Period"), there were "myriad deficiencies that plagued the Bayview facility and created the persistent risks of contamination of COVID vaccine drug product." *Id.* ¶ 59. These deficiencies included widespread mold, poorly disinfected equipment, inadequate staffing and training, substandard quality control procedures, and improper waste procedures. To support these allegations of undisclosed deficiencies, the Plaintiffs rely on confidential witness statements, FDA

and other inspection reports, news reports, preliminary Congressional findings, and final Congressional findings published on May 10, 2022 ("2022 Congressional Report").

The Plaintiffs identify ten confidential witnesses ("CWs") who observed and reported various deficiencies at Bayview. They include: (1) CW1, a Senior Project Manager at corporate headquarters from April to December 2020; (2) CW2, a Senior Program Manager, Operational Excellence from December 2018 to January 2021, then Director, Operational Excellence from January to December 2021, based at Bayview and other facilities; (3) CW3, a Quality Assurance Analyst at the Bayview facility from November 2020 to November 2021; (4) CW4, a Quality Control ("QC") Microbiology Analyst II at the Bayview facility from July 2019 to July 2020; (5) CW5, a Project Analyst at corporate headquarters from August 2020 to January 2021; (6) CW6, a QC Microbiology Specialist, Data Review Supervisor at the Bayview facility from October 2020 to May 2021; (7) CW7, a Lead QC Biological Laboratory Support Technician at the Bayview facility from March to October 2020; (8) CW8, a QC Supervisor at the Bayview facility from June to December 2020; (9) CW9, a Manufacturing Assistant and then Bioprocess Associate at the Bayview facility from July 2020 to October 2021; and (10) CW10, a QC Analyst II – Microbiology at the Bayview facility from April 2020 to May 2021. The CWs generally allege that when Emergent took on COVID-19 contracts in spring and early summer 2020, the Bayview facility did not have the properly trained personnel, equipment, quality control processes, physical space, or functional capability needed to handle the work—in short, that Emergent was unqualified and unprepared for mass production of vaccine drug substance. These deficiencies, the CWs allege, persisted throughout the Class Period.

Beginning in April 2020, a series of internal and external audits of the Bayview facility took place. On April 1, a BARDA audit found that Bayview had "substantial evidence of site

cGMP non-compliance" and "risk to CIADM readiness" due to "inadequate quality unit oversight" and "failure of quality systems," including improper procedures, mishandling of products, and unqualified staff. *See* ECF 79-4, at 3. The FDA inspected the Bayview facility in April 2020 and issued an inspection report on April 20. Though the inspection was initially intended as a preapproval inspection regarding an anthrax drug, when the FDA investigator observed "multiple deficiencies with data integrity and general cGMP practices," the FDA expanded the scope of the inspection. ECF 54, ¶ 110(d). After the inspection, the FDA issued a Form 483 noting five issues:

> 1) appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel; 2) established specifications, test procedures and laboratory control mechanisms are not followed and documented at the time of performance; 3) the responsibilities and procedures applicable to the quality control unit are not in writing and fully followed; 4) employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices; 5) separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected components before disposition.

Id. ¶ 110(f).[2]

On May 8, Emergent issued a response to the Form 483 stating it had taken "immediate, holistic and comprehensive measures to address the deficiencies noted" and providing details in response to each issue. *Id.* ¶ 136. These measures included "counseling sessions" with quality

[2] According to the FDA's website, a Form 483 is used at the end of an inspection

> when an investigator(s) has observed any condition that in their judgment may constitute violations of the [FD&C] Act . . . . Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device, or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health . . . .

ECF 54, ¶ 71. The FDA's website also states that "[c]ompanies are required to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist." *Id.*

control staff and training on updated procedures. *Id.* ¶ 136(b). According to CW10, however, the Bayview facility's quality control staff were never given detailed information about issues that needed to be addressed.

More audits took place in June. A report by an OWS advisor (the "Warp Speed Report") stated that most of Bayview's existing equipment was "not suitable" for the task and that its personnel and compliance risks were "significant." *Id.* ¶ 124(a). An audit by J&J's subsidiary flagged problems with Bayview's quality review systems, mold, poor disinfection of equipment, untested raw materials, inadequate training, and microbial contamination control strategy. A simultaneous AZ audit identified similar deficiencies as well as documentation and computerized systems issues. Another BARDA audit during June and July identified three "critical" observations in quality control, microbial contamination, and documentation. ECF 79-18, at 10–11.

On June 23, the FDA forwarded a letter from its Office of Pharmaceutical Manufacturing Assessment ("OPMA") to Emergent stating that Emergent's written responses to its April inspection report were insufficient. ECF 79-9, at 2; ECF 79-10, at 4. The letter stated that OPMA "does not consider your facility ready to support commercial operations." ECF 79-9, at 2. It identified deficiencies that remained unaddressed, including ongoing data integrity issues and inadequate responses to the FDA's drug testing and quality control concerns. *Id.* at 3.

In summer 2020, Emergent conducted internal audits of the Bayview facility. One internal audit from July found that the "flow of workers and materials through the plant was not adequately controlled 'to prevent mix-ups or contamination.'" ECF 54, ¶ 118. In August, another internal audit found that a manager "knowingly deviated" from standards by approving raw materials for

AZ's vaccine without fully testing them. *Id*. Internal logs from October showed similar deviations occurring twice a week.

The Bayview facility continued to experience problems throughout the Class Period. As flagged by the J&J and AZ audits, there was "a persistent problem with mold in areas required to be kept clean." *Id*. The mold posed a contamination risk affecting "every inch of that building," particularly in Area 4 but also in Areas 2 and 3. *Id.* ¶ 68. According to CW6, the situation did not improve after the audits—instead, the number of contamination alerts increased from October 2020 to May 2021. *Id.* ¶ 65.

In addition to mold, there were other violations of standard operating procedures. These included incomplete drug testing data in batch records, improper inventory practices (which on at least one occasion led to Emergent being unable to locate a specimen requested by the FDA), and inadequate cleaning of lab equipment. Problems stemmed in part from the Bayview facility's physical limitations. For example, the facility's sample receiving room "did not have enough freezer and refrigerator space to store product samples for multiple different client vaccines"; as a result, "samples were broken and lost." *Id.* ¶ 67.

According to the CWs, because of these deficiencies, the COVID-19 vaccine projects faced significant delays and missed deadlines. Despite these issues, Emergent continued to seek additional contracts. During summer 2020, it added a "significant" number of new employees. *Id.* ¶ 153. According to CW9, however, there was no training department at Bayview and "little to no training for new employees," who were largely in their early 20s with "little to no pharmaceutical or manufacturing experience." *Id.* ¶ 68. The QC Microbiology team in particular was "severely understaffed, under-equipped, and undertrained." *Id.* ¶ 65.

D. News of contamination

On March 31, 2021, *The New York Times* ("the *NYT*") broke the news that Emergent had destroyed a batch of J&J drug substance due to contamination at the Bayview facility. The *NYT* reported that in February, Emergent employees at the Bayview facility had mixed up ingredients for J&J and AZ batches, contaminating up to 15 million doses of the J&J vaccine and prompting quarantine of others. The error was not discovered, however, until J&J conducted final pre-release testing of actual vaccine doses. The day after news of the contamination broke, Emergent confirmed that it had in fact destroyed a J&J drug substance batch totaling approximately 15 million vaccine dose-equivalents that "did not meet specifications." *Id.* ¶ 187. Another 62 million J&J doses required examination to see if they too were contaminated.

On April 3, the *NYT* reported that a review of earlier audits and investigations by J&J, AZ, federal agencies, and Emergent itself revealed "repeated shortcomings in efforts to disinfect and prevent contamination." *Id.* ¶ 118. The *NYT* also exposed that in addition to the J&J batch that was destroyed in February, between October 2020 and January 2021, Emergent had discarded five batches of the AZ vaccine due to contamination or suspected contamination. In November 2020, a J&J batch was discarded due to worker error. In December 2020, workers making AZ's vaccine reportedly deviated from proper standards more than three times a day on average, with one-fifth of those deviations classified as major.

E. Aftermath of contamination news

After news of the February contamination incident broke, Emergent's stock price declined from $92.91 per share on March 31 to $80.46 per share on April 1, a drop of 13.4% per share. The government soon thereafter placed J&J in control of the Bayview facility. At the government's request, Emergent halted manufacture of any new vaccine material at Bayview, quarantined all

previously produced material, and permanently stopped producing the AZ vaccine. After these measures were announced, Emergent's stock price fell to $67.87 per share on April 19.

Throughout April 2021, the FDA again inspected the Bayview facility, including by reviewing data, video, and other materials from January through April 2021. CW9 stated that just before one of these April inspections, a supervisor "wrapped tubing around the mold so FDA inspectors could not see the mold from the outside." *Id.* ¶ 68. CW9 also stated that before the FDA inspected Bayview in early 2021, the Head of Manufacturing had employees carry bags of hazardous, unsterilized waste through sterile areas of the facility to large hazardous waste containers every Wednesday morning, because the facility "did not have the capacity to handle the volume of hazardous trash produced by COVID-19 vaccine manufacturing." *Id.*

On April 21, the FDA issued another Form 483 report detailing nine observations of material deficiencies:

> (1) Failure to conduct thorough investigations into unexplained discrepancies;
> (2) The building used for the manufacture of the [J&J and AZ viral vaccine drug substances] is not maintained in a clean and sanitary condition;
> (3) [That building] is not of suitable size, design, and location to facilitate cleaning, maintenance, and proper operations;
> (4) Written production and process control procedures to prevent cross-contamination are not followed in the execution of production and process control functions and are not documented at the time of performance;
> (5) The components, product containers and/or closures were not handled and/or stored in a manner to prevent contamination;
> (6) Written procedures designed to assure that the drug substances manufactured in the facility have the identity, strength, quality, and purity they purport or are represented to possess are inadequate;
> (7) Employees were not trained in the particular operation that they performed and/or in CGMPs related to their job function;
> (8) Equipment used is not of adequate size to facilitate operations for its intended use or for cleaning and maintenance; and
> (9) Equipment and/or utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug substance.

ECF 72-46, at 2–13. On April 29, Emergent announced Husain's resignation. The next day, Emergent issued a 52-page response to the FDA's report.

On June 11, the *NYT* reported that an additional 60 million doses of the J&J vaccine that had been quarantined due to the February contamination incident would be destroyed, and another 10 million could be distributed with a warning that regulators could not guarantee Emergent had used proper manufacturing practices. A week later, the *NYT* reported that over 100 million doses of both the J&J and AZ vaccines were being held in limbo pending FDA review.

The FDA permitted Emergent to resume manufacturing the J&J vaccine in July 2021. According to some CWs, despite Emergent's representations that staff would be re-trained and standard operating procedures would be updated, "not a single thing" happened while production was halted. ECF 54, ¶ 68.

On November 4, 2021, Emergent announced that the government had terminated its $650 million contract, lowering the contract's realized value by $180 million. Emergent's participation in the CIADM program also ended. Emergent reversed $86 million in Q3 2021 revenue and lowered its backlog by $171 million. These changes lowered the midpoint of its revenues by $50 million. From November 4 to November 5, Emergent's stock price declined by over 37%, closing at $33.11 per share on November 5.

F. Congressional investigation

In April 2021, the U.S. House of Representatives Committee on Oversight and Reform and Select Subcommittee on the Coronavirus Crisis (the "Committees") launched a year-long investigation into Emergent, gathering documents and taking testimony from Emergent, J&J, AZ, HHS, and the FDA. On May 19, the Committees issued a memorandum with preliminary findings. Also that day, on behalf of Emergent, Kramer testified that a single J&J batch was affected by the

contamination and that Emergent was taking corrective action to address the issue. Both J&J and AZ testified to Congress that as early as June 2020, they had identified corrective actions Emergent needed to implement to be ready for manufacturing.

Almost a year later, on May 10, 2022, the Committees published a staff report titled "The Coronavirus Vaccine Manufacturing Failures of Emergent BioSolutions" along with underlying materials. The 2022 Congressional Report made six key findings:

> (1) Nearly 400 million doses of coronavirus vaccines have been destroyed as a result of Emergent's failure to meet or maintain quality standards;
> (2) Emergent hid evidence of contamination from government investigators;
> (3) Emergent executives promoted the company's manufacturing capabilities despite being warned of severe deficiencies;
> (4) FDA, Johnson & Johnson, and AstraZeneca identified multiple deficiencies at Bayview which Emergent failed to remediate despite urgent warnings;
> (5) Inexperienced staff and high staff turnover contributed to the vaccine contaminate; and
> (6) Under the Biden Administration, HHS terminated its contract with Emergent because the company failed to follow federal manufacturing standards.

ECF 79-2, at 4–5. The nearly 400 million destroyed doses was a higher total than previously revealed and included an additional 90 million newly-manufactured J&J doses (from *after* Emergent was permitted to resume manufacturing in July 2021) that had to be destroyed. An additional 135 million doses remained sequestered pending testing at the time the report was published. The report included the June and July 2020 audits that found that the Bayview facility had a deficient contamination control strategy, among other issues. Additional details in the report included that before the FDA's inspection in April 2021, Emergent personnel removed "hold tags" (which indicate that containers have a potential quality control issue) from J&J batches so as not to draw FDA inspectors' attention. Emergent also had waited until March 26, 2021 to inform HHS of the February batch cross-contamination despite the fact that J&J had notified Emergent of it ten days earlier.

