

**Not for Publication**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.**

This putative class action concerns allegations of securities fraud. D.E. 58. Plaintiffs assert that Galena Biopharma, Inc. (“Galena”) and several 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. D.E. 58. Currently pending before the Court is Defendants’ motion to dismiss Plaintiffs’ First Amended Class Action Complaint (“FAC”) for failure to state a claim pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), as well as the Private Securities Litigation Reform Act of 1995 (“PSLRA”), 15 U.S.C. § 78u *et seq.* D.E. 62. The Court reviewed the parties’ submissions in support and in opposition<sup>1</sup> and decided the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons stated below, Defendants’ motion to dismiss is granted.

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<sup>1</sup> Defendants’ moving brief will be referred to as “Def. Br.,” D.E. 62-1; Plaintiffs’ opposition will be referred to as “Pl. Opp’n,” D.E. 65; and Defendants’ reply will be referred to as “Def. Reply,” D.E. 66.

## I. INTRODUCTION<sup>2</sup>

### A. Background

Plaintiffs are persons and entities that purchased Galena common stock from August 11, 2014 through January 31, 2017 (the “Class Period”). FAC ¶ 1. Defendant Galena is a biopharmaceutical company that develops hematology and oncology therapeutics. *Id.* ¶ 2. Defendant Mark J. Ahn was the President, CEO, and Director of Galena until August 20, 2014. *Id.* ¶ 40. Defendant Mark W. Schwartz was the COO of Galena from 2011 to August 20, 2014, and then President and CEO of Galena from August 20, 2014 through the end of the Class Period. *Id.* ¶¶ 41, 130. Defendant Ryan M. Dunlap was the Vice President and CFO of Galena during the Class Period until December 31, 2015. *Id.* ¶ 43. Defendant Christopher S. Lento was the Senior Vice President of Oncology Commercial Operations at Galena from May 2013 through December 31, 2014. *Id.* ¶ 43. Defendant Remy Bernarda was the Senior Vice President of Investor Relations at Galena throughout the Class Period. *Id.* ¶ 44.

In March 18, 2013, Galena acquired the commercial product Abstral (fentanyl) Sublingual Tablets (“Abstral”) and announced the product’s launch on October 23, 2013. *Id.* ¶¶ 2-3. Abstral is a powerful opioid narcotic approved by the U.S. Food and Drug Administration (“FDA”) as “a sublingual (under the tongue) tablet for the management of breakthrough pain in patients with cancer, 18 years of age or older, who are already receiving, and who are tolerant to, opioid therapy for their persistent baseline cancer pain.” *Id.* ¶¶ 4, 51, 58. This is the only FDA-indicated use for

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<sup>2</sup> The facts are derived from Plaintiffs’ FAC. D.E. 58. When reviewing a motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Additionally, a district court may consider “exhibits attached to the complaint and matters of public record” as well as “an 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.” *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

Abstral; using the drug for other indications is considered off-label. *Id.* ¶¶ 51, 56. While physicians are permitted to prescribe a medication for a legitimate medical off-label purpose, it is illegal for drug companies to promote a product for off-label use. *Id.* ¶ 59.

Abstral is made from fentanyl, which is reportedly 50 times more potent than heroin and up to 100 times stronger than morphine, making it the most powerful opioid pain medication available. *Id.* ¶ 48. As a result, Abstral users face a high risk of addiction and dependence. *Id.* ¶ 48. Abstral is subject to the FDA's TIRF-REMS<sup>3</sup> Access Program, which is designed to "mitigate the risks of misuse, abuse, addiction, [and] overdose" for certain "highly addictive and dangerous" TIRF medications. *Id.* ¶¶ 60-61. Federal law also has anti-kickback provisions that apply to federal healthcare programs, as well as the Sunshine Act, which requires pharmaceutical companies to disclose "transfers of value" to physicians. *Id.* ¶¶ 62-65.

During the Class Period, Abstral was the only commercial product sold by Galena. *Id.* ¶ 6. In July 2014, Galena also acquired Zuplenz, a medication used to treat nausea and vomiting, primarily for persons undergoing chemotherapy. *Id.* However, during the Class Period, Galena did not have any sales of Zuplenz. *Id.*

On March 3, 2014, Galena announced Galena Patient Services ("GPS"). *Id.* ¶ 52. GPS was designed to enhance access to Abstral by helping patients with the health benefits investigation and prior authorization processes, the appeals and denials processes, and locating a pharmacy. *Id.* Galena also kept an internal document, which it circulated on a quarterly basis, that tracked all of the Abstral prescribers in the country along with the amount each prescribed. *Id.* ¶ 84, Ex. 1.

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<sup>3</sup> TIRF-REMS is an acronym for the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy Program.

Plaintiffs allege that two physicians – Drs. Xiulu Ruan and Patrick Couch – accounted for more than 30% of Galena’s Abstral revenues. *Id.* ¶ 66. Both doctors figure prominently in Plaintiffs’ case. Drs. Ruan and Couch owned two pain management clinics, as well as a pharmacy attached to one of the clinics, in Alabama. *Id.* ¶ 67. From the third quarter of 2013 through at least the end of 2014, the doctors were the number one and two prescribers of Abstral in the United States. *Id.* ¶ 71. Dr. Rho, a “good friend” of Ruan, accounted for another 10% of Abstral revenues. *Id.* ¶¶ 66 n. 3, 84.

In October 2013 emails between Lento and Dr. Ruan, on which Schwartz was copied, Lento encouraged Ruan to enroll patient’s in Galena’s “RELIEF” program. *Id.* ¶ 85. The RELIEF program tracked how Abstral patients were doing with the drug but also paid doctors \$500 for every patient who enrolled. *Id.* Ruan responded that he did not think that he was eligible because he did not treat many cancer patients, but Lento explained that the RELIEF program was open to cancer and non-cancer patients. *Id.* The two pain management clinics did not treat many cancer patients. *Id.* ¶ 86.

Executives and representatives from Galena frequently visited the two physicians at one of the clinics. *Id.* ¶ 87. Schwartz and Lento frequently communicated with Drs. Ruan and Couch and also visited the doctors in person. *Id.* Schwartz made at least two trips to the clinic, in November 2014 and February 2015, because Ruan demanded the meetings. *Id.* ¶ 89. Schwartz also directed other high-level Galena employees to visit the physicians regularly. *Id.* ¶ 90.

In 2014, Galena and the doctors’ pharmacy entered into a marketing services agreement also known as a rebate agreement. *Id.* ¶ 94. Schwartz signed on behalf of Galena. *Id.* The agreement paid the pharmacy between 8.75 and 20% for each Abstral prescription the pharmacy filled. *Id.* An Abstral prescription ranged from several thousand dollars up to approximately

\$10,000. *Id.* After the rebate agreement took effect, the number of Abstral prescriptions written by the two physicians increased. *Id.* ¶ 95. In February 2015, Galena wired \$97,924 to the pharmacy's bank account; Plaintiff contends that the payment was made pursuant to the rebate agreement. *Id.* Galena also had rebate agreements with several oncology dispensing clinics, as well as two non-oncology dispensing clinics. *Id.* ¶ 97.

Beginning in November 2013, Ruan and Couch also bought more than \$1.6 million in Galena stock and "sought to manipulate the stock price by driving up Abstral sales." *Id.* ¶¶ 71, 99. In February 2014, Lento met with the physicians in Alabama because the doctors were upset that Galena's stock price dropped due to stock sales by corporate insiders. *Id.* ¶ 88. Ruan and Couch demanded that Galena fire its board of directors and its CEO. *Id.* ¶¶ 88, 109. In March 2014, Ruan emailed Bernarda, copying Lento, requesting a chance to speak with Galena's board. *Id.* ¶ 106. Ruan explained that he, Couch, and Rho were not only Galena shareholders "but also your clients and customers to some extent." *Id.* Bernarda responded that the doctors could speak with a board member and that Bernarda would participate by phone. *Id.* ¶ 107. Ruan explained to Rho that he wanted to push Galena to replace the CEO and indirectly communicate that the physicians were willing to switch to other companies and products because they represented a significant portion of Galena's business. *Id.* ¶ 108. Ahn, Galena's then-CEO, was ultimately fired. *Id.* ¶ 88.

