UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Lead Plaintiff John C. LEVON, individually and on behalf of all others similarly situated, Plaintiffs, v. CORMEDIX INC., KHOSO BALUCH, ROBERT COOK, MATTHEW DAVID, PHOEBE MOUNTS, JOHN L. ARMSTRONG, and JOSEPH TODISCO, Defendants.	**Civil Action No. 21-14020 (JXN) (CLW)** **OPINION**

NEALS, District Judge:

This matter comes before the Court on Defendants CorMedix Inc. ("CorMedix"), Khoso Baluch ("Baluch"), Robert Cook ("Cook"), Matthew David ("David"), Phoebe Mounts ("Mounts"), John L. Armstrong ("Armstrong"), and Joseph Todisco's ("Todisco") (collectively, "Defendants") motion to dismiss the Third Amended Consolidated Class Action Complaint (ECF No. 97) ("Third Amended Complaint" or "TAC"), pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, *et. seq.* (ECF No. 104). Jurisdiction is proper under 28 U.S.C. § 1331 and 15 U.S.C. § 78aa. Venue is proper under 28 U.S.C. § 1391(b) and § 27 of the Securities Exchange Act of 1934 ("Exchange Act"). The Court has carefully considered the parties' written submissions and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1(b). For the reasons stated below, Defendants' motion to dismiss (ECF No. 104) is **DENIED**.

I. BACKGROUND[1]

A. Plaintiff, CorMedix, and DefenCath

Plaintiff John C. Levon brings this putative securities class action on behalf of himself, and all others similarly situated who purchased or otherwise acquired common stock of CorMedix between October 16, 2019, and August 8, 2022 (the "Class Period"). (TAC ¶ 1). This class action arises from CorMedix's efforts to obtain U.S. Food and Drug Administration ("FDA") approval of its New Drug Application ("NDA") for DefenCath. (*Id.* at ¶¶ 1, 12, 144).[2]

CorMedix is a publicly traded biopharmaceutical company headquartered in New Jersey, focused on the development and commercialization of products for the prevention and treatment of infectious diseases. (*Id.* at ¶ 47). Its lead product candidate, DefenCath (formerly known as Neutrolin) ("DefenCath"), is an antimicrobial catheter lock solution that is placed into catheters when not in use, designed to reduce catheter related infections. (*Id.* at ¶¶ 2, 47).

Baluch, Cook, David, Mounts, Armstrong, and Todisco were executive officers of CorMedix during part or all of the Class Period. (*Id.* at ¶¶ 48-54). Baluch served as CorMedix's Chief Executive Officer ("CEO") and on its Board from October 2016 to October 4, 2021. (*Id.* at ¶ 48). Cook served as CorMedix's Chief Financial Officer ("CFO") from February 1, 2017, through January 31, 2020. (*Id.* at ¶ 49). David has served as CorMedix's CFO and Executive Vice President ("EVP") since May 2020. (*Id.* at ¶ 50). Mounts serves "as EVP, General Counsel, and Secretary of CorMedix as well as its Head of Regulatory, Compliance & Legal." (*Id.* at ¶ 51). Armstrong served as CorMedix's EVP for Technical Operations from March 2017, through

[1] The following factual allegations are taken from Plaintiff's Third Amended Complaint, which are accepted as true. *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010).

[2] "If an NDA is accepted, the FDA performs a substantive review and either approves the NDA or issues a Complete Response Letter ("CRL") rejecting the NDA." *Paice v. Aldeyra Therapeutics, Inc.*, No. 23-11737, 2025 WL 815065, at *2 (D. Mass. Mar. 14, 2025). (*See also* TAC ¶ 21 ("Having been kept in the dark by Defendants, investors were shocked when, on March 1, 2021, CorMedix issued a press release announcing the First CRL instead of FDA approval.")).

October 4, 2021. (*Id.* at ¶ 52). Todisco has served as CorMedix's CEO and on its Board since May 10, 2022. (*Id.* at ¶ 54).

B. The Alleged Fraud and Ultimate Disclosure

1. The Audit

In 2017, CorMedix selected ROVI Contract Manufacturing, S.L. ("ROVI"), a third-party commercial manufacturing organization ("CMO") located in Spain, to assist with the manufacturing process of DefenCath. (*Id.* at ¶¶ 3-4, 79). Thereafter, in 2018, CorMedix hired Former Employee 1 ("FE1") to conduct an audit ("the Audit") of ROVI. (*Id.* at ¶¶ 80-81). FE1 and a support team conducted the Audit over a span of weeks and included an on-site visit to ROVI's facilities. (*Id.* at ¶ 81). The formal Audit report, which was prepared in 2019, recommended that CorMedix not use ROVI "and directly stated that ROVI would never be able to pass an FDA inspection." (*Id.* at ¶ 83; *see also id.* at ¶ 5). According to Plaintiff, "CorMedix did not disclose the existence of this audit or its conclusions[] and inexplicably pushed ahead with ROVI as CMO." (*Id.* at ¶¶ 5, 81-85).[3] Defendants allegedly concealed these findings from the public, despite commenting on their ability to manage the manufacture of DefenCath through ROVI. (*Id.* at ¶¶ 40, 88).

Former Employee 2 ("FE2") "was the Senior Director of Quality Assurance at CorMedix from February 2020 until they resigned in May 2023." (*Id.* at ¶ 82). FE2 averred that despite FE1's

[3] The Court properly considers the following: (1) the Third Amended Complaint and documents referenced therein; (2) SEC filings; and (3) public information capable of judicial notice, such as stock prices or FDA guidance. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (court "must consider" documents "incorporated . . . by reference" and matters subject to judicial notice); *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (court may consider a document "integral to or explicitly relied upon in the complaint" on motion to dismiss). *Accord Pinkney v. Meadville, Pa.*, No. 21-1051, 2022 WL 1616972, at *2 (3d Cir. May 23, 2022) (A court may look beyond the pleadings and "consider 'document[s] integral to or explicitly relied upon in the complaint,' or any 'undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.'" (quoting *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 (3d Cir. 2016))).

recommendation that ROVI not be utilized, ROVI was selected due to "the close personal friendship between ROVI's head and [] Baluch." (*Id.* at ¶ 83). The Audit "was placed on an internal [] shared drive, where FE2 was able to access it." (*Id.* at ¶ 85). Additionally, according to FE2, "Baluch was closely involved in the production and distribution of FE1's report[]" and believes Mounts received a copy of it. (*Id.* at ¶ 86).

2. Defendants' Actions and Impact on CorMedix's Stock Value

On October 16, 2019, CorMedix issued a press release claiming that "[t]he FDA was supportive of [DefenCath]'s proposed manufacturing program, including the active pharmaceutical ingredients ("API"), the container closure and testing" and that "[DefenCath] can be approved in the second half of 2020." (*Id.* at ¶¶ 7, 89-90, 178-79). Following the press release, CorMedix's stock increased over 9 percent. (*Id.*)

Subsequently, in February 2020, the FDA accepted the DefenCath NDA for rolling review. (*Id.* at ¶ 12). In May 2020, the FDA conditionally approved DefenCath. (*Id.* at ¶ 13). Thereafter, in July 2020, CorMedix completed its submission.[4] (*Id.* at ¶ 98).

In July 2020, after CorMedix completed the DefenCath NDA, CorMedix advised investors that CorMedix and its CMO were "successfully collecting the information [] and data required to meet FDA standards: all that was left was approval" and assured investors that "it had not been informed of any delays by the FDA in the review of the NDA" (*Id.* at ¶¶ 14, 98, 100). CorMedix's stock increased 7 percent. (*Id.* at ¶ 14). On July 29, 2020, CorMedix conducted a public offering, which was originally issued on November 27, 2020.[5] (*Id.* at ¶¶ 16, 99). CorMedix sold 832,676 shares of common stock at a weighted average price of $8.69 per share, realizing net proceeds of

[4] The Court notes Plaintiff alternatively alleges, earlier in the Third Amended Complaint, that CorMedix completed its NDA submission in June 2020. (TAC ¶ 12).

[5] According to the Third Amended Complaint, CorMedix supplemented its public offering on August 12, 2021. (TAC ¶ 16).

approximately $7.0 million during 2020, and during the first six months of 2021, CorMedix sold an aggregate 3,737,862 shares of common stock at an average price of $11.10 per share, with net proceeds of $41.5 million. (*Id.* at ¶ 102).

On August 31, 2020, CorMedix issued a press release announcing the FDA's acceptance for filing and priority review[6] of the DefenCath NDA. (*Id.* at ¶ 206; *see also id.* at ¶ 15). CorMedix also set a Prescription Drug User Fee Act ("PDUFA") "date of February 28, 2021, for the completion of its review." (*Id.* at ¶ 206; *see also id.* at ¶ 15). CorMedix "noted that [the FDA] . . . had not identified any potential review issues at this time." (*Id.* at ¶ 100). CorMedix reiterated this message on November 5, 2020, when reporting its 3Q20 financial results, stating it "ha[d] not been informed of any delays by the FDA in the review of the NDA, but . . . pre-approval inspections are required for manufacturing sites. (*Id.*)

On February 26, 2021, the FDA issued DefenCath's first CRL ("First CRL"), which explained "(1) the drug product manufacturing facility (ROVI Pharma Industrial Services S.A.) was found inadequate following a 704(a)(4) based review; and (2) inadequate in-process controls were proposed for . . . the drug product manufacturing process." (*Id.* at ¶¶ 20, 105, 218).[7] On

[6] "Under Priority Review, the FDA reduces its review time from ten months to six." (TAC ¶ 15 n.2 (citing U.S. FOOD & DRUG ADMIN., *Priority Review* (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approvalpriority-review/priority-review).

[7] Notwithstanding, by July 9, 2020, Plaintiff alleges Defendants "knew or recklessly ignored that ROVI had agreed to do large-scale, commercial fill-finish manufacturing of Moderna's COVID-19 vaccine candidate at ROVI's Madrid facility. (TAC ¶ 163). In March 2021, CorMedix disclosed the "proposed future installation of new equipment" at its CMO's facility as well as "delays" at its CMO relating to "issues . . . unrelated to DefenCath manufacturing activities[,]" which Plaintiff avers related to its manufacturing of Moderna. (*Id.* at ¶ 164). Additionally, according to the Third Amended Complaint, "Defendants knew or recklessly ignored that ROVI would be investing in new production lines at its Madrid facility "where it bottles, or 'fills and finishes' Moderna vaccines for markets" other than the US in order to "double its capacity to bottle" the vaccine." (*Id.* at ¶ 165). Plaintiff alleges "based on FDA guidelines" and communication with the FDA "CorMedix knew or recklessly ignored that it needed to provide the FDA information about any new production lines at the facility manufacturing DefenCath—even if they were unrelated to the manufacturing of DefenCath." (*Id.*) Plaintiff also alleges "Defendants knew or recklessly ignored contaminants in vials manufactured by ROVI" and that "CorMedix knew or should have known that it needed to provide the FDA with information about testing being done at the facility manufacturing DefenCath" even if it were unrelated to DefenCath. (*Id.* at ¶ 166).

March 1, 2021, Defendants publicly disclosed the First CRL. (*Id.* at ¶¶ 21, 106, 219). On that same date, CorMedix's stock price decreased approximately 54.4 percent. (*Id.* at ¶¶ 22, 106, 220).

On March 9, 2021, during CorMedix's first call after the First CRL, "Defendants downplayed the issues underlying the [First] CRL," by stating that one of the deficiencies cited in the First CRL was because it was unclear to the FDA that the future installation of new equipment at the facility was unrelated to DefenCath and that the FDA's requested manual extraction and airflow visualization studies would be "completed in the next several weeks." (*Id.* at ¶ 24; *see also id.* at ¶¶ 113-119, 223). Further, FE2 stated that after the first CRL, "there were near constant remediation meetings . . . (sometimes up to four meetings per day)" and that Mounts, Ortiz, Berrios, FE1, and Baluch attended these meetings. (*Id.* at ¶ 112).

However, on April 14, 2021, CorMedix issued a press release advising that representatives from ROVI and CorMedix met with the FDA "to discuss proposed resolutions for the deficiencies identified in the First CRL and the corresponding Post-Application Action Letter ("PAAL") received by [ROVI]." (*Id.* at ¶ 125). That same day, investors learned CorMedix could not resubmit the NDA until the third quarter of 2021 because more remedial steps were necessary than previously identified. (*Id.* at ¶¶ 25, 125). Notwithstanding, "Defendants stressed that CorMedix and [ROVI will] continue to work closely to ensure that the identified deficiencies are resolved prior to resubmission of the DefenCath NDA[,]" within the "next several weeks." (*Id.* at ¶ 127). Subsequently, CorMedix's stock price fell 18.36 percent. (*Id.* at ¶¶ 25, 126, 236).

Despite Defendants' assurances, on May 13, 2021, CorMedix announced it could not resubmit the NDA until the fourth quarter of 2021. (*Id.* at ¶¶ 27, 129). CorMedix's stock fell approximately 20 percent. (*Id.* at ¶ 237). Notwithstanding, Defendants "touted" CorMedix and ROVI's ability to resolve the manufacturing deficiencies and assured investors that "we have the

right team and appropriate resources in place to resolve the third-party manufacturing deficiency[]" and that they were on schedule to resubmit the NDA in the fourth quarter. (*Id.* at ¶¶ at 28, 130).

Yet, in September 2021, investors learned CorMedix "ha[d] encountered delays" at ROVI and that the timeline to address deficiencies at ROVI's facility was "uncertain." (*Id.* at ¶¶ 29, 135, 261). CorMedix's stock fell over 27 percent. (*Id.* at ¶ 262).

In October 2021, CorMedix "announced that, effective immediately, [] Baluch was retiring from his role as CEO and resigning from CorMedix's Board and [] Armstrong was retiring[,]" and [] Mounts would be taking over CorMedix's "technical operations group, including a group of consultants that are working on addressing the situation with [ROVI]." (*Id.* at ¶ 137).

The following month, despite CorMedix's repeated assurances they had "the right team," Mounts announced, "we have engaged [a] team of external consultants to provide additional expertise on FDA's expectations for addressing the specific deficiencies at the manufacturing facility, and to assist in preparations for a pre-approval inspection." (*Id.* at ¶¶ 31, 138).[8]

On February 4, 2022, unbeknownst to investors, the FDA issued a Form 483 to CorMedix's API manufacturer for heparin for the United States market. (*Id.* at ¶ 149). Plaintiff alleges the Form 483 "warranted requests for corrective actions, yet, Defendants said nothing." (*Id.*)

On February 28, 2022, Defendants resubmitted the NDA and announced that "[CorMedix] and the manufacturer [had] adequately addressed the concerns" noted in the First CRL. (*Id.* at ¶¶ 32, 144, 266).