G. Securities fraud allegations

1. Material misrepresentations and omissions

The Plaintiffs allege that throughout the Class Period, the Defendants were aware that severe and persistent deficiencies at the Bayview facility undermined Emergent's ability to produce large quantities of drug substance for two different clients at once; that these known problems were not disclosed to the public; and that the public statements that the Defendants did make were false and misleading (and drove up Emergent's stock price). They also allege that once news of contamination and other issues broke, the Defendants continued to make false and misleading public statements designed to reassure investors and mute the extent of Emergent's stock price decline. In particular, the Plaintiffs allege that the Defendants violated Section 10(b) of the Exchange Act through three types of fraud: (1) a "business operations" fraud, in which the Defendants misrepresented Emergent's performance and capabilities, particularly its anti-contamination measures, both before and after news broke on March 31, 2021 of the contamination incident that led to the destruction of 15 million vaccine doses; (2) a "reported results" fraud, in which the Defendants' financial filings reported positive financial results that concealed underlying negative trends; and (3) an "internal controls" fraud, in which the Defendants' Sarbanes-Oxley Act ("SOX") certifications misrepresented the sufficiency of Emergent's internal controls.

a. Business operations fraud

For the alleged business operations fraud, the Plaintiffs identify numerous public press releases, reports, filings, interviews, presentations, and other announcements by the Defendants that contain alleged misstatements and omissions regarding Emergent's operations and capabilities, equipment, staffing, and training at the Bayview facility during the Class Period. ECF

54, ¶¶ 129–219. For ease of reference, the Court will discuss separately the statements made before and after the March 31, 2021 *NYT* news article about the contamination incident at Bayview.

Statements made before March 31, 2021 generally announced new COVID-19 contracts and touted Emergent's capabilities and the Bayview facility's particular attributes. For instance, on March 10, 2020, Emergent issued a press release announcing that "Emergent will produce the COVID-19 experimental vaccine candidate" and drug substance at the CIADM-designated Bayview location. *Id.* ¶ 129. Husain stated, "Emergent is proud to demonstrate ***its ability to rapidly deploy capabilities, capacities, and expertise as part of our molecule-to-market CDMO offering***." *Id.*[3] Emergent frequently stressed its "***extremely successful track record of development and manufacturing abilities***." *Id.* ¶ 168(b). In another press release, on July 6, Emergent touted the Bayview facility's

> ***unique capabilities across four independent suites to produce at clinical scale to get candidates rapidly into the clinic, while at the same time scaling up to enable large-scale manufacturing to up to 4000L to prepare for production of commercial volumes to meet customer demand. The CIADM has the capacity to produce tens to hundreds of millions of doses of vaccine on an annual basis, based upon the platform technology being used.***

Id. ¶ 148. Once batch production of the J&J and AZ drug substance began, Emergent also made statements emphasizing Bayview's ability to manufacture multiple products at once, explaining that it was "***designed to handle multiple products . . . so right now, [the Bayview facility] is predicated on multiple products being in there***." *Id.* ¶ 168(b); *see also id.* ¶¶ 164, 185.

After the *NYT* published the March 31, 2021 article on contamination at Bayview, Emergent made a series of statements about the incident. In an April 1, 2021 press release, Emergent stated that "***a single batch of drug substance was identified that did not meet***

[3] Bold and italicized emphases in quotes are in the amended complaint, ECF 54, unless otherwise noted.

specifications and our rigorous quality standards" and that it "***isolated this batch and it will be disposed of properly***." ECF 54, ¶ 187. The press release further stated that the Bayview facility was "***designed and validated to meet all current Good Manufacturing Practices***," "there are ***rigorous quality checks throughout [its] vaccine manufacturing processes***," those "***quality control systems worked as designed***," and "***[d]iscarding a batch of bulk drug substance . . . does occasionally happen***." *Id.* Kramer published an op-ed on April 14 reiterating that the incident involved a single batch. His testimony to Congress on May 19 likewise emphasized that the incident was isolated. After Kramer's Congressional testimony, Emergent made statements announcing when additional batches were released and indicating that it was addressing issues identified by the FDA.

b. Reported results fraud

For the alleged reported results fraud, the Plaintiffs identify SEC filings and public statements reporting revenues, net income, and earnings in which the Defendants allegedly failed to disclose that the figures were artificially inflated through unreported operational setbacks and undisclosed negative trends. ECF 54, ¶¶ 220–27. These statements were made between April 20, 2020 and September 30, 2021. *See id.* In addition to reporting financial figures, these filings attributed those results to the company's CDMO portfolio and proclaimed Emergent's CDMO services as part of the company's "***Highlights and Business Accomplishments for 2020***." *Id.* ¶ 224(b).

c. Internal controls fraud

For the alleged internal controls fraud, the Plaintiffs again point to Emergent's SEC filings (specifically, its Forms 10-Q and 10-K) in which the Defendants allegedly misrepresented the sufficiency of the company's internal controls. *Id.* ¶¶ 231–35. In these filings, Kramer and Lindahl

attested that the contents did not contain any untrue statements or material omissions and that they "***fairly present[ed] in all material respects the financial condition, results of operations, and cash flows***" of Emergent. *Id.* ¶ 232. They also certified that they disclosed "***[a]ll significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information***" as well as "***[a]ny fraud, whether or not material, that involves management or other employees who have a significant role in [Emergent's] internal controls over financial reporting***." *Id.*

2. Scienter

The Plaintiffs allege that the Defendants knew about the Bayview facility's deficiencies and contamination risks and, starting in October 2020, the destroyed batches. To support their scienter allegations, the Plaintiffs cite CWs, FDA and other reports, internal Emergent emails, news reports, and the initial and final Congressional reports. They allege that, in April 2020, the FDA investigator relayed the inspection report with his findings of deficiencies to senior management. And on June 23, 2020, the FDA emailed Emergent staff a letter informing them that deficiencies remained after reviewing Emergent's responses to the Form 483 and that "OPMA does not consider your facility ready to support commercial operations." ECF 79-9, at 2. An executive forwarded the FDA email to Kramer on June 24 and referred to his and Kramer's parking lot discussion about Bayview the prior week and to the fact that AZ and J&J audits also had found Bayview unready for commercial production. Kramer later testified to Congress that he had read the FDA reports and did not dispute the FDA's findings. Husain was included on a July 22 reply to an email from AZ's senior vice president that referenced the Form 483 and OPMA's determination that Emergent's responses were inadequate. Husain also led regular meetings about

Bayview's COVID-19 vaccine efforts in which mold issues were discussed. Audit reports by J&J, AZ, BARDA, and Emergent itself found deficiencies similar to those identified by the FDA. The *NYT* and other reporting indicated that as many as six batches were discarded before the February 2021 contamination incident.

In addition to allegations that the Defendants ignored these red flags, the Plaintiffs point to additional facts in support of their scienter allegations. They allege the Individual Defendants were financially motivated to commit fraud because they engaged in insider trading and reaped suspicious compensation and bonuses during the Class Period. They also assert that the departure of Husain and other executives shortly after news broke of the contamination incident was suspicious, and that Emergent collected unearned, windfall payments from the government in the form of reservation fees, particularly during the period when the FDA halted production at Bayview. Finally, the Plaintiffs allege that scienter is supported by the fact that the fraud implicated Emergent's "core operations"—vaccine manufacturing.

II. Standards of Review

A. Rule 12(b)(6)

Under Rule 12(b)(6), a party may seek dismissal for failure "to state a claim upon which relief can be granted." *Robertson v. Anderson Mill Elementary Sch.*, 989 F.3d 282, 290 (4th Cir. 2021) (quoting Fed. R. Civ. P. 12(b)(6)). To survive the challenge, the opposing party must have pleaded facts demonstrating it has a plausible right to relief from the Court. *Lokhova v. Halper*, 995 F.3d 134, 141 (4th Cir. 2021) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). A plausible claim is more than merely conceivable or speculative. *See Holloway v. Maryland*, 32 F.4th 293, 299 (4th Cir. 2022).

When ruling on a Rule 12(b)(6) motion, the Court must accept the allegations as true and draw all reasonable inferences in favor of the pleader. *Williams v. Kincaid*, 45 F.4th 759, 765, 777 (4th Cir. 2022). But the Court does not accept "legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments." *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 189 (4th Cir. 2022) (quoting *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013)). Merely reciting a claim's elements "and supporting them by conclusory statements does not meet the required standard." *Sheppard v. Visitors of Va. State Univ.*, 993 F.3d 230, 234 (4th Cir. 2021) (quoting *ACA Fin. Guar. Corp. v. City of Buena Vista, Va.*, 917 F.3d 206, 212 (4th Cir. 2019)). The Court "does not resolve contests surrounding facts, the merits of a claim, or the applicability of defenses." *Ray v. Roane*, 948 F.3d 222, 226 (4th Cir. 2020) (quoting *Tobey v. Jones*, 706 F.3d 379, 387 (4th Cir. 2013)).

B. Private Securities Litigation Reform Act and Rule 9(b)

The plaintiffs must meet the heightened pleading standards under Federal Rule of Civil Procedure 9(b) and the PSLRA, which govern Section 10(b) and 20(a) securities fraud claims. Under Rule 9(b), the plaintiffs must "state with particularity the circumstances constituting fraud." These circumstances include "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Weidman v. Exxon Mobil Corp.*, 776 F.3d 214, 219 (4th Cir. 2015) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999)).

Under the PSLRA, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). For each alleged

misrepresentation or omission, the complaint also must "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2) (emphasis added). If a complaint fails to meet the PSLRA's requirements, it must be dismissed. *Id.* § 78u-4(b)(3)(A); *Yates v. Municipal Mortg. & Equity, LLC*, 744 F.3d 874, 894 (4th Cir. 2014) (affirming dismissal of securities fraud class action complaint for, among other reasons, failure to meet the PSLRA's pleading requirements).

III. Relevant Legal Principles

A. Section 10(b) of the Exchange Act

The purpose of the Exchange Act is to "ensure that companies disclose the information necessary for investors to make informed investment decisions." *Yates*, 744 F.3d at 884 (citation omitted). To accomplish this purpose, Section 10(b) of the Exchange Act prohibits the use of "any manipulative or deceptive device or contrivance" in connection with the sale of a security in violation of SEC rules. *Id.* (citing 15 U.S.C. § 78j(b)). Rule 10b-5, which implements Section 10(b), makes it unlawful, in connection with the sale of a security:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b-5. Section 10(b) "provides an implied right of action for purchasers or sellers of securities who have been injured by violations of the statute." *Yates*, 744 F.3d at 884 (citing *Stoneridge Inv. Partners v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

To succeed on a claim under Section 10(b) and Rule 10b-5, a plaintiff must establish: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between

the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Singer v. Reali*, 883 F.3d 425, 437 (4th Cir. 2018) (quoting *Stoneridge Inv. Partners*, 552 U.S. at 157). The Defendants challenge the pleading sufficiency of only the first two elements. They argue the Plaintiffs have not adequately alleged that they made material misrepresentations or omissions with the requisite scienter.

1. Material misrepresentations and omissions

To satisfy the first element of a claim under Section 10(b), a plaintiff must demonstrate that the defendant made a statement or omission "that was *misleading* as to a *material* fact." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011). The challenged statement must meet three requirements: (1) the alleged misrepresentation or omission must be a factual one—"that is, one that is demonstrable as being true or false"; (2) the "statement itself must be *false*, or the omission must render public statements *misleading*"; and (3) "any statement or omission of fact must be *material*." *Longman v. Food Lion, Inc.*, 197 F.3d 675, 682 (4th Cir. 1999); 17 C.F.R. § 240.10b-5. "Materiality is an objective concept, involving the significance of an omitted or misrepresented fact to a reasonable investor." *Longman*, 197 F.3d at 682–83 (internal quotation omitted). A statement or omission is material "if there is a substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact." *Id.* (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)).

Section 10(b) does not "create an affirmative duty to disclose any and all material information." *Matrixx Initiatives*, 563 U.S. at 44. Rather, disclosure is required "only when

necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10-b5(b)); *Singer*, 883 F.3d at 440. "Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market." *Matrixx Initiatives*, 563 U.S. at 45.

2. Scienter

Section 10(b)'s scienter element requires a plaintiff to demonstrate that the defendant possessed "a mental state embracing intent to deceive, manipulate, or defraud." *Yates*, 744 F.3d at 885 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007)); 15 U.S.C. § 78u-4(b)(2). At the pleading stage, a complaint that "alleg[es] either intentional or severely reckless conduct" suffices. *Yates*, 744 F.3d at 884. In the Section 10(b) context, "[r]ecklessness is an act so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *KBC Asset Mgmt. NV v. DXC Tech. Co.*, 19 F.4th 601, 608 (4th Cir. 2021) (quoting *Maguire Fin., LP v. PowerSecure Int'l, Inc.*, 876 F.3d 541, 547 (4th Cir. 2017) (internal quotation omitted)).

The PSLRA mandates that, "with respect to *each act or omission alleged*," a plaintiff must "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphases added); *San Antonio Fire & Police Pension Fund v. Syneos Health, Inc.*, No. 21-2309, --- F.4th ---, 2023 WL 4688178 , at *3 (4th Cir. July 24, 2023) ("Plaintiffs must raise a strong inference that Defendants intended to deceive them or created such a high risk of misleading them that Defendants must have known that they were being deceptive." (citation omitted)). To allege fraud against a corporation, a plaintiff must "allege

facts that support a strong inference of scienter with respect to at least one authorized agent of the corporation." *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 182 (4th Cir. 2009) (internal quotation marks omitted). To allege fraud against an individual defendant, a plaintiff "must allege facts supporting a strong inference of scienter as to that person." *Yates*, 744 F.3d at 885 (citing *Matrix Capital*, 576 F.3d at 182).