Galena also offered for the physicians to attend advisory board meetings. *Id.* ¶ 98. Couch attended at least one meeting and was reportedly paid \$5,000 for his attendance plus expenses; Ruan declined in January 2014 because he did not want to learn inside information that could prevent him from trading his stock. *Id.* ¶¶ 98, 101. In February 2014, Ruan indicated to Couch that he (Ruan) planned to hold his Galena stock for at least three quarters because he and Couch

could “play a big role” in Abstral. *Id.* ¶ 103. Both doctors put more patients on Abstral after buying Galena stock. *Id.* ¶ 105.

The FAC also relies on confidential witnesses (“CW”). CW1 was a Territory Business Manager for Galena from August 2013 to December 2014. *Id.* ¶ 76. CW1 indicates that he was pushed to see pain specialists, rather than oncologists, and that CW1 felt that this amounted to impermissible off-label marketing. *Id.* CW2, who was also a Territory Business Manager from April 2014 to April 2015, worked in Ohio, Indiana, and Kentucky. *Id.* ¶ 77. CW2 was let go for not meeting his/her sales quota, but states that oncologists did not have many pain patients and hospices would not prescribe Abstral due to cost. *Id.*

CW3, another Territory Business Manager from August 2014 through August 2015, states that Galena pushed its sales force to market to non-oncologists. *Id.* ¶ 78. CW3 provided a February 5, 2015 email from David Corin, Galena’s National Sales Director, which copied Lento. *Id.* ¶ 79. The email referred to lower Abstral sales in January 2015, and instructed the recipients to remedy the situation. *Id.* A spreadsheet attached to the email showed Dr. Ruan and Dr. Couch as to the two highest prescribers in the country from the fourth quarter 2013 through the fourth quarter 2014. *Id.* CW3 continues that Galena circulated Risk Evaluation and Mitigation Strategy (“REMS”) reports, which contained information concerning prescribers of Subsys. *Id.* ¶ 80. Subsys was another fentanyl drug with a limited indication and owned by Insys. *Id.* ¶¶ 70, 84.<sup>4</sup> CW3 was instructed to visit those physicians to “chase those prescriptions” even though Galena knew that Insys “was openly buying pain doctors[.]” *Id.* Following another Corin email on July 20, 2015, on which Lento was again copied, CW3 decided to leave Galena. *Id.* ¶ 81. The email

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<sup>4</sup> Galena’s internal document, which tracked prescribers of Abstral, also tracked whether those prescribers received payments from Insys. *Id.* ¶ 84.

concerned disappointing July 2015 sales figures, and CW3 informed Galena's human resources in an exit interview that CW3 had been encouraged to "get prescriptions off label." *Id.* ¶¶ 81-82.

### **B. Public Disclosures**

The Class Period begins on August 11, 2014, and Plaintiffs allege that Defendants made severally materially false or misleading statements that day in a press release, a Form 10-Q filing, and an earnings call. *Id.* ¶¶ 128-29. Specifically, Plaintiffs claim that statements concerning net sales and revenues were actionable because they failed to disclose that (1) the results were achieved through illegal off-label marketing and kickbacks, and that (2) 30% of all Abstral sales came from doctors who overprescribed in order to earn kickbacks and manipulate the company's stock.<sup>5</sup> *Id.* ¶ 129. Plaintiffs add that Defendants improperly attributed Galena's growth in market share to implementation of GPS, to ensuring insurance coverage, and to customers' "belief in the unique benefits of Abstral." *Id.*

On September 25, 2014, Galena held a press conference during which Schwartz spoke with Bernarda and Dunlap in attendance. *Id.* ¶ 131. Plaintiffs argue that Schwartz made materially false or misleading statements when he claimed that Galena primarily targeted oncology practices. *Id.* ¶ 132. Plaintiffs next assert that on November 3 and 4, 2014, materially false or misleading statements were made in a Galena press release, and by Lento and Schwartz. *Id.* ¶¶ 133-34. In support, Plaintiffs point to statements concerning Abstral's sales to "appropriately indicated patients," that Galena sales were focusing on "oncology focused providers," and that Galena's sales strategy was ensuring "long-term viability and profitability." *Id.* ¶ 134.

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<sup>5</sup> These allegations – that Defendants made materially false or misleading statements because they failed to disclose illegal kickbacks and off-label promotion, as well as the roles of Drs. Ruan and Couch – are repeated by Plaintiffs throughout the FAC in some variation or form. As a result, the Court does not recite the allegations in connection with each allegedly false or actionable statement.

Plaintiffs similarly point to Schwartz and Lento's statements, along with a Form 10-K and press release, on March 5, 2015. *Id.* ¶¶ 135-36. Plaintiffs list statements attributing Galena's revenues to "Galena's commercial business within the oncology space" and that providers were becoming more comfortable "prescribing Abstral for their breakthrough cancer pain patients." *Id.* ¶ 136. Plaintiffs continue that the Form 10-K's "Risk Factors" were deficient although they disclosed that a company could not improperly promote off-label uses (or face substantial monetary penalties and prosecution) and that Galena could be adversely affected if it did not "achieve and maintain regulatory compliance[.]" *Id.* ¶ 137. Plaintiffs say that the Risk Factors failed to disclose that Galena was actively promoting Abstral for off-label uses and also paying kickbacks. *Id.* Plaintiffs likewise maintain that the May 7, 2015 statements (in a press release, in a Form 10-Q, by Lento, and by Schwartz) were materially false or misleading because they attributed revenues to prescriptions for "oncology" and noted Abstral's sales to "medical oncologists, radiation oncologists," palliative care specialists, or "pain specialists who are treating a large number of cancer patients." *Id.* ¶¶ 139-40. Plaintiffs also make the same criticisms of the Form 10-Q's Risk Factors as those attributed to the Risk Factors in the March 2015 Form 10-K. *Id.* ¶¶ 142-43.

Drs. Ruan and Couch's clinics were raided by federal law enforcement on May 20, 2015, which led to criminal charges and a trial. *Id.* ¶¶ 68-69, 144. The clinics were shut down on the same day as the raid. *Id.* ¶¶ 119, 144. During the trial, evidence showed that Drs. Ruan and Couch prescribed Abstral and Subsys almost exclusively for neck, back, and joint pain. *Id.* ¶ 70. The physicians were ultimately convicted of numerous criminal offenses.<sup>6</sup> *Id.* ¶ 72. As a result of the

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<sup>6</sup> On May 26, 2017, Ruan and Couch were sentenced to 252 months and 240 months, respectively. *Id.* ¶ 199. Defendants indicate that the physicians' criminal trial focused on their relationship with Insys. Defendants continue that only one count concerned Galena and that this count was



clinics being shut down in May 2015, Galena's Abstral revenues dropped significantly and could not be made up from another source or sources. *Id.* ¶ 119.

On August 6, 2015, Plaintiffs allege that Galena, in a Form 10-Q and press release, along with Schwartz and Lento, made materially false or misleading statements. *Id.* ¶¶ 147. Because Galena lost 30% of its revenue sources as a result of the clinics being shut down, Plaintiffs argue that Defendants falsely asserted that Abstral's "underlying metrics were all trending upwards" or in the "right direction" and the Abstral business "is growing[.]" *Id.* ¶ 146. Plaintiffs add that Defendants were misleading when they attributed lower earnings to "ongoing market dynamics[.]" *Id.* The Form 10-K acknowledged that Galena may not be able "to achieve profitability with our commercial operations[.]" *Id.* ¶ 147. The 10-Q continued that strategic changes may be necessary, including "increased investment in our commercial operations, significant expansion or reduction to our sale[s] force, acquisition of additional commercial products, or partial or full divestiture of our commercial products and operations." *Id.* The 10-Q concluded that any "significant change" to Galena's commercial strategy could "materially affect" future revenues, future costs incurred, and financial results. *Id.* Following the release of the public information, Galena's stock price fell 7.4% to \$1.63 on August 6, 2015. *Id.* ¶ 148. Plaintiffs contends that the 10-Q revelations were only "partially corrective," and that the stock price would have fallen further if full disclosure had been made. *Id.*

On November 9, 2015, Schwartz said in a press release that Galena was divesting its commercial business and instead focusing exclusively on clinical development programs. *Id.* ¶ 149. Plaintiffs assert that Defendants' press release concealed the "true reasons" for discontinuing

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ultimately dismissed. If Defendants' position is accurate, then the Court finds the FAC to be misleading in that it gives the strong impression that Drs. Ruan and Couch's criminal charges and convictions related to their activity with Galena.

commercial operations, that is the shut-down of the Alabama clinics, as opposed to the stated “careful examination” of “operations and assets to determine the optimal strategy” for the company. *Id.* ¶ 150. That same day, Galena’s Form 10-Q indicated that the carrying value of the commercial business asset exceeded its fair value resulting in a \$8.1 million impairment charge as of September 30, 2015. *Id.* ¶ 151. On November 10, 2015, Galena’s stock price fell 11% to close at \$1.53. *Id.* ¶ 152. Plaintiffs, again, maintain that the November 9 information was “only partially corrective[.]” *Id.*

On November 20, 2015, Galena announced that it had sold its Abstral product to a private company for up to \$12 million. *Id.* ¶ 153. The company was to be paid \$8 million in cash up-front, with up to an additional \$4 million if certain sales milestones were met. *Id.* Plaintiffs do not indicate how, if at all, this news affected Galena’s stock price.

