

Not for Publication**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

In re GALENA BIOPHARMA, INC.
SECURITIES LITIGATION

Civil Action No. 17-929

OPINION**John Michael Vazquez, U.S.D.J.**

In this putative class action, Plaintiffs assert that Galena Biopharma, Inc. (“Galena”) and some of its key officers and/or employees engaged in fraud under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. § 78a *et seq.*, as to public statements relating to Galena’s product Abstral (fentanyl) Sublingual Tablets. Currently pending before the Court is Defendants’ motion to dismiss Plaintiffs’ Second Amended Class Action Complaint (“SAC”), D.E. 90. The Court reviewed the parties’ submissions in support and in opposition¹ and decided the motion 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 is **GRANTED**.

¹ Defendants’ moving brief will be referred to as “Def. Br.,” D.E. 90-1; Plaintiffs’ opposition will be referred to as “Pl. Opp’n,” D.E. 94; and Defendants’ reply will be referred to as “Def. Reply,” D.E. 96.

I. INTRODUCTION

A. Background

This putative class action is brought by five named Plaintiffs “on behalf of persons and entities that acquired Galena’s securities from November 3, 2014 through January 31, 2017.” SAC ¶ 1. Each named Plaintiff purchased Galena common stock during the class period and allegedly “suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions” raised in the SAC. *Id.* ¶¶ 23-27.

Defendant Galena “is a biopharmaceutical company that develops hematology and oncology therapeutics.” SAC ¶ 2. Galena is a Delaware corporation headquartered in California, and its common stock trades on the NASDAQ Stock Market. *Id.* ¶ 28. Defendant Mark W. Schwartz was the President and CEO of Galena from August 20, 2014 until the end of the class period. *Id.* ¶ 29. He previously served as Galena’s Executive Vice President and Chief Operating Officer. *Id.* Defendant Christopher S. Lento was the Senior Vice President of Oncology Commercial Operations at Galena from approximately May 2013 through December 31, 2015. *Id.* ¶ 30.

Much of the extensive factual background the Court included in its November 12, 2019 opinion (“Prior Opinion”) dismissing Plaintiffs’ First Amended Complaint (“FAC”) is realleged in the SAC. The Court incorporates that background by reference here and briefly reviews the new allegations in Plaintiffs’ SAC that are relevant to the pending motion. First, the SAC modifies the Class Period. While the FAC sought a Class Period of August 11, 2014 through January 31, 2017, the SAC proposes a Class Period of November 3, 2014 through January 31, 2017. SAC ¶ 1. Second, the SAC adds allegations relevant to Galena’s rebate agreement with Drs. Ruan and Couch and their pharmacy, C&R Pharmacy. Notably, the SAC includes a chart which shows the

monthly Abstral sales from Drs. Ruan and Couch, individually, from August 2014 through January 2015. *Id.* ¶ 74. The SAC alleges that the rebate agreement had a material impact on the Company's total Abstral sales due to a significant increase in each doctor's sales following execution of the agreement. *Id.* ¶¶ 75-76. Third, the SAC adds allegations to clarify questions raised in the Prior Opinion: the SAC (1) states that no criminal charges were brought against Drs. Ruan and Couch for their relationship with Galena,² *id.* ¶ 49; and (2) clarifies that Dr. Ruan did not participate in the RELIEF program, although Dr. Couch did,³ *id.* ¶ 61. Finally, the SAC adds allegations explaining why statements made by Defendants were materially false or misleading and what the undisclosed risks were for each of these statements. *Id.* ¶¶ 94-95, 97-98, 100, 103. The SAC also bolsters Plaintiffs' explanation as to why certain statements made between December 22, 2015 and January 9, 2017 amounted only to partially corrective disclosures. *Id.* ¶¶ 109, 111.