[8] The Third Amended Complaint references Sarbanes-Oxley ("SOX") certifications during the Class Period signed by Baluch and David. (TAC ¶¶ 192, 204, 212, 231, 254). These SOX certifications consecutively contained the following statement: "to my knowledge . . . the information contained in the [[] 10-K] Report fairly presents, in all material respects, the financial condition and results of operations of the Company." (*Id.*)

On March 28, 2022, "CorMedix announced that the DefenCath NDA resubmission had been accepted for filing as a Class 2 response, warranting a 6-month review cycle." (*Id.* at ¶¶ 32, 147). In a press release issued that day, Mounts stated, "CorMedix and [ROVI] have adequately addressed the concerns the [FDA] identified during the review of the original NDA, and we are committed to working jointly to ensure a successful inspection." (*Id.* at ¶¶ 147-48, 267).

In May 2022, Todisco provided his opening remarks as CEO, however, he did not disclose the manufacturing deficiencies identified at CorMedix's API for heparin, and one month later, while presenting at a conference, he reiterated the CMO's ability to maintain Current Good Manufacturing Practice ("cGMP")[9] standards, which prompted the question "has the company addressed all the [FDA's] questions appropriately?" to which he answered "yes, yes." (*Id.* at ¶¶ 152-54, 279).

However, on August 4, 2022, the FDA issued a second CRL ("Second CRL"), citing unresolved deficiencies at both ROVI and the API supplier for heparin. (*Id.* at ¶¶ 33, 34, 156, 281). On August 8, 2022, CorMedix disclosed this Second CRL and stated ROVI needed "an independent CGMP consultant" prompting another drop in its stock price by approximately 57 percent. (*Id.* at ¶¶ 35-36, 157, 159, 281-82).[10]

Ultimately, in the Third Amended Complaint, Plaintiff alleges that throughout the Class Period Defendants consistently made materially false and misleading statements and omissions

[9] cGMP "includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351; *see also* 21 C.F.R. Parts 210 and 211. The cGMP is the mandatory standard of compliance set by the FDA for pharmaceutical manufacturing. *See* 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211. "The regulations help guarantee that the drug in the bottle matches what is on the label." *In re Digitek Prods. Liab. Litig.*, 821 F. Supp. 2d 822, 826 n.3 (S.D. W. Va. 2011).

[10] Plaintiff notes that if Defendants disagreed with either the First or Second CRL, they were entitled to appeal. (TAC ¶ 160). Plaintiff alleges that "FDA regulations 21 CFR 312.48 and 21 CFR 314.103 address dispute resolution as it relates specifically to . . . new drug applications (NDA)" but alleges Defendants did not appeal, indicating that Defendants knew the manufacturing deficiencies were material. (*Id.*)

concerning CorMedix's ability to secure FDA approval.[11] (*Id.* at ¶ 40). Specifically, Plaintiff contends that Defendants—despite their awareness of the Audit—misrepresented or omitted material facts related to: (1) deficiencies that existed at ROVI and CorMedix's API supplier for heparin; (2) ROVI's regulatory readiness (or lack thereof) and compliance with FDA guidance and cGMP standards; (3) the deficiencies in the DefenCath NDA, which would likely lead to the DefenCath NDA being rejected; (4) the true scope of the deficiencies after the first CRL; and (5) ROVI's manufacture of contaminated products. (*Id.* at ¶ 40).

C. Procedural History

On July 22, 2021, Plaintiff filed the initial class action complaint. (ECF No. 1). Thereafter, on October 13, 2021, an order was entered to consolidate Civil Action Nos. 21-16855 and 21-14020 into the present action. (ECF No. 39).

On December 14, 2021, Plaintiff filed the First Amended Complaint ("FAC"), asserting claims under both the Securities Act of 1933 and the Exchange Act. (ECF No. 43). On March 28, 2022, Defendants moved to dismiss the FAC. (ECF No. 57).[12]

On August 30, 2022, the parties entered a stipulation allowing the filing of a Second Amended Complaint and permitting Defendants to file a motion to dismiss in response thereto. (ECF No. 75). On December 9, 2022, the Court granted in part and denied in part the motion, dismissing Plaintiff's Securities Act claims with prejudice while allowing Plaintiff to amend the Exchange Act claims. (ECF Nos. 65-66).

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[11] The Court does not re-print the entirety of the statements quoted in the Third Amended Complaint in the Background Section because such statements are alleged in voluminous paragraphs, totaling over one hundred (100) pages of the Third Amended Complaint. Rather Defendants' specific statements are quoted and discussed in the Discussion section. *See, e.g., Dang v. Amarin Corp. PLC*, 750 F. Supp. 3d 449 n.4 (D.N.J. 2024).

[12] On February 21, 2022, Defendants moved to dismiss the First Amended Complaint. (ECF No. 50). The Court administratively terminated the motion at ECF No. 50 based on the parties' joint stipulation amending the briefing schedule. (*See* ECF No. 55). The motion to dismiss was refiled under ECF No. 57.

On October 10, 2022, Plaintiff filed the Second Amended Complaint alleging claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. (ECF No. 79). On November 23, 2022, Defendants moved to dismiss the Second Amended Complaint. (ECF No. 86). On March 21, 2024, the Court denied Defendants' motion without prejudice and granted Plaintiff leave to amend. (ECF No. 91).

On April 22, 2024, Plaintiff filed the Third Amended Complaint. (ECF No. 97). The Third Amended Complaint raises two causes of action against Defendants: (i) violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder (codified at 17 C.F.R. § 240.10b-5), against all Defendants (Count I); and (ii) violation of Section 20(a) of the Exchange Act, against the Individual Defendants (Count II). (TAC ¶¶ 309-25).

On June 6, 2024, Defendants moved to dismiss the Third Amended Complaint. ("Defs.' Br.") (ECF No. 104). On July 22, 2024, Plaintiff opposed. ("Pl.'s Br.") (ECF No. 106). On August 21, 2024, Defendants replied. ("Defs.' Rep. Br.") (ECF No. 107). Defendants' motion to dismiss is now ripe for adjudication.[13]

II. LEGAL STANDARD

A. Rule 12(b)(6)

Rule 8 requires that a pleading include "a short and plain statement of the claim showing that the pleader is entitled to relief" and provide the defendant with "fair notice of what the claim is and the grounds upon which it rests[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation modified). On a Rule 12(b)(6) motion, the "facts alleged must be taken as true" and dismissal is not appropriate where "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir.

[13] On June 30, 2025, the Court inadvertently issued a preliminary draft opinion, which the Court withdrew from the docket. (ECF No. 126).

2008) (citation modified). A complaint will survive a motion to dismiss if it provides a sufficient factual basis to state a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To determine whether a complaint is sufficient, the Third Circuit requires a three-part inquiry: (1) the court must first recite the elements that must be pled in order to state a claim; (2) the court must then determine which allegations in the complaint are merely conclusory and therefore need not be given an assumption of truth; and (3) the court must "assume the[] veracity" of well-pleaded factual allegations and ascertain whether they plausibly "give rise to an entitlement for relief." *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (citation modified).

B. Rule 9(b)

Under Rule 9(b) and in conjunction with Rule 12(b)(6), fraud-based claims are subject to a heightened pleading standard, requiring a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A court may dismiss a fraud-based claim if the plaintiff fails to plead with the required particularity, i.e., sufficient details to put the defendant "on notice of the precise misconduct with which [it is] charged." *See Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). At a minimum, Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006) (quoting *In re Rockefeller Ctr. Prop. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)); *see also U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016). Accordingly, "[t]o satisfy the particularity standard, 'the plaintiff must plead or allege the date, time and place of the alleged fraud or

otherwise inject precision or some measure of substantiation into a fraud allegation.'" *Feingold v. Graff*, 516 F. App'x 223, 226 (3d Cir. 2013) (quoting *Frederico*, 507 F.3d at 200). This heightened standard is designed to "ensure that defendants are placed on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of fraud." *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (citation modified). The heightened pleading standard set forth in Rule 9(b) applies to fraud claims brought under the Exchange Act. *See, e.g., In re Suprema*, 438 F.3d at 276.

C. The PSLRA[14]

"In addition to Rule 9(b)'s heightened pleading requirements, Congress enacted the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u, *et seq.*, to require an even higher pleading standard for plaintiffs bringing private securities fraud actions." *City of Warwick Ret. Sys. v. Catalent*, No. 23-1108, 2024 WL 3219616, at *3 (D.N.J. June 28, 2024) (citing *In re Suprema*, 438 F.3d at 276); *see also Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 241 (3d Cir. 2013) ("The PSLRA establishe[s] heightened pleading requirements for a plaintiff to meet in order to plead a cause of action successfully in class actions alleging securities fraud."). This heightened pleading standard is targeted at preventing abusive securities litigation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) ("Private securities fraud actions, . . . if not

[14] "To plead falsity, Rule 9(b) and the PSLRA each demand specificity." *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 680 (3d Cir. 2023). "Although the pleading standards in Rule 9(b) and the PSLRA can be generally reconciled harmoniously for allegations of falsity, the PSLRA's requirements for allegations of scienter control over the more lenient standard in Rule 9(b) for mental-state allegations." *Id.* at 681 n.1 (emphasis omitted) (citing *Avaya*, 564 F.3d at 253 ("The PSLRA's requirement for pleading scienter . . . marks a sharp break with Rule 9(b)."); *Tellabs*, 551 U.S. at 323-24); *compare* Fed. R. Civ. P. 9(b) (permitting "[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally"), *with* 15 U.S.C. § 78u-4(b)(2)(A) (requiring a particularized statement of the "facts giving rise to a strong inference that the defendant acted with the required state of mind"). Notably, "Rule 9(b) and the PSLRA do not insist upon irrefutable evidence of a statement's falsity at the pleading stage; rather, a complaint must contain particularized factual allegations that plausibly allege that a statement was misleading." *City of Warren*, 70 F.4th at 681.

adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law.").

"The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss." *City of Warwick*, 2024 WL 3219616, at *3 (citing *Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009)); *see also Tellabs*, 551 U.S. at 313 (stating the PSLRA requires a complaint to "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12 (1976))). "First, under 15 U.S.C. § 78u–4(b)(1), the complaint must 'specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity.'" *City of Warwick*, 2024 WL 3219616, at *3 (quoting *Avaya*, 564 F.3d at 252). "Second, the complaint must, 'with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Id.* (quoting *Avaya*, 564 F.3d at 252).

"Both provisions of the PSLRA require facts to be pled with 'particularity.'" *Id.* (quoting *Avaya*, 564 F.3d at 253). "This particularity language echoes the requirements of Rule 9. *Id.* (citing *Avaya*, 564 F.3d at 253); *see* Fed. R. Civ. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake."); *see also Rahman*, 736 F.3d at 241 n.3. "Indeed, although the PSLRA replaces Rule 9(b) as the pleading standard governing private securities class actions, Rule 9(b)'s particularity requirement "is comparable to and effectively subsumed by" PSLRA § 78u–4(b)(1)." *Id.* (citing *Avaya*, 564 F.3d at 253).

III. DISCUSSION

A. Violation of Exchange Act Section 10(b)

The private right of action under Section 10(b) and Rule 10b-5 "creates liability for false or misleading statements or omissions of material fact that affect trading on the secondary market." *In re Burlington*, 114 F.3d at 1417. To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege: "(1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation." *Gold v. Ford Motor Co.*, 577 F. App'x 120, 122 (3d Cir. 2014) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)); *see also Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011); *City of Warren*, 70 F.4th at 679; *Fan v. StoneMor Partners LP*, 927 F.3d 710, 714 (3d Cir. 2019); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). Principally at issue is whether the Third Amended Complaint sufficiently pleads three elements of securities fraud for their Section 10(b) claim—misrepresentations or omission, scienter, and loss causation. The Court addresses each of these elements in turn.

(1) Plaintiff Adequately Alleges Material Misrepresentation

Under Section 10(b) and Rule 10b-5, a misrepresentation or omission of fact is material "if there is a substantial likelihood that a reasonable shareholder would consider it important" in making an investment decision, and there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (quoting *TSC Indus. v. Northway*, 426 U.S. 438, 440 (1976)); *see also In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *11 (D.N.J. May 19, 2017); *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992). Importantly, to be actionable, a statement or omission must

have been materially misleading at the time it was made; liability cannot be imposed based on subsequent events. *City of Warren*, 70 F.4th at 693; *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002).

Notably, because materiality is a mixed question of law and fact, "[o]nly if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality is it appropriate for the district court to rule that the allegations are inactionable as a matter of law." *Shapiro*, 964 F.2d at 280 n.11 (citation modified). "The Third Circuit has warned that the task of determining materiality can be especially difficult when the statement at issue contains 'soft' information, i.e., statements of subjective analysis or extrapolation, such as opinions, motives, and intentions, or forward[-]looking statements, such as projections, estimates, and forecasts." *Roofer's Pension Fund v. Papa*, No. 16-2805, 2018 WL 3601229, at *8 (July 28, 2018) (citing *Craftmatic*, 890 F.2d at 642). "The ultimate issue of materiality should not be decided as a matter of law unless 'the disclosures or omissions are so clearly unimportant that reasonable minds could not differ.'" *Carmignac Gestion, S.A. v. Perrigo Co. PLC*, No. 17-10467, 2019 WL 3451523, at *9 (D.N.J. July 31, 2019) (quoting *In re Galena Biopharma, Inc. Sec. Litig.*, 336 F. Supp. 3d 378, 390 (D.N.J. 2018)); *see also In re Enzymotec Sec. Litig.*, No. 14-5556, 2015 WL 8784065, at *15 (D.N.J. Dec. 15, 2015) ("[T]he question of whether disclosure was required is best left to the trier of fact, since whether a prior disclosure is inaccurate, incomplete, or misleading in light of all of the evidence is a mixed question of law and fact." (citing *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 317 (3d Cir. 1997))); *Ieradi v. Mylan Lab'ys, Inc.*, 230 F.3d 594, 599 (3d Cir. 2000) ("[W]here there is room for differing opinions on the issue of materiality, the question should be left for jury determination.") (citation modified).