### **C. Additional Public Disclosures**

On December 11, 2015, Galena announced that Dunlap was leaving effective December 31, 2015 because he was unable to relocate to the company’s new headquarters. *Id.* ¶ 154. That day, Galena’s stock price fell 4.5% to close at \$1.49 per share. *Id.* ¶ 155.

On December 22, 2015, Galena announced in a press release that it had received a subpoena, from the United States Attorney’s Office for the District of New Jersey (“DNJ”), as to the company’s Abstral marketing and promotional practices. *Id.* ¶ 156. Plaintiffs’ state that the release was materially misleading because it concealed Galena’s level of exposure based on, among other things, off-label promotion; kickback payments; Drs. Ruan, Couch, and Rho’s intention to manipulate the company’s stock; and Galena’s efforts to have physicians “excessively prescribe Abstral for non-medical purposes[.]” *Id.* ¶ 157. Upon the disclosure, Galena’s stock dropped 3.6% to close at \$1.57 on December 23, 2015. *Id.* ¶ 158.

In a March 10, 2016 Form 10-K/A, the Risk Factors again disclosed the DNJ subpoena, noting that Galena could face substantial penalties if it had not complied with the law. *Id.* ¶ 159. The disclosure also referenced the False Claims Act, the Anti-Kickback Statute, and the Sunshine Act. *Id.* The filing further referenced the federal investigation of Drs. Ruan and Couch (“two of the high-prescribing physicians for Abstral”), noting that the company had received subpoenas for documents in the upcoming criminal trial. *Id.* The company’s stock then fell 3.3% to \$.86, although Plaintiffs assert that Defendants again concealed the true level of exposure faced by Galena. *Id.* ¶¶ 160-61. A May 10, 2016 Form 10-Q filing revealed similar information as that disclosed on March 10, 2016. *Id.* ¶ 162. The new filing added that the two physicians had been subject to a second superseding indictment that added information about Galena’s rebate agreement with the doctors and the physicians’ ownership of company stock. *Id.* Galena’s stock again fell, by 7.2%, to close at \$1.38 on May 11, 2016, and Plaintiffs again allege that the disclosure was materially misleading by omitting certain information. *Id.* ¶¶ 163-64.

On August 9, 2016, the company’s Form 10-Q filing indicated that “[w]e are, and in the future may be subject to legal or administrative actions that could adversely affect our financial condition and our business.” *Id.* ¶ 165. The filing added that Galena was cooperating with the DNJ “in the production of requested documents[.]” *Id.* Plaintiffs do not indicate what, if any, impact the disclosure had on the company’s stock value, but they do allege that the disclosure was deficient. *Id.* ¶¶ 167-68.

In a Form 8-K filing on January 9, 2017, Galena revealed that the Department of Justice (“DOJ”) was working with the DNJ and that the investigations were both criminal and civil in nature. *Id.* ¶ 169. Galena noted that the investigations “could ultimately involve the Company as well as one or more current and/or former employees.” *Id.* Galena also updated the Risk Factors

from its Form 10-K for the period ending December 31, 2015. *Id.* Plaintiffs allege that the disclosure was insufficient. *Id.* ¶ 170. Following the filing, Galena's stock price fell 1.9% to close at \$2.03 on January 9, 2017. *Id.* ¶ 171.

On January 31, 2017, Galena announced that Schwartz was resigning as President, CEO, and member of the board of directors. *Id.* ¶ 195. Business and financial writers commented on the timing of the resignation in light of the January 9 filing revealing the criminal investigation. *Id.* ¶¶ 196-97. Following the news, Galena's stock price fell 22.4% to close at \$1.28 on February 1, 2017, and an additional 12.5% the following day. *Id.* ¶ 198.

In September 2017, Galena settled the DOJ and the DNJ investigation for \$7.55 million. *Id.* ¶ 73. A September 8, 2017 press release from the DOJ indicated that the allegations concerned Galena paying kickbacks to physicians, in violation of the False Claims Act, to induce the doctors to prescribe Abstral. *Id.* The kickbacks were alleged to be in the form of (1) 85 free meals to doctors and staff at one practice, (2) paying physicians between \$5,000 and \$6,000 to attend an advisory board that was run in part by Galena's sales team, (3) paying \$92,000 to a physician-owned pharmacy in a rebate program, and (4) improperly using Galena's RELIEF program. *Id.* The release also referred to the prosecution and convictions of Drs. Ruan and Couch. *Id.* This release, however, is not within the Class Period. Plaintiffs do not indicate how, if at all, Galena's stock price was affected by the DOJ press release.

#### **D. Item 303 of Regulation S-K**

The Securities and Exchange Commission's ("SEC") Regulation S-K contains Item 303, which requires a company to disclose certain information in its Form 10-Q and Form 10-K filings. *Id.* ¶ 172. As to the 10-K, Item 303(a) requires a registrant to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable

or unfavorable impact on net sales or revenues or income from continuing operations.” *Id.* ¶ 173. Plaintiffs also cite to an SEC amicus brief in a 2017 Supreme Court case. *Id.* ¶¶ 176-77. Plaintiffs point to the management discussion and analysis (“MD&A”) sections in numerous Galena filings: (1) the August 11, 2014 Form 10-Q, (2) the November 5, 2014 Form 10-Q, (3) the March 5, 2015 Form 10-K, (4) the May 7, 2015 Form 10-Q, and (5) the August 6, 2015 Form 10-Q. *Id.* ¶¶ 179-94. The gist of Plaintiffs’ arguments as to each is that they failed to disclose that Galena’s net sales and revenues were the result of off-label promotions and kickbacks as well as the 30% of revenues attributable to Drs. Ruan and Couch. *Id.* ¶¶ 181, 184, 187, 190, 193. The August 6, 2015 filing suffered from an additional infirmity, according to Plaintiffs-- the failure to disclose that the Alabama clinics had been shut down in May 2015. *Id.* ¶ 193.

#### **E. Motive**

Plaintiffs allege that Defendants used Galena’s artificially inflated stock to finance operations. On November 18, 2014, Galena entered into a purchase agreement which led to Galena ultimately receiving a total of \$13.4 million for common stock. *Id.* ¶ 201. At the end of 2014 and 2015, Galena received a total of \$2.3 million by way of at market issuance sales agreements. *Id.* ¶ 202. In March 2015, Galena sold units of common stock and warrants for \$40.8 million. *Id.* ¶ 203.

#### **F. Procedural History**

Plaintiffs filed their Complaint on February 13, 2017. D.E. 1. Plaintiffs then filed an Amended Complaint on October 6, 2017, alleging two counts: (I) violation of Item 303 of Regulation S-K, or alternatively, Section 10(b) of the Exchange Act and Rule 10b-5; and (II) violations of Section 20(a) of the Exchange Act by Defendants Ahn, Schwartz, and Dunlap. D.E. 40 ¶¶ 202-216. Judge McNulty dismissed the Complaint without prejudice on August 21, 2018,

finding that Plaintiffs (1) do not have a private right of action under Item 303 pursuant to *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000); (2) failed to articulate clear theories of securities fraud liability; and (3) failed to plead fraud on a statement-by-statement basis as required by the PSLRA. D.E. 56 (“Prior Op.”), 57.