B. Procedural History

Plaintiffs filed their initial Complaint on February 13, 2017, D.E. 1, and filed an Amended Complaint on October 6, 2017, D.E. 40. Judge McNulty dismissed the Amended Complaint without prejudice on August 21, 2018. D.E. 56. On September 20, 2018, Plaintiffs filed their First Amended Complaint ("FAC").⁴ D.E. 58. Defendants filed a motion to dismiss the FAC on

² In the Prior Opinion, the Court acknowledged Defendants' assertion that the only criminal count against Drs. Ruan and Couch as to Galena was ultimately dismissed. The Court explained that, if this was true, the FAC was misleading because "it gives the strong impression that Drs. Ruan and Couch's criminal charges and convictions related to their activity with Galena." Prior Opinion at 8-9.

³ The FAC included allegations about Galena's encouragement of Dr. Ruan's participation in the RELIEF program, however, the Prior Opinion noted that the FAC failed to indicate that Ruan actually joined the program. Prior Opinion at 21.

⁴ The FAC was technically Plaintiffs' Second Amended Complaint; however, the Court referred to it as the FAC because the parties referred to it as such. Likewise, the Court refers to the SAC as the SAC even though it is actually Plaintiffs' Third Amended Complaint.

October 22, 2018. D.E. 62. This Court granted the motion and dismissed the FAC without prejudice on November 12, 2019. D.E. 75, 76.

Plaintiffs' then filed their Second Amended Complaint ("SAC"). D.E. 79. Like the FAC, the SAC states that Plaintiffs are proceeding under the fraud-on-the-market doctrine and asserts two counts: (1) violation of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants; and (2) violation of Section 20(a) of the Exchange Act against Defendant Schwartz. SAC ¶¶ 134-137, 139-151. The current motion followed.

II. LEGAL STANDARDS

A. Federal Rule of Civil Procedure 12(b)(6)

To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (internal quotation marks and citations omitted). As a result, a plaintiff must "allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of [his] claims." *Id.* at 789.

In evaluating the sufficiency of a complaint, a district court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). A court, however, is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions

disguised as factual allegations.” *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007). If, after viewing the allegations in the complaint most favorable to the plaintiff, it appears that no relief could be granted under any set of facts consistent with the allegations, a court may dismiss the complaint for failure to state a claim. *DeFazio v. Leading Edge Recovery Sols., LLC*, No. 10-2945, 2010 WL 5146765, at *1 (D.N.J. Dec. 13, 2010).

B. Federal Rule of Civil Procedure 9(b)

“Independent of the standard applicable to Rule 12(b)(6) motions, Rule 9(b) imposes a heightened pleading requirement of factual particularity with respect to allegations of fraud.” *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). Thus, pursuant to Rule 9(b), when “alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake . . . [m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). A party alleging fraud must therefore support its allegations with factual details such as “the who, what, when, where and how of the events at issue.” *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) (citing *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)). This heightened pleading 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) (internal quotation marks omitted).

C. The Private Securities Litigation Reform Act (PSLRA)

The PSLRA imposes further pleading requirements. “The PSLRA established heightened pleading requirements for a plaintiff to meet in order to plead a cause of action successfully in class actions alleging securities fraud.” *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 241 (3d Cir. 2013). The PSLRA “requires that a complaint 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.” *Id.* at 241-42 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007)) (internal quotations omitted). In other words, plaintiffs bringing a claim involving an allegedly false or misleading statement must “(1) ‘specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading,’ 15 U.S.C. § 78u-4(b)(1), and (2) ‘state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,’ § 78u-4(b)(2).” *Rahman*, 736 F.3d at 242 (quoting *Tellabs*, 551 U.S. at 321).

Both provisions of the PSLRA pleading standard require that facts be pled “with particularity,” echoing the requirement set forth in Federal Rule of Civil Procedure 9(b). *Id.* at 241 n.3. Although the “PSLRA replaced Fed. R. Civ. P. 9(b) as the applicable pleading standard in private securities class actions,” Rule 9(b)’s particularity requirement “is comparable to and effectively subsumed by the requirements” of the PSLRA. *Id.* This standard “requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story.” *Institutional Inv’rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009). Section 78u-4(b)(1) also adds the requirement that where “an allegation regarding [a defendant’s] statement or omission is made on information or belief,” plaintiffs must “state with particularity all facts on which that belief is formed”; that is, they must describe the sources of information with particularity,

including “the who, what, when, where and how of the sources, as well as the who, what, when, where, and how of the information those sources convey.” *Id.*; *see* 15 U.S.C. § 78u-4(b)(1).