After analyzing each scienter allegation, courts "ultimately evaluate [the] plaintiff[s'] allegations of scienter holistically" and afford them "the inferential weight warranted by context and common sense." *Id.* (quoting *Matrix Capital*, 576 F.3d at 176). The inference of scienter must be "cogent and compelling." *Maguire Fin.*, 876 F.3d at 547 (quoting *Tellabs*, 551 U.S. at 324). Courts engage in a necessarily "comparative inquiry" by "compar[ing] the malicious and innocent inferences cognizable from the facts pled . . . and only allow[ing] the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Yates*, 744 F.3d at 885 (quotation omitted); *Syneos Health*, 2023 WL 4688178, at *4 (citing *Tellabs*, 551 U.S. at 324)).

B. Section 20(a) of the Exchange Act

Under Section 20(a),

> Every person who directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). Thus, "the liability of a control person under section 20(a) is derivative of—and dependent upon—liability of a controlled person under Section 10(b)." *Singer*, 883 F.3d at 438; *In re Under Armour Securities Litigation*, 540 F. Supp. 3d 513, 523 (D. Md. 2021) (noting that a Section 20(a) claim for controlling person liability must allege a predicate violation of

Section 10(b)). Section 20(a) confers a private right of action on buyers and sellers of securities who trade "contemporaneously" with an insider in possession of material nonpublic information. *See* 15 U.S.C. § 78t-1(a).

IV. Analysis

Before delving into the specific claims, the Court addresses two of the Defendants' overarching challenges to the amended complaint. First, the Defendants argue that the amended complaint should be dismissed because the Plaintiffs engaged in impermissible "puzzle pleading." For the reasons stated on the record during the motion hearing, this argument is unpersuasive. Though far from a model of clarity, the amended complaint bolds and italicizes the specific alleged false or misleading statements, an approach used in other cases without criticism by this court. *See In re Marriott Int'l, Inc. Cust. Data Sec. Breach. Litig.*, 543 F. Supp. 3d 96, 112 n.3 (D. Md. 2021) (identifying allegedly misleading portions of block quotes with bolded and/or italicized emphasis); *Sinnathurai v. Novavax, Inc.*, No. TDC-21-2910, 2022 WL 17585715, at *6 (D. Md. Dec. 12, 2022) (same). In paragraphs 129–218, the Plaintiffs identify over sixty allegedly false and misleading statements in support of their business operations fraud claim. Paragraph 219 then identifies the reasons why the statements were allegedly false or misleading. Paragraphs 220–27 and 231–34 identify the alleged statements that support their reported results and internal controls fraud claims, respectively. Paragraphs 228–29 and 235 then include the reasons why certain of those statements were allegedly false or misleading. This approach is sufficient, even if imperfect. *See In re Tyco Int'l, Ltd. Multidistrict Litig.*, No. MDL 02-1335-B, 2004 WL 2348315, at *9 (D.N.H. Oct. 14, 2004) (rejecting defendants' puzzle pleading argument where complaint referred reader to sections listing multiple reasons why statements are misleading). The Defendants' cited authorities are distinguishable. In those cases, the complaints were dismissed not due to "puzzle

pleading," but because the allegations did not actually indicate that the defendants' statements were false or misleading. *See In re Marriott*, 543 F. Supp. 3d at 114, 116 (granting motion to dismiss because the allegations either supported the truth of the statements or did not support the inference that the statements were false or misleading); *Teachers' Ret. Sys. of LA v. Hunter*, 477 F.3d 162, 175 (4th Cir. 2007) (affirming dismissal because the "facts alleged in support of these formulaic reasons fail to support a reasonable belief that the statements were in fact misleading"). The Court notes, too, that any remedy for improper "puzzle pleading" would be amendment, which would further delay the case and almost certainly lengthen the 225-page pleading.

The second of the Defendants' overarching arguments concerns the CW allegations. The Defendants argue the CW allegations should be disregarded entirely because they are unreliable and non-particularized, vague, or conclusory. Under the PSLRA, "[w]hen the complaint chooses to rely on facts provided by confidential sources, it must describe the sources with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged or in the alternative provide other evidence to support their allegations." *Tchrs.' Ret. Sys. of La.*, 477 F.3d at 174 (internal quotations omitted). At the motion to dismiss stage, a plaintiff may describe an anonymous source with sufficient particularity by alleging the "position, period of employment, responsibilities, and supervisors for each confidential witness." *In re Marriott*, 543 F. Supp. 3d at 143 (finding CW allegations to be credible and considering them to be true for purposes of the motion to dismiss). And CW allegations may be reinforced by other allegations that bolster their reliability. *See In re Mun. Mortg. & Equity, LLC, Sec. & Derivative Litig.*, 876 F. Supp. 2d 616, 640 (D. Md. 2012), *aff'd sub nom. Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874 (4th Cir. 2014). Here, the plaintiffs describe the CWs by their position, period of employment, responsibilities, and supervisor. ECF 54, ¶¶ 27–37. And

many of the CW allegations are corroborated by FDA and other reports, news reports, and the 2022 Congressional Report. While some CW allegations are vague or conclusory, others are specific and well-pled. *See, e.g.,* ECF 54, ¶ 63 (according to CW4, Area 4 was not qualified for mass production when Emergent announced the J&J and AZ contracts, and mold was caused by HEPA filters not working properly in the HVAC system); ¶ 67 (according to CW8, the sample receiving room did not have enough freezer and refrigerator space to manufacture multiple vaccines); ¶ 68 (according to CW9, a specific supervisor wrapped tubing around mold in advance of an April 2021 FDA inspection, and in early 2021, staff carried bags of hazardous waste through sterile facility areas at 7:00 a.m. every Wednesday). The Defendants' request to summarily disregard all CW allegations as unreliable or vague and unspecific is denied. The Court will consider the specific, reliable CW allegations where appropriate.

A. Business operations fraud claim under Section 10(b)

The Plaintiffs allege that the Defendants engaged in a "business operations" fraud by misrepresenting Emergent's vaccine manufacturing capabilities, particularly its anti-contamination measures, with the requisite scienter. The "business operations" fraud section of the amended complaint identifies roughly sixty public press releases, reports, filings, presentations, and other announcements by the Defendants in which they allegedly made misstatements and omissions during the Class Period. ECF 54, ¶¶ 129–219. The Court finds the Plaintiffs plausibly allege that, beginning on July 6, 2020, the Defendants made, with the requisite scienter, material misstatements or omissions regarding Emergent's capabilities to undertake large-scale manufacturing at the Bayview facility. The Plaintiffs also plausibly allege that after news broke on March 31, 2021 of the contaminated J&J batch and continuing until May 19, 2021, the

Defendants made, with the requisite scienter, material misstatements or omissions regarding the scope of Bayview's contamination issues.

1. Material misrepresentations or omissions before March 31, 2021

a. Pre-manufacturing statements about Bayview's capabilities

On July 6, 2020, Emergent announced in a press release that its initial agreement to manufacture drug substance for J&J's COVID-19 vaccine had been expanded to a five-year deal, valued at $480 million for the first two years alone. The release includes statements about Bayview's physical layout and particular capabilities. It describes the Bayview facility as a "***CIADM designed for rapid manufacturing of vaccines and treatments in large quantities during public health emergencies***." ECF 72-18; ECF 54, ¶ 148. It touts the Bayview facility's

> ***unique capabilities across four independent suites to produce at clinical scale to get candidates rapidly into the clinic, while at the same time scaling up to enable large-scale manufacturing to up to 4000L to prepare for production of commercial volumes to meet customer demand. The CIADM has the capacity to produce tens to hundreds of millions of doses of vaccine on an annual basis, based upon the platform technology being used.***

ECF 54, ¶ 148. Emergent and the Individual Defendants repeated similar statements about the capabilities of the Bayview facility's four suites, efforts to scale up Bayview to enable large-scale manufacturing, and the facility's dosage capacity several times between July 2020 and March 2021. *See id.* ¶¶ 155, 164, 181.[4]

These statements were not necessarily false on their face. According to the amended complaint, the Bayview facility did carry a CIADM designation and, as early as 2012, the U.S.

[4] The statements on July 6, 2020 and later about the capability of the Bayview facility to undertake large-scale manufacturing are similar to earlier public statements Emergent made in the preceding four months, but, for reasons stated later in this opinion, the Plaintiffs have not alleged the pre-July 6 statements were made with the requisite scienter. The Court, therefore, need not decide whether the pre-July 6 statements were materially false or misleading.

government had heavily invested in it so that it would be ready "for mass production in a crisis." ECF 54, ¶ 49. The Bayview facility was, in fact, comprised of four independent suites capable of testing drug candidates on a clinical scale. Emergent did not state on July 6 that its Bayview facility was *then* able to produce at commercial volumes; rather, it stated that it was "scaling up to enable large-scale manufacturing." And the Bayview facility would, in fact, go on to produce uncontaminated batches of COVID-19 drug substance that totaled over 100 million vaccine doses. *See* ECF 79-2, at 4.

The Plaintiffs need not, however, allege that a statement was literally false; they must plead that a misrepresentation or omission was false *or* misleading. The Plaintiffs plausibly allege that when the Defendants made statements on July 6, 2020 and later that Bayview could rapidly manufacture vaccines in large quantities and utilize four independent suites to do so, they misleadingly omitted known problems at Bayview that jeopardized large-scale manufacturing—problems that, by July 6, the FDA had determined to be ongoing despite Emergent's efforts to "scale up."

As support for the misleading nature of these statements, the Plaintiffs cite the CWs.[5] Collectively, the CWs allege that the Bayview facility was not ready for rapid, large-scale manufacturing in spring and summer 2020. According to CW4 and CW10, Area 4 of the facility was not qualified or meant for mass production. ECF 54, ¶¶ 63, 69. According to CW1 and CW4,

[5] The Plaintiffs also cite inspections and reports of deficiencies at Emergent manufacturing facilities other than Bayview that predated the pandemic. See ECF 54, ¶¶ 73–107. The Plaintiffs allege these inspections and reports at other facilities demonstrate "a litany of issues . . . across Emergent's operations," *id.* ¶ 73, and that they "put the Defendants on notice . . . of the myriad failures at Emergent's facilities" requiring correction, *id.* ¶ 108. The Plaintiffs do not allege, however, that any problems identified at those other facilities—occurring years before the COVID-19 pandemic even began—affected COVID-19 drug substance production at Bayview or alerted the Defendants to particular issues at Bayview. These allegations are irrelevant to the Court's analysis.

when the J&J contract was first announced on April 23, 2020, the Bayview facility did not have the necessary equipment or functional capacity for mass production. *Id.* ¶¶ 61, 63. This concern was echoed by CW8, who stated that the facility's sample receiving room did not have enough freezer or refrigerator space to properly store products for multiple vaccines. *Id.* ¶ 67. These CW allegations are corroborated by the April 2020 FDA inspection report, which observed that "separate or defined areas to prevent contamination or mix-ups are deficient," and by the accompanying Form 483. ECF 54, ¶ 110(f).[6] They are also corroborated by the April 1 BARDA audit, which found that Bayview had "substantial evidence of site cGMP non-compliance" and "risk to CIADM readiness" due to mishandling of products, among other issues. *See* ECF 79-4, at 3.

The CW allegations further indicate that conditions and protocol did not improve after the FDA's April 2020 inspection despite Emergent's May 8 response to the FDA that it would take "immediate, holistic and comprehensive measures to address the deficiencies noted." ECF 54,

[6] The Defendants take issue with the Form 483 in two respects. First, they argue that the Plaintiffs have not alleged that the April 2020 FDA Form 483 was unavailable to the public during the Class Period. *See* ECF 72-1, at 28 n.15. Not so. The Plaintiffs plausibly allege the form was not publicly available because it was published only as a "heavily redacted version . . . summarizing its findings . . . with significantly less detail, much of it obscured by the redactions." ECF 54, ¶ 111. Second, the Defendants argue that the Form 483 (and, presumably, the inspection report) contains only preliminary findings about correctable issues and, thus, does not support falsity. *See Schaeffer v. Nabriva Therapeutics plc*, No. 19-Civ-4183, 2020 WL 7701463, at *2 (S.D.N.Y. Apr. 28, 2020) (describing a Form 483 as a form of "interim feedback rather than a final FDA decision" identifying significant conditions that the company is then "responsible for taking corrective action to address," but holding that a Form 483 may support falsity depending on the circumstances). That logic may hold water while Emergent was still preparing its FDA response. But once the FDA indicated to Emergent on June 23 that its responses were inadequate, the Plaintiffs plausibly allege that Emergent misleadingly omitted material facts about Bayview's uncorrected deficiencies. *See Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 982–83 (8th Cir. 2012) (holding that Form 483s "may render a defendant's statement . . . misleading . . . depending on a number of factors, including . . . whether a company has failed to address or correct the deficiencies noted by the FDA").