However, regardless of whether a piece of information is material, Section 10(b) and Rule 10b–5 "do not create an affirmative duty to disclose any and all material information." *Matrixx*, 563 U.S. at 44; *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 281 (D.N.J. 2007) ("[W]hen an allegation of fraud is based upon nondisclosure, there can be no fraud absent a duty to speak."). Indeed, "[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5." *City of Edinburgh Council*, 754 F.3d at 174 (quoting *Basic*, 485 U.S. at 239 n.17). Although, "[t]here is no affirmative duty to disclose all material information, [] such a duty may arise when a company chooses 'to speak about a material subject to investors.'" *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022) (quoting *City of Edinburgh Council*, 754 F.3d at 174); *see also Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017) ("Once a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."); *In re Bristol-Meyers Squibb Sec. Litig.*, No. 00-1990, 2005 WL 2007004, at *23 (D.N.J. Aug. 17, 2005) ("[A] defendant may choose silence or speech based on the then-known factual basis, but cannot choose half-truths." (citation modified). "Importantly, Section 10(b) and Rule 10b-5 only prohibit omissions that engender 'half-truths.'" *Zhou v. Desktop Metal, Inc.*, 120 F.4th 278, 292 (5th Cir. 2024) (quoting *Macquarie Infrastructure v. Moab Partners, L. P.*, 601 U.S. 257, 263 (2024))); *see also id.* at 265 (explaining "[a]n omission, even if material, is actionable only if it 'renders affirmative statements made misleading.'" (quoting *Macquarie Infrastructure*, 601 U.S. at 265)). *Accord Matrixx*, 563 U.S. at 44 ("Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" (quoting 17 C.F.R. § 240.10b-5(b)); *In re Burlington*, 114 F.3d at 1432 ("[P]ossession of material nonpublic information alone does not create a duty to disclose

it."). In sum, "there is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses 'to speak about a material subject to investors.'" *In re Amarin Corp.*, 2022 WL 2128560, at *3 (quoting *City of Edinburgh Council*, 754 F.3d at 174); *Kline v. First W. Gov't Sec., Inc.*, 24 F.3d 480, 491 (3d Cir. 1994) ("'[E]ncompassed within that general obligation [to speak truthfully] is also an obligation or "duty" to communicate any additional or qualifying information, then known, the absence of which would render misleading that which was communicated.'" (quoting *Rose v. Ark. Valley Env't & Util. Auth.*, 562 F. Supp. 1180, 1207 (W.D. Mo. 1983))).

i. **Misstatements and Omissions Related to ROVI**

The Court first considers the following statements Plaintiff alleges were made regarding ROVI:

- "[T]he drug product manufacturer . . . is in place and processes have been established and appropriate validation testing completed to enable manufacture of launch quantities." (TAC ¶185).
- The First CRL disclosed on March 1, 2021 posed minimal hurdles, as one deficiency would be resolved within "several weeks" and the other was "unrelated to the manufacture[]" of DefenCath. *(Id.* at ¶ 223).
- CorMedix, following receipt of the First CRL, "[s]uccessfully concluded . . . validation of the drug product manufacturing process, which has enabled production at 2 different manufacturing locations[,]" and "[l]aunch quantities are already in production[.]" *(Id.* at ¶ 240).
- "[W]e and the manufacturer have adequately addressed the concerns the [FDA] identified in the CRL and PAAL." *(Id.* at ¶ 266).
- "CorMedix and [its CMO] have adequately addressed the concerns the [FDA] identified during the review of the original NDA . . . ." *(Id.* at ¶ 147).
- CorMedix was "going to work closely with [its] CMO for any observations that are related to DefenCath" so the only risk in the FDA inspection of the manufacturing operations were "observations that didn't involve [its] product." (*Id.* at ¶ 279). But its "highly reputable European manufacturer" would "work

> with the FDA on, if necessary, improving any compliance concerns FDA could raise." (*Id.*)

The Court finds each of these statements are actionable. By discussing ROVI's manufacturing readiness, the first CRL, and the FDA's concerns regarding the DefenCath NDA, Defendants put those specific issues "in play." This, in turn, entitled investors to know that, in fact, the Audit concluded ROVI would likely not pass FDA inspection and that numerous manufacturing deficiencies existed at the CMO. *See City of Warwick*, 2024 WL 3219616, at *8; *Roofer's Pension Fund*, 2018 WL 3601229, at *13 (agreeing with the plaintiffs that statements were actionable because the defendants "described the integration in entirely positive terms . . . while omitting known extensive problems that brought key integration processes to a halt"); *see also Shapiro*, 964 F.2d at 280 n.11. "Accordingly, the Court finds that the statements are actionable because disclosure of this other material information which was omitted would have 'significantly altered the mix of information available to a reasonable investor.'" *City of Warwick*, 2024 WL 3219616, at *8 (first quoting *Roofer's Pension Fund*, 2018 WL 3601229, at *14; then citing *Shapiro*, 964 F.2d at 280 n.11).

Additionally, after the first CRL, CorMedix had a duty to disclose that it could not quickly resolve the identified manufacturing deficiencies to comply with cGMP standards, especially in light of the Audit and the FDA's concerns. (TAC ¶¶ 149, 221, 228, 241, 269, 280). *See Kline*, 24 F.3d at 490-91 (finding actionable omissions where, as here, executives "elected to speak" but "failed to include . . . information that, if included, would have undermined the conclusions" in the alleged misstatements). *Cf. SLF Holdings, LLC v. Uniti Fiber Holdings, Inc.*, 499 F. Supp. 3d 49, 64-65 (D. Del. 2020), *aff'd*, No. 20-3427, 2022 WL 3442353 (3d Cir. Aug. 17, 2022) (stating there is "no duty to disclose a risk that had not 'actually materialized' at the time of the allegedly misleading prior disclosure" (quoting *Williams*, 869 F.3d at 243). Accordingly, Defendants'

alleged failure to disclose the Audit is sufficient to maintain a Section 10(b) claim at this stage. *See, e.g.*, *Williams*, 869 F.3d at 241 (finding that "[o]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading"); *id.* at 242 ("[A] company may be liable under Section 10[(b)] for misleading investors when it describes as hypothetical a risk that has already come to fruition."); *Curran v. Freshpet, Inc.*, No. 16-2263, 2018 WL 394878, at *4-5 (D.N.J. Jan. 12, 2018) (denying motion to dismiss where the defendants' statements on earning calls were materially misleading because the "[d]efendants knew . . . that [the company] was facing substantial obstacles that would impede [its] growth . . . [including] alleged manufacturing problems").

ii. Misstatements and Omissions Related to Being "On Track"

The TAC alleges that Defendants withheld known risks about the NDA's sufficiency and ROVI's manufacturing capabilities while assuring investors the DefenCath NDA was on track for FDA approval. (TAC ¶¶ 107-38). Additionally, during the Class Period, Defendants represented, *inter alia*:

- "We have remained on schedule towards an anticipated approval in the second half of 2020, subject of course to possible delays at FDA due to the coronavirus pandemic." (TAC ¶ 194).
- "[W]e are maintaining our guidance for an anticipated decision on approval of the NDA in the second half of 2020." *(Id.* at ¶ 196).
- "[W]e look forward to continuing to work together [with the FDA] expeditiously to complete the review of the DefenCath NDA to address an unmet medical need." *(Id.* at ¶ 207).
- CorMedix "has not been informed of any delays by the FDA in the review of the NDA . . . ." *(Id.* at ¶ 100). "CorMedix remains on schedule for a potential NDA approval during the second half of 2020." *(Id.* at ¶ 187).

- "[I]n terms of activities that we are currently undertaking, we are doing right now all the typical prelaunch planning." *(Id.* at ¶¶ 153, 277).

- "So from everything that we can see, I'm optimistic that everything is moving in the right direction." *(Id.* at ¶ 279).

CorMedix's statements regarding the timeline for FDA approval created a parallel duty to disclose the issues at ROVI's facility impeding the proscribed timeline. *In re Amarin Corp.*, 2022 WL 2128560, at *3 ("There is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses 'to speak about a material subject to investors.'" (quoting *City of Edinburgh Council*, 754 F.3d at 174)); *see also Williams*, 869 F.3d at 241 ("Once a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."); *In re Bristol-Meyers Squibb*, 2005 WL 2007004, at *23 ("[A] defendant may choose silence or speech based on the then-known factual basis, but cannot choose half-truths." (citation modified)); *see also In re Digital Island Sec. Litig.*, 357 F.3d 322, 329 n.10 (3d Cir. 2004) (duty to affirmatively disclose "may arise when there is . . . an inaccurate, incomplete or misleading prior disclosure[]" (citation modified)); *Roofer's Pension Fund*, 2018 WL 3601229, at *12 ("[T]he Court agrees, that once [d]efendants' chose to speak about generic drug pricing, they could not 'omit material facts related to that issue so as to make the disclosure misleading.'" (quoting *PTC Therapeutics*, 2017 WL 3705801, at *14)); *Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co.*, 620 F. Supp. 3d 167, 186 (D.N.J. 2022) ("Defendants may not describe 'a favorable picture' of [a] material issue 'without including the details that would have presented a complete and less favorable one.'" (quoting *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 897 (E.D. Pa. 2018))). *Accord In re Viropharma Inc., Litig.*, No. 02-1627, 2003 WL 1824914, at *6 (E.D. Pa. April 7, 2003) ("Statements regarding the overall efficacy of the drug . .

. cannot be simply dismissed as immaterial . . . . [T]he Plaintiffs have pleaded that the statements made by Defendants were contrary to the then existing state of facts, for example, that Pleconaril was effective for all adults when it was not.")).

Defendants' statements that DefenCath was "on track" are similarly actionable because the statements misrepresented the status of the DefenCath NDA at the time the statements were made. *See In re Cigna Corp. Sec. Litig.*, No. 02-8088, 2005 WL 3536212, at *11 (E.D. Pa. Dec. 23, 2005) (finding statement that "we are on track with our own schedule" actionable where company was not "on track"); *see also Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 348-49 (E.D. Pa. 2014) (concluding defendants "systemically misled investors about the key components of the . . . NDA and the nature of FDA feedback while presenting predictions about FDA approval . . . that [they] should have known were unreasonable under the circumstances").

Moreover, courts have consistently determined alleged misstatements that selectively disclosed to investors what information was provided to the FDA are actionable. *In re Celgene*, 2019 WL 6909463, at *18 (finding "that Defendants told investors about the positive clinical study results but failed to disclose the Metabolite discovery was misleading"); *Tomaszewski v. Trevena, Inc.*, 482 F. Supp. 3d 317, 331 (E.D. Pa. 2020) (determining omissions were actionable where the defendant knew that the NDA would be deficient because he knew that Trevena's studies did not conform to FDA requirements); *SEB Inv. Mgmt.*, 351 F. Supp. 3d at 898 (falsity alleged where defendants failed to disclose unfavorable data that would inform the FDA's decision); *id.* at 902 (first citing *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 707-08 (9th Cir. 2016) (finding that once the defendants affirmatively represented that all its animal studies supported its case for FDA approval, they had a duty to disclose the adverse study showing tumor growth related to their drug) then citing *In re Viropharma*, 21 F. Supp. 3d at 471 (determining defendants made material

omissions by failing to reveal the FDA's conclusion that its Genzyme Study was deficient because it bore directly on its discussions regarding market exclusivity)).

Defendants contend that because the FDA gave no indication that the Moderna contamination would impact its NDA approval, they had no duty to disclose that information. (Defs.' Br. at 22). To support their argument, Defendants cite *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 43 (1st Cir. 2014), which held that the defendant had no obligation to disclose bioreactor failures at one plant where failures "bore no relation to FDA approval of [the NDA]" at *another plant* and where FDA had not given "any indication that the bioreactor failures would hinder approval" of the NDA. (Emphasis added).

However, the Court finds *Genzyme* distinguishable because the failures at ROVI were relevant to the FDA's approval of DefenCath and the FDA indicated as much, and also involved the same facility. The First CRL cited concerns about "the proposed future installation of new equipment," [15] (TAC ¶ 24) and "regarding the qualification of the filling operation." (*Id.* at ¶ 25). Thus, Defendants were made aware via the First CRL that ROVI's fill lines—even those that Defendants contend are unrelated to DefenCath—were of concern to the FDA and could impact DefenCath's approval. (*Id.* at ¶ 24). Next, Plaintiff alleges Defendants were responsible for providing the FDA with information about the fill lines. (*Id.* at ¶ 163) ("Based on FDA guidelines and/or communications with the FDA, CorMedix knew or should have known that it needed to provide to the FDA, information about any new production line and/or equipment at the facility manufacturing DefenCath—even if it was unrelated to the manufacturing of DefenCath."); (*see also id.* at ¶¶ 165-66). Yet Plaintiff alleges that Defendants did not provide the FDA with information concerning new production lines at the ROVI facility or testing for contaminants in

[15] The new equipment to be installed were fill lines for the manufacturer of Moderna.

the Moderna vaccine being done at ROVI. (*Id.* at ¶¶ 163, 166). The new fill lines were found to be the source of the contaminants in the Moderna vaccines. (*Id.* at ¶ 167). Additionally, Plaintiff alleges, based on cGMP and Defendants' dialogue with the FDA, that Defendants were responsible for ensuring processes were in place to ensure control of outsourced activities and quality of purchased substances. (*Id.* at ¶ 17). Relatedly, Plaintiff notes:

> [S]ince the CMO manufactured multiple different drug products, Defendants also knew or recklessly ignored that they needed to ensure that its protocols relating to changeover of manufacturing lines . . . met cGMP standards and that deficient protocols relating to changeover of manufacturing lines . . . could and would cause contaminated vials, which would delay the CMO's ability to obtain the data requested by the FDA relating to the qualification of the filling operation.

(*Id.* at ¶ 118).