As to the second element, the PSLRA’s approach for pleading scienter sharply deviates from Rule 9(b), which allows plaintiffs to plead the scienter element generally. *Avaya*, 564 F.3d at 253. Under the PSLRA, the court must evaluate whether all the facts in the complaint as alleged, taken collectively, give rise to a “strong inference of scienter” – not whether any individual allegation viewed in isolation meets that standard. *Tellabs*, 551 U.S. at 323. In determining whether the pleaded facts give rise to a strong inference of scienter, the court must “take into account plausible opposing inferences.” *Id.* This involves a comparative inquiry that evaluates how likely one conclusion is as compared to others, in light of the pleaded facts. *Id.* Thus, the court must consider plausible, nonculpable explanations for the defendant’s conduct as well as inferences favoring the plaintiff. *Id.* at 324. Although the inference that the defendant acted with scienter need not be irrefutable, the inference must be more than merely “reasonable” or “permissible.” *Id.* A complaint will survive only 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.*

III. ANALYSIS

A. Deficiencies Identified in the Prior Opinion

The Prior Opinion highlighted several areas in which the FAC’s allegations fell short of sufficiently stating a claim for securities fraud: (1) allegations not linked to any particular violation, (2) disclosures concerning the government investigation of Galena, (3) Item 303 allegations, (4) statements attributable to particular Defendants, (5) motive, and (6) past earnings, targeted providers, and related allegations. Prior Opinion at 20-32. The SAC does not include any

allegations to remedy the deficiencies noted in the first and second areas and fails to replead allegations pertinent to the third area. As for the fourth area, the Court's Prior Opinion found that the allegations concerning statements made by three individual Defendants – Mark J. Ahn, Ryan M. Dunlap, and Remy Bernarda – were insufficient to adequately state a claim. *Id.* at 23-25. The SAC removes these three individuals as Defendants.

With respect to the fifth area – motive – the Prior Opinion noted that “[c]orporate officers always have an incentive to improve the lot of their companies, but this is not, absent unusual circumstances, a motive to commit fraud.” Prior Opinion at 26 (quoting *Avaya*, 564 F.3d at 279). The Court suggested that this case “arguably reflects unusual circumstances because Galena only had one commercial product, Abstral, during the class period” and because “Galena was a relatively small public company.” *Id.* at 27. However, the Court concluded that the FAC's allegations were insufficient because they failed to (1) “indicate the other aspects of Galena's business vis-à-vis its commercial product,” and (2) “allege that any adverse consequences occurred to the stated financings when Galena announced that it was selling Abstral to a third party.” *Id.* The SAC attempts to address these shortfalls through additional allegations. The SAC indicates that, during the Class Period, the Company's operating losses increased significantly. SAC ¶ 122. Galena's 2014 operating losses were \$52.2 million compared to \$33.8 million in 2013. *Id.* Plaintiffs allege that, as a result of these operating losses, “the Company needed outside financing to maintain its operations and to finance the ongoing clinical trials of its primary drug candidate Neu Vax.” *Id.* However, the SAC does not include any allegations concerning the impact to the stated financings after Galena announced that it was selling Abstral. The SAC's allegations do not demonstrate that this case presents “unusual circumstances” by which the Defendants' desire

to improve Galena's lot translates to a sufficient motive to commit fraud. Therefore, like the FAC, the SAC fails to sufficiently allege motive.