¶ 136.[7] According to CW10, who performed quality control tests at Bayview from April 2020 to May 2021, the Quality Control staff were "not given detailed information about FDA violations that needed to be addressed." *Id.* ¶ 69. Even though Emergent hired significant numbers of new employees in summer 2020, according to CW9, there was "little to no training for new employees," who were largely in their early 20s with "little to no pharmaceutical or manufacturing experience." *Id.* ¶ 68; *see also id.* ¶ 66 (according to CW7, in September 2020, new lab technicians deviated from standard operating procedures by improperly cleaning lab equipment, and Emergent lost a COVID-19 specimen requested by the FDA due to improper inventory practices). The QC Microbiology team in particular was "severely understaffed, under-equipped, and undertrained." *Id.* ¶ 65. Additionally, several CWs recount that the Bayview facility's mold issues existed throughout their employment. *See id.* ¶¶ 63, 68–69. And CW9 indicated that in early 2021, staff carried bags of hazardous waste through sterile facility areas at 7:00 a.m. every Wednesday. *Id.* ¶ 68. These CW allegations are corroborated by the 2022 Congressional Report, which found that the Bayview facility's deficiencies (including widespread mold, poorly disinfected equipment, inexperienced staff, substandard quality control procedures, and improper waste procedures) contributed to contamination risks. Similarly, an audit by J&J from June 9–18, 2020 found that Bayview's quality review, virus contamination control strategy, and disinfectant procedures were deficient. Simultaneous AZ and BARDA audits also identified documentation and computerized

[7] Emergent's 16-page response to the FDA 483 did not contain actionable misstatements because the Plaintiffs do not allege it was public. Instead, they allege that the response "was posted in redacted form on the FDA's website," stressing that "[d]iscovery into the unredacted version . . . , supporting documents, and related communications would support the allegations and claims pled herein." ECF 54, at ¶ 136. The Plaintiffs tried to change course in a post-hearing submission in which they asserted Emergent's Form 483 response was publicly available on or shortly after May 8. *See* ECF 119. But they did not allege that fact in the amended complaint and may not amend their complaint through briefing.

systems issues, among other faulty manufacturing practices. And the Warp Speed Report in June and Emergent internal audits in July and August documented similar issues.

Even if, as the Defendants stress, Emergent was merely "scaling up" to enable large-scale manufacturing and attempting to address the FDA's concerns, the Plaintiffs have plausibly alleged that the statements nevertheless were misleading because Emergent's efforts were unsuccessful. The FDA communicated to Emergent on June 23 that its response to the April inspection was insufficient and that OPMA "does not consider your facility ready to support commercial operations of the subject drug application." ECF 79-9, at 2; ECF 79-10, at 4. BARDA's July audit report stated that Emergent had not yet addressed the FDA's April 2020 finding that Bayview was not ready for commercial operations. AZ stated in a letter to Congress that, in late July 2020, Emergent began manufacturing AZ batches without remediating all deficiencies. The FDA again found after a September 2020 site visit that Bayview's manufacturing practices were not compliant.

The Plaintiffs have plausibly alleged that when Emergent chose to state, on July 6 and later, that it was "scaling up to enable large scale manufacturing" at Bayview, it needed to disclose that the FDA deemed those efforts to be as-yet unsuccessful in order "'to make . . . [the] statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10-b5(b)). The same is true when Emergent continued to state that Bayview was "designed for rapid manufacturing of vaccines . . . in large quantities," that it had capabilities across four independent suites, and that it could produce tens to hundreds of millions of vaccine doses per year. It is plausible that a reasonable investor deciding whether to invest in Emergent would find it important that Bayview was not equipped for mass production and that it remained unequipped after the FDA deemed insufficient Emergent's efforts

to address the deficiencies.[8] The Plaintiffs plausibly allege that these statements were materially misleading.

b. Post-manufacturing statements about Bayview's capabilities

Once Emergent began manufacturing J&J and AZ products, the Plaintiffs allege that it made misleading statements about its ability to manufacture two products simultaneously. In a November 5 press release, after simultaneous manufacturing had begun, Husain stated that Bayview was "***designed to handle multiple products . . . so right now, [the Bayview facility] is predicated on multiple products being in there.***" *Id.* ¶ 168(b). During a March 3, 2021 interview with CNBC, Kramer stated, "***we're producing on a daily basis, 24/7, both AZ and the J&J products . . . because of the large-scale infrastructure we put in place, we were able to take on J&J and AstraZeneca's products . . . .***" *Id.* ¶ 185.

Even if Husain's statement that Bayview was "designed" to handle more than one product or Kramer's statement that Bayview's infrastructure was "able" to take on both products were true on their face, the Plaintiffs plausibly allege that these statements touting Emergent's ability to manufacture two products at the same time were misleading. Husain and Kramer omitted the many deficiencies cited by the FDA and other auditors, including that the Bayview facility had widespread mold, poorly disinfected equipment, and inadequate storage or waste disposal space to prevent contamination or mix-ups—deficiencies that jeopardized Bayview's ability to successfully manufacture two products at once, at scale. And they omitted that beginning in

[8] Even if, after the FDA's June 23 letter, Emergent continued to work with the FDA and others to improve Bayview in an iterative process, the fact that the persistent deficiencies may have been correctable (or even later corrected) does not render them immaterial to a reasonable investor weighing the risks of investing in Emergent at the time. Moreover, the AZ letter to Congress and the FDA's September 2020 site visit both indicate that, even after the June 23 letter, deficiencies remained uncorrected.

October 2020, Emergent had to destroy batches allegedly due to the facility's deficiencies. The *NYT* reported that between October 2020 and January 2021 (mostly after simultaneous production of both J&J and AZ drug product began), Emergent discarded five AZ batches due to contamination or suspected contamination and a J&J batch due to worker error. The 2022 Congressional Report found that by early 2021, Emergent's failure to sufficiently remediate known issues led to the destruction of approximately 240 million vaccine doses. ECF 79-2, at 4. As time went on and more batches were destroyed, Emergent's statements touting its ability to manufacture two products while omitting the ongoing batch destruction became more misleading.

The Plaintiffs plausibly allege that these omissions were material. A reasonable investor likely would have found deficiencies that jeopardized mass production of two products important in deciding whether to buy or sell Emergent stock. With each instance of batch destruction—through which Emergent eventually destroyed far more batches than it ever successfully produced—the likely importance of these omissions to investors only increased.

In sum, the Plaintiffs plausibly allege that beginning July 6, Emergent's statements touting Bayview's manufacturing capabilities misleadingly omitted the facility's persistent, serious issues. And they plausibly allege that once manufacturing was underway, Emergent's statements touting its ability to handle multiple products at once likewise misleadingly omitted these ongoing issues.

The Plaintiffs plausibly allege that if disclosed, these facts would have significantly altered the total mix of information about the Bayview facility available to investors. In *Sinnathurai v. Novavax, Inc.*, No. TDC-21-2910, 2022 WL 17585715 (D. Md. Dec. 12, 2022), a biotechnology company faced similar allegations. The plaintiffs alleged that the company overstated its abilities to produce the COVID-19 vaccine on a large scale when facilities critical to that production were shut down due to multiple incidents of bacterial contamination and other difficulties. The court

denied the company's motion to dismiss the Section 10(b) claims, reasoning that when the company chose to speak about its manufacturing progress, its omission of contamination issues at its facilities could constitute material omissions. *Id.* at *16–17. Had the problems been disclosed, "that information would have significantly altered the total mix of information available to a reasonable investor because such an investor would have understood" that the company's "ability to . . . produce the vaccine at scale was in jeopardy." *Id.* at *16 (internal quotation omitted). While the Bayview facility was not fully shut down as was the case in *Sinnathurai*, the FDA deemed it unready for commercial operations. Here, as in *Sinnathurai*, information about the Bayview facility's deficiencies would have led a reasonable investor to understand that Emergent's ability to "scale up" was at risk. These issues, along with the batch destructions that occurred once production began, likewise would indicate to a reasonable investor that Emergent's ability to produce vaccine drug substance en masse was in jeopardy.[9]

c. The Defendants' arguments challenging falsity of pre-March 31, 2021 statements

The Defendants argue that the challenged statements were unactionable puffery; that they made no material omissions because they adequately disclosed contamination and other risks; that the allegations about the severity of the risks of contamination or other manufacturing problems are irrelevant; and that the Plaintiffs impermissibly allege fraud by hindsight. The Court addresses each argument in turn.

[9] The Plaintiffs allege that the Defendants repeated statements similar to those discussed here on numerous occasions between July 6, 2020 and March 31, 2021. These repetitive statements about Bayview's manufacturing capabilities and ability to handle multiple products at once are materially misleading for similar reasons.

i. Puffery

The Defendants argue that their statements about Bayview's capabilities were mere puffery. Puffery consists of non-factual boasting statements. *See Sinnathurai*, 2022 WL 17585715, at *18 (defining puffery as "loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available" (quotation omitted)). Puffery statements are unactionable under Section 10(b). *Dunn v. Borta*, 369 F.3d 421, 431 (4th Cir. 2004) ("The judiciary has long distinguished between mere puffing statements utilizing opinion and exaggeration . . . on the one hand, and factual statements that constitute fraudulent misrepresentations, on the other.").

Some of Emergent's statements were mere puffery. For instance, on July 6, Kramer highlighted Emergent's "***manufacturing strength to address the COVID-19 pandemic***." ECF 54, ¶ 148. On July 27, Husain stated, "***Emergent stands ready alongside leading innovators to rapidly deploy our CDMO services to help meet the substantial demand for a vaccine***." *Id.* ¶ 55. On July 30, Emergent included the COVID-19 contracts as part of a list of "***recent business accomplishments***." *Id.* ¶ 157(a). In November 2020, Emergent touted its CDMO services as "***[holding] a unique position in the landscape***" and, more generally, its "***extremely successful track record of development and manufacturing abilities***." *Id.* ¶ 168 (b)–(c). These statements—which describe Emergent's strengths and track record in non-specific terms, characterize Emergent as a leader, and take pride in the contracts Emergent secured—are at most generic statements of boasting. *See In re Marriott*, 543 F. Supp. 3d at 117. As boasts, they are not factual assertions and thus not demonstrable as being true or false. *See Longman*, 197 F.3d at 685 (finding that defendant's statements that its prices and stores were "especially well suited to the demands of our

customers" were unactionable puffery); *Raab v. Gen. Physics Corp.*, 4. F.3d 286, 289 (4th Cir. 1993) (finding defendant's statement that it was "poised to carry the growth and success of the prior year well into the future" and other statements of "commonplace commercial puffery" were not actionable).[10]

But these unactionable puffery statements are different in kind from Emergent's statements describing the Bayview facility's readiness for large-scale manufacturing and its ability to manufacture multiple products at once. In attempting to dispose of those statements as puffery, the Defendants analogize to statements that this court held to be puffery in *In re Marriott*, in which a company stated that data protection was "critical" but then experienced a cyberattack. 543 F. Supp. 3d at 136. There, the court reasoned that the company's statements were puffery because they were not "specific and verifiable and [did] not assign a quality to Marriott's cybersecurity that it did not have." *Id.* Here, by contrast, Emergent made specific statements about the Bayview

[10] The Defendants made similar statements throughout the Class Period, including after March 31, 2021. *See, e.g.*, ECF 54, ¶ 217 (September 14, 2021 presentation stating Emergent "combines the best of both worlds: ***the customer focus and capacity of a pure play CDMO***"). These, too, were unactionable boasting or opinion statements. *See Dunn*, 369 F.3d at 431. Some statements, though, present a much closer call as to whether they are boasts or opinions that nevertheless convey facts. *See Omnicare, Inc. v. Laborers Dist. Council Const. Industry Pension Fund*, 575 U.S. 175, 176 (2015) ("[A] reasonable investor may, depending on the circumstances, understand an opinion to convey facts . . . about the speaker's basis for holding that view. And if the real facts are otherwise, but not provided, the opinion statement will mislead the audience."). For instance, Emergent's November 5 press release praises its "enterprise team of more than 1,400 technical and quality compliance professionals." ECF 54, ¶¶ 168(b)–(c); *see also id.* ¶ 175. And, on February 18, Kramer described biologics manufacturing as "***an exacting process that requires specialized equipment, disciplined processes and a highly trained staff . . . . Emergent has been able to thrive in this environment***." *Id.* ¶ 179(b). While the November 5 and February 18 statements convey opinions about an "enterprise" team and Emergent's ability to "thrive," they also arguably convey facts about the quality of Emergent's staffing and equipment. But the mere omission of "some fact cutting the other way" is not enough to render an opinion statement misleading. *Id*. These statements are opinions about Emergent as a whole, not Bayview in particular, and even though they omit details about the quality of staff and equipment at Bayview that "cut the other way," a reasonable investor would not take them to convey such particular facts.

facility's layout and capacity and about its ability to manufacture multiple products. These statements that the Bayview facility had the capability to rapidly produce vaccines on a large scale across its four suites and that it could handle multiple products at once "could be proven true or false and cross the line from puffery into material statements." *Id.* (*citing Dunn*, 369 F.3d at 431). These statements were not puffery. Had the Defendants not touted the facility's unique attributes and capabilities, they may not have needed to disclose persistent deficiencies. But once they made those statements, it was misleading not to disclose them.

ii. Risk disclosures

The Defendants next argue that even if the statements they made about the Bayview facility's readiness and manufacturing capability triggered some duty for them to disclose risks related to contamination and manufacturing problems, Emergent adequately disclosed those risks in its 2020 and 2021 Forms 10-Q and 10-K filed with the SEC, and any omissions, therefore, were not material. These filings stated:

> Manufacturing biologic products, especially in large quantities is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. *Problems during manufacturing may arise for a variety of reasons, including . . . failure to follow specific protocols and procedures*. In addition, slight deviations anywhere in the manufacturing process, *including . . . contamination including from particulates among other things . . . may result in lot failure or manufacturing shut-downs, delays in the release of lots, production recalls, spoilage or regulatory action* . . . . From time to time, we may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, *may affect manufacturing output* and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, . . . result in litigation or regulatory action against us, including warning letters and other restrictions on the . . . manufacturing of a product, or cause the FDA to cease releasing product until the deviations are explained and corrected, *any of which could be costly to us, damage our reputation and negatively impact our business*.