Plaintiffs then filed their FAC.<sup>7</sup> D.E. 58. The FAC indicates that Plaintiffs are proceeding under a theory of presumption of reliance based on the fraud-on-the market doctrine. *Id.* ¶¶ 211-215. The FAC 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 Defendants Ahn, Schwartz, and Dunlap. Defendants again moved to dismiss, D.E. 62, which Plaintiffs opposed, D.E. 65, and to which Defendants replied, D.E. 66. The matter was then transferred to the undersigned. D.E. 74.

## II. LEGAL STANDARD

### Rule 12(b)(6)

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a count for “failure to state a claim upon which relief can be granted[.]” 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

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<sup>7</sup> Technically, the FAC is Plaintiff’s Second Amended Complaint. However, because it is entitled “First Amended” Complaint and because the parties refer to it as such, the Court uses the same terminology here. It appears that Plaintiffs considered the Amended Complaint to be a “consolidated” pleading. D.E. 40.

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.*, No. 10-2945, 2010 WL 5146765, at \*1 (D.N.J. Dec. 13, 2010).

#### Rule 9(b)

Federal Rule of Civil Procedure 9(b) imposes additional pleading requirements. “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).

### 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).” *Id.* 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 Fed. R. Civ. P. 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 is one conclusion 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.*

These pleading requirements apply whether the alleged fraudulent statement at issue is an assertion of current fact or a prediction of the future. *Avaya*, 564 F.3d at 253-54. However, when an allegation involves a prediction, the Safe Harbor Provision of the PSLRA immunizes any forward-looking statement from liability, provided that “the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood.” *Id.* at 254; *see* 15 U.S.C. § 78u-5(c).

### III. ANALYSIS

As a preliminary matter, the Court notes that Galena is a relatively small public company that had one commercial product: Abstral.<sup>8</sup> Approximately 30% of all Abstral prescriptions originated from Drs. Ruan and Couch – who were shut down during the Class Period and ultimately sentenced to prison. This matter is not a securities fraud action against a larger public company with various commercial product lines and significantly greater insulation between the top-level executives and day-to-day marketing decisions regarding any specific product.

In addition, Plaintiffs allegations all relate to Abstral. As noted, Galena sold Abstral to a third party in November 2015. In the Court’s view, and as will be explained, Plaintiffs fail to sufficiently plead any improper conduct following Galena’s divestment of the drug. As to allegations of wrongdoing before November 2015, Plaintiffs make allegations that could potentially support a viable cause of action, that is, statements after Drs. Ruan and Couch’s

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<sup>8</sup> As noted, during the Class Period, Galena acquired a second commercial product, Zuplenz, but never realized any sales or revenues from this product during the relevant period.

businesses were raided by the FBI. The Court, however, cannot sustain the FAC for the reasons that follow. The Court permits Plaintiffs an additional opportunity to re-plead consistent with the following analysis.<sup>9</sup>

Plaintiffs first allege a violation of Section 10(b) and Rule 10b-5. The Third Circuit has described such a claim in the following terms:

Section 10(b) of the Exchange Act prohibits the “use or employ[ment], in connection with the purchase or sale of any security . . . [, of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe.” 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements this provision by making it unlawful to, among other things, “make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5(b). The Supreme Court has implied a private cause of action from the text and purpose of [S]ection 10(b). *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 36-37, 131 S. Ct. 1309, 1317, 179 L. Ed. 2d 398 (2011). To state a claim for securities fraud, 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.” *Id.* at 1317-18; *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010).

*City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014).

Among other things, Defendants argue that Plaintiffs fail to sufficiently plead any material misrepresentation or omission. Def. Br. at 11-29. As to this first element, Plaintiffs must “identify a false representation of material fact or omission that makes a disclosed statement materially

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<sup>9</sup> The Court also notes that the proposed Class Period does not end on either of the two seemingly important events: (1) Galena’s November 9, 2015 announcement that it was selling its commercial business (or its November 20, 2015 announcement that it had sold Abstral); or (2) Galena’s September 2017 announcement that it settled the DOJ and DNJ investigation. The second event also suffers from the infirmity that Plaintiffs have not sufficiently alleged any wrongful conduct following Galena’s November 2015 announcements.

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)). “However, 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. *City of Edinburgh Council*, 754 F.3d at 168-69 (citing *Burlington Coat Factory*, 114 F.3d at 1426; *Tellabs*, 551 U.S. at 322). Given the quantity and variety of alleged improprieties in this case, the Court first addresses the areas in which the FAC falls short.

#### **A. Deficiencies in the FAC**

The FAC suffers from several pleading shortcomings which fall generally into the following areas: (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. The Court reviews each in turn. To be clear, the Court is not prohibiting Plaintiffs from reasserting the foregoing items in an amended complaint, provided that Plaintiffs can cure the deficiencies noted herein. At the same time, if Plaintiffs file an amended pleading that again takes a scattershot approach consisting of an amalgamation of allegations, the entire pleading may be construed as defective.

##### **1. Allegations not Linked to Any Alleged Material Misstatement or Omission**

The FAC makes several allegations of misfeasance that are seemingly untethered to any particular material misstatement or omission. While such allegations, if true, could potentially be

relevant to scienter, they cannot provide a basis for a Section 10(b) violation as pled. As to Drs. Ruan and Couch, the FAC alleges that in October 2013 emails, Ruan was encouraged to enroll in Galena's RELIEF program. But the FAC never indicates that Ruan actually joined the program. Similarly, the FAC claims that both physicians were substantial shareholders of Galena and sought "to manipulate the stock." FAC ¶ 71. Again, the FAC fails to sufficiently allege what the illicit stock scheme consisted of. The FAC indicates that after both doctors became shareholders, they prescribed Abstral to more patients, but the FAC fails to indicate whether there was a material increase to the overall prescriptions written by the two. The FAC further indicates that Ruan did not want to learn inside information so that he would not be restricted from selling his stock. Yet, the FAC does not indicate how such conduct is illegal or improper. To the contrary, such action could reasonably be inferred to be completely appropriate.

## **2. Disclosures Concerning the Government Investigation of Galena**

Plaintiffs assert that Defendants made material misrepresentations in omitting information about the government investigation into Galena. Pl. Opp'n at 19-22. As noted, these disclosures occurred after Galena announced in November 2015 that it sold Abstral to another entity. As to Galena's public disclosures of the DOJ and DNJ investigation, Plaintiffs essentially contend that Galena's releases were misleading because the company did not disclose the full extent of its illegal conduct. In other words, Plaintiffs appear to argue that disclosing the existence of a government investigation or subpoena is insufficient. Instead, Plaintiffs seem to contend that a company must also make a complete *mea culpa* when disclosing the investigation and its potential legal implications. Such a position does not find support in the law.

The Second Circuit addressed the precise issue as follows:

As we have explained, "[d]isclosure is not a rite of confession," [*In re Morgan Stanley Tech. Funds Secs. Litig.*, 592 F.3d 347, 365 (2d

Cir. 2010),] and companies do not have a duty “to disclose uncharged, unadjudicated wrongdoing.” [*Ciresi v. Citicorp*, 782 F. Supp. 819, 823 (S.D.N.Y. 1991), *aff’d without opinion*, 956 F.2d 1161 (2d Cir. 1992).] By disclosing its involvement in multiple legal proceedings and government investigations and indicating that its involvement could expose UBS “to substantial monetary damages and legal defense costs,” as well as “injunctive relief, criminal and civil penalties[,] and the potential for regulatory restrictions,” UBS complied with its disclosure obligations under our case law.

*City of Pontiac Policemen’s & Firemen’s Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014). See also *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (“[T]he federal securities laws do not require a company to accuse itself of wrongdoing.”), *aff’d sub nom. Albert Fadem Tr. v. Citigroup, Inc.*, 165 F. App’x 928 (2d Cir. 2006); *cf. Ieradi v. Mylan Lab., Inc.*, 230 F.3d 594, 599-600 (3d Cir. 2000) (noting that a reasonable investor would want to know that the defendant company was subject to an FTC investigation but not the underlying specific facts that could lead to antitrust liability).