Regarding the sixth area, the SAC (like the FAC) includes many of the same allegations concerning prior earnings but raises no allegations that any prior earnings figures were inaccurate. *See, e.g.* SAC ¶¶ 93(a), 93(b), 93(c). For the same reasons expressed in the Prior Opinion, these past earnings statements are not materially misleading. However, the Prior Opinion explained that “even when a company accurately recites its past earnings, attributing such earnings to lawful activity when in fact they are not attributable to such activity constitutes materially misleading statements.” Prior Opinion at 27. In the FAC, Plaintiffs alleged that Defendants falsely attributed their earnings to (1) targeting oncology providers, (2) customer confidence, and (3) legally sustainable practices. *Id.* at 28. The SAC raises many of the same allegations as the FAC concerning statements attributing earnings to targeting oncology providers, *see, e.g.*, SAC ¶¶ 96(c), 99(a), and the Court again concludes that these statements are not materially misleading for the same reasons expressed in the Prior Opinion.⁵ As for the second category – statements attributed to consumer confidence – the Court finds that these alleged statements are not materially misleading for the same reasons expressed in the Prior Opinion. However, as discussed below, the Court finds that the SAC sufficiently alleges facts to cure the deficiencies noted in the Prior Opinion concerning materially misleading statements attributed to sustainable business practices.

B. Allegations Sufficiently Pled in the SAC

The SAC makes some allegations that could support a Section 10(b) claim, including (1) Defendants' pre-August 6, 2015 statements that tied Abstral's success to legitimate and sustainable

⁵ The FAC also raised allegations through confidential witnesses that Galena pushed sales representatives to market Abstral off-label. These allegations were not raised in the SAC.

practices despite Defendants' knowledge of the illegal rebate program with C&R Pharmacy; and (2) August 6, 2015 statements made after Drs. Ruan and Couch's businesses were raided and shut down. Nevertheless, the SAC suffers from the same shortcoming as the FAC. In the Prior Opinion, the Court found the FAC deficient for "us[ing] a shotgun approach and essentially argu[ing] that *all* allegations comprise the Section 10(b) claim," which resulted in the Court's inability "to effectively separate the wheat from the chaff." Prior Opinion 33. The SAC suffers from the same issue – it fails to distinguish allegations as independent bases for Section 10(b) violations and instead, argues that all allegations included in the SAC comprise the Section 10(b) claim. Additionally, the SAC's proposed Class Period cannot stand.

Plaintiffs allege in Count One that Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereafter. Defendants assert that Plaintiff's Section 10(b) claim must fail because the SAC fails to plead an actionable misrepresentation or omission. Def. Br. 9. To state a securities fraud claim under Section 10(b) and Rule 10b-5, Plaintiffs "must allege (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014).

1. Material Misrepresentations or Omissions

To satisfy the first element, a plaintiff must "identify a false representation of material fact or omission that makes a disclosed statement materially misleading." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1419 (3d Cir. 1997)). "[A] fact or omission is material only if 'there is a substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered

the “total mix” of information’ available to the investor.” *Id.* (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231-232 (1988)). In other words, courts must “examine statements in the full context of the documents which they are a part” and not engage in a “selective reading” of the statements. *Pfizer, Inc.*, 754 F.3d at 168-69 (citing *Burlington Coat Factory*, 114 F.3d at 1426; *Tellabs*, 551 U.S. at 322).

a. Statements Made Prior to August 6, 2015

The SAC asserts that statements made on November 3 and 5, 2014; March 5, 2015; and May 7, 2015 in press releases, SEC filings, and earnings conference calls were materially false or misleading because they led investors to believe that Abstral sales were legitimate and stable when, in reality, they were based upon Galena’s illegal promotion of the drug for off-label purposes and illegal kickbacks paid to proscribing doctors. SAC ¶¶ 93-101. Defendants contend that these statements “are the same allegations that this Court has twice rejected” and should be dismissed. Def. Br. 10-11. Specifically, Defendants argue that the SAC does not sufficiently plead that Galena took part in in underlying illegal conduct because it fails to adequately allege that Plaintiffs engaged in off-label marketing or violated the Anti-Kickback Statute. *Id.* at 11-12. Even if Plaintiffs did adequately allege illegal conduct, Defendants continue, the SAC fails to plead any duty to disclose the allegedly illegal conduct. *Id.* at 14.