Consequently, Defendants knew or should have known based on FDA guidelines, FDA communications, and cGMP standards, that the outstanding fill line concerns at ROVI—although unrelated to DefenCath—would impact DefenCath's approval. Defendants continued to comment on the likelihood of DefenCath's approval, which created a duty that Defendants address the Moderna contamination and its impact on DefenCath's approval. *See In re Intelligroup*, 527 F. Supp. 2d at 281-82 ("'When an allegation of fraud is based upon nondisclosure, there can be no fraud absent a duty to speak[.]' . . . '[S]uch a duty to disclose may arise [only] when . . . [there was] an inaccurate, incomplete or misleading *prior* disclosure [requiring a corrective statement].'") (citation modified). Defendants did not meet this duty.

iii. Misstatements and Omissions Related to the FDA's Support for the DefenCath NDA

The Court next considers alleged statements made regarding the FDA's support for the DefenCath NDA:

- "The FDA was supportive of Neutrolin's proposed manufacturing program . . . ." (TAC ¶¶ 178, 181).

- "As our press release of 16 October indicated the outcome of our interaction with the FDA was very positive. FDA was supportive of the core manufacturing processes for the drug product and the active pharmaceutical ingredients for the inclusion as part of the NDA submission." (*Id.* at ¶¶ 93, 184).

- The FDA "noted that . . . it had not identified any potential review issues at this time." (*Id.* at ¶ 211).

- Responding "Yes, yes" to the question of "has the company addressed all the questions [from the FDA] appropriately?" (*Id.* at ¶ 154).

These alleged material misstatements and omissions are actionable; they contradicted information known by Defendants and failed to disclose unfavorable information that would have painted a fuller, more accurate picture for investors. *See SEB Inv. Mgmt.*, 351 F. Supp. 3d at 898 (claims sustained where defendants, while "instilling hope in their investors . . . failed to disclose the unfavorable data that would inform the FDA's decision"); *Frater*, 996 F. Supp. 2d at 348-49 (E.D. Pa. 2014) (claim adequately pled that "Hemispherx systemically misled investors about the key components of the [ ] NDA and the nature of FDA feedback while presenting predictions about FDA approval . . . that it should have known were unreasonable under the circumstances."); *Gorlamari v. Verrica Pharm., Inc.*, 2024 WL 150341, at *12 (E.D. Pa. Jan. 11, 2024) (falsity alleged where "White's partial response 'yes' could suggest that White had not received news inconsistent with approval in late May, which would contradict the FDA's findings in February 2022 that quality problems persisted."); *see also Skiadas v. Acer Therapeutics Inc.*, 2020 WL 4208442, *8 (S.D.N.Y. July 21, 2020) (complaint upheld where the "Defendants knew that the FDA had not agreed to approve [Edsivo] but . . . chose to say the opposite.").

iv. The Misstatements and Omissions Related to the ROVI Manufacturer, Being "On Track," and the FDA's Support for the DefenCath NDA are Material

The materiality of a misrepresentation or omission is measured by the effect of the disclosure of the facts on the stock's price. *In re Constar Int'l Inc. Sec. Litig.*, 585 F.3d 774, 783 (3d Cir. 2009) (citation modified); *see also In re Merck Derivative & "ERISA" Litig.*, 543 F.3d 150, 168 (3d Cir. 2008).[16]

The materiality of the misstated and omitted information was evidenced by the allegations of subsequent disclosure of the information and its significant impact on the market. (*See* TAC ¶¶ 21-22, 106, 219-20 (alleging CorMedix's stock price decreased approximately 54.4 percent after Defendants publicly disclosed the First CRL); *id.* at ¶¶ 25, 125-26, 236 (alleging CorMedix's stock price fell 18.36 percent after investors learned CorMedix could not resubmit the NDA until the third quarter of 2021 because more remedial steps were necessary than previously identified); *id.* at ¶¶ 27, 129, 237 (alleging CorMedix's stock fell approximately 20 percent after it announced it could not resubmit the NDA until the fourth quarter of 2021); *id.* at ¶¶ 29, 135, 261, 262 (alleging CorMedix's stock fell over 27 percent after investors learned CorMedix "ha[d] encountered delays" at ROVI and that the timeline to address deficiencies at ROVI's facility was "uncertain"); *id.* at ¶¶ 35-36, 157, 159, 281-82 (alleging CorMedix's stock fell approximately 57 percent after it disclosed the existence of the Second CRL and stated ROVI needed "an independent CGMP consultant")). Courts have found this sufficient to satisfy the requirement for pleading materiality at the motion to dismiss stage. *See, e.g.*, *In re Able Labs. Sec. Litig.*, No. 05-2681, 2008 WL 1967509, at *15 (D.N.J. Mar. 24, 2008) ("[T]he significant decrease in stock price immediately

[16] *See In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (stating that the Third Circuit, "as compared to the other courts of appeals, has one of the 'clearest commitments' to the efficient market hypothesis"). Additionally, the Court notes it takes judicial notice of CorMedix's stock price. *Id.* at 264 n.3 (a court may take judicial notice of stock prices at any stage of the proceeding because they are "not subject to reasonable dispute and are capable of accurate and ready determination by resort to a source whose accuracy cannot be reasonably questioned") (citation modified).

following the disclosure of the adverse information satisfies the Third Circuit's standard for pleading materiality."); *Frater*, 996 F. Supp. 2d at 347 (requisite materiality demonstrated where stock price "plummeted" after "misleading statements were contradicted by the FDA").

v. **Forward-Looking Statements**[17]

Defendants assert that some of the alleged misstatements are forward-looking and accompanied by adequate cautionary language, thus immunizing Defendants under the PSLRA's safe harbor provision. (Defs.' Br. at 24). Plaintiff argues that Defendants lack immunity for Defendants' failure to disclose adverse events and risks that had already occurred or were occurring, making the purported forward-looking statements neither forward-looking, nor supported by cautionary language. (Pl.'s Br. at 22-24). Plaintiff specifically alleges in the Third Amended Complaint that the forward-looking statements are misleading—not because they fail to "correctly predict that the FDA would not approve DefenCath[,]" but because "Defendants concealed events that had occurred or were occurring." (Pl.'s Br. at 22). The Court finds that Plaintiff sufficiently alleges at this stage that the statements are not forward-looking.

Under the PSLRA's safe harbor provision, "forward-looking" statements are not actionable if they are "(1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 278-79 (3d Cir. 2010) (citing 15 U.S.C. § 78u-5(c)); *see also Avaya*, 564 F.3d at 254. The PSLRA's definition of "forward-looking statement" includes "projections of future performance, plans and objectives for future operations,

[17] The Court notes that its preliminary determination regarding Defendants' purported forward-looking statements is not dispositive. Such statements are given minimal weight and do not substantially alter the Court's finding of material misstatements and omissions discussed *supra*. At this juncture, the Court accepts Plaintiff's allegations as true. *Tellabs*, 551 U.S. at 322. Discovery will likely provide information to further elucidate whether these professed forward-looking statements were adequate.

and assumptions underlying statements about future financial, economic or operational performance." *In re Aetna*, 617 F.3d at 279 (citing 15 U.S.C. § 78u–5(i)(1)).

Additionally, to be protected under the PSLRA safe harbor, the forward-looking statements must be accompanied by cautionary language that is "extensive and, specific." (citing *Avaya*, 564 F.3d at 256 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004)). "[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge." *Id.* (quoting *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000)); *see also OFI Asset Mgmt v. Cooper Tire & Rubber*, 834 F.3d 481, 491 (3d Cir. 2016) (noting cautionary statements are "meaningful" when they are "substantive and tailored to the specific future projections, estimates or opinions in the [documents] which the plaintiffs challenge."); *National Junior Baseball League v. Pharmanet*, 720 F. Supp. 2d 517, 530 (D.N.J. 2010) (explaining cautionary statements are tailored when they "'[identify] important factors that could cause actual results to differ materially from those in the forward-looking statement.'" (quoting *EP MedSystems, Inc. v. EchoCath*, Inc., 235 F.3d 865, 872-73 (3d Cir. 2000))).

However, the safe harbor provision does not apply to a "'mixed present/future statement . . . with respect to the part of the statement that refers to the present.'" *Roofer's Pension Fund*, 2018 WL 3601229, at *7 (quoting *Avaya*, 564 F.3d at 255); *see also In re Majesco Sec. Litig.*, No. 05-3557, 2006 WL 2846281, at *4 (D.N.J. Sept. 29, 2006) (noting "'allegations based upon omissions of existing facts or circumstances do not constitute forward[-]looking statements

protected by the safe harbor'" (quoting *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998)).

The PSLRA's "safe harbor [provision] for forward-looking statements overlaps with the Third Circuit's 'bespeaks caution' doctrine, under which 'cautionary language, if sufficient, renders the alleged [forward-looking] omissions or misrepresentations immaterial as a matter of law.'" *Dang*, 750 F. Supp. 3d at 466 (citing *EP MedSystems*, 235 F.3d at 874 (quoting *In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357, 371 (3d Cir. 1993))). "Under both the PSLRA and the bespeaks caution doctrine, cautionary language must be extensive, specific, and directly related to the alleged misrepresentation . . . ." *Id.* at 466 (quoting *Lewakowski v. Aquestive Therapeutics, Inc.*, No. 21-3751, 2023 WL 2496504, at *5 (D.N.J. Mar. 14, 2023) (citing *In re Aetna*, 617 F.3d at 282; *In re Donald J. Trump*, 7 F.3d 357 at 371-72).

The purported forward-looking statements are not protected by the PSLRA's safe harbor. Defendants analogize their statements to cases that found similar statements regarding the FDA to be forward-looking. (Defs.' Br. at 24-25). However, Plaintiff does not allege that the forward-looking statements are misleading because their predictions are incorrect, rather that the forward-looking statements are misleading because adverse events and risks underlying their predictions were not disclosed. (Pl.'s Br. at 22). Cautionary statements are not truly cautionary when the defendant knows that an identified risk has or will occur. *See In re Bristol-Myers Squibb*, 2005 WL 2007004, *51-52. The *Bristol-Myers* Court found that "even though these statements [we]re forward-looking . . . and even if these statements were accompanied by adequate cautionary language, [the] [p]laintiff adequately alleges that [the] [d]efendants had enough information . . . to know that this status would not be attained." *Id.* Importantly, "safe harbor . . . provides no protection to someone who warns his hiking companion to walk slowly because there might be a

ditch ahead when he knows with near certainty that the Grand Canyon is one foot away." *Id.* at 51.

For the purported forward-looking statements made before the First CRL, Plaintiff adequately alleges that Defendants failed to disclose that the FDA raised concerns and deficiencies at ROVI's facility, which make the statements misleading. (TAC ¶¶ 205, 208, 213). For the forward-looking statements made after the First CRL, Plaintiff adequately alleges in the Third Amended Complaint that Defendants failed to disclose various events and risks that affected ROVI's ability to address the deficiencies identified in the First CRL, which make the statements misleading. (*Id.* at ¶ 228).

Since the "alleged misstatements are assertions of current fact, not predictions, they do not qualify for safe harbor protection." *In re PTC Therapeutics, Inc. v. Sec. Litig.*, at *15 (citing *In re Viropharma*, 21 F. Supp. 3d at 471 ("[O]missions of existing facts or circumstances are not forward-looking, and thus do not qualify for safe harbor protection.")).

Additionally, when viewed in isolation, the cautionary language regarding the likelihood of FDA approval of the DefenCath NDA facially appear to be forward-looking statements that are within the safe harbor provision. However, these statements appear less so when considered in context with Plaintiff's allegations, specifically, omitting the manufacturing issues at ROVI, misstatements about being "on track," and the FDA's Support for the DefenCath NDA, as well as withholding the Audit. (*See generally* TAC). *See, e.g., SEB Inv. Mgmt.*, 351 F. Supp. 3d at 902 (finding that while qualified cautionary statements about prospect of FDA approval appear to be forward looking, when statements are considered in context they are not protected because certain defendants failed to identify data contradicting statements and expressed optimism regarding labeling approval); *cf. In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 131 & n.10 (3d Cir.

2017) (finding no false or misleading statement in part because the defendants never stated that its special protocol assessment would be accepted by the FDA and warned approval was not guaranteed).[18]

Contrary to Defendants' argument, statements regarding the timing of the FDA's decision on DefenCath's NDA similarly do not fall within the PSLRA's safe harbor because Plaintiff alleges Defendants concealed adverse events and risks that occurred or were in the process of occurring. *See Frater*, 996 F. Supp. 2d at 348-49 (rejecting argument that plaintiff's claim turned on likelihood of approval "irrelevant to whether Hemispherx systemically misled investors about the key components of [ ] NDA and the nature of FDA feedback . . . ."); *Shanawaz v. Intellipharmaceutics Int'l Inc.*, 348 F. Supp. 3d 313, 324-25 (S.D.N.Y. 2018) ("At issue here are not Defendants' opinions about the NDA's prospects before the FDA, but [their] allegedly false descriptions of the contents of the NDA itself."). Moreover, where alleged misstatements addressed already-known issues, "it cannot be that the mere inclusion of 'words of futurity or belief' brings otherwise non-forward-looking statements within the PSLRA safe harbor." *Frater*, 996 F. Supp. 2d at 348; *see also Bristol-Myers*, 2005 WL 2007004, *24 (holding statement that trial results "are very impressive results" not puffery because they "refer[] specifically to the results from the [drug] trials—a matter of historical fact"). Indeed, Plaintiff alleges Defendants proffered unrealistic timeline statements based on the manufacturing issues at ROVI. (*See, e.g.*, TAC ¶¶ 28-29, 113, 118, 121-22, 187, 194, 196, 264, 269, 280). *See In re MGM Mirage Sec. Litig.*, No. 09-1558, 2013 WL 5435832, at *7 (D. Nev. Sep. 26, 2013) ("[E]ven though an estimate is a future projection, Defendants' statements were misleading because, at the time the statement was

[18] Plaintiff alleges that "to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as 'forward-looking statements' when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements." (TAC ¶ 291).

made, Defendants knew the estimate was not accurate and that actual costs were reasonably expected to exceed the stated budget.").[19]

vi. Opinion and Non-Actionable Statements of Corporate Optimism

Defendants contend that Plaintiff wrongly characterizes non-actionable statements of corporate optimism and opinion statements as material misstatements. (Defs.' Br. at 26). Defendants subcategorize the purported opinion/non-actionable statements into three groups: (1) statements about having the right team, (2) opinion statements that CorMedix had adequately addressed FDA concerns, and (3) the SOX certifications. (Defs.' Br. at 26-28). The Court finds categories 1 and 2 are actionable statements.[20]

"[T]he omission of a fact can make a statement of opinion . . . , even if literally accurate, misleading to an ordinary investor." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 187 (2015); *see also City of Warren*, 70 F. 4th at 685 ("Omnicare's framework for evaluating opinion falsity applies to claims under [Section] 10(b) for violations of [SEC] Rule 10b-5."). "'An opinion is 'a belief[,] a view,' or a 'sentiment which the mind forms of persons or things,' whereas a fact is a 'thing done or existing' or '[a]n actual happening.'" *City of Warren*, 70 F. 4th 668 at 684 (quoting *Omnicare*, 575 U.S. at 183). As such, a statement of opinion is not misleading simply because external facts show the opinion to be incorrect. *Omnicare,* 575 U.S. at 188. However, opinion statements can still be false or misleading. *City of Warren*, 70 F. 4th at 684. The "magic words[,] ["we think" or "we believe,"] can preface nearly

[19] Moreover, Plaintiff alleges Defendants had actual knowledge that the forward-looking statements were materially false or misleading. (TAC ¶ 292). At this motion to dismiss stage, Plaintiff's allegations adequately plead with particularity that Defendants had actual knowledge their statements were false or misleading. Thus, the alternative basis for safe harbor provision is not applicable.