Plaintiffs do not claim that Defendants made a misrepresentation or actionable omission concerning the nature of the investigation itself nor as to the potential legal liability faced by Galena. Plaintiffs do contend, however, that Galena’s disclosures were misleading because they concealed the true extent of the company’s legal exposure in light of off-label promotion; kickback payments; Drs. Ruan, Couch, and Rho’s intention to manipulate the company’s stock; and Galena’s efforts to have physicians “excessively prescribe Abstral for non-medical purposes,” among other things. FAC ¶ 157; see also *id.* ¶¶ 160-61, 163-64, 167-68, 170. As noted, Plaintiffs’ theory is not supported by precedent. The law required Galena to disclose the investigation and its potential legal ramifications, which Galena appears to have done.

### 3. Item 303 Allegations

As noted, Plaintiffs originally asserted a claim based on a violation of Item 303 of Regulation S-K. Relying on *Oran*, 226 F.3d at 285-86, Judge McNulty ruled that Plaintiffs do not have a private right of action under Item 303. Prior Op. at 18-21. Yet, Judge McNulty indicated that a violation of Item 303 could give rise to a private cause of action if Plaintiffs demonstrated that Defendants had a separate duty to disclose. *Id.* at 19. Citing *Oran* and *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046 (9th Cir. 2014), Judge McNulty stated that “an omission in the context of Item 303 can give rise to a Rule 10b-5 claim *if the Item 303 omission renders other statements materially misleading.*” *Id.* at 20 (emphasis in original).

In the FAC, Plaintiffs attempted to meet this standard by citing to an SEC *amicus* brief. While the Court appreciates the creative advocacy displayed, Plaintiffs do not cite to an SEC regulation or even a no-action letter. More importantly, however, Plaintiffs do not plausibly indicate how the alleged Item 303 violations rendered other statements materially misleading. Instead, for the most part, Plaintiffs merely reiterate the same litany of allegations as to off-label promotions, kickbacks, and the large percentage of sales attributable to Drs. Ruan and Couch. *Id.* ¶¶ 181, 184, 187, 190, 193.

### 4. Statements by Particular Defendants

Group pleadings are not permissible. Mere “conclusory allegations against defendants as a group” which “fail[] to allege the personal involvement of any defendant” are insufficient to survive a motion to dismiss. *Galicki v. New Jersey*, No. 14-169, 2015 WL 3970297, at \*2 (D.N.J. June 29, 2015). A plaintiff must allege facts that “establish each individual [d]efendant’s liability for the misconduct alleged.” *Id.* When a number of defendants are named in a complaint, plaintiff cannot refer to all defendants “who occupied different positions and presumably had distinct roles

in the alleged misconduct” without specifying “which defendants engaged in what wrongful conduct.” *Falat v. County of Hunterdon*, No. 12-6804, 2013 WL 1163751, at \*3 (D.N.J. Mar. 19, 2013) (emphasis in original omitted). A complaint that contains “impermissibly vague group pleading” will be dismissed. *Id.* at \*11.

This prohibition on group pleading extends to the PSLRA, meaning that a plaintiff cannot simply “name corporate officers as individual defendants without pleading the particulars of the defendants’ respective participation in the preparation and dissemination of corporate statements.” *In re Bio-Tech. Gen. Corp. Sec. Litig.*, 380 F. Supp. 2d 574, 583-84 (D.N.J. 2005). Additionally, “the plain language of § 10(b) and corresponding Rule 10b-5 *do not* contemplate the general failure to rectify misstatements of others.” *United States v. Schiff*, 602 F.3d 152, 167 (3d Cir. 2010) (emphasis added). In other words, plaintiffs must allege a *specific statement by each individual defendant* that was (a) a misrepresentation, or (b) misleading because it omitted crucial information. *Id.* at 168 (noting that “the Government’s contention that [a defendant] ‘actually made the omissions’ by not rectifying [another]’s purported misstatements conflates the two independent grounds,” as “[the defendant] did not make those statements, [another person] did (and vice versa)”).

As to Defendant Ahn, he is alleged to have left Galena on August 20, 2014 - *nine* days after the beginning of the class period, August 11, 2014. Putting aside the implausibility of Ahn’s participation in the purported fraudulent scheme in light of the timing, he is alleged to have made one actionable statement. FAC ¶ 128. But such claim is not plausible in light of Plaintiffs’ other contentions, specifically that Dr. Ruan wanted Ahn replaced as CEO in 2014. Indeed, Plaintiffs



attribute Ahn's firing to Drs. Ruan and Couch. *Id.* ¶¶ 88, 110.<sup>10</sup> In other words, it is not reasonable to infer that Ahn was involved in an Abstral scheme involving the physicians, when the physicians wanted Ahn ousted.

Plaintiffs' allegations concerning Bernarda fair no better. First, the FAC makes numerous allegations that Bernarda was present when others made allegedly actionable statements or omissions. *See, e.g.*, FAC ¶¶ 128, 131. Yet, as noted, "the plain language of § 10(b) and corresponding Rule 10b-5 do not contemplate the general failure to rectify misstatements of others." *Schiff*, 602 F.3d at 167. Otherwise, the FAC indicates that Bernarda had email communications, in March 2014, with Ruan before the start of the Class Period concerning Ruan's request to speak with Galena's board. FAC ¶¶ 106-07. Similarly, the FAC references another email that Ruan sent Bernarda in April 2014. *Id.* ¶ 109. Such allegations are outside the relevant period and do not suggest any misstatement or omission, much less a public one. The remaining allegations as to Bernarda are, at best, sparse.

The Court reaches a similar result as to Dunlap. He is also said to have been in attendance when Schwartz allegedly made false or misleading statements, *see, e.g., id.* ¶ 131, but Dunlap is not liable based on his mere presence. The remaining allegations as to Dunlap are meager. *Id.* ¶¶ 128, 133, 135. The press releases which Dunlap signed indicate historically accurate financial information and a forward-looking statement that Galena "anticipate[s]" enhancing its relationship with the oncology community. *Id.* ¶¶ 133, 135, 139, 145.

As discussed below, however, Plaintiffs did make sufficient allegations concerning certain statements of Defendants Schwartz and Lento.

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<sup>10</sup> On the reason for Ahn's leaving, Plaintiffs are not consistent. Plaintiffs also attribute Ahn's resignation to his involvement in a prior, unrelated insider trading matter. *Id.* ¶ 130 n.6.

## 5. Motive

As to scienter for PSLRA pleading purposes, the United States Supreme Court has addressed assertions of motive. Specifically, the Court has observed that “[w]hile it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of scienter inferences, . . . the absence of a motive allegation is not fatal.” *Tellabs*, 551 U.S. at 325. Thus, contentions as to motive are not required but may be relevant to scienter.

In *Avaya*, the Third Circuit provided guidance as to analyzing allegations of motive:

According to our pre-*Tellabs* jurisprudence, “[m]otive must be supported by facts stated with particularity, and must give rise to a strong inference of scienter.” *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004) (internal quotation marks omitted). That proposition is no less true after *Tellabs*, although we no longer make an independent search for scienter on the basis of motive and opportunity allegations alone. “[M]otives 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.” *Id.* (quoting *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001)); *see id.* (“In every corporate transaction, the corporation and its officers have a desire to complete the transaction, and officers will usually reap financial benefits from a successful transaction. Such allegations alone cannot give rise to a ‘strong inference’ of fraudulent intent.”); *cf. Tellabs*, [551 U.S. at 325] (“[P]ersonal financial gain may weigh heavily in favor of a scienter inference.” (emphasis added)). Here, we do not look at motive allegations alone, but the same reasoning undermines any inference of scienter resting upon general motives to aid the company. *Corporate officers always have an incentive to improve the lot of their companies, but this is not, absent unusual circumstances, a motive to commit fraud.* Certainly, the LYONs redemption and the acquisition of the credit facility fail to contribute meaningfully to a “strong inference” of scienter here. Both actions reflect merely a general corporate desire to retire debt and raise funds and obtain credit on favorable terms. *Cf. Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) (“[T]he motivations to raise capital or increase one’s own compensation are common to every company and thus add little to an inference of fraud.”).