A company’s accurate recitation of its past earnings can be materially misleading if it attributes such earnings to lawful activity when they are not in fact attributable to such activity. *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999); Prior Opinion at 27. Like the FAC, the SAC alleges that Defendants falsely attributed their earnings during the pre-August 6, 2015 portion of the Class Period to (1) targeting oncology providers, (2) customer confidence, and (3) legal, sustainable practices. As mentioned above, the SAC does not remedy the deficiency of the

allegations concerning targeting oncology providers or consumer confidence. However, the SAC does adequately allege that Defendants made materially misleading statements that incorrectly attributed earnings to legally sustainable practices.

In the Prior Opinion, the Court determined that Plaintiffs sufficiently pled that Defendants were engaged in an illegal kickback agreement by way of the October 14, 2014 rebate agreement but failed to demonstrate that the kickback agreement had an impact on Galena's earnings. Prior Opinion at 32. The SAC cures this deficiency by adequately alleging that the amount of Abstral prescriptions written by Drs. Ruan and Couch "notably increased after the rebate agreement was executed." SAC ¶ 74. The SAC alleges that Dr. Ruan's Abstral prescriptions increased from \$150,683 in October 2014 to \$245,783 in November 2014. *Id.* And Dr. Couch's prescriptions increased from \$188,934 in October 2014 to \$228,631 in November 2014. *Id.* Although these numbers decreased in December 2014 and January 2015, the numbers remained higher than those from August and September 2014 – the months immediately preceding the execution of the rebate agreement. *Id.* The SAC further alleges that "the rebate agreement had a material impact to Galena" because "the Company's total previous *quarterly* revenues were in the range of around \$1 million to \$2.3 million," and in just the fourth quarter of 2014, Drs. Ruan and Couch's prescriptions alone created a combined total of \$1,257,745 in revenue. *Id.* ¶ 75. The Court finds that Plaintiffs have sufficiently alleged the materiality vis-à-vis the unlawful rebate agreement.⁶

⁶ Defendants contend that the rebate fits within the safe harbor provision of the Anti-Kickback Statute and, therefore, the rebate agreement does not constitute illegal conduct. Def. Br. 13-14. Under 42 C.F.R. § 1001.952(h)(4), "a rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." Defendants' argument misses the mark because it presupposes a lawful rebate program. Plaintiffs, however, have made the exact opposite allegation – the rebate program itself was an unlawful kickback.

Therefore, the pre-August 2015 statements that attribute Galena's earnings to sustainable business practices are adequately plead as material misstatements.⁷

b. August 6, 2015 Statements

On May 20, 2015, Drs. Ruan and Couch's clinic was raided by law enforcement and their business was effectively shut down. SAC ¶ 49. As discussed in the Prior Opinion,⁸ following that event, Defendants were aware that their largest prescribers – accounting for 30% of Abstral sales – were no longer producing. Prior Opinion at 34. Like the FAC, the SAC alleges that in August 2015, Defendants made material misstatements indicating that Abstral business was doing well. *Id.* ¶¶ 102-104. On an August 6, 2015 earnings call, Lento stated that “our Abstral business is growing” and Schwartz stated that Abstral’s “underlying metrics are all trending upwards.” *Id.* ¶ 102(c). Although Defendants argue that these statements contained historical information and referred to the second quarter of 2015 – which had shown increases in Abstral sales – Def. Br. 19-20, the Court again concludes that these statements are misleading. These statements are not purely forward-looking statements protected by the PSLRA’s safe harbor, nor do they convey only historical information about a past quarter. Instead, these statements indicate that at the time they were made, Abstral sales were “growing” and “trending” in the right direction, despite Defendants’ knowledge that 30% of Abstral sales were lost when the physicians’ business was shuttered. For the reasons expressed in the Prior Opinion, the Court finds that the SAC adequately alleges that

⁷ The Court notes that, for the same reasons expressed in the Prior Opinion, Plaintiffs have failed to adequately allege that Defendants engaged in illegal off-label promotion of Abstral. Prior Opinion 28-31, 32.