[20] Since the parties discuss the SOX certifications both in their discussions of actionable misstatements or omissions as well as scienter, the Court will address the SOX certifications in the scienter section *infra*. *See, e.g., In re PayPal Holdings Inc. Sec. Litig.*, No. 22-5864, 2025 WL 325603, at *16 n.16 (D.N.J. Jan. 29, 2025) (citing *In re Celgene*, 2019 WL 6909463, at *18 n.24).

any conclusion, and the resulting statements . . . remain perfectly capable of misleading investors." *Omnicare*, 575 U.S. at 193. An opinion statement is misleading if it: (1) "was not sincerely believed when made;" (2) "contains an expressly embedded, untrue factual assertion;" or (3) "reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren*, 70 F. 4th at 686. This is not a conjunctive test but rather three separate scenarios by which an opinion may be actionable. *Id.* at 685. This standard does not "allow investors to second-guess inherently subjective and uncertain assessments" nor is it "an invitation to Monday morning quarterback an issuer's opinions." *Omnicare*, 575 U.S. at 186. In sum, opinions may still be actionable "if they do not reflect the speaker's subjective belief or if they omit known material information undermining that belief." *Roofer's Pension Fund*, 2018 WL 3601229, at *10.

Moreover, "the Supreme Court has held that statements of opinion by top corporate officials may be actionable if they are made without a reasonable basis" since "such statements can be materially significant to investors because investors know that these top officials have knowledge and expertise far exceeding that of the ordinary investor." *In re Cambrex Corp. Sec. Litig.*, No. 03-4896, 2005 WL 2840336 (D.N.J. Oct. 27, 2005) (citing *In re Burlington*, 114 F.3d at 1428).

Additionally, while material misrepresentations may be actionable, such "representations must be contrasted with statements of subjective analysis or extrapolations, such as opinions, motives and intentions, or general statements of optimism." *EP MedSystems*, 235 F.3d at 872. "[V]ague and general statements of optimism 'constitute no more than 'puffery' and are understood by reasonable investors as such.'" *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (quoting *In re Burlington*, 114 F.3d at 1428 n.14), *abrogated by*, *City of Warren*, 70 F.4th at 668; *see also In re Aetna*, 617 F.3d at 283 (citation modified).

"'Puffery' statements do not violate the securities laws because they lack an underlying factual basis and they fail to meet Rule 10b-5's materiality requirement." *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 548 (W.D. Pa. 2019). "However, '[i]f a statement is material, then it cannot be puffing.'" *In re Aetna*, 34 F. Supp. 2d at 945; *see also In re Enzymotec*, 2015 WL 8784065, at *14 ("A statement is considered puffery only when it is immaterial."). "Context [also] informs the puffery analysis." *Howard,* 395 F. Supp. 3d at 548.

a. "Right Team" Statements

Defendants argue that statements such as Defendants have "a very experienced and competent team" "the team", and "the right team and appropriate resources" constitute statements of non-actionable corporate optimism. (TAC ¶¶ 185, 202, 210, 232). However, Defendants statements about having the "right team" were determinable, verifiable statements rather than mere vague, aspirational statements. For example, Defendants did not only assert that they have "a very experienced and competent team," but also Armstrong went further, stating "I have working with me a very experienced and competent team, *they have the needed breadth and depth in the requirements for sourcing, manufacturing, distribution and quality assurance that is necessary for both the US and foreign markets*." (*Id.* at ¶ 185) (emphasis added). This statement was made on November 14, 2019, after the Audit report allegedly concluded that ROVI would not pass FDA inspection and should not be used. (*Id.* at ¶ 181). The statement specifically comments on the qualifications of Armstrong's team and its ability to meet manufacturing requirements. This information is highly material because this action revolves around CRLs issued because of manufacturing issues at ROVI related to the DefenCath NDA—CorMedix's principal business goal. Highly material information cannot be mere puffery. *In re Aetna*, 34 F. Supp. 2d at 945. Plaintiff specifically alleges that "CorMedix's 'team,' including the Individual Defendants, failed to ensure that the methods used in manufacturing and the controls used to maintain the quality of

its drug product were adequate to preserve DefenCath's identity, strength, quality, and/or purity." (TAC ¶ 186). Moreover, Defendants' statements regarding the DefenCath NDA were not puffery because investors had a basis to and did rely on them. (*Id.* at ¶¶ 186, 205, 213, 228, 235, 255, 260). *Cf. Fan*, 927 F.3d at 716 ("'[V]ague and general statements of optimism' are non-actionable precisely because they are not material— a reasonable investor would not base decisions on such statements."); *United States S.E.C. v. Kearns*, 691 F. Supp. 2d 601, 617 (D.N.J. 2010) (finding that medical transcriptions company's statements about "disciplined business practice" and the experience and discipline of its management team, were merely puffery because no reasonable investor would have relied on them); *In re Hertz Glob. Holdings, Inc. Sec. Litig.*, No. 13-7050, 2017 WL 1536223, at *11 (D.N.J. Apr. 27, 2017), *aff'd sub nom*, 905 F.3d 106 (3d Cir. 2018) (finding that statements about "strong" and "record" financial results, as well as the generally optimistic statements, constituted puffery because they "are not determinate, verifiable statements.").

Further, to the extent Defendants argue that the subject statements related to DefenCath's NDA being "on track" were opinions, the Court finds that they are actionable as they contain "embedded" falsities and concern a central part of CorMedix's business. *City of Warren*, 70 F. 4th at 686; *see also West Palm Beach Police Pension Fund v. DFC Glob. Corp.*, No. 13-6731, 2015 WL 3755218, at *13 (E.D. Pa. June 16, 2015) ("Far from being a vague statement of intention or optimism, fraudulent comments regarding . . . a fundamental aspect of [the defendant]'s business are of vital importance to investors.").

b. Statements Related to the FDA's Concerns

Next, Defendants posit that statements they made expressing their belief that CorMedix adequately addressed the deficiencies identified by the FDA in the First CRL were opinion

statements which Plaintiff has failed to allege were not sincerely held or omitted material facts. (Defs.' Br. at 27). The Court disagrees.

Defendants contend the statement "we believe that we and the manufacturer have adequately addressed the concerns [the] [FDA] identified in the CRL and PAAL" is not actionable. (Defs.' Br. at 27 (citing TAC ¶ 266) (second alteration in the original); *see also* TAC ¶ 267-68)). However, this statement is indicative of an actionable opinion. Such a statement falls within the third *Omnicare* scenario: it "reasonably implies untrue facts and omits appropriate qualifying language." *City of Warren*, 70 F. 4th at 686. Defendants proffered such an opinion: (1) despite Defendants' failure to disclose the Audit, which cautioned CorMedix of the very issues the FDA subsequently identified at ROVI; (2) without evidence of "satisfactory resolution of [the] objectionable conditions that the FDA had already told Defendants was required . . . before this application may be approved"; and (3) despite Defendants' failure to disclose that CorMedix "had not ensured [ROVI] complied . . . with cGMP standards." (TAC ¶ 269). As such, the Court finds Plaintiff has sufficiently pled that Defendants' statement regarding their handling of the deficiencies identified by the FDA in the First CRL is implying untrue factual assertions, making the opinion statement actionable under *Omnicare*.

(2) Plaintiff Adequately Alleges Scienter[21]

Unlike Rule 9(b), which permits state of mind to be plead generally, PSLRA's "[e]xacting pleading standard for scienter" requires that a securities fraud complaint, as to each act or

[21] The Third Circuit has "explicitly approved of scienter analyses that assess individual categories of scienter allegations individually when it is clear, as it is here, that a district court ultimately considered the allegations as a whole." *Hertz*, 905 F.3d at 115 (citing *OFI Asset Mgmt.*, 834 F.3d at 493(concluding that just because a court is "thorough in explaining why it found scienter lacking as to each asserted misrepresentation does not suggest that it did not consider the allegations as a whole")); *see also Avaya*, 564 F.3d at 280 ("Although we have discussed each of the alleged facts bearing on defendants' scienter one at a time, we have heeded *Tellabs*'s command to evaluate [the plaintiffs'] allegations collectively rather than individually."). Accordingly, the Court will, therefore, follow this approach and consider the alleged facts bearing on scienter individually, while at the same time considering whether, holistically, they give rise to a strong inference of scienter.

omission, 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); *Tellabs*, 551 U.S. at 313; *City of Warren*, 70 F.4th at 681 n.1; *Avaya*, 564 F.3d at 267 (quoting 15 U.S.C. § 78u–4(b)(2)) (citation modified); *see also In re Elecs. for Imaging, Inc. Sec. Litig.*, No. 17-5992, 2019 WL 397981, at *6 (D.N.J. Jan. 31, 2019) (same).

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quoting *Ernst & Ernst*, 425 U.S. at 193 n.12). A plaintiff alleging scienter must assert facts giving rise to a strong inference of reckless or conscious behavior. *Avaya*, 564 F.3d at 267 (quoting *In re Advanta Corp.*, 180 F.3d at 534-35); *see also Fain v. USA Techs., Inc.*, 707 F. App'x 91, 95 (3d Cir. 2017).

"A reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 267 n.42 (quoting *Advanta*, 180 F.3d at 535).[22] *See also In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001) (The relevant inquiry for recklessness is whether defendants "should have known that they were misrepresenting material facts related to the corporation[,]" *i.e.*, when defendants had "knowledge of facts or access to information contradicting their public statements.") (citation modified); *In re Suprema*, 438 F.3d at 276. *Accord McLean v. Alexander*, 599 F.2d 1190, 1197 (3d Cir. 1979) (adopting definition for reckless conduct associated with either omissions or misstatements in the context of suits under Section 10(b) and Rule 10b-5).

[22] "*Advanta* noted that applying the recklessness standard in the securities fraud context promotes the 'policy objectives of discouraging deliberate ignorance and preventing defendants from escaping liability solely because of the difficulty of proving conscious intent to commit fraud.'" *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 154 n.10 (3d Cir. 2018) (quoting *Advanta*, 180 F.3d at 535).

Conscious behavior exists where a plaintiff "specifically allege[s] defendants' knowledge of facts or access to information contradicting their public statements." *In re Campbell Soup*, 145 F. Supp. 2d at 599; *see also Aviva Partners LLC v. Exide Techs.*, No. 05-3098, 2007 WL 789083, at *12 (D.N.J. Mar. 13, 2007). "[T]he key inquiry is whether 'defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.'" *National Junior Baseball League*, 720 F. Supp. 2d at 553 (quoting *In re Campbell Soup*, 145 F. Supp. 2d at 599 (quotations omitted)).

"In the Third Circuit, '[s]cienter may be established by setting forth facts that constitute circumstantial evidence of either recklessness or conscious behavior and supported by evidence of motive and opportunity to commit fraud.'" *Roofer's Pension Fund*, 2018 WL 3601229, at *15 (quoting *In re Anadigics, Inc., Sec. Litig.*, No. 08-5572, 2011 WL 4594845, at *32 (D.N.J. Sept 30, 2011), *aff'd*, 484 F. App'x 742 (3d Cir. 2012)). "A plaintiff can rely on direct or circumstantial evidence to show the defendants had (1) both a motive and opportunity to commit the fraud; or (2) conscious misbehavior or recklessness." *Allegheny Cnty. Emps.' Ret. Sys. v. Energy Transfer LP*, 744 F. Supp. 3d 350, 390 (E.D. Pa. 2024) (citing *Roofer's Pension Fund v. Papa*, 687 F. Supp. 3d 604, 617 (D.N.J. 2023).

"Demonstrating that a defendant had a motive, such as personal financial gain, to commit a securities fraud violation is a 'relevant consideration' that 'may weigh heavily in favor of a scienter inference[.]'" *Hertz Glob. Holdings*, 905 F.3d at 119 (quoting *Tellabs*, 551 U.S. at 325); *see also Rahman*, 736 F.3d 237, 245 (3d Cir. 2013) ("Though it is not necessary to plead motive to establish that a defendant acted with scienter, its presence can be persuasive when conducting a holistic review of the evidence."). However, "motive and opportunity" do not "serve as an

independent route to [establishing] scienter." *Avaya*, 564 F.3d at 277; *Roofer's Pension Fund*, 2018 WL 3601229, at *17 (citation modified).

A plaintiff relying upon circumstantial evidence to support a strong inference of scienter "must sufficiently plead 'defendants' knowledge of facts or access to information contradicting their public statements . . . . [i.e., that] defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.'" *Roofer's Pension Fund*, 2018 WL 3601229, at *18 (quoting *In re Campbell Soup*, 145 F. Supp. 2d at 599).[23]

To determine if allegations in a complaint satisfy the scienter requirement the Court engages in a three-part analysis. *Tellabs*, 551 U.S. at 322-23. First, the Court accepts all factual allegations in the complaint as true. *Id.* at 322. Next, the Court determines "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322-23 (emphasis added). Finally, to determine whether the allegations give rise to a "strong" inference of scienter, the Court "take[s] into account plausible opposing inferences." *Id.* at 323. That is, the Court must consider "plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. "An inference that a defendant acted with scienter need not be irrefutable." *Martin*, 757 F. App'x at 154 (citing *Tellabs*, 551 U.S. at 324). "However, it must be more than merely 'reasonable or permissible—it must be cogent and compelling.'" *Id.* (quoting *Tellabs*, 551 U.S. at 324). A securities fraud complaint will therefore only survive a 12(b)(6) motion to dismiss if "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

[23] "When plaintiffs attempt to establish scienter through circumstantial evidence of recklessness, the strength of the circumstantial allegations must be even greater." *Stichting Pensionenfonds Metaal En Techniek v. Verizon Commc'ns, Inc.*, 775 F. Supp. 3d 826, 849 (D.N.J. 2025) (citing *National Junior Baseball League*, 720 F. Supp. 2d at 553).