ECF 72-4, at 18 (emphasis added); *see also* ECF 72-5, at 17; ECF 72-6, at 17–18; ECF 72-7, at 18. These disclosures also stated that following several inspections, regulatory authorities issued

"inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions" and that if authorities were not satisfied with Emergent's corrective actions, they could take enforcement action against Emergent including "restrictions on the marketing or manufacture of a product." ECF 72-4, at 15; *see also* ECF 72-5, at 15; ECF 72-6, at 15; ECF 72-7, at 15–16. With regard to manufacturing COVID-19 vaccine drug substance specifically, the filings stated that

> [t]here can be no assurance that any of these product candidates will be safe or effective. There can be no assurance that any of these product candidates with receive approval or be authorized for emergency use . . . . Even if these product candidates are safe and/or effective and receive approval or authorization by a health regulatory authority, the manufacturing process for these programs are under development and will be complex. As a result, there can be no assurance that we will be able to produce any significant quantity of these products on a timely basis *or at all*.

ECF 72-4, at 23 (emphasis added); *see also* ECF 72-5, at 22; ECF 72-6, at 23; ECF 72-7, at 7. Even though these risk warnings were not included in each of the public statements and press releases cited in the amended complaint, the Defendants emphasize that they did include cautionary language in press releases that pointed investors towards the risk disclosures. *See, e.g.*, ECF 72-10, at 2 (March 10, 2020 press release stating that "[i]nvestors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements"). The Defendants contend that because of these risk disclosures, any omission of the risks related to contamination and manufacturing problems at Bayview was immaterial.

The Fourth Circuit recently addressed the effect of risk disclosures on the materiality of omissions in the context of a Section 14(a) claim.[11] Risk disclosures are considered part of the

[11] The Supreme Court has adopted the Section 14(a) definition of materiality for Section 10(b) claims. *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988).

"total mix of information made available" to investors. *Syneos Health*, 2023 WL 4688178, at *7 (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 438 (1976)). If, given the risk disclosures, it is "not substantially likely that adding an additional truthful fact would have changed a reasonable investor's mind about their investment decision, then adding that fact would not have significantly altered how they viewed the total mix, and that fact is thus immaterial." *Id.* (internal quotations omitted). The warnings, however, must be "specific and tailored to address the alleged misrepresentation or omission . . . . Vague, boilerplate disclaimers will not cut it." *Id.* (citations omitted). In *Syneos Health*, the plaintiffs alleged that a company's statements about the prospects of a biopharmaceutical merger misleadingly omitted that the company had not yet secured any large sales contracts that year and that those types of contracts were important to its success. *Id.* at *4. The Court found that the company did not make any material omissions because it included "specific warnings, tailored to address" the plaintiffs' specific concerns, including that the projections were based on "'pipeline discussions' with customers rather than finalized deals" and may be based on flawed assumptions. *Id.* at *8 (citations omitted). These and other tailored warnings "warn[ed] the investor not to rely too heavily on, or read too deeply into, a certain proposition," rendering any omissions immaterial. *Id.* The court observed that "because materiality is contextual, it can be 'negate[d]' by adequate warnings and disclaimers." *See id.* at *7 (citing *Gasner v. Bd. Of Supervisors*, 103 F.3d 351, 358 (4th Cir. 1996)).

Unlike in *Syneos Health*, there were no adequate warnings here. Emergent did not neglect to mention that an important business milestone, such as securing a large sales contract, had not yet occurred. It neglected to mention events that negatively impacted its core mission and business operations—the FDA stating that it did not consider the Bayview facility ready to support commercial operations and the ongoing batch destruction due to contamination and other

problems—did, in fact, occur. These omissions, even if paired with cautionary language, are nevertheless "omissions of present or historical fact, which generally *are* actionable." *Id.* at *4 n.9 (citing *Boykin v. K12, Inc.*, 54 F.4th 175, 183–84 (4th Cir. 2022)) (emphasis in original).

This case is analogous to *Singer v. Reali,* 883 F.3d 425 (4th Cir. 2018), in which the Fourth Circuit rejected an argument similar to Emergent's. There, a medical device company made statements about its revenue that omitted the fact that it was instructing its surgeons to miscode certain procedures in what amounted to a fraudulent reimbursement scheme. In its motion to dismiss the Section 10(b) claims, the company argued that, in its Form 10-K filings, it disclosed risks of the consequences it could face for failure to comply with federal and state healthcare laws, which included "general warnings about the risks of regulatory scrutiny and litigation" and substantial penalties for noncompliance. *Id.* at 442. The Fourth Circuit held that despite these "general warnings," the statements were materially misleading because the company did not disclose the fraudulent reimbursement scheme. *Id.* Having chosen to speak about its reimbursement practices, the company was obligated to disclose its reimbursement scheme. *Id.* In reaching this conclusion, the Fourth Circuit explicitly endorsed the Second Circuit's rejection of generic risk warnings that fail to acknowledge important "facts on the ground":

> A generic warning of a risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor's calculations of probability. One cannot, for example, disclose in a securities offering a business's peculiar risk of fire, the installation of a comprehensive sprinkler system to reduce fire danger, and omit the fact that the system has been found to be inoperable, without misleading investors.

Id. (quoting *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 251 (2d Cir. 2014)).

That is what the Plaintiffs allege the Defendants did here. The Defendants could not tout Bayview's pre-manufacturing readiness and at the same time omit that Emergent's response to the FDA's observations was deemed inadequate, that the facility was not considered manufacturing-

ready, and that it had not remediated critical deficiencies. True, the disclosures acknowledged that regulatory authorities already had issued "some" significant inspectional observations, but they also stated that these issues were being "addressed through corrective actions"—without acknowledging that Emergent had been informed that its corrective actions were as-yet unsuccessful. The Plaintiffs plausibly allege that these are material omissions that implicate how risky it would be to invest in Emergent's ability to manufacture vaccine drug substances on a large scale. *See Matrixx Initiatives*, 563 U.S. at 47 (affirming holding that omissions were material where the company had, but did not disclose, "information indicating a significant risk to its leading revenue-generating product").

Once production was underway, the Defendants continued to make the same positive statements about Bayview—without disclosing "facts on the ground" that repeated issues (including contamination, inadequate staffing and training, a lack of robust quality control policies, and inadequate facility space and equipment) led to the destruction of 240 million vaccine doses by early 2021. The Defendants argue that they never represented that cross-contamination or destruction of batches would not occur. And they point to risk disclosure language that incidents like lot failure "may occur." But it is one thing for Emergent to state that it never guaranteed that issues would not arise or even that issues "may" arise. It is another thing entirely for Emergent to fail to disclose risks that *actually materialized*—such as cross-contamination and batch destruction or the FDA determination that Emergent was not manufacture-ready. General risk disclosures notwithstanding, it is plausible that a reasonable investor would consider these omissions to be "important in deciding whether to buy or sell the security" and that the omissions would

significantly affect investors' calculation of how risky their investment was. *Singer*, 883 F.3d. at 449 (citation omitted).[12]

The Plaintiffs have plausibly alleged that the omissions were material notwithstanding Emergent's risk disclosures.

iii. Severity of risk

Next, the Defendants contend that the Plaintiffs' allegations that Bayview's deficiencies posed a "grave" risk of contamination are irrelevant because the risk disclosures stated that there was no assurance that Emergent would manufacture any drug substance at all. For instance, they parse through each of the six findings in the 2022 Congressional Report, arguing that regardless of the seriousness of the described conduct, "it does not demonstrate that the risks were greater than disclosed" given that they disclosed that contamination could occur and that they could fail to produce any drug substance "at all." ECF 115, at 25.

This argument misses the mark. According to the risk disclosures, the reason why Emergent may not produce any products "at all" is that the COVID-19 vaccine manufacturing process was novel, complex, and uncertain, and thus production could fail altogether "as a result." *See* ECF 72-4, at 23. But the deficiencies plaguing the Bayview facility—persistent mold, lack of adequate space, and substandard quality control procedures, among others—were not caused by the complexities or novelties of the COVID-19 manufacturing process. These issues existed at least as early as April 2020, before batch production ever began. Thus, Emergent's cautionary

[12] The Defendants also argue that the fact that Emergent discarded other batches before the February 2021 contamination incident does not indicate that discarding batches is unusual or that the issues plaguing those prior batches were the same as those that caused the February 2021 cross-contamination. *See* ECF 72-1, at 29. But even if discarding batches was common in the industry or if there were different reasons for the spoilation of the other batches, that does not render their destruction (or the different underlying issues that caused it) immaterial to a reasonable investor.

statements that they may fail to produce any product at all "as a result" of an uncertain COVID-19 vaccine manufacturing process do not meaningfully disclose to investors the risks that led to batch destruction.

More fundamentally, the extent of Bayview's deficiencies and the severities of the risks are relevant because they "substantially affect a reasonable investor's calculations of probability." *See Singer*, 883 F.3d at 442. The risk disclosure may have warned about the possibility that contamination could occur or that no batches would be produced at all, but the omitted deficiencies substantially affect an assessment of how likely that scenario would be. The 2022 Congressional Report found, among other things, that Emergent destroyed nearly 400 million doses; that 240 million of those doses were destroyed in late 2020 and early 2021 due to poor quality control at the Bayview facility; and that Emergent concealed quality control failures from the FDA and others. ECF 79-2, at 4. The Plaintiffs have plausibly alleged that a reasonable investor would consider these omitted facts important notwithstanding generic risk disclosures that Emergent may not have produced any batches at all.

iv. Fraud by hindsight

Finally, the Defendants argue that the Plaintiffs impermissibly plead "fraud by hindsight." A plaintiff alleging a Section 10(b) violation does not get the benefit of hindsight to prove that statements were false when made if their falsity was not known at the time. *In re Marriott*, 543 F. Supp. 3d at 139 ("Quite simply, Plaintiffs do not get the benefit of 20/20 hindsight." (quoting *In re Under Armour Sec. Litig.*, 342 F. Supp. 3d 658, 677 (D. Md. 2018))). In *In re Marriott*, the plaintiffs alleged that Marriott misled investors when it acquired a different hotel company, made statements that it successfully merged that company's IT systems with its own, and then later discovered that it had suffered a massive data breach. The plaintiffs challenged Marriott's

statements that it had run due diligence when integrating the systems and its privacy statements about protections in place for customer data. The court held that the plaintiffs failed to plausibly allege that these statements were false or misleading because at the time they were made, Marriott was unaware of the extent of the data breach and that any customer information had been compromised. *Id.* at 139.

In re Marriott is distinguishable. Here, the Plaintiffs allege that the Defendants knew about the problems at the Bayview facility at least by April 2020, when the FDA issued an inspection report and Form 483 that documented issues with its training and quality control processes and raised questions about its ability to prevent cross-contamination. These issues were repeatedly flagged in other audits by BARDA, J&J, AZ, and Emergent itself. At least by June 24, Emergent became aware that the FDA had deemed its efforts to rectify the issues insufficient. The Plaintiffs also allege that Emergent destroyed five batches between October 2020 and January 2021. The 2022 Congressional report indicated that the number of batches Emergent destroyed was even higher than initially reported. Unlike in *In re Marriott*, in which the plaintiffs argued that the company's statements were misleading because of facts discovered *after* those statements were made, the Plaintiffs allege that Kramer, Husain, and Lindahl knew Emergent was not ready for commercial operations and, when manufacturing began, was destroying these batches, even as they made allegedly misleading statements.

The Defendants also argue the Plaintiffs' reliance on *NYT* reporting shows they have pled fraud by hindsight. But the March 31 *NYT* article broke the news of an event that Emergent was

already aware had occurred—the contamination of a J&J batch—and thus the Plaintiffs' reliance on that article is not impermissible pleading of fraud by hindsight.[13]

The Plaintiffs have plausibly alleged that when touting the Bayview facility's capabilities between July 6 and March 31, the Defendants made statements that were misleading as to a material fact. *Matrixx Initiatives, Inc.*, 563 U.S. at 38.

2. Scienter for pre-March 31, 2021 statements

The Plaintiffs also plausibly allege that Emergent, Kramer, and Husain made these misleading statements about the Bayview facility's capabilities with the requisite scienter between July 6, 2020 and March 31, 2021. Before discussing the allegations supporting scienter, the Court clarifies the contours of the scienter inference that the Plaintiffs attempt to draw. The Defendants frame the Plaintiffs' scienter theory as alleging that Emergent and the Individual Defendants "orchestrated a fraud whereby they invested immense time, effort, and money in what they secretly knew would be a futile effort to manufacture COVID-19 vaccine drug substance." ECF 72-1, at 36. But the Plaintiffs' theory is not that Emergent knew at the outset that the Bayview facility was "doomed to fail" to produce any vaccines, as in the cases that the Defendants rely on that rejected such scienter theories. *See Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) (rejecting scienter theory where it was not probable that a company would stake its existence on a clinical trial it thought was "doomed to fail"). The Plaintiffs' theory is that the Defendants concealed from investors ongoing, serious deficiencies in the Bayview facility's ability to comply with FDA requirements and to safely manufacture, on a large scale, drug substances for vaccines,

[13] The Defendants also argue that the Plaintiffs impermissibly plead fraud by hindsight because Emergent could not have known that this specific February 2021 contamination would take place. But this argument misconstrues the Plaintiffs' allegations, which encompass not just one destroyed J&J batch but also the persistent problems that plagued the Bayview facility as well as the additional destroyed batches that Emergent did not disclose throughout the Class Period.

downplaying risks of contamination and other problems that might spoil a significant amount of the drug substance batches.