⁸ The Prior Opinion incorrectly cites these statements as occurring on August 8, 2015, however, both the FAC and the SAC indicate that these statements were made during an August 6, 2015 earnings call.

the August 6, 2015 statements about Galena's growing Abstral business were material misrepresentations. Prior Opinion at 34-35.

Thus, Plaintiffs have adequately alleged that the (1) pre-August 6, 2015 statements which attributed Galena's earnings to sustainable business practices; and (2) August 6, 2015 statements which indicated that Abstral sales were "growing" and "trending" in the right direction were material misstatements under PSLRA. The Court next considers whether Plaintiffs have adequately pled scienter.

2. Scienter

"Scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind."⁹ *Avaya*, 564 F.3d at 252 (internal citations and quotations omitted). The PSLRA scienter standard "requires plaintiffs to allege facts giving rise to a 'strong inference' of 'either reckless or conscious behavior.'" *Id.* at 267 (quoting *Advanta*, 180 F.3d at 534-35). 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." *Id.* at 267 n.42 (citing *Advanta*, 180 F.3d at 535). "[C]laims essentially grounded on corporate mismanagement' do not adequately plead recklessness." *Id.* (citing *Advanta*, 180 F.3d at 540).

A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 267 (quoting *Tellabs*, 551 U.S. at 324). It is more than "merely 'reasonable' or 'permissible.'" *Tellabs*, 551 U.S. at 324. To make this

⁹ This standard is distinguishable from the required mental state for future looking statements under the PSLRA Safe Harbor provision, which requires actual knowledge. *See* 15 U.S.C. § 78u-5(c).

determination, a court must “weigh the plausible nonculpable explanations for the defendant’s conduct against the inferences favoring the plaintiff.” *Avaya*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 324) (internal quotations omitted). However, “[t]he 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.” *Id.* (quoting *Tellabs*, 551 U.S. at 324). “The pertinent question is ‘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 267-68 (quoting *Tellabs*, 551 U.S. at 323). “Omissions and ambiguities ‘count against inferring scienter.’” *Id.* at 268 (quoting *Tellabs*, 551 U.S. at 326). “Motive and an opportunity to commit fraud” are just a factor in this analysis. *Advanta*, 180 F.3d at 534-35. In sum, “[a] complaint will survive . . . only 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.*

First, for the reasons set forth in the Prior Opinion, the Court finds that Plaintiffs sufficiently established scienter as to Lento and Schwartz for their August 6, 2015 statements about Abstral sales “growing” and “trending” in the right direction. Prior Opinion at 35-38.

Second, the Court finds that the SAC sufficiently alleges scienter with respect to the pre-August 6, 2015 statements vis-à-vis the rebate program. The SAC alleges that Lento and Schwartz made misleading statements attributing Galena’s strong Abstral sales to legitimate and sustainable practices, despite knowing that the increased sales were based on the rebate program, which was an illegal kickback scheme as alleged. SAC ¶¶ 93-101. Galena entered into the rebate agreement with C&R Pharmacy on October 1, 2014, and the SAC alleges that Drs. Ruan and Couch’s Abstral prescriptions notably increased after the execution of the rebate agreement. *Id.* ¶¶ 64, 74. The November 3 and 5, 2014 statements discussed Galena’s results from the third quarter of 2014, *id.*

¶ 93; the March 5, 2015 statements discussed Galena's fourth quarter and year-end results for 2014, *id.* ¶ 96; and the May 7, 2015 statements discussed Galena's results from the first quarter of 2015, *id.* ¶ 99. Thus, the favorable numbers reported within those statements were allegedly attributable (at least in material part) to increased revenue from the rebate program. The SAC further alleges that Lento and Schwartz were aware of the rebate program – Schwartz was a signatory on the rebate agreement with C&R Pharmacy, *id.* ¶ 64, and Lento was copied on an email detailing the increase in Drs. Ruan and Couch's prescriptions after the rebate agreement went into effect, *id.* ¶ 74. Based on these allegations, along with their executive positions within the company, Lento and Schwartz were either aware that their statements attributing successful Abstral sales to legitimate practices were false, or they were reckless in disregarding the risk that they were misleading the public through these statements.