A plaintiff does not need to come forward with "smoking-gun" evidence to meet the PSLRA's pleading requirements. *In re Hertz*, 905 F.3d at 114 (citing *Tellabs*, 551 U.S. at 324); *see also Tellabs*, 551 U.S. at 324 ("The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the most plausible of competing inferences."); *Fain*, 707 F. App'x at 95. Although courts "aggregate the allegations in the complaint to determine whether [they] create[ ] a strong inference of scienter, plaintiffs must create this inference with respect to each individual defendant in multiple defendant cases." *Winer Family Tr. v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007) (citation modified).

i. **The Statements of the Confidential Witnesses Supports a "Strong Inference" of Scienter**

A plaintiff may plead "falsity by alleging various sources for the 'true facts' known or recklessly disregarded by defendants[,]" including documentary evidence and "representations of confidential witnesses." *Avaya*, 564 F.3d at 260. "Even though all allegations relating to the falsity of a defendant's statement must be pled with particularity, *see* 15 U.S.C. § 78u–4(b)([1]) and (2), a plaintiff in securities fraud actions can support a complaint by reliance on information attributed to confidential sources." *In re Intelligroup,* 527 F. Supp. 2d at 290. Such reliance is not without limitation:

> [U]ndisclosed confidential sources can be used only in two situations: (1) if the complaint sets forth other factual allegations, such as documentary evidence, which are sufficient alone to support a fraud allegation, . . . or (2) when the confidential sources are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the [confidential] source would possess the information alleged.

In re Intelligroup, 527 F. Supp. 2d at 290 (citation modified); *see also National Junior Baseball League*, 720 F. Supp. 2d at 538-39. "Where, as here, plaintiff[] lack[s] documentary evidence such as internal memoranda, 'reliance on confidential sources to supply the requisite particularity for

their fraud claims . . . assumes a heightened importance.'" *Avaya*, 564 F.3d at 261 (quoting *California Pub. Emps.' Ret. Sys. v. Chubb*, 394 F.3d 126, 148 (3d Cir. 2004)).

In considering the reliability of a confidential witness's statements, courts should consider "the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Chubb*, 394 F.3d at 147; *see Urban Outfitters*, 103 F. Supp. 3d at 648-49; *see also National Junior Baseball League*, 720 F. Supp. 2d at 553 ("[I]n order to rely on the statements of a confidential witness, even for the purpose of pleading scienter, the plaintiff must allege: (1) the time period that the confidential source worked at the defendant-company, (2) the dates on which the relevant information was acquired, and (3) the facts detailing how the source obtained access to the information.") (citing *Intelligroup*, 527 F. Supp. 2d at 290) (citation modified).

In *Chubb*, the Third Circuit disregarded statements by confidential witnesses for plaintiffs' failure to allege when the witnesses were employed by the company, the dates they acquired the information alleged, or how they had access to such information. *Chubb*, 394 F.3d at 148. The confidential witnesses' statements left the court "to speculate whether the anonymous sources obtained the information they purport[ed] to possess by firsthand knowledge or rumor." *Id.*; *see also In re PayPal*, 2025 WL 325603, at *17 (declining to consider confidential witnesses statements where "[n]one of the above representative allegations—of any similar allegations in the Complaint—contain[ed] details about actual meetings or communications where Defendants learned information that contradicted their public statements."). In contrast, in *Avaya*, the plaintiff shareholders who relied on confidential witnesses for information about alleged securities fraud violations adequately described "the who, what, when, where and how" about the sources and their

acquisition of information in satisfaction of the PSLRA's pleading requirements. *Id.* at 253, 263-64.

Here, the Third Amended Complaint alleges with the requisite particularity "the who, what, when, where and how" about Plaintiff's confidential witnesses and the basis of their knowledge about the alleged securities fraud. *See Avaya*, 564 F.3d at 253. According to the Third Amended Complaint, FE1 was hired in 2018 by CorMedix to audit ROVI, its CMO, in Spain. (TAC ¶¶ 80-81). FE1 personally conducted the audit, which "took a couple of weeks and included an on-site visit to ROVI's facilities in Spain." (*Id.* at ¶ 81). FE1 then prepared the Audit in 2019 and "recommended that ROVID not be used, and directly stated that ROVI would never be able to pass an FDA inspection." (*Id.* at ¶ 83).

Further, the Third Amended Complaint identifies FE2 as "the Senior Director of Quality Assurance at CorMedix from February 2020 until they resigned in May 2023." (*Id.* at ¶ 82). FE2 reported to John Ortiz, the Director of Quality, who reported to Mounts. (*Id.*) According to FE2, while the report from the Audit recommended ROVI not be used by CorMedix, it was "chosen anyway based on the close personal friendship between ROVI's head and . . . Baluch." (*Id.* at ¶ 84). FE2 accessed the report because it was placed on CorMedix's internal shared drive. (*Id.* at ¶ 85) Baluch was "closely involved in the production and distribution of FE1's report" and FE2 believed Mounts received a copy of the report. (*Id.* at ¶ 86). FE2 identified problems with ROVI's "manufacturing, validation, test methods, and[] critically the ROVI facility itself: ROVI had not maintained a sterile manufacturing facility, and its plant was not compliant with International Sterilization Organization standards." (*Id.* at ¶ 87).

The Court finds that FE1 and FE2's accounts are described with sufficient particularity to support the probability that the confidential witnesses possessed the information alleged. *Avaya*,

564 F.3d at 263. As such, "the factors used to evaluate the overall reliability of information from confidential sources do not reveal a basis to steeply discount the information," and the Court will therefore take the information from FE1 and FE2 as true. *City of Warren*, 70 F.4th at 693.

ii. Defendants' Public Representations of Expertise and Direct Oversight Support a "Strong Interference" of Scienter

Courts have consistently found scienter where defendants represent knowledge about the misrepresented topics. *See City of Warwick*, 2024 WL 3219616, at *14 (finding scienter where the defendants "spoke frequently about how involved they were in all aspects of the company's business[]" and where the CFO was presented with problematic findings of internal audit); *see also Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, *22 (D.N.J. Dec. 27, 2019) (finding CEO who "repeatedly professed to have knowledge regarding" issues at the heart of alleged misstatements acted with scienter); *SEB Inv. Mgmt.*, 351 F. Supp. 3d at 906 (finding scienter where the plaintiff alleged that company executives made "public comments regarding the clinical data in press releases and earnings calls" because the "officers were speaking as authoritative sources who possessed the information to support their statements. When they did so, they knew that withholding the negative data that contradicted their public statements was misleading to investors."); *Frater,* 996 F. Supp. 2d at 349-50 (finding scienter where executives' public statements about FDA compliance were contradicted by internal findings); *id.* at 350 (citing *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 811 (C.D. Cal. 2011) ("When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity.")); *In re PTC Therapeutics*, 2017 WL 3705801, *17 ("[S]tatements to investors during earnings calls and healthcare conferences implied that they had first-hand knowledge of ACT DMD results and PTC's conversations with the FDA."). *Accord Utesch v. Lannett Co., Inc.*, 385 F. Supp. 3d 408,

422 (E.D. Pa. 2019) (finding scienter when "a high-ranking officer 'evinc[es] certitude' as to a matter, particularly where the underlying substance is being publicly questioned" (quoting *Avaya*, 564 F.3d at 270)).

Defendants publicly and repeatedly represented, (i) their knowledge of "successfully submit[ing] multiple NDAs that were ultimately approved;" (ii) "Armstrong's more than 45 years of experience in the pharmaceutical industry with broad senior level cross functional experience, as well as his having held a number of general management positions;" and (iii) CorMedix and the team's "requisite knowledge and experience to oversee and manage the manufacture of [DefenCath]," which support a "strong inference" of scienter. (TAC ¶¶ 6, 52, 88). Indeed, from the Class Period's inception, Armstrong stated to investors that "CorMedix has been manufacturing and selling Neutrolin outside the U.S. for the last five years. We have successfully carried out technical transfer and validation of the manufacturing process, which has enabled the successful production of product at three different manufacturing sites" and went on to assure "[t]his should give you comfort that we understand Neutrolin's manufacturing, technical, analytical processes as well as the quality controls and the systems that go with it . . . [a]nd importantly, the key members of my staff, including me, have in our past experience, successfully submitted multiple NDAs that were ultimately approved." (*Id.* at ¶¶ 6, 88).[24]

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[24] The Third Amended Complaint also alleges Armstrong stated:

> We have been diligently working and interacting with the FDA on this topic continually during the product development in the U.S.
>
> . . .
>
> Our press release of July 9 was an update on our ongoing discussions with FDA to ensure that all the CMC information required for the NDA will be in place. It was intended to be a clear signal from CorMedix to life science investors that we understand the importance of manufacturing data and that we are on top of it.

(TAC ¶ 88).

Additionally, Defendants provided responses to specific questions about DefenCath and the NDA process, which implied firsthand knowledge to investors. *See Roofer's Pension Fund*, 2018 WL 3601229, at *21 (finding that defendant repeatedly responded to questions from analysts and investors with answers that indicated knowledge about drug pricing and the repeated inquiries "would have made Defendants aware of the importance of generic drug pricing to the investing public" thus defendants' failure to disclose certain facts in its answers was indicative of scienter (citing *New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 14 (2d Cir. 2011) (finding that executives had reason to focus on the subject of alleged misrepresentations because it was a "subject about which investors and analysts often inquired[]"))); *see also id.* at *22.

a. Defendants' Access to the Audit Results Further Supports a "Strong Interference" of Scienter

"In some cases, a plaintiff can establish scienter by showing the defendants had 'knowledge of facts or access to information contradicting their public statements.'" *Roofer's Pension Fund*, 687 F. Supp. at 622 (quoting *Novak v. Kasaks*, 216 F. 3d 300, 308 (2d. Cir. 2000); *Avaya Inc.*, 564 F.3d at 259-60; *see also National Junior Baseball League*, 720 F. Supp. 2d at 553 ("A plaintiff alleging a strong inference of scienter from circumstantial evidence must sufficiently plead 'defendants' knowledge of facts or access to information contradicting their public statements . . . . [i.e., that] defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation.'" (quoting *In re Campbell Soup*, 145 F. Supp. 2d at 599 (alteration in the original))); *In re Great Atl. & Pac. Tea Co., Inc. Sec. Litig.*, 103 F. App'x 465, 469 (3d Cir. 2004) ("[W]hen the alleged fraud is based on non-disclosure of facts, evidence that the defendants had actual knowledge of the facts is sufficient to show scienter.").

Here, the Third Amended Complaint, through the averments of FE1 and FE2, alleges that

Defendants had access to the Audit cautioning that ROVI would "never be able to pass an FDA inspection." (TAC ¶¶ 5, 40, 80-87). Despite Defendants' alleged knowledge of the Audit, Defendants assured investors that manufacturing issues at ROVI had been and would be rectified, and DefenCath's NDA was on track.[25] (*Id.* at ¶¶ 180, 182, 188, 193, 195, 197, 208, 213, 217). These allegations "are sufficient to raise a strong inference of at least reckless disregard on the part of the individual Defendants with respect to [DefenCath's NDA] . . . ." *City of Warwick*, 2024 WL 3219616, at *15 (citing *McCullough v. Advest, Inc.*, 754 F. App'x 109, 113 (3d Cir. 2018) (acknowledging access to information in finding that scienter adequately alleged)); *see also Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (access to facts contradicting statements to investors is "classic evidence of scienter"); *In re Campbell Soup*, 145 F. Supp. 2d at 599 (stating that a claim of recklessness can be based on allegations that the defendants had access to information which contradicted their public statements); *cf. Spar v. Celsion Corp.*, No. 20-15228, 2023 WL 2069725, at *7 (D.N.J. Feb. 6, 2023) ("Defendants reiterate that Plaintiff cannot and does not allege that Defendants had access to the data at the time such statements were made."); *Roofer's Pension Fund*, 2018 WL 3601229, at *19 (finding that the defendants having access to publicly available reports is not as compelling as a competing inference that the defendants did not act with scienter)).

Here, Plaintiff "ha[s] specifically alleged [D]efendants' knowledge of facts or access to information contradicting [Defendants'] public statements[]" and accordingly, the Court finds a sufficient "strong inference" of scienter. *In re Campbell Soup*, 145 F. Supp. 2d at 599; *see also In re Viropharma,* 2003 WL 1824914, at *9 (finding "Defendants had access to non-public annual

[25] Defendants argue that the Audit should be discounted because it predates the NDA submission by two years and involves a third-party entity. (Defs.' Reply Br. at 2-3). However, the Audit addressed precisely the type of manufacturing deficiencies that later formed the basis of the FDA's CRLs. (TAC ¶¶ 7, 40).

reports which contained the results of the clinical trials, the NDA for Pleconaril which contained data from the Phase II and III trials, and the Case Report Forms prepared during the clinical trials."); *In re RAIT Fin. Tr. Sec. Litig.*, 2008 WL 5378164, at *12-13 (E.D. Pa. Dec. 22, 2008) (finding scienter where the plaintiff alleged that the individual defendants were senior executives, with access to information contradicting their public statements). *Accord Frater*, 996 F. Supp. 2d at 350 ("When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity."). Further, considering the Third Amended Complaint in its entirety, "Plaintiff[] properly allege[s] scienter based on Defendants' conscious decision to omit presently known facts," particularly when presented with "information about difficulties facing" DefenCath NDA's FDA approval. *See Curran*, 2018 WL 394878, at *5.

iii. The Core Operations Doctrine

The core operations doctrine also supports a finding of scienter. The core operations doctrine provides that when misrepresentations and omissions involve "core matters of central importance" to the corporate defendant, "a 'core operations inference' supports scienter." *Avaya*, 564 F.3d at 268; *see also In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 653-54 (E.D. Pa. 2015) ("[U]nder the core operations doctrine, misstatements and omissions made on 'core matters of central importance' to the company and its high-level executives gives rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge.") (quoting *Rahman*, 736 F.3d at 246); *see also Martin*, 757 F. App'x at 155; *In re Amarin Corp. PLC.*, No. 13-6663, 2015 WL 3954190, at *12 (D.N.J. June 29, 2015)).