564 F.3d at 278-79 (emphases added) (footnotes omitted).

Here, Plaintiffs do not claim that any of the individual Defendants received a personal benefit. FAC ¶¶ 201-03. Thus, such motive allegations are of little value absent “unusual circumstances.” *Avaya*, 564 F.3d at 279. Plaintiffs allege that Defendants artificially inflated the value of Galena’s stock to finance the company’s operations. FAC ¶¶ 201-03. The current case arguably reflects unusual circumstances because Galena only had one commercial product, Abstral, during the class period. Moreover, Galena was a relatively small public company. Yet, Plaintiffs’ allegations nevertheless fall short because (1) the FAC fails to indicate the other aspects of Galena’s business vis-à-vis its commercial product, and (2) the FAC does not allege that any adverse consequences occurred to the stated financings when Galena announced that it was selling Abstral to a third party.

#### **6. Past Earnings, Targeted Providers, and Related Allegations**

Plaintiffs assert that Defendants’ statements describing prior earnings and attributing such earnings to lawful sales practices were materially misleading. Pl. Opp’n at 9-19. Yet, “[f]actual recitations of past earnings, so long as they are accurate, do not create liability under Section 10(b).” *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999). Here, there is no allegation or indication that Defendants inaccurately stated prior earnings. Therefore, Defendants’ statements detailing Galena’s historical revenue for prior periods, *e.g.*, FAC ¶¶ 128(a), 128(d), 133(a), 135(a), 139(a), 139(d), 145(a), are not materially misleading.

Courts have, however, recognized 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. *See City of Roseville Emps.’ Ret. Sys. v. Horizon Lines, Inc.*, 686 F. Supp. 2d 404, 416 (D. Del. 2009) (“Even though the statements may have accurately depicted [the defendant]’s financial performance, attributing such performance to

only lawful conduct falls below the level of honesty required by the securities laws.”); *see also In re ATI Techs., Inc. Sec. Litig.*, 216 F. Supp. 2d 418, 436 (E.D. Pa. 2002) (“Accurately depicting successful financial performance, but attributing the performance to the wrong source, is misleading under the securities laws.”). Here, Plaintiffs argue that Defendants falsely attributed their earnings to (1) targeting oncology providers, (2) customer confidence, and (3) legal, sustainable practices. Pl. Opp’n at 11-19.

**a. Targeting Oncology Providers**

First, Defendants’ statements about targeting oncology practices were not materially misleading as pled. Defendants did repeatedly state that they were focused on oncology providers, *e.g.*, FAC ¶ 133(b) (“We’re focused on building a long-term oncology supportive-care business.”) (November 3, 2014 Earnings call); ¶ 139(c) (“our long-term strategy is to develop lasting relationships with medical oncologists”) (May 7, 2015 Earnings call). Yet, Defendants also disclosed that their current business was not made up of entirely (or even predominantly) oncology sales, but included pain management specialists, *see* D.E. 62-20 at 4 (“We are working with top prescribing pain specialists . . . who serve as the foundation of our current business,” while “oncology and palliative care providers . . . drive[] approximately 25% of our Abstral sales.”) (also November 3, 2014 Earnings call); D.E. 62-22 at 5 (“[W]e now have 34% [of] our business coming from oncology-focused specialists”) (May 7, 2015 Earnings call).<sup>11</sup> Thus, the selected quotes from the FAC do not provide the full context in which the statements were made.

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<sup>11</sup> The full transcripts of these earnings calls, attached as exhibits to Defendants’ motion to dismiss (and portions of which are cited in Plaintiffs’ FAC), contradict Plaintiffs’ assertion that “Defendants *exclusively* represented that Galena’s sales were targeting, and that revenues were coming from, oncologists and other doctors treating cancer patients,” Pl. Opp’n at 12 n. 1 (emphasis in original).

Plaintiffs, through confidential witnesses, also establish that certain individuals at Galena pushed sales representatives to illegally market Abstral off-label. *Id.* ¶¶ 76, 77, 82. The FAC relies on three confidential witnesses or CWs. The Third Circuit has indicated how such allegations must be viewed in light of the PSLRA:

In our view, the case law interpreting the Supreme Court's *Tellabs* opinion confirms the position we took in [*Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146 (3d Cir. 2004)]. The PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter. 15 U.S.C. § 78u-4(b)(1), (b)(2). In the case of confidential witness allegations, we apply that requirement by evaluating 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. If anonymous source allegations are found wanting with respect to these criteria, then we must discount them steeply. This is consistent with *Tellabs*'s teaching that "omissions and ambiguities count against inferring scienter" under the PSLRA's particularity requirements. *Tellabs*, [551 U.S. at 325]. If, on the other hand, a complaint's confidential witness allegations are adequately particularized, we will not dismiss them simply on account of their anonymity. In short, *Chubb* remains good law.

*Avaya*, 564 F.3d at 263 (footnote omitted).

Here, the three CWs were territory business managers for Galena. CW1 indicates that she<sup>12</sup> was urged to see pain specialists, rather than oncologists, which the CW1 considered to be illegal off-label marketing. CW2 was fired for not meeting his sales quotas because the oncologists on which he called did not have many pain patients. CW3 refers to an email (on which Lento was copied) from Corwin, Galena's National Sales Director, which instructed Galena's sales staff to try to obtain business from physicians, who Insys (Galena's competitor) was "openly buying."

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<sup>12</sup> The FAC refers to the CWs with pronouns ("he/she") that protect the CWs' gender. The Court refers to the CWs in alternate gender for ease of reading.

In light of their positions and the detail of their allegations, the CWs' information sufficiently demonstrates that there was an effort by Galena to procure off-label prescriptions. Yet, there are several pleading deficiencies which undercut the materiality of such information. None of the CWs indicate that she actually attempted to perform, much less succeeded in, off-label promotion. None indicate that she ever had contact with Drs. Ruan or Couch, much less impermissibly marketed to the physicians. Again, while such allegations, if true, may be relevant to Galena's scienter, they fail to establish a nexus to any material false statement or omission as pled.

Moreover, Plaintiffs do not sufficiently link any of these off-label marketing discussions to any of the individual Defendants, specifically. Instead, the CWs identify Galena's National Sales Director, David Corin – a non-party in this action – as the individual driving the off-label marketing. *Id.* ¶¶ 77, 82. The fact that Corin reported to Defendant Lento, *id.*, and copied Defendant Lento on an email breaking down Abstral sales (while not explicitly mentioning off-label marketing), *id.* ¶ 79, is insufficient to show that Lento (or any other individual Defendant) was aware of illegal off-label marketing serving as a foundation of Abstral sales.<sup>13</sup>

Additionally, Plaintiffs do not demonstrate that the “push” of off-label marketing was successful – that sales representatives followed through with the illegal conduct and secured

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<sup>13</sup> This failure to link the individual Defendants to the illegal, off-label marketing also defeats Plaintiffs' argument that the risk factor disclosures are material misrepresentations. Plaintiffs argue that Defendants made material misrepresentations in their risk factor disclosures because they warned that Galena may “not be able to achieve and maintain regulatory compliance” with off-label marketing, while simultaneously “aggressively promoting Abstral for off-label purposes.” Pl. Opp'n at 23. In other words, Plaintiffs argue that Defendants should have outright stated that they are not complying with FDA regulations as to off-label promotions. *Id.* However, Plaintiffs have not sufficiently established that the individual Defendants were aware of such off-label marketing (or even that employees actually engaged in this off-label promotion, rather than simply being urged to do so). Thus, the risk factor disclosures are similarly not material misrepresentations.

prescriptions as a result, increasing earnings. As noted, the CWs do not indicate that they marketed off-label. The CWs similarly fail to indicate that they were aware of any successful off-label marketing by other Galena employees or representatives.