3. Loss Causation

Plaintiffs assert a “materialization of the risk” theory to support their claims. Pl. Opp'n at 40. Loss causation requires “a causal connection between the material misrepresentation and the loss.” *McCabe v. Ernst & Young, LLP.*, 494 F.3d 418, 424 (3d Cir. 2007) (quoting *Dura Pharms., Inc.*, 544 U.S. at 341-42). Specifically, the “loss causation inquiry asks whether the misrepresentation or omission proximately caused the economic loss.” *Id.* at 426 (citing *Semerenko v. Cendant Corp.*, 223 F.3d 165, 185-87 (3d Cir. 2000)). Plaintiffs can utilize the “materialization of the risk” approach to demonstrate when a misrepresentation or omission “proximately causes” the economic loss in the context of an undisclosed risk. *Id.* Under the “materialization of the risk” approach, Plaintiffs must prove that “the materialization of the undisclosed risk caused the alleged loss.” *McCabe*, 494 F.3d at 429 (quoting Dane A. Holbrook,

Measuring & Limiting Recovery Under Rule 10b-5: Optimizing Loss Causation and Damages in Securities Fraud Litigation, 39 Tex. J. Bus. L. 215, 260-62 (2003)).

The SAC alleges that the undisclosed risks in the pre-August 6, 2015 statements were that Abstral sales were unsustainable and that Galena's illegal conduct exposed the company to litigation and/or liability. SAC ¶¶ 95, 98, 101. The alleged undisclosed risk in the August 6, 2015 statements was that Abstral sales would drop off dramatically because Drs. Couch and Ruan's business had been closed and Galena could not otherwise makeup the lost sales. SAC ¶ 104.

Plaintiffs allege that Galena made a series of "partially corrective statements," beginning on August 6, 2015, with statements about the Company's lower earnings and expectations. *Id.* ¶ 104. According to Plaintiffs, these statements "revealed the materialized risk that Abstral sales would drop off when the . . . illegal prescriptions for Abstral written by Galena's top two prescribers could not be sustained." *Id.* Following this disclosure, Galena's stock fell 7.4% from its closing price on August 6, 2015 to its closing price on August 7, 2015, and Plaintiffs allege that the price would have dropped more had the full truth been revealed. *Id.* Second, on November 9, 2015, Galena announced its decision to divest its commercial business. *Id.* ¶ 105. The SAC alleges that this disclosure "revealed the risk . . . that the commercial operations of Galena could not be sustained without" Drs. Ruan and Couch's illegal prescriptions. *Id.* ¶ 106. Following this news, Galena's price dropped 11%. *Id.* Plaintiffs allege that the November 9, 2015 statements were only partially corrective because "they did not disclose the underlying causes of the risks that materialized and thus concealed Galena's potential civil and criminal exposure." *Id.* The third partial disclosure was made on December 22, 2015 when the Company announced that it received a subpoena in connection with Abstral sales. *Id.* ¶ 108. The SAC alleges that this disclosure was only partially corrective because it did not also reveal that Abstral's top two prescribers had their

practices shut down and were under investigation, and that Galena employees were providing kickbacks to these doctors. *Id.* ¶ 109. Galena stock fell 3.6% following this disclosure. *Id.* Fourth, on March 10, 2016, Galena disclosed that its top two prescribing doctors were criminally charged, that Galena received a subpoena for documents in connection with the investigation, and that the federal government may be investigating the company's Abstral promotional practices. *Id.* ¶ 110. Following this disclosure, Galena stock fell 3.3%. *Id.* ¶ 111. Plaintiffs allege that this was only a partial disclosure and, had the full truth been revealed, the stock would have dropped more. *Id.* The fifth partial disclosure occurred on May 10, 2016, in statements included in the Company's Form 10-Q. *Id.* ¶ 112. In it, Galena disclosed that a second superseding indictment was filed in the criminal case against the doctors, which added information about the rebate agreement. *Id.* ¶ 113. The statements also revealed that the FDA and other governmental agencies may be investigating Galena's Abstral promotion practices. *Id.* The stock fell 7.2% following this disclosure. *Id.* The final partial disclosure occurred on January 9, 2017 in a Form 8-K when Galena revealed that the Company and one or more of its current or former employees were under criminal investigation. *Id.* ¶¶ 114-115. The stock price fell 1.9%. *Id.* ¶ 115.