However, "'corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter[.]'" *Rahman*, 736 F.3d at 247 (quoting *Avaya*, 564

F.3d at 270). Rather, in order to support a finding of scienter based upon the core operations doctrine, there must be "'some additional allegations of specific information conveyed to management and related to fraud.'" *Id.* (quoting *Avaya*, 564 F.3d at 270).

Notably, the core operations doctrine on its own is not sufficient to establish scienter but should be taken "in consideration when viewing the entirety" of the TAC's allegations. *In re Enzymotec*, 2015 WL 8784065, at *18.

Here, Plaintiff alleges that DefenCath's approval was critical to CorMedix's viability and the issues at the CMO effected the core of CorMedix's business. (TAC ¶¶ 2, 5, 37, 40, 293). Defendants do not contend otherwise. Additionally, the Third Amended Complaint boasts the experience of the Individual Defendants. For instance, Plaintiff characterizes Armstrong, the EVP of Technical Operations, as an executive officer with "more than 45 years of experience in the pharmaceutical industry with broader senior level cross functional experience, as well as his having held a number of general management positions." (*Id.* at ¶ 52). Baluch "boasted" about:

> The significant experience Phoebe [Mounts] brings in regulatory, Jack [Armstrong] in manufacturing and supply chain, Paul in medical affairs and Liz in clinical operation, coupled with my Cialis and Byetta launch experience in the US just to name a few recent launches makes for a winning team. Together, we have a combined experience of over 170 years in the pharmaceutical business.

(*Id.* at ¶ 95) (alterations in the original).

At this juncture, these allegations are sufficient to support scienter based upon the core operations doctrine. *See*, *e.g.*, *Urban Outfitters*, 103 F. Supp. 3d at 654 (holding core operations doctrine was allowed to support scienter where business wherein fraud was alleged to have occurred accounted for 44 percent of all sales by Urban Outfitters during the year in question); *Avaya*, 564 F.3d at 271-72 (holding the core operations doctrine supported scienter where CEO and CFO of a communications company affirmatively denied the existence of intense price

competition at a time when the company actively was granting steep price discounts even though no confidential witness statement or particular document showed a defendant's knowledge); *Carmignac Gestion, S.A.*, 2019 WL 3451523, at *16 (holding scienter met where senior executives made statements concerning a product line that accounted for 22 percent of revenue—and were specifically alleged to have reviewed reports showing declining market share); *Hall*, 2019 WL 7207491, at *21 (finding scienter adequately pled where the defendants made public misstatements about a "flagship product" despite internal knowledge of adverse information); *In re Allergan Generic Drug Pricing Sec. Litig.*, No. 16-9449, 2019 WL 3562134, at *12 (D.N.J. Aug. 6, 2019) (applying core operations doctrine and finding scienter was supported where alleged misrepresentations addressed three drugs that made up a "substantial portion" of the defendant company's revenues and operations during the class period); *In re Toronto-Dominion Bank Sec. Litig.*, No. 17-1665, 2018 WL 6381882, at *19 (D.N.J. Dec. 6, 2018) (holding core operations doctrine supported scienter at pleading stage where the plaintiffs alleged Canadian retail segment of business was "flagship business" and contributed over 60 [percent] of earnings); *SEB Inv. Mgmt.*, 351 F. Supp. 3d at 906-07 (holding that a plaintiff sufficiently pled scienter where the the plaintiff alleged that the defendants recklessly disregarded facts they knew contradicted their public statements about a product that was a critical part of defendants' business); *Enzymotec*, 2015 WL 8784065, at *17 (finding scienter where the misstatements "about which Defendants regularly spoke" concerned their core business); *In re Viropharma*, 21 F. Supp. 3d at 473 (finding that "sales of Vancocin comprised ViroPharma's 'core business,' also supports the inference that Defendants either knew or should have been aware of the issues concerning the drug's approval" and noting Vanocin accounted for more than 50 percent of ViroPharma's revenue); *In re Cell Pathways, Inc., Sec. Litig.*, No. 99-725, 2000 WL 805221, at *7 (E.D. Pa. June 20, 2000) (finding

"where the alleged fraud relates to the core business of the company, knowledge of the fraud may be imputed to the individual defendants" (citation modified)); *cf. Tibbs v. electroCore, Inc.*, No. 23-2655, 2024 WL 4987243, at *7 (3d Cir. Dec. 5, 2024) (affirming dismissal for lack of scienter on the basis that "high-level allegations that individual defendants had knowledge of [the company]'s business, standing alone, were not enough"); *Rahman*, 736 F.3d at 246-47 (refusing to allow the core operations doctrine to support scienter because the scheme involved only comprised a small percentage of the defendants' annual business and declining to apply doctrine in the absence of allegations demonstrating that the defendants knew the information they disseminated was false); *Stichting Pensionenfonds*, 775 F. Supp. 3d at 850 (finding the core operations doctrine inapplicable where the plaintiffs fail to allege that the defendants "specifically received information related to the alleged liability of the lead-sheathed copper cables and nonetheless omitted that information in their statements concerning the cost benefits of removing copper cables and implementing fiber cables."); *In re Heartland Payment Sys., Inc. Sec. Litig.*, No. 09-1043, 2009 WL 4798148, at *7 (D.N.J. Dec. 7, 2009) ("[I]t is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question."); *In re Advanta Corp.*, 180 F.3d at 539 (rejecting "allegations that a securities-fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading"); *In re Amarin Corp.*, 2015 WL 3954190, at *12 (refusing to infer scienter from core operations doctrine "absent particularized allegations showing that defendants had ample reason to know of the falsity of their statements").

Moreover, the content and context of many of the alleged misleading statements further enhances the finding of scienter with respect to the individual defendants whom the Court has

found to have the requisite scienter. *See Utesch*, 385 F. Supp. 3d at 422 ("'[T]he most powerful evidence of scienter is the content and context' of the misleading statements.") (quoting *Avaya*, 564 F.3d at 269)); *see also In re Urban Outfitters*, 103 F. Supp. 3d at 653-54. In *Avaya*, the company's CEO made statements "repeatedly assur[ing] analysts and investors that, although there was pressure in the market, there were no significant changes to the pricing environment." 564 F.3d at 260. The plaintiffs alleged that the CFO made these statements while "kn[owing] of or recklessly disregard[ing] the fact that competition was forcing unusually large 20 [percent] to 40 [percent] price discounts that were hurting profit margins." *Id.*

Here, for instance, in May 2022, Todisco provided his opening remarks as CEO, but failed to disclose the manufacturing deficiencies identified at CorMedix's API for heparin, and one month later, while presenting at a conference, he reiterated the CMO's ability to maintain cGMP standards, which prompted the question "has the company addressed all the [FDA's] questions appropriately?" to which he answered "yes, yes." (*Id.* at ¶¶ 152-54, 279). Notwithstanding, on August 4, 2022, the FDA issued a Second CRL, which cited unresolved deficiencies at both ROVI and the API supplier for heparin. (*Id.* at ¶¶ 33, 34, 156, 281). Further, on August 8, 2022, CorMedix disclosed this Second CRL and stated ROVI needed "an independent CGMP consultant." (*Id.* at ¶¶ 35, 157, 281). This further supports a finding of scienter at this stage. *See Roofer's Pension Fund*, 2018 WL 3601229, at *21 (finding content and context of "high-ranking executive" defendants' repeated answers to analysts questions regarding generic drug pricing indicated personal knowledge of the subject and further supported scienter); *see also In re PTC Therapeutics*, 2017 WL 3705801, at *17 (finding "persuasive" the content and context of the statements of two executives "implied that they had first-hand knowledge" of the matter at issue, which, while not conclusive, bolstered an inference of scienter).

iv. SOX Certifications

"Under the Sarbanes-Oxley Act, principal executive and financial officers of public companies must make a number of certifications about their financials." *In re Elecs. for Imaging*, 2019 WL 397981, at *9 (citing 15 U.S.C. §§ 78m, 78o(d), 7241(a)(4)). "Specifically, officers must certify the general truthfulness of the company's quarterly and annual reports and the establishment and adequacy of the company's internal controls." *Id.* (citing *In re Intelligroup*, 527 F. Supp. 2d at 287).

Here, the Third Amended Complaint references SOX certifications during the Class Period signed by Baluch and David. (TAC ¶¶ 192, 204, 212, 231, 254). These SOX certifications contained the following statement: "to my knowledge . . . the information contained in the [[] 10-K] Report fairly presents, in all material respects, the financial condition and results of operations of the Company." (*Id.*)

"An allegation that a defendant signed a SOX certification attesting to the accuracy of an SEC filing that turned out to be materially false does not add to the scienter puzzle in the absence of any allegation that the defendant knew he was signing a false SEC filing or recklessly disregarded inaccuracies contained in an SEC filing." *In re Hertz*, 905 F. 3d at 118; *see also In re Intelligroup*, 527 F. Supp. 2d at 288 (holding that for Sarbanes-Oxley certifications to establish scienter "plaintiffs must allege facts indicating that certifying defendants had clear reasons to doubt the validity of financials being certified but kept turning their blind eye to all 'red flags'" in order to "create the requisite strong inference of scienter[]"); *Roofer's Pension Fund*, 2018 WL 3601229, at *16 ("Courts have found that SOX certifications themselves are not actionable and, that to support an inference of scienter, something more is needed.") (citation modified). *Accord In re Global Brokerage, Inc.*, No. 17-916, 2019 WL 1428395, at *14 (S.D.N.Y. Mar. 28, 2019)

(holding that the defendants cannot be held liable for their SOX certifications with respect to statements where a plaintiff fails to adequately allege actionable misstatements or omissions); *Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 277 F. Supp. 3d 500, 517 (S.D.N.Y. 2017) ("SOX certifications . . . do not constitute a standalone basis for liability.").

The Court finds that Defendants' SOX certifications minimally support an inference of scienter. As addressed *supra*, the Court has already found the CWs' statements may support a finding that Individual Defendants—including those who filed SOX certifications (Baluch and Armstrong) either knew (or were reckless in not knowing) about the Audit and the manufacturing deficiencies at ROVI that would materially impact the DefenCath NDA. *See In re Toronto Bank*, 2018 WL 6381882, at *19 (considering the SOX certifications to further scienter where court had already found CWs' statements "may support" a finding that defendants "either knew (or were reckless in not knowing) the alleged improprieties occurring at [the] Bank."). Additionally, Plaintiff has alleged Defendants knew or recklessly disregarded the results of the Audit as well as the manufacturing deficiencies at ROVI. (TAC ¶¶ 85-86, 149, 221). Accepting these allegations as true, as the Court must at this stage, the Court considers the SOX certifications and allocates minimal weight to these certifications. *See In re Intelligroup*, 527 F. Supp. 2d at 358. *Cf. Roofer's Pension Fund*, 2018 WL 3601229, at *16; *In re Campbell Soup Co.*, 18-14385, 2020 WL 7022655, at *9 (D.N.J. Nov. 30, 2020) (holding the "[p]laintiffs have failed to allege facts to support the conclusion that Defendants knew the information in the SOX Certifications was false or recklessly disregarded any inaccuracies contained in an SEC filing.").

v. Whether Any Factors Weigh Against Scienter

In support of their motion, Defendants advance several factors which they contend undercut Plaintiff's scienter allegations, including *inter alia*: (1) Defendants did not sell stock

during the Class Period; (2) Baluch and Armstrong's resignations were retirements; and (3) Defendants' filing of SOX Certifications.[26] (Defs.' Br. at 10, 17).[27]

a. Defendants Did Not Sell Stock During the Class Period

Defendants assert that the absence of insider stock sales undermines scienter. (Defs.' Br. at 11; Defs.' Reply Br. at 3). Plaintiff does not allege that Defendants sold stock during the Class Period. (*See generally* TAC). Rather, according to Defendants, one of the Individual Defendants bought CorMedix stock. (Defs.' Br. at 11 (citing Declaration of David Kotler ("Kotler Decl."), ECF No. 104-12, Ex. J)). "Although not determinative, courts have consistently weighed this fact against an inference of scienter." *See Lewakowski*, 2023 WL 2496504, at *12 (collecting cases); *see also National Junior Baseball League*, 720 F. Supp. 2d at 558 ("[T]he fact that [the individual defendants] did not sell any [of the company's] stock during the Class Period tends to negate scienter."); *Avaya*, 564 F.3d at 279 ([W]e will not infer fraudulent intent from the mere fact that some officers sold stock) (quoting *Advanta*, 180 F.3d at 540) (quoting *In re Burlington*, 114 F.3d at 1424)); *In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, No. 15-7658 2017 WL 1658822, at *11 (D.N.J. Apr. 28, 2017) ("Because it is plausible that the Exchange Act [d]efendants were caught before they had a chance to sell their shares, the mere fact that the Exchange Act [d]efendants did

[26] As discussed *supra*, Defendants' SOX certifications minimally support an inference of scienter.