To support a strong inference of scienter, the Plaintiffs allege that (1) the Defendants ignored red flags as described by CWs, FDA and other reports, news reports, and Congressional findings; (2) the Individual Defendants' own statements support scienter; (3) the Individual Defendants had the motive and opportunity to mislead investors to support their insider trading and suspicious compensation; and (4) other aspects of Emergent's business support a strong inference of scienter. The Court addresses each of these allegations in turn before assessing them holistically. The Court then separately considers scienter allegations as to Lindahl.

a. Red flag allegations

"Red flag" allegations are allegations that there were signals that must have alerted the Defendants to the deficiencies. *See Matrix Capital*, 576 F.3d at 183–84. The Plaintiffs' "red flags" allegations include statements by CWs, FDA and other reports, news reports, and Congressional findings. "The presence of 'red flags,' coupled with the 'breadth and gravity' of a company's problems, may provide 'substantial weight' to an inference that high level corporate agents 'must have been aware of the problems.'" *Yates*, 744 F.3d at 888 (quoting *Matrix Capital*, 576 F.3d at 183–85). "The more significant the error the stronger the inference it supports." *Id.*

i. CWs

To allege scienter, the Plaintiffs rely on the statements of the CWs, including Emergent senior project managers, the director of operational excellence, quality control supervisors and analysts, and lab technicians at the Bayview facility. In general, plaintiffs are "free to use the allegations of confidential witnesses to support an inference of scienter." *KBC Asset Mgmt.*, 19 F.4th at 609 (citing *Yates*, 744 F.3d at 885–88.) But CW allegations are only "afforded the weight

they are due given their indicia of reliability." *Id.* To support an inference of scienter, the complaint must describe the CW allegations with "sufficient particularity to support the probability that a person in the CWs position would possess the information alleged, or, in the alternative, provide other evidence to support their allegations." *Teachers' Ret. Sys. of La.*, 477 F.3d at 174 (quotation omitted).

The amended complaint contains allegations from several CWs indicating that Emergent officials, and Husain in particular, were made aware of the contamination, quality control, physical space, and other issues at the Bayview facility. CW1, a senior project manager at corporate headquarters who was responsible for overseeing the vaccine projects and attended bi-monthly project management meetings that were co-led by Husain, alleged that (1) Husain was "intimately involved" with overseeing progress on all of the COVID-19 projects; (2) in summer and fall 2020, Husain sought additional contracts with new customers despite significant delays in existing COVID-19 projects; (3) these delays (caused by the lack of necessary personnel, equipment, and functional capacity at the Bayview facility) were discussed in the bi-monthly meetings that Husain co-led, including in summer and fall 2020; and (4) CW1 personally informed Husain about Bayview's mold problems. ECF 54, ¶ 60. CW5, a project analyst who reported to CW1, alleged that CW1 was fired shortly after informing a supervisor about Bayview's issues, then CW5 (who was closely associated with CW1) was fired shortly thereafter. *Id.* ¶ 64. CW6, a data review supervisor at Bayview, alleged that two particular supervisors forced him to sign off on data for a lot release after discovering problems with its testing data and to use mold test data in batch records after finding that the assay used to test the mold was flawed. CW9, a bioprocess associate at Bayview, alleged that after contamination investigations were complete, an email was sent to the entire manufacturing staff about the results, including the head of manufacturing. *Id.* ¶ 68. Finally,

CW10, a quality control analyst at Bayview, sent "many emails to management" about understaffing of the quality control department and the mold issues in the manufacturing suite. *Id.* ¶ 69.

Even though the CWs do not allege that they personally informed the Individual Defendants of all the problems at Bayview, allegations of scienter need not provide "smoking-gun" evidence. *Sinnathurai*, 2022 WL 17585715, at *21 (citing *Inst. Inv. Grp. v. Avaya*, 564 F.3d 242, 268–69 (3rd Cir. 2009)). The CWs' concerns about quality control, equipment, and mold containment efforts, which they raised with management, are probative of scienter. Moreover, the gravity of these deficiencies strengthens the inference of scienter. *See Yates*, 744 F.3d at 888. That said, because they provide mostly circumstantial evidence that Husain and others knew about the deficiencies at Bayview, they are "not alone sufficient to establish a strong inference of scienter." *Sinnathurai*, 2022 WL 17585715, at *21; *KBC Asset Mgmt.*, 19 F.4th at 609 (noting that a lack of direct contact between CWs and the defendants "weakens the inference of scienter").

ii. FDA inspection report and OPMA letter

The Plaintiffs allege that FDA reports, including the April 2020 inspection report and Form 483 detailing Bayview's contamination and quality control issues, are typically presented to a company and its leadership. ECF 54, ¶ 72. The inspection report itself stated that "during the opening meeting, daily closure meetings, and at the inspectional closeout meeting, multiple senior members of the Firm's management team were in attendance" and the investigator "explained to the firm's management team . . . that each event should have been investigated at the time of detection." ECF 54, ¶ 110(b), (g). Emergent's May 8 response to the April 2020 Form 483 was signed by Emergent's head of quality at Bayview. *Id.* ¶ 111. The Plaintiffs also allege "on

information and belief" that Emergent's Form 483 response was authorized by Husain, Kramer, and Lindahl. *Id.* ¶ 136.

The fact that the FDA investigator discussed his findings with "firm management" is probative of scienter.[14] When testifying before Congress on May 19, 2021, Kramer admitted that he had read the majority of the FDA reports; that the FDA's observations were "correct" and "accurate"; and that he did not dispute them. ECF 54, ¶ 114. Though he did not specifically identify when he read the FDA reports, his admission supports the inference that he was aware of the reports when making the alleged misstatements.

Likewise, the materials accompanying the 2022 Congressional Report reveal that Kramer and Husain were aware of the June 23 OPMA letter informing Emergent that Bayview was still considered not ready for commercial operations. On June 24, Emergent's EVP of Manufacturing and Technical Operations, Sean Kirk, forwarded the FDA's OPMA letter to Kramer. ECF 79-9; ECF 79-10; ECF 79-11. Kirk stated, "To our parking lot discussion at bayview last Friday, see below," noted that "[t]hankfully, we navigated the AZ and JNJ audits although they designated our systems as not ready for commercial," and added that "the rejection by the fda is even more disconcerting." ECF 79-11, at 2. Kramer responded that day, "We should discuss bringing in outside resources to get in front of this, while we recruit permanent resources to lead." *Id.* The following month, on July 22, Kirk included Husain on a reply to an email from AZ's senior vice

[14] The Defendants argue that the inspection reports and Form 483s were available to the public and, therefore, they are not probative of scienter because a scienter theory that the Defendants would attempt fraud by not disclosing information that was already public is implausible. ECF 72-1, at 38. But the Plaintiffs allege that the FDA published these reports only in heavily-redacted form that obscured much of their detail. ECF 54, ¶ 72, 111. Moreover, they allege that they first obtained copies of the inspection report through a FOIA request and that the report they obtained did not contain any of the underlying internal Emergent documents relied on in the report. *See id.* ¶ 110(b) n.5. The non-public inspection reports and Forms 483 are probative of scienter.

president that referenced the FDA Form 483 and the fact that OPMA did not accept Emergent's responses and found deficiencies "associated with inadequate responses." ECF 79-15, at 2–3. The AZ executive said, "this of course raises concern within AZ and with our customer/partners in BARDA/OWS who has raised this with us repeatedly in the last week." *Id.* at 4. Kramer's testimony and these emails to Kramer and Husain support a strong inference of scienter as to those two executives. They indicate that Kramer and Husain were aware of (and, at least in Kramer's case, engaged in active discussions about) the initial Form 483, the AZ and J&J audits, and the OPMA letter—all of which indicated that Bayview was not ready to begin commercial manufacturing of drug substances for COVID-19 vaccines.

The Defendants attempt to dispose of Kramer's testimony and these telling emails by reiterating that Emergent was actively working to reduce the identified deficiencies. But that argument, rather than weaken the inference of scienter, only strengthens it: to try to correct an issue, one must first be aware that it exists. Under the Defendants' view, the innocent inference is that Emergent knew about the deficiencies, but somehow failed to comprehend their significance or the significance of the fact that the FDA deemed their remediation plans insufficient. The malicious inference—that the Defendants were aware that their plans to address known deficiencies were considered insufficient, but nevertheless recklessly omitted those deficiencies so that they could give rosy public statements—is at least as compelling. The Defendants next argue that the statements and emails do not indicate that the risk was any greater than those disclosed in their SEC filings. But this argument concerns whether the statements were misleading, not whether Husain and Kramer were aware of the risks, and is unpersuasive for the reasons previously discussed. The FDA report, OPMA letter, and related internal emails support a strong inference of scienter beginning with the allegedly misleading statements on July 6.

iii. Batch destruction

The ongoing batch destructions, reported by various news sources and then corroborated by Congress, further strengthen the inference of scienter. The 2022 Congressional Report found that starting in October 2020, Emergent discarded nearly 400 million doses of vaccine drug substance (90 million of which were destroyed after it resumed manufacturing in July 2021). The report includes a January 25, 2021 email amongst AZ employees indicating that in an upcoming meeting "with Syed [Husain] at Emergent," they plan to discuss with him "10 rejected batches to-date (nearly $30M in liability), some very clearly GmP deficiency related." ECF 79-29, at 2. More broadly, the fact that Emergent discarded nearly 400 million doses (240 million of which were discarded by early 2021)—when contrasted with the fact that they successfully produced only approximately 180 million uncontaminated doses throughout the entire Class Period—supports an inference of scienter that strengthens over time as more batches are destroyed. The "innocent" inference, that the Individual Defendants repeatedly touted and quantified the Bayview facility's capacity to produce vaccines yet were unaware that their company was destroying significantly *more* vaccine batches than it ever produced, is implausible.

b. The Defendants' alleged admissions

Kramer's admission that he read the FDA reports detailing serious deficiencies in the Bayview facility's quality controls, coupled with his later admission that failures in those controls led to the February 2021 contamination, further support a strong inference of scienter. The Plaintiffs contend that the Defendants effectively conceded scienter when Kramer stated on April 29, 2021 that the February contamination incident was caused by a failure in quality controls. ECF 54, ¶ 261(f). The Defendants respond that this "admission" was made in hindsight and cannot support an inference that Kramer was aware that the contamination incident would occur at the

time he made the challenged statements. The Defendants are correct that Kramer made this statement after the February 2021 incident occurred. But to adequately allege scienter, the Plaintiffs do not need to allege that Kramer could have predicted that this particular incident would occur in the future. They need only allege that the Defendants were severely reckless in omitting material facts that could mislead investors. Kramer's admission that he had read the majority of the FDA's reports of serious deficiencies at Bayview and did not dispute their findings, while not itself sufficient, supports the inference that he was severely reckless when making statements that omitted those deficiencies.[15]

c. The Defendants' alleged motive

The Plaintiffs allege that the Defendants had a financial motivation to commit the alleged fraud: drive up Emergent's profits and share value, then use that success to benefit themselves financially. They argue that the Individual Defendants' motive to commit fraud is evidenced primarily by insider trades.[16] Insider trading allegations support an inference of scienter "if the

[15] The Plaintiffs also allege that the scienter inference is supported by Emergent's Code of Conduct, which requires employees' public statements to be truthful, commits the company to complying with current Good Manufacturing Practices, and prohibits insider trading. For support, they cite to *Chamberlain v. Reddy Ice Holdings, Inc.*, in which the court considered a company's code of conduct as part of its analysis finding scienter sufficiently pled. 757 F. Supp. 2d 683, 712 n.7 (E.D. Mich. 2010). The court noted that company ethics codes generally are "inherently aspirational" and do not support a scienter inference. *Id.* But the court considered "th[e] particular" ethics code before it because the plaintiffs alleged that a defendant had carefully studied it and it specifically discussed the illegality of certain pacts that the defendants allegedly formed. *Id.* There are no similar allegations here. Emergent's generic Code of Conduct does not strengthen the scienter inference.

[16] The Plaintiffs also allege that the Defendants' motive to commit the alleged fraud is supported by suspicious executive compensation and bonuses and the fact that Emergent raised funds overall. But "motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud." *Cozzarelli v. Inspire Pharmaceuticals Inc.*, 549 F.3d 618, 627 (4th Cir. 2008). They allege, too, that Emergent's "unjust acceptance" of $27 million from the government in monthly reservation fees supports scienter because the company accepted these fees even after manufacturing halted, then eventually had to reverse $86 million in revenue when the government terminated the contract. *See* ECF 80, at 60. But Emergent's

timing and amount of a defendant's trading were unusual or suspicious." *Yates*, 744 F.3d at 890 (quotation omitted). To determine if an insider's sales were "unusual in scope," courts consider factors like "the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved." *KBC Asset Mgmt.*, 19 F.4th at 610 (quoting *Yates*, 744 F.3d at 890 (internal quotations omitted)).

The insider trader allegations support a strong inference of scienter as to Kramer beginning in November 2020. According to the amended complaint, Kramer sold shares yielding over $1 million outside of any 10b5-1 plan and yielding over $10 million pursuant to his 10b5-1 plan, the latter of which occurred over three weeks in January to February 2021. These sales were suspicious in timing because they were made shortly after multiple batches were destroyed and around the same time as the alleged misstatements. They were suspicious in amount because Kramer's gross proceeds were 31 times larger than in the comparable pre-Class Period timeframe; because his 10b5-1 plan had never sold over $161,000 in any year from 2016 onward; and because the $8.61 million he reaped in net gains was far higher than his base salary in 2020 ($875,000) and 2021 ($1 million).