The Class Period closes on January 31, 2017. On that date, Galena announced Schwartz's resignation as President, CEO, and a member of the Board of Directors. *Id.* ¶ 116. The Company filed a Form 8-K that same day, which indicated Schwartz's resignation was without "good reason." *Id.* ¶ 117. Plaintiffs allege that business and financial writers associated Schwartz's departure with the pending criminal investigation into Galena's Abstral promotional practices. *Id.* ¶¶ 118-119. The SAC alleges that this disclosure, coupled with the other partially corrective disclosures, "sufficiently revealed the material risks that had been concealed by Defendants during the Class Period." *Id.* ¶ 120. Following the announcement, Galena's stock price fell 22.4%. *Id.*

First, for the same reasons expressed in the Prior Opinion, the Court finds that Plaintiffs have adequately pled loss causation through a materialization of the risk approach for the August 6, 2015 statements, but only insofar as the November 9, 2015 announcement that Galena was divesting its commercial business. Prior Opinion at 40. According to the SAC, the undisclosed risk inherent in the August 6, 2015 misrepresentations was that Abstral sales would drop precipitously once Drs. Ruan and Couch were no longer prescribing the drug. SAC ¶ 104. Like the FAC, the SAC fails to adequately allege how this risk was not fully materialized once Galena divested itself of Abstral. Prior Opinion at 40, n.21. Once Galena divested itself of the drug, its sales were going to drop to 0%.¹⁰

Second, as for the second undisclosed risk alleged with respect to the pre-August 6, 2015 statements – that Galena’s illegal conduct exposed the company to litigation and/or liability – the Court finds that the SAC fails to adequately allege when the risk was fully materialized. The SAC cites January 31, 2017 as the relevant date and the announcement of Schwartz’s resignation as the relevant event. SAC ¶¶ 116-120. But when Schwarz resigned, he did not indicate that he had engaged in any wrongdoing, and Plaintiffs have not cited any authority to support their argument that this event would qualify as a materialization of the risk. In short, Plaintiffs have failed to adequately allege that the risk of Galena’s liability was fully materialized on that date.

¹⁰ Relatedly, the purported Class Period’s starting date is deficient as to these statements. It appears that the Class Period for these misstatements would begin when the alleged misstatements were made, that is, August 6, 2015. The Court can also envision allegations that support an earlier date but certainly no earlier than the date that the physicians’ business was shut down. Of course, to sustain an earlier date, Plaintiffs would have to sufficiently allege what Defendants knew and when they knew it, along with a duty to disclose.

4. Control Person Liability

Plaintiffs' second claim alleges a violation of Section 20(a) of the Exchange Act against Defendant Schwartz. SAC ¶¶ 148-151. For the same reasons expressed in the Prior Opinion, Plaintiffs' Section 20(a) claim is dismissed. Prior Opinion at 40-41.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motion to dismiss Plaintiffs' SAC, D.E. 90. The dismissal is without prejudice and Plaintiffs will have *one* additional opportunity to plead their claims. The Court is reluctant to grant Plaintiffs an additional opportunity because Plaintiffs are represented by experienced counsel and because the Court took pains to detail the shortcomings of Plaintiffs' pleading in the Prior Opinion. Plaintiffs shall have thirty (30) days to file a third amended complaint, which cures the deficiencies noted herein. If Plaintiffs do not do so, this matter will be dismissed with prejudice. An appropriate Order accompanies this Opinion.

Dated: January 5, 2021


John Michael Vazquez, U.S.D.J.