**b. Consumer Confidence**

Second, Defendants' statement attributing increased earnings to consumer confidence in Abstral was not materially misleading as pled. On the August 11, 2014 earnings call, Defendants stated that the increase in Abstral prescriptions was "a direct result of our team's focus and our customers' belief in the unique benefits of Abstral." FAC ¶ 128(c). The Third Circuit recognizes that "vague and general statements of optimism 'constitute no more than "puffery" and are understood by reasonable investors as such.'" *Advanta*, 180 F.3d at 538 (quoting *Burlington Coat Factory*, 114 F.3d at 1428 n. 14). Thus, "[s]uch statements, even if arguably misleading, do not give rise to a federal securities claim because they are not material." *Id.* (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)); see also *In re Merck & Co., Inc. Sec., Derivative & Erisa Litig.*, No. 05-1151, 2012 WL 3779309 (D.N.J. Aug. 29, 2012); *Galati v. Commerce Bancorp, Inc.*, No. 04-3252, 2005 WL 3797764 (D.N.J. Nov. 7, 2005), *aff'd*, 220 F. App'x 97 (3d Cir. 2007). In *Merck*, the district court found the defendant's statements attributing growth to "acceptance by physicians, patients and payors" and its products' "unique competitive advantage in the market" to be nonactionable puffery. 2012 WL 3779309, at \*5. In *Galati*, the district court found the defendant's remarks attributing growth to its "unique business model" and "convenience" to be nonactionable puffery. *Galati*, 2005 WL 3797764, at \*4. Similarly here, attributing earnings to "our team's focus" and "our customers' belief in the unique benefits of Abstral" are nonactionable puffery.

### c. Sustainable Business Practices

Third, Plaintiffs argue that by attributing growth to legal, sustainable business practices – rather than illegal conduct – Defendants made material misrepresentations. Pl. Opp’n at 13. Specifically, Plaintiffs argue that Defendants failed to disclose that 30% of Abstral sales came from Drs. Ruan and Couch, who were allegedly (a) receiving illegal kickbacks from Defendants, and (b) illegally prescribing Abstral. *Id.* As to the kickbacks, Plaintiffs detail a 2014 rebate agreement between Galena and the physicians, whereby Galena paid the doctors’ pharmacy a rebate of anywhere from 8.75% to 20% of the pharmacy’s monthly Abstral prescriptions. FAC ¶ 94. The Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(b)(2), provides that

[w]hoever knowingly and willfully . . . pays any remuneration . . . to any person to induce such person . . . to refer an individual . . . for the furnishing . . . of any item . . . for which payment may be made . . . under a Federal health care program . . . shall be guilty of a felony.

Plaintiffs plausibly plead that Defendants were engaged in an illegal kickback agreement as of October 14, 2014, the date of the 2014 rebate agreement. However, Plaintiffs fail to sufficiently demonstrate that this kickback agreement had a necessary impact on Galena’s earnings, which would have made omission of this agreement a material misrepresentation. Plaintiffs allege that Drs. Ruan and Couch’s Abstral prescriptions increased after the rebate agreement, FAC ¶ 95, but Plaintiffs do not detail by how much the prescriptions increased. Plaintiffs also fail to allege how the increase impacted Galena’s earnings. As to the two doctors prescribing Abstral to patients who were not indicated by the FDA, the allegations are discussed below. For these reasons, the Court finds that Plaintiffs failed to sufficiently allege the materiality of the improper agreement.



## **B. Allegations Sufficiently Pled in the FAC**

The FAC makes some allegations that could potentially support a Section 10(b) claim, specifically as to statements made after the businesses of Drs. Ruan and Couch were raided and shut down. Yet, the FAC is dismissed because the FAC as written does not distinguish these allegations as an independent basis for the Section 10(b) violation, instead opting to use a shotgun approach and essentially argue that *all* allegations comprise the Section 10(b) claim. The Court is unable to effectively separate the wheat from the chaff, when reviewing the entire FAC, in light of this approach. More importantly, in light of the Court's ruling, the current Class Period cannot stand.

### **1. Material Misstatements**

As to Drs. Ruan and Couch illegally prescribing Abstral, the Court finds issues with Plaintiffs' pleadings regarding Defendants' statements prior to May 20, 2015. Plaintiffs sufficiently alleged that Defendants were aware that 30% of the Abstral prescriptions were originating from Drs. Ruan and Couch<sup>14</sup> via, among other things, internal quarterly reports. *Id.* ¶¶ 71, 84. While it is illegal for Galena to promote Abstral off-label, it was not illegal for the physicians to prescribe the drug for a non-indicated use. As noted above, Plaintiffs do not sufficiently plead that Defendants were marketing off-label to the two doctors. Therefore, prior to May 20, 2015, Plaintiffs failed to sufficiently allege that Defendants knew that Drs. Ruan and Couch's sales were attributable to illegal conduct.<sup>15</sup> However, on May 20, 2015, this changed.

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<sup>14</sup> When combined, 40% of Abstral prescriptions were originating from Drs. Ruan, Couch, and Rho. *Id.* ¶ 84.

<sup>15</sup> These allegations also fall well short of sufficiently pleading scienter but the Court declines to undertake a detailed analysis of scienter on this point given that the FAC is deficient on the material misstatement/omission prong of the Section 10(b) claim.

On May 20, 2015, the federal government raided and effectively shut down Drs. Ruan and Couch's businesses. FAC ¶ 68. At this point (or soon thereafter), regardless of whether Defendants were aware of illegal conduct surrounding Abstral marketing and sales by the physicians, Defendants knew that their largest prescribers – who accounted for 30% of their sales, ¶¶ 71, 84 – were no longer producing. Nonetheless, a mere two and a half months later, on an August 8, 2015 earnings call, Defendant Schwartz indicated that “our metrics for Abstral *are trending* in the right direction,” FAC ¶ 145(b) (emphasis added), and Defendant Lento indicated that “our Abstral business *is growing*,” *id.* ¶ 145(c) (emphasis added). Both statements concern present conditions; they are not forward-looking.<sup>16</sup> In fact, three months later, on November 9, 2015, Galena announced that it was discontinuing its commercial operations – effectively terminating its Abstral business. *Id.* ¶ 149. The Court finds that the August 2015 statements that the Abstral business is growing, sandwiched in-between (a) the shutdown of the drug's largest two

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<sup>16</sup> Because the statements are not forward-looking, they are not in the purview of the PSLRA Safe Harbor. The PSLRA Safe Harbor “immunizes from liability any *forward-looking statement*, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood.” *Avaya, Inc.*, 564 F.3d at 254 (citing 15 U.S.C. § 78u-5(c)) (emphasis added). A statement is “forward-looking” if it contains a “projection of revenues, income [], earnings [] per share, capital expenditures, dividends, capital structure, or other financial items,” or statements of “future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management.” *Id.* at 255 (citing 15 U.S.C. § 78u-5(i)(1)(A)–(C)). However, “[a] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present.” *Id.*

Here, at a minimum, Defendants' statements that “our metrics for Abstral *are trending* in the right direction,” and that “our Abstral business *is growing*,” FAC ¶ 145 (emphases added), include an assertion that the Abstral business was currently or presently – *at that moment* – excelling. These statements fall outside the scope of the safe harbor. *See Makor Issues & Rights, Ltd. v. Tellabs Inc. (“Tellabs II”)*, 513 F.3d 702, 705 (7th Cir. 2008) (interpreting the statement “still going strong” as “saying both that current sales were strong and that they would continue to be so, at least for a time, since the statement would be misleading if Tellabs knew that its sales were about to collapse.”).

prescribers (accounting for 30% of sales) and (b) the discontinuance of the product line, sufficiently allege material misrepresentations for purposes of the PSLRA pleading requirements.

## 2. Scienter

“Scienter is a mental state embracing intent to deceive, manipulate, or defraud, and requires a knowing or reckless state of mind.”<sup>17</sup> *Avaya*, 564 F.3d at 252 (internal citations and quotations omitted) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n. 12 (1976) and citing *Advanta*, 180 F.3d at 534-35). 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 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

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<sup>17</sup> 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).

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.*

In *Avaya*, the shareholder plaintiffs brought a securities fraud action against Avaya, Inc. and its executives for statements about earnings and growth potential. 564 F.3d at 245. Avaya’s CFO 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.” *Id.* at 268. 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% to 40% price discounts that were hurting profit margins.” *Id.* On appeal, the Third Circuit addressed whether the plaintiffs’ complaint sufficiently established scienter as to these pressure-pricing statements. *Id.* The Third Circuit ultimately determined that given the totality of the circumstances, “the culpable explanation of [the CFO]’s March discounting statements is at least as compelling as the nonculpable alternatives.” *Id.* at 272. Specifically, the Third Circuit found that

[t]aken together, the extent of the alleged discounting, the importance to the “Avaya story” of maintaining margins, the amount by which the second quarter results missed expectations, the proximity of [the CFO]’s statements to the end of the quarter and the release of results, [the CFO]’s position as Chief Financial Officer, and most significantly, the content and context of the statements themselves, give rise to a strong inference that [the CFO] either

knew at the time that his statements were false or was reckless in disregarding the obvious risk of misleading the public.