The Defendants stress that roughly $10 million of the $11 million in Kramer's trades during the Class Period were made pursuant to his 10b5-1 plan, arguing that this plan renders the sales not suspicious.[17] "Under Rule 10b5-1, corporate insiders can set up trading plans to sell company shares at predetermined times and amounts to avoid accusations of illegal insider trading." *Yates*,

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acceptance of funds pursuant to the terms of its government contract does not evince motive beyond the company's general motivation to make money.

[17] Contrary to the Plaintiffs' argument, it is not premature to consider Kramer's 10b5-1 plan at the motion to dismiss stage. *See KBC Asset Mgmt.*, 19 F.4th at 611–12 (considering 10b5-1 plan on motion to dismiss).

744 F.3d at 891; *see* 17 C.F.R. § 240.10b5-1(c) (listing "adopt[ing] a written plan for trading securities" as an affirmative defense in insider trading cases). The fact that a defendant trades shares pursuant to a 10b5-1 plan "weakens any inference of fraudulent purpose." *KBC Asset Mgmt.*, 19 F.4th at 611 (quoting *Yates*, 744 F.3d at 891). But when the timing in which a defendant enters or revises a 10b5-1 plan is suspicious, the plan itself does not mitigate a suggestion of motive for insider trading. *See id.* The Plaintiffs allege that Kramer revised his plan on November 13, 2020, after at least one batch of the AZ vaccine had been destroyed. Though the Defendants counter that the Plaintiffs fail to allege that Kramer was aware of that destroyed batch, this argument ignores other allegations that the Bayview facility had known quality control issues, including those documented by the April FDA investigation and other audits in June and July, as well as the OPMA letter sent to Emergent on June 23. Because the Plaintiffs have plausibly alleged that the timing of the revision to the 10b5-1 plan was suspicious, the fact that $10 million of Kramer's sales were made pursuant to a 10b5-1 plan does not weaken the inference of scienter drawn from the sales.

Nor does the fact that Kramer's holdings increased during this period weaken or negate the inference of scienter. The Defendants rely on the Fourth Circuit's observation in *Cozzarelli v. Inspire Pharmaceuticals, Inc.* that the increase in the defendants' holdings "hardly suggest[s] that the defendants sought to dump their shares at an inflated price." 549 F.3d at 628. But in *Cozzarelli*, the sales were modest in comparison to the defendants' total number of shares and vested stock options, and the defendants resigned around the same time as their sales, indicating that their departure, not an intent to defraud, prompted them to sell. *See id.* In *Proter v. Medifast, Inc.*, which the Defendants likewise rely on, the defendants had publicly disclosed their intention to sell shares far in advance, and no defendant sold stock in an amount that was unusual or suspicious in

comparison to their prior trading histories. No. GLR-11-720, 2013 WL 1316034, at *21 (D. Md. Mar. 28, 2013) (finding plaintiffs failed to allege a strong inference of scienter). Here, Kramer allegedly sold 70% of his pre-Class Period holdings, and only increased his holdings via exercise of no-cost mechanisms. His stock sales were unlike any sales he had previously made. Under these circumstances, the insider trader allegations support an inference of scienter notwithstanding the net increase in holdings.

d. Holistic analysis

When viewed holistically, the Plaintiffs' allegations raise a strong inference that Emergent, Kramer, and Husain either knowingly or recklessly misled investors between July 6 and March 31. This inference is strengthened by the core operations doctrine. Under this doctrine, if a defendant's alleged misstatements are related to his company's core operations, he is more likely to have known that his statements were false. *See KBC Asset Mgmt.*, 19 F.th at 612. Thus, allegations that individual defendants were senior executives and that the relevant operations represented a core business of their company are relevant to a court's holistic scienter analysis, provided, of course, that they are accompanied by particularized allegations that a defendant was aware of problems in those operations. *Yates*, 744 F.3d at 890. Husain and Kramer were senior executives at a biopharmaceutical company that contracted with the federal government and two pharmaceutical companies to manufacture drug substances for vaccines during the early days of the global pandemic. These executives repeatedly touted Emergent's ability to rapidly and on a large scale manufacture drug substances for COVID-19 vaccines. That their statements related to Emergent's core operations strengthens the inference of scienter. Viewed holistically, their statements and admissions, Kramer's alleged motives, the CW allegations, the FDA and other

reports, the contemporaneous emails, and the ongoing batch destruction indicate that Kramer and Husain were aware of contamination problems and other significant deficiencies at Bayview.[18]

This malicious inference is at least as compelling as any innocent inference, including the Defendants' suggested inference that Emergent "worked in good faith to manufacture vaccine drug substance in response to a pandemic, disclosed the risks, suffered an unfortunate contamination incident, and worked to address it." ECF 72-1, at 36. Emergent, Kramer, and Husain may well have been working in good faith to manufacture vaccine drug substance rapidly. But the Plaintiffs have raised a strong inference that while doing so, they omitted the myriad known deficiencies at Bayview that undercut the success of that endeavor and did so with reckless disregard for how those omissions could mislead investors. The Plaintiffs' allegations raise a cogent and strong inference of scienter as to Kramer, Husain, and Emergent.[19]

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[18] Also supporting a strong inference of scienter is the fact that Emergent announced the resignation of Husain (along with Sean Kirk, the senior executive who oversaw quality assurance at Bayview) on April 29, 2021, just one month after the *NYT* broke news of the contamination and one day before Emergent issued a response to the FDA's April 21 report. *See Cambridge Ret. System v. Jeld-Wen Holding, Inc.*, 496 F. Supp. 3d 952, 967–68 (E.D. Va. 2020) (finding that a senior executive's resignation supported the inference of scienter when viewed holistically).

[19] There is a strong inference of scienter for misleading statements made on July 6 and later. For similar statements made before July 6, there is not. Before then, no batch production had begun at Bayview (hence no batches had been destroyed). No alleged insider trading had occurred. While the Plaintiffs plausibly allege that Emergent, Kramer, and Husain were aware of the April 2020 FDA inspection report and Form 483 and the J&J and AZ audits documenting serious deficiencies, they also allege that Emergent was, at the time, formulating plans to address those deficiencies. There is no allegation that any defendant received the OPMA letter stating that the FDA still did not consider Bayview to be ready for commercial operations until June 24. Although one of the ten pre-July 6 statements occurred *on* June 24—the day Kramer received and responded to the email about the OPMA letter—the Plaintiffs do not allege the statement was made after Kramer read the email. Under these circumstances, the innocent inference—that Emergent knew Bayview had serious issues but thought it was adequately addressing them—is more compelling than any malicious inference that Emergent, Kramer, and Husain recklessly made public statements touting the Bayview facility despite knowing that Emergent's efforts to improve were inadequate.

3. Scienter allegations as to Lindahl

Before discussing the scienter allegations as to Lindahl, it bears repeating that to allege securities fraud against an individual defendant, a plaintiff "must allege facts supporting a strong inference of scienter as to that person." *Yates*, 744 F.3d at 885. The Plaintiffs, in contrast to their allegations concerning Kramer and Husain, do not allege that Lindahl was personally informed of the issues plaguing the Bayview facility. There are no CW allegations that Lindahl was aware of "red flags," as there are for Husain; no admissions that Lindahl read FDA reports, as there are for Kramer; and no forwarded email threads referencing Bayview's persistent deficiencies, as there are for both Husain and Kramer. Instead, the allegations supporting an inference of scienter for Lindahl are that he was the CFO and he engaged in insider trading. These do not suffice to raise the strong scienter inference required by the PSLRA.

To be sure, the fact that Lindahl was CFO of a drug manufacturing company supports the inference that he would be aware of drug manufacturing issues, particularly given the volume of batch destruction. Under the core operations doctrine, it may be likely that he would be aware that Emergent's statements were misleading. But scienter cannot rest only on the inference that an individual defendant must have known of the alleged fraud given his position in the company. *Yates*, 744 F.3d at 890 (citation omitted)); *Syneos Health*, 2023 WL 4688178, at *5 ("[W]e cannot impute factual knowledge to individuals merely based on their professional position or because 'such knowledge relates to the business's core operations.'" (quoting *KBC Asset Mgmt.*, 19 F.4th at 612)). Without "additional detailed allegations establishing the defendants' actual exposure to the . . . problem, the complaint falls short" of the PSLRA's requirements as to Lindahl. *Yates*, 744 F.3d at 890.

The Plaintiffs' insider trading allegations as to Lindahl do not transform the weak scienter inference into a strong one. Lindahl's trades during the relevant period constituted roughly 17% of his holdings. There is no bright-line test to determine what amount or percentage of holdings must be sold to give rise to a strong inference of scienter. *Proter*, 2013 WL 1316034, at *21 n.20. Courts have, however, found no inference of scienter in cases involving similar and greater percentages of sales. *See id.* (citing cases). Compared to his prior trading history, Lindahl's sales are roughly eight times larger (not, for instance, thirty-one times larger, as with Kramer). While these allegations may support an inference of scienter, they are not sufficient to raise a strong inference.

The Plaintiffs have not raised a strong inference of scienter as to Lindahl.

4. Statements after March 31, 2021 regarding the scope of contamination

The day after the *NYT* broke the news of the February cross-contamination and destruction of 15 million J&J vaccine dose-equivalents, Emergent issued a press release. In the April 1 press release, Emergent stated that "***a single batch of drug substance was identified that did not meet specifications*** and our rigorous quality standards" and that it "***isolated this batch and it will be disposed of properly***." ECF 54, ¶ 187. In various fora, Kramer repeated similar statements that portrayed the contamination as a single, isolated incident. *Id.* ¶ 195 (April 14, 2021 op-ed stating that "[d]uring ***our rigorous quality control process, we found*** a batch of [J&J] vaccines ***that did not meet specification***."); ¶ 205(a) (May 19, 2021 testimony to Congress stating that "a ***single batch*** of [J&J]'s COVID-19 vaccine candidate ***failed routine quality control testing***" and that ***testing*** was also conducted ***on other batches*** that were in process, which ***did not detect the presence of the [AZ] virus***"). Emergent also stated on April 1 that the "Bayview facility has been ***designed and validated to meet all current Good Manufacturing Practices***," "there are ***rigorous***

quality checks throughout [its] vaccine manufacturing processes," those "***quality control systems worked as designed***," and "***[d]iscarding a batch of bulk drug substance . . . does occasionally happen***." *Id.* ¶ 187. Similar statements that the Bayview facility was in compliance with regulatory standards and that its quality control systems worked as designed were repeated. *See id.* ¶¶ 191, 195; *see also id.* ¶ 205(b)(i) (Kramer's Congressional oral testimony asserting first that Emergent's own quality control procedures detected the contamination and that the material "never left our facility," then conceding, in response to questioning, that the contamination was detected by J&J in the Netherlands).

Also on April 1, CNBC interviewed Kramer. When asked how ingredients from the J&J vaccine could contaminate another vaccine in the plant, he responded:

> Kramer: And just to be clear, Meg, ***it isn't the case or wasn't the case where an ingredient from one vaccine contaminated or impacted the other. It was more simply the fact that a one production run, one batch of product was determined to be inconsistent with our quality specifications of Emergent and J&J and subsequently, that batch was pulled aside and will not be processed further.***
>
> [Interviewer]: So, there wasn't a mix-up with the AstraZeneca vaccine is what you're saying because there's reporting from NBC, the New York Times, Washington Post citing senior administration officials saying that there was basically a contamination with the AstraZeneca vaccine of the J&J vaccine. That's not what happened?
>
> Kramer: ***So, it was again, an out of specification result for one batch of product. And to put it in proper context, Meg, for your viewers, this was one of many other batches of product that has been successfully manufactured in accordance with our and J&J's product specifications. And, again, it's unfortunate that it happened, but it's one of many batches that had been successfully manufactured***.

Id. ¶ 189. In written and live testimony before Congress on May 19, Kramer reiterated a similar message. He testified that "a ***single batch*** of [J&J's] COVID-19 vaccine candidate ***failed routine quality control testing***," and that the incident was "***isolated to a single batch***." *Id.* ¶ 205(a).[20]

a. Material misrepresentations or omissions

The Plaintiffs have plausibly alleged that Emergent's statements and Kramer's testimony that an isolated, "single batch" did not meet specifications were false. As of February 2021, Emergent had destroyed not just the February 2021 contaminated batch but also five AZ batches and an additional J&J batch due to contamination and other worker errors.

The Plaintiffs also have plausibly alleged that Emergent's statements that the Bayview facility was "validated" to meet all current Good Manufacturing Practices, that its quality checks were "rigorous," or that those systems "worked as designed" were false. The CWs, FDA reports, and audits by J&J, AZ, BARDA, and Emergent indicate that quality control systems were deficient even before manufacturing began, and despite improvement attempts, Emergent failed to bring the Bayview facility into compliance with basic Current Good Manufacturing Practices.

Kramer's statements during the April 1 CNBC interview may not be literally false when considered in the context of the interviewer's inartful phrasing, but they are plausibly misleading. His statement that the issue was "an out of specification result for one batch of product" and "one of many other batches of product" that had been successfully manufactured omits the (at least) six additional batches that had been destroyed before this particular J&J batch. Kramer chose to speak

[20] The Plaintiffs point to another statement in April 2021 as misleading: Emergent's April 30, 2021, 52-page response to the FDA's April 2021 Form 483. But as with Emergent's response to the FDA's April 2020 Form 483, the Plaintiffs do not plausibly allege that this response was public. They claim "on information and belief" that it was posted to the FDA's website after April 30, 2021 and possibly after May 19, 2021, but at the same time, allege it was redacted when published and that discovery into the unredacted version would support their allegations. *See* ECF 54, ¶ 201 n.15, 16.

about the "many other batches of product that has been successfully manufactured," and having done so, the Plaintiffs plausibly allege, he needed also to disclose the many other batches that had been destroyed in order to render that statement not misleading. The materiality of this omission has been pled. It is plausible that a reasonable investor would find the destruction of those other batches important in assessing risks, including whether the February 2021 incident really was an isolated occurrence.