[27] "While 'motive and opportunity' do not offer an 'independent route to scienter following *Tellabs*, particularized allegations regarding motive and opportunity may, in combination with other allegations, support a strong inference of scienter." *Dang*, 750 F. Supp. 3d at 478 (quoting *Avaya*, 564 F.3d at 277); *see also Avaya*, 564 F.3d at 277-78; *Hoey*, 2018 WL 902266, at *21-22. Plaintiff alleges that Defendants had significant financial motives to hide material risks regarding the DefenCath NDA because CorMedix's survival virtually depended on it. (TAC ¶ 293). Additionally, Plaintiff alleges that Defendants' false and misleading statements allowed CorMedix to raise tens of millions of dollars through secondary stock that it otherwise would not have been able to. (*Id.* at ¶¶ 102, 134). However, "the desire to raise funds is [a] motive shared by all corporate executives and officers, and 'a motivation of avoiding an event that would threaten the survival of a company is . . . too generalized (and generalizable).'" *Paxton v. Provention Bio, Inc.*, No. 21-11613, 2022 WL 3098236, at *17 (D.N.J. Aug. 4, 2022) (quoting *In re Chembio Diagnostics, Inc. Sec. Litig.*, No. 20-02706, 2022 WL 541891, at *10 (E.D.N.Y. Feb. 23, 2022)); *see also Rahman*, 736 F.3d at 245-46 ("Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud."). Notwithstanding, "the absence of a motive allegation is not fatal." *Tellabs*, 551 U.S. at 325.

not sell their shares is insufficient to render [the p]laintiffs' allegations deficient."). *Accord In re Urban Outfitters*, 103 F. Supp. 3d at 655; *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 572-73 (E.D. Pa. 2009). *Cf. In re Suprema Specialties*, 438 F.3d at 278 (finding complaint "plausibly alleged that the sales were not normal or routine" for defendant officers who each "is alleged to have sold over 30 percent of his holdings"); *In re Enzymotec*, 2015 WL 8784065, at *19 (finding complaint alleged stock sales "unusual in scope" where one defendant sold 35 percent of his total holdings and another sold 42 percent). Accordingly, the lack of stock sales during the Class Period neither bolsters nor defeats scienter. *City of Warwick*, 2024 WL 3219616, *13, 15 (finding scienter adequately pled notwithstanding "no allegations that Defendants engaged in irregular stock sales or profited from the purported fraud.").

b. Armstrong and Baluch's Resignations Do Not Further Bolster Scienter

Generally, "[t]he departure of corporate executive defendants is a factor that can strengthen the inference of scienter." *In re Hertz*, 905 F.3d at 118 (citation modified); *but see In re Par Pharm. Sec. Litig.*, No. 06-3226, 2008 WL 2559362, at *12 (D.N.J. June 24, 2008) ("The Third Circuit has generally found resignations of key officers to be insufficient to show that they acted with the requisite scienter to commit the alleged fraud."); *see also Hoey v. Insmed Inc.*, No. 16-4323, 2018 WL 902266, at *23 (D.N.J. 2018) (if "the resignation both takes place within a couple of months of the announcement of the errors committed and is accompanied by an extraordinary corporate punishment measure, e.g., denial of severance payment" it can support scienter) (quoting *In re Intelligroup*, 527 F. Supp. 2d at 347); *see also Fain*, 707 F. App'x at 97. "For a resignation to add to an inference of scienter, a pleading must set forth allegations suggesting a compelling inference that the resignation was the result of something other than 'the reasonable assumption that the resignation occurred as a result of' the release of bad news." *Hertz*, 905 F.3d at 118 (quoting *Zucco*

Partners, LLC v. Digimarc Corp., 552 F.3d 981, 1002 (9th Cir. 2009), *amended on other grounds*, (Feb. 10, 2009)). "[E]ven the termination of an executive after the announcement of so-called bad news (e.g. accounting irregularities) requires 'more than pleading a link between bad news and an executive's resignation.'" *In re Toronto-Dominion Bank*, 2018 WL 6381882, at *18 (quoting *In re Hertz*, 905 F.3d at 119). "There must still be allegations which cogently suggest that the resignations resulted from the relevant executives' knowing or reckless involvement in a fraud." *Id.*

As the Third Circuit explained in *Hertz*, "[c]hanges in leadership are only to be expected when leadership fails. That is not, in itself, a symbol of fraud. Corporate resignations do not strengthen an inference of scienter, when, as here, the allegations do not cogently suggest that the resignations resulted from the relevant executives' knowing or reckless involvement in a fraud." *Hertz*, 905 F.3d at 118. Here, the resignations of Armstrong and Baluch do not provide additional support of scienter. Both resignations—which were characterized both in the TAC and by Defendants as retirements—occurred seven months *after* the first CRL, which undercuts an inference of scienter. (TAC ¶ 137). *Intelligroup*, 527 F. Supp. 2d at 347. Plaintiff also fails to adequately allege an extraordinary corporate punishment against Armstrong or Baluch. *Hoey*, 2018 WL 902266, at *23 (inference of scienter not found even where executive resigned "shortly after" negative results announced). Indeed, Defendants state Baluch remained as an advisor and note both Defendants received severance. (Defs.' Br. at 17 (citing Kotler Decl., ECF No. 104-13, Ex. K at 1-2)). *See In re Toronto-Dominion*, 2018 WL 6381882, at *18 (declining to find resignations or reassignment of certain defendants supported scienter and noting if the defendants knew or reckless in not knowing the alleged fraud, "why would [the b]ank retain them in an advisory role[.]"); *Dang*, 750 F. Supp. 3d at 477-78 (finding two departures from company that

were neither contemporaneous with bad news nor accompanied by punishment, which occurred seven months after negative decision by court of appeals insufficient to demonstrate scienter); *see also Roofer's Pension Fund*, 2018 WL 3601229, at *20 (finding "some probative value," in employee's resignation, which was announced the same day as an investigation into company's revenue recognition practices but noting that departure was not "involuntary or accompanied by some form of corporate sanction."); *In re Intelligroup*, 527 F. Supp. 2d at 347-49 (finding officers' resignations insufficient evidence of scienter and declining to find sudden resignation of auditor contributed to inference of scienter where the plaintiffs failed to explain how resignation provided insight into defendants' mental state). *Accord In re Great Atl. & Pac. Tea Co.*, 103 F. App'x at 470 (finding that resignations of key officers are insufficient to show that they acted with the requisite scienter). *Cf. Van Dongen v. CNinsure Inc.*, 951 F. Supp. 2d 457, 474 (S.D.N.Y. 2013) (inference of scienter supported by retirement of executive "on the same day" a research firm released a negative report about the company). Accordingly, Armstrong and Baluch's resignations without more do not further support scienter.

Notwithstanding, because "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged[,]" the Court concludes that Plaintiff adequately alleges scienter. *Tellabs*, 551 U.S. at 324. Accepting Plaintiff's allegations as true, and considering competing inferences, the inference that Defendants have acted with scienter is "*at least as likely as* any plausible opposing inference." *Id.* at 328 (emphasis in original). Thus, the Third Amended Complaint gives rise to a strong inference of scienter that is "cogent and compelling," satisfying the heightened requirements of the PSLRA. *Id.* at 323.[28]

[28] The Court notes Defendants argue: "Taking the [Third Amended Complaint] as a whole, the much more compelling

(3) Plaintiff Adequately Alleges Loss Causation[29]

"In the context of Rule 10b–5 claims, the Third Circuit applies the general causation principles of tort law to the element of loss causation." *City of Warwick*, 2024 WL 3219616, at *15. In determining loss causation, the Court asks, "whether the misrepresentation or omission proximately caused the economic loss." *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 426 (3d Cir. 2007). A plaintiff must show that "the revelation of th[e alleged] misrepresentation or omission was a *substantial factor* in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff." *Id.* at 425-26 (emphasis added) (citing *Semerenko*, 223 F.3d at 184-85). Loss causation focuses on "'whether the defendant should be held responsible as a matter of public policy for the losses suffered by the plaintiff.'" *Id.* at 425 (quoting *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 222 (3d Cir. 2006)). It is not enough for a plaintiff to show that the price of a security was artificially inflated at the time of purchase because of a defendant's misrepresentations. *In re DVI, Inc. Sec. Litig.*, No. 03-05336, 2010 WL 3522090, at *5 (E.D. Pa. Sept. 3, 2010). Rather, a plaintiff must show that "the share price fell significantly after the truth became known." *Id.* at *5 (citing *Dura Pharms.*, 544 U.S. at 347); *see also In re Bradley Pharms., Inc.*, 421 F. Supp. 2d 822, 828 (D.N.J. 2006) (holding that plaintiffs pled sufficient facts to satisfy

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inference is that Defendants, while disclosing the risks, sincerely believed that DefenCath would be approved by [the] FDA, provided regular updates to investors on the status of the NDA, but experienced some significant setbacks at third-party suppliers and manufacturers during the pandemic." (Defs.' Br. at 17-18). The Court recognizes it must "take into account plausible opposing inferences." *Martin*, 757 F. App'x at 154 (quoting *Tellabs*, 551 U.S. at 323); *see also Avaya*, 564 F.3d at 267 (noting courts obligation to weigh the "plausible nonculpable explanations for the defendant's conduct against "inferences favoring the plaintiff.") (quoting *Tellabs*, 551 U.S. at 324). As discussed *supra*, the Court finds Plaintiff has adequately alleged an inference of scienter at the motion to dismiss stage. Moreover, the Court finds Defendants' cursory arguments regarding the nonculpable inferences are less plausible than Plaintiff's allegations.

[29] The Court applies Rule 8 rather than the heightened 9(b) pleading standard in determining loss causation. *See, e.g., Dura*, 544 U.S. at 347; *Hall*, 2019 WL 7207491, at *27 (collecting cases); *National Junior Baseball League*, 720 F. Supp. 2d at 558 ("Plaintiff need not satisfy the PSLRA or Rule 9(b)'s heightened pleading requirements to survive a motion to dismiss for loss causation; rather, a plaintiff need only satisfy the requirements of Rule 8(a)(2)).") (citation modified); *Hull v. Glob. Digital Sols., Inc.*, No. 16-5153, 2017 WL 6493148, at *11 (D.N.J. Dec. 19, 2017) ("Importantly, alleging loss causation or economic loss does not require a plaintiff to satisfy the heightened pleading standard under Rule 9(b)[.]").

loss causation by alleging that the price of defendants' stocks dropped after the truth about defendants' alleged misrepresentation became known.).

"Courts in this district have held loss causation is adequately pled when a company's stock price declines after media reports and disclosures presented new information about the alleged fraud to the public." *City of Warwick*, 2024 WL 3219616, at *15 (first citing *In re Aurora Cannabis Inc. Sec. Litig.*, No. 19-20588, 2023 WL 5508831, at *5-7 (D.N.J. Aug. 24, 2023); then citing *Hall*, 2019 WL 7207491, at *27-28); *but see Omanoff v. Patrizio & Zhao, LLC*, No. 14-723, 2015 WL 1472566, at *6 (D.N.J. Mar. 31, 2015) ("The fact that a misrepresentation occurred and the share price declined is not enough.").

Importantly, "[t]he issue of loss causation is usually not resolved on a motion to dismiss." *Dudley v. Haub*, No. 11-05196, 2013 WL 1845519, at *18 (D.N.J. Apr. 30, 2013) (citing *EP MedSystems*, 235 F.3d at 884 ("Whether the plaintiff has proven [loss] causation is usually reserved for the trier of fact.")); *see also Gross v. GFI Grp., Inc.*, 162 F. Supp. 3d 263, 269 (S.D.N.Y. 2016) ("[Plaintiff]'s burden to plead loss causation is not a heavy one, and when it is unclear whether the plaintiff's losses were caused by the fraud or some other intervening event, the chain of causation is . . . not to be decided on a Rule 12(b)(6) motion to dismiss.") (citation modified).

Here, Plaintiff adequately pleads loss causation.[30] For each alleged corrective disclosure, Plaintiff alleges: (1) the information that was provided in each disclosure; (2) the ways in which each disclosure relates to the concealment (or that the truth became known); and (3) that stock

[30] Plaintiff relies on two theories to plead loss causation: corrective disclosure and materialization of concealed risk. (Pl.'s Br. at 38). However, "the ultimate loss causation inquiry under either the corrective disclosure theory or the materialization of a concealed risk theory is the same: whether a 'misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security.'" *De Vito v. Liquid Holdings Grp., Inc.*, No. 15-6969, 2018 WL 6891832, at *39 (D.N.J. Dec. 31, 2018). This Court will evaluate the alleged corrective disclosures by addressing "the ultimate loss causation inquiry" as it relates to this matter. *Id.*

prices dropped following each disclosure. For example, Plaintiff alleges that in a press release on March 1, 2021, CorMedix disclosed that it received its first CRL based on the FDA's review of records requested from the CMO. (TAC ¶ 219). Plaintiff alleges that the first corrective disclosure relates to CorMedix's misrepresentations and omissions regarding the "true scope" of the CMO's deficiencies. (*Id.* at ¶ 221). CorMedix stock price fell 54.4 percent, purportedly as a result of the first corrective disclosure. (*Id.* at ¶ 220). Plaintiff also alleges that each corrective disclosure represents the market discovering the truth (or partial truth) of the fraud. (*Id.* at ¶¶ 286-290) ("The price of CorMedix securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed"). Each corrective disclosure informed the market that Defendants did or must have previously misstated and/or omitted material facts that artificially inflated the stock price. Thus, Plaintiff plausibly alleges a causal link between Defendants' statements regarding the DefenCath NDA and Plaintiff's losses through allegations connecting multiple stock price drops to the misleading nature of such statements. *See also Semerenko*, 223 F.3d at 184 ("[W]here the claimed loss involves the purchase of a security at a price that is inflated due to an alleged [omission], there is a sufficient causal nexus between the loss and the alleged [omission] to satisfy the loss causation requirement."). Accordingly, the Court finds that Plaintiff adequately plead loss causation.

B. Violation of Section 20(a)

Section 20(a) of the Exchange Act is a derivative cause of action against individuals who exercise control over a "controlled person," including a corporation, that has committed a violation of Section 10(b). 15 U.S.C. § 78t(a); *In re Suprema*, 438 F.3d at 284; *Avaya, Inc.*, 564 F.3d at 252; *In re Viropharma*, 21 F. Supp. 3d at 468. To state a claim under Section 20(a), Plaintiff must

demonstrate (1) the defendant controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud." *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 466 (D.N.J. 2017); *see also In re Suprema*, 438 F.3d at 284 n.16; *In re Intelligroup*, 527 F. Supp. 2d at 280 (citation modified).

Defendants argue that Plaintiff's Section 20(a) claim for control person liability must be dismissed because Plaintiff has failed to state an actionable Section 10(b) claim. *Avaya*, 564 F.3d at 252. However, the Court has determined that Plaintiff sufficiently pleads underlying violations of Section 10(b) against Defendants in Count I of the TAC. Accordingly, Plaintiff's Section 20(a) claim survives. *In re Coinbase Global, Inc. Sec. Litig.*, No. 22-04915, 2024 WL 4053009, at *18 (D.N.J. Sep. 5, 2024); *In re Enzymotec*, 2015 WL 8784065, at *19-20; *In re Viropharma*, 21 F. Supp. 3d at 474. *Cf. Martin*, 757 F. App'x at 155 n.26 ("Because the district court correctly dismissed the 10b-5 claim, the derivative § 20(a) claim necessarily fails.").

IV. CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss (ECF No. 144) is **DENIED**. An appropriate Order accompanies this Opinion.

DATED: August 19, 2025

JULIEN XAVIER NEALS
United States District Judge