*Id.*

Here, the circumstances warrant a similar conclusion. The extent of the loss in Abstral business on May 20, 2015 with the shutdown of Drs. Ruan and Couch's businesses – which accounted for 30% of all Abstral sales, FAC ¶ 71 – is significant. Abstral sales were certainly important to Galena, as Abstral was its only revenue-churning commercial product. *Id.* ¶¶ 6, 39. On the August 6, 2015 earnings call, Defendant Schwartz and Defendant Lento represented that the Abstral business is “growing” and “trending in the right direction” – despite lower earnings – which Schwartz attributed to “ongoing market dynamics.” *Id.* ¶ 145. Then, the proximity of these statements to Galena's announcement that it was discontinuing its commercial business (which solely consisted of Abstral) in the “best interest” of the company on November 9, 2015 – a mere three months later – is telling. *Id.* ¶ 149. Further, Defendant Lento's position as Vice President of Oncology Commercial Operations, and Defendant Schwartz' position as President/CEO certainly suggest that they were aware of the loss of their largest prescribers when making the August 6, 2015 statements, or were at least reckless in not discovering such in investigating why they were experiencing lower earnings at the time.<sup>18</sup> Thus, the Court finds a strong inference that Defendants Lento and Schwartz either knew on August 6, 2015 that their statements were false or

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<sup>18</sup> Courts generally take a jaundiced view of inferring scienter based on a defendant's position within a company. *Advanta*, 180 F.3d at 539. Yet, *Tellabs* requires that a court consider all allegations in ruling on scienter. And, as demonstrated in *Avaya*, sometimes a Defendant's position (there CFO) strongly supports a finding of sufficient scienter allegations. Thus, while certain allegations in the FAC may not independently support a Section 10(b) violation, they are relevant to scienter. Here, the allegations support an inference of scienter based on Schwartz and Lento's positions with Galena. Among others, the FAC alleges that Abstral was Galena's only commercial product, that Drs. Ruan and Couch accounted for 30% of Abstral sales, and that Schwartz and Lento knew that the physicians were responsible for 30%.

were reckless in disregarding the obvious risk that they were misleading the public. Plaintiffs have sufficiently established scienter as to these two Defendants for these statements.

### 3. Loss Causation

“[A p]laintiff 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).” *Nat’l Junior Baseball League v. Pharmanet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 558 (D.N.J. 2010) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005)). 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.* Here, Plaintiffs assert a “materialization of the risk” theory to support their claims. Pl. Opp’n at 42-49.

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 Third Circuit addressed this approach in *McCabe*.<sup>19</sup> In *McCabe*, the class action plaintiffs

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<sup>19</sup> *McCabe* dealt with a “non-typical” Section 10(b) case, where “the plaintiffs did not allege that the price of a publicly traded security was affected but instead that the price of their investment was artificially inflated.” *Id.* at 426. Under a “typical” Section 10(b) case, “the plaintiff shareholder alleges that a fraudulent misrepresentation or omission has artificially inflated the price of a publicly-traded security, with the plaintiff investing in reliance on the misrepresentation

sued Ernst & Young (“EY”) for its audit opinion on Vertex Interactive, Inc. (“Vertex”), which it made in the course of Vertex’s acquisition of Applied Tactical Systems, Inc. (“ATI”). *Id.* at 420-22. The plaintiffs were shareholders of ATI who agreed to exchange their shares of ATI for shares of Vertex in connection with this acquisition. *Id.* The plaintiffs alleged that EY knowingly omitted material information “that Vertex had defaulted on prior registration obligations [and] had been threatened with litigation as a result.” *Id.* at 422. Under the plaintiffs’ theory, “had they known of the prior registration defaults and associated threats of litigation, they would not have closed the [deal].” *Id.*

The *McCabe* plaintiffs argued that they were damaged *at the very moment* of the undisclosed event that negatively impacted the company. *Id.* at 432. The Circuit rejected this argument, recognizing that if “the purchaser sells the shares quickly before the relevant truth begins to leak out, the misrepresentation will not have led to any loss.” *Id.* at 433 (quoting *Dura Pharm., Inc.*, 544 U.S. at 342-43). In other words, the undisclosed risk would not yet have materialized, therefore it could not have caused the purchaser injury. *Id.* The Circuit then concluded that the plaintiffs failed to create a genuine issue of material fact<sup>20</sup> as to loss causation. *Id.* at 439. The plaintiffs alleged that “[a]mong the reasons for Vertex’s failure to meet earnings and revenue targets was Vertex’s . . . breach of its various agreements to make payments and to register the shares of stock used as consideration for various acquisitions.” *Id.* at 436. The court in *McCabe* noted that “[t]his might have been a sufficient allegation of loss causation to survive a

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or omission.” *Id.* at 425-26. The typical approach is often referred to as the fraud-on-the-market theory. The current matter presents a “typical” Section 10(b) case. However, neither *McCabe*, nor its progeny, limit application of the “materialization of the risk” theory to “non-typical” Section 10(b) actions.

<sup>20</sup> The Circuit in *McCabe* was addressing this issue at the summary judgment stage. *Id.*

motion to dismiss,” but that the allegation was not sufficiently supported by actual evidence to create a genuine issue of material fact as to whether these registration defaults alone caused Vertex’s failure to meet earnings and revenue targets. *Id.* at 436-38. Thus, the *McCabe* court affirmed summary judgment in favor of the defendants. *Id.* at 439.

Here, Plaintiffs sufficiently plead loss causation via a materialization of the risk approach. On May 20, 2015, law enforcement raided Drs. Ruan and Couch’s businesses, effectively shutting them down. *Id.* ¶ 68. On that day, Galena lost 30% of Abstral sales. There is no indication that Galena had a plan to make up this loss. On the August 6, 2015 earnings call, as noted, Defendant Schwartz and Defendant Lento made material misstatements in light of the May 20, 2015 raid. On November 9, 2015, Galena announced its discontinuance of its commercial business, which can reasonably be considered as a materialization of the undisclosed risk of Abstral’s future profitability. Galena’s stock price then fell \$0.19, or 11%, to \$1.53. *Id.* ¶¶ 149, 152. *See Oran*, 226 F.3d at 285 (indicating that a “four-percent drop in share prices” indicates the materiality of the relevant misstatement or omission). Plaintiffs plausibly alleged loss causation as to August 2015 statements but only insofar as the November 2015 announcements.<sup>21</sup>

#### **4. Control Person Liability<sup>22</sup>**

Plaintiffs also assert claims for control person liability against Ahn, Schwartz, and Dunlap under Section 20(a). FAC ¶¶ 225-228. “Section 20(a) of the Exchange Act imposes joint and several liability on any individual who exercises control over a ‘controlled person’ who violates

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<sup>21</sup> Plaintiffs have not sufficiently shown, as analyzed above, that the risk was not fully materialized after Galena divested itself of Abstral.

<sup>22</sup> The Court notes that “[a] difference of opinion has emerged among district courts of this Circuit as to the pleading requirements for a § 20(a) claim.” *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 466 (D.N.J. 2017) (quoting *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 485 (3d Cir. 2013)).



Section 10(b).” *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 466 (3d Cir. 2017) (citing 15 U.S.C. § 78t(a); *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 275 (3d Cir. 2005)). The three elements to this claim are: “(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.” *Id.* (citing *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 286 (3d Cir. 2006)). Thus, “liability under Section 20(a) is contingent upon sufficiently pleading an underlying violation of Section 10(b) by the controlled person.” *Id.* Because the Section 10b claims are dismissed for failure to state a claim in this instance, Plaintiffs’ Section 20(a) claims must also be dismissed in their entirety.

#### IV. CONCLUSION

For the foregoing, the Court grants Defendants’ motion to dismiss Plaintiffs’ FAC, D.E. 62. The dismissal is without prejudice. Plaintiffs shall have thirty (30) days to file a second 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: November 12, 2019

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