The Plaintiffs point to six statements made after Kramer's May 19 Congressional testimony that they allege were false or misleading. Many of these statements are mere puffery, touting the "***relentless determination of [the] Emergent team***," ECF 54, ¶ 213(a), or boasting that "***[o]ur business remains durable, resilient and poised for growth; we are on track with our 2024 strategy***." *Id.* ¶ 213(b). Some, however, announce that Emergent is "***committing extensive resources"*** to bring operations up to FDA standards during the production halt, *id.* ¶ 213(d), and otherwise proceeding with "***facility improvements and capability building***." *Id.* ¶ 213(b). These statements, made in July, August, and September, may have been misleading, as they omitted mention of the persistent deficiencies at Bayview (deficiencies that led to destruction of an additional 90 million newly manufactured J&J doses *after* production resumed in July 2021). But the Court need not decide the issue, because even if they were misleading, they were not material. After the Congressional hearing on May 19 (and accompanying media fanfare), the public was aware that batches from the Bayview facility were frequently destroyed; that contamination risks were high; and that the Bayview facility was deficient. *See Longman*, 197 F.3d at 684 (finding that challenged statements were not actionable because the allegedly omitted facts "were in fact well known to the market before the [statements], and therefore [the defendant's] omissions were not material" (citing *Hillson Partners Ltd. Partnership v. Adage, Inc.*, 42 F.3d 204, 212–13 (4th

Cir. 1994) (noting that the securities laws do not require disclosure of information that is already in the public domain))). It is not plausible that mentioning these facts in Emergent's post-May 19 statements would have significantly altered "the total mix of information made available" to a reasonable investor. *See Longman*, 197 F.3d at 683–84.

The Plaintiffs plausibly allege that the Defendants' statements regarding the scope of the contamination incident after the news of contamination broke on March 31 until the Congressional hearing on May 19 were false or misleading.[21]

b. Scienter

For the same reasons that the Plaintiffs adequately plead a strong inference of scienter for misleading statements made between July 6, 2020 and March 31, 2021, they likewise have done so for the false and misleading statements made after March 31 as to Emergent, Kramer, and Husain.[22] According to the CWs and Kramer's Congressional testimony, Emergent, Kramer, and Husain were aware that contamination risks were widespread and that their efforts to improve had been deemed insufficient by OPMA. Indeed, emails attached to the 2022 Congressional Report indicate that at least by December 2020 (three months before Emergent's statements that "a single batch" did not meet specifications), Husain was aware that cross-contamination was an ongoing issue during drug substance production at Bayview. On December 19, 2020, Husain forwarded to certain Emergent employees an email from AZ noting a "very serious risk" of cross-contamination of control cells at various sites. ECF 79-28, at 2–3. One employee replied to Husain, "It shows 8 events of control cell cross-contamination, with the most recent earlier this week. Perhaps you all

[21] The Court need not address each and every statement pled in the amended complaint (which are similar to those discussed here), as it concludes that the Plaintiffs have sufficiently pled actionable statements by the Defendants between July 6, 2020 and May 19, 2021.

[22] For the reasons discussed earlier in this opinion, the Plaintiffs have not pled a strong inference of scienter as to Lindahl regarding any statements.

were already aware that this is an ongoing issue. I thought it happened once, perhaps twice, and that it had been remediated." *Id.* at 2. Even assuming these prior incidents did not involve the same means of cross-contamination as the February 2021 incident, they nevertheless indicate that Husain was aware that statements implying only a "single batch" failed to meet specifications were misleading. More broadly, the fact that there were more destroyed batches than successful ones strengthens the scienter inference that Emergent, Kramer, and Husain knew or recklessly disregarded that statements about an isolated contamination incident were false or misleading. Viewed holistically, the Plaintiffs' allegations support a strong inference that Emergent, Kramer, and Husain were aware that the contamination was in fact not isolated to a single incident. The competing inference—that the Defendants were somehow unaware or neglected to find out that additional batches had been previously destroyed—is implausible.

* * *

The Defendants' motion to dismiss the Section 10(b) business operations fraud claim against Emergent, Kramer, and Husain for alleged statements they made between July 6, 2020 and May 19, 2021 is denied. The motion is granted as to the Section 10(b) business operations fraud claim against Emergent, Kramer, and Husain for alleged statements they made before July 6, 2020 and after May 19, 2021 and granted as to the business operations fraud claim against Lindahl.

B. Reported results fraud claim under Section 10(b)

The Plaintiffs allege that Emergent's Forms 10-Q and 10-K reported positive quarterly and annual financial results and operating metrics attributed to its COVID-19 contracts with the U.S. government, J&J, and AZ. They allege that these statements were materially false and misleading under Section 10(b) because they concealed negative underlying trends in manufacturing

capabilities that eventually required Emergent to reverse $86 million in revenues and lower its reported forecasts and backlog. ECF 1, ¶¶ 228–30.

The Plaintiffs do not allege that Emergent falsely or inaccurately reported its past earnings statements. This is fatal to their reported results fraud claim. Accurate reporting of past performance in SEC filings is generally considered unactionable under Section 10(b). *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (holding that "[f]actual recitations of past earnings, so long as they are accurate, do not create liability under Section 10(b)"); *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 404 (S.D.N.Y. 2016) (collecting cases and noting that "the allegation that a corporation properly reported income that is alleged to have been, in part, improperly obtained is insufficient to impose Section 10(b) liability"); *In re Toronto-Dominion Bank Sec. Litig.*, No. 17-1665, 2018 WL 6381882, at *9 (D.N.J. Dec. 6, 2018) (collecting cases and dismissing claims premised on numbers accurately reported in earnings statements "[c]onsidering the strength of the case law in this area").

Ignoring these holdings, the Plaintiffs insist that "courts nationwide" have found that GAAP-compliant financials and operating metrics were false or misleading because the company failed to disclose negative underlying facts or trends in violation of Regulation S-K, Item 303.[23]

[23] Regulation S-K, Item 303 requires a registrant to "[d]escribe any known trends or uncertainties that have had or that the registrant expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(a)(3)(iii). To the extent that the Plaintiffs attempt to cast a violation of SEC Regulation S-K, Item 303 as a violation of Section 10(b), they are unsuccessful. There is "no private right of action under SEC Regulation SK," and because its materiality standards differs "significantly" from Rule 10b-5's, "a violation of Regulation S-K does not lead to a failure to disclose under 10b-5." *Shah v. GenVec, Inc.*, No. DKC-12-0341, 2013 WL 5348133, at *15 n.16 (D. Md. Sep. 20, 2013) (quoting *Iron Workers Local 16 Pension Fund v. Hilb Rogal & Hobbs Co.*, 432 F. Supp. 2d 571, 583 (E.D. Va. 2006)). Moreover, where "plaintiffs have failed to plead any actionable misrepresentation or omission under [Rule 10b-5], SK-303 cannot provide a basis for liability." *Id.* (quoting *Oran v. Stafford*, 226 F.3d 275, 288 (3d Cir. 2000)).

The three district court cases they cite are not persuasive. In *In re Toronto-Dominion Bank*, the plaintiffs alleged that reported financial growth of the company was based on improper, illegal, or unauthorized sales. 2018 WL 6381882, at *10. The court held that while recitations of past financial performance are not actionable under Section 10(b), "attributing that financial performance to particular sources may" be misleading and material. *Id*. But unlike in that case, where the plaintiffs alleged that the company omitted the true (and improper) source of the revenue, the Plaintiffs do not contend that Emergent's reported revenue was derived from some undisclosed source. In *Kendall v. Odonate Therapeutics, Inc.*, a case concerning clinical results from a patient drug trial, the court held that the plaintiffs plausibly alleged that concealing an emergency change in protocol and other safety concerns during drug testing rendered statements about the testing results in SEC filings misleading. No. 3:20-cv-01828-H-LL, 2021 WL 3406271, at *6 (S.D. Cal. Aug. 4, 2021). The court did not hold or suggest that the *financial* statements in those filings were misleading. Finally, in *Perez v. Higher One Holdings, Inc.*, the court held, with limited analysis, that the plaintiffs plausibly pled an "Operating Results Fraud" based on "press releases and filings with the SEC . . . announcing its financial and operating results." 2017 WL 4246775, at *8 (D. Conn. Sep. 25, 2017). The opinion does not discuss which statements were allegedly false or misleading and whether such statements included the financial results themselves (as opposed to just the operating results, as the court's label of "Operating Results Fraud" would imply). *Perez* thus does not appear to support the Plaintiffs' position, and even if it does, the Court is not persuaded to follow it.

The Defendants' motion to dismiss is granted as to the Plaintiffs' alleged reported results fraud claim.

C. Internal controls fraud claim under Section 10(b)

The Plaintiffs allege that Emergent's SOX-certified quarterly and annual reports from May 1, 2020 until July 31, 2021, signed by Kramer and Lindahl, contained materially false and misleading statements and omissions under Section 10(b). They rely on the following certification language repeated in each Emergent 10-K and 10-Q form during this period:

> 1. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***
> 2. ***Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;*** [. . .]
> 5. ***The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):***
>
> ***a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which re reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and***
>
> ***b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.***

ECF 54, ¶¶ 232–34. The Plaintiffs allege that these statements were misleading because they omitted the fact that Kramer and Lindahl were aware of the deficiencies that plagued the Bayview facility and led to destroyed batches. As evidence that these SOX certifications misrepresented Emergent's internal controls, the Plaintiffs stress that during his May 19, 2021 testimony before Congress, Kramer apologized for "*the failure in our controls* that led to the contamination" and took "full responsibility" for the Bayview facility's manufacturing shutdown. *Id.* ¶ 205(a) (emphasis added).

On their face, the 10-K and 10-Q certification statements concern Emergent's internal controls over *financial reporting*. The Plaintiffs do not allege that Emergent had material weaknesses in any aspect of its internal controls over financial reporting. Instead, the Plaintiffs would broaden these certifications' reach to encompass Emergent's operational controls over the manufacturing process at Bayview. But their cited cases do not support extending SOX certifications so far beyond finance-related controls, and this Court is not aware of any cases to do so. The Plaintiffs rely first on *City of Roseville Employees' Retirement System v. Horizon Lines, Inc.*, in which the plaintiffs alleged that, despite accurate reporting of financial figures and non-defective financial internal controls, a company's SOX certifications were misleading because they failed to disclose that the reported revenue was obtained partially through unlawful conduct. 686 F. Supp. 2d 404, 418–19 (D. Del. 2009) (noting that Sarbanes-Oxley "is not directed solely at ensuring numerical accuracy and preventing dishonest accounting practices"). In particular, the plaintiffs in that "unusual" case alleged that the defendants were engaged in an illegal price-fixing conspiracy that rendered numerically accurate financial reports misleading because they "did not fairly present a complete picture of [the defendant's] financial condition." *Id.* The alleged misrepresentations thus did extend beyond purely financial internal controls, but they still concerned the source of the company's funds—an illegal price-fixing scheme. Similarly, in *In re Toronto-Dominion Bank*, the plaintiffs alleged the defendants had deficient internal controls and misattributed certain financial growth without revealing that the growth was based on improper, illegal, or unauthorized sales. 2018 WL 6381882, at *10. Here, by contrast, the Plaintiffs do not assert that Emergent misrepresented its finances by omitting they were derived from an illegal or

unauthorized source.[24] The SOX certifications of internal controls over financial reporting cannot be read to include certifications that Bayview did not have operational deficiencies related to manufacturing and contamination risks.

The Defendants' motion to dismiss is granted as to the Plaintiffs' alleged internal controls fraud claim.

D. Section 20(a) claim

In the second count of the amended complaint, the Plaintiffs allege secondary liability under Section 20(a) of the Exchange Act against the Individual Defendants. ECF 54, ¶¶ 345–50. The Defendants move to dismiss this claim solely on the basis that the Plaintiffs fail to adequately state a Section 10(b) claim. ECF 72-1, at 45. For the reasons discussed above, the Plaintiffs have adequately stated a claim under Section 10(b). Further, they allege that they purchased or otherwise acquired Emergent common stock during the Class Period. ECF 54, ¶¶ 2, 19–20. The Plaintiffs thus state a plausible claim for relief under Section 20(a). *See In re Under Armour*, 540 F. Supp. 3d at 523 (denying motion to dismiss Section 20(a) claim because plaintiffs adequately alleged Section 10(b) claim); *Sinnathurai*, 2022 WL 17585715, at *11 (denying motion to dismiss Section 20(a) claim where defendants did not argue that Section 20(a) claim failed for reasons beyond rejected Section 10(b) claim arguments).

The Defendants' motion to dismiss is denied as to the Section 20(a) claim to the extent the Section 10(b) claim proceeds.

[24] The Plaintiffs also cite *Kendall v. Odonate Therapeutics, Inc.*, 2021 WL 3406271 (S.D. Cal. Aug. 4, 2021) and *In re Enzymotec Sec. Lit.*, 2015 WL 8784065 (D.N.J. Dec. 15, 2015). Neither sway the analysis: *Kendall* does not discuss SOX certifications, and *Enzymotec* concerns internal controls over financial reporting.

V. Conclusion

For the foregoing reasons, the motion to dismiss is granted in part and denied in part. A separate order follows.

9/1/2023
Date

Deborah L. Boardman
United States District Judge