

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE GALENA BIOPHARMA, INC.
SECURITIES LITIGATION**

No. 2:17-cv-929-KM-JBC

OPINION

MCNULTY, U.S.D.J.:

The plaintiffs have filed a class-action complaint alleging securities fraud against Galena Biopharma, Inc. (“Galena”) and several of its officers or key employees. The complaint alleges that the defendants failed to make appropriate disclosures under Item 303 of Regulation S-K and therefore committed securities fraud. Now before the court are defendants’ motions to dismiss the complaint. For the reasons expressed herein, those motions are granted without prejudice to the submission of a second amended complaint within 30 days.

I. BACKGROUND¹

A. Relevant Parties

Plaintiffs, holders of Galena common stock, allege that they suffered damages because of defendants’ violations of securities laws. (AC ¶¶ 34-38). They bring a class action on behalf of all persons and entities that acquired Galena securities from August 11, 2014 through January 31, 2017 (the “Class Period”). (AC ¶ 1). Defendants are Galena and several officers or key employees of Galena.

¹ All facts and inferences are construed in favor of the nonmoving party on a motion to dismiss. Citations to the amended complaint (ECF No. 40) are abbreviated as “AC.”

Plaintiffs sue Mark J. Ahn (“Ahn”), who was the President, CEO, and a Director at Galena until his resignation effective August 20, 2014; Mark W. Schwartz (“Schwartz”), who was Galena’s COO from 2011 until his appointment as CEO, and who was President and CEO from August 20, 2014 through the end of the Class Period; Ryan M. Dunlap (“Dunlap”), who was the Vice President and CFO of Galena until his resignation effective December 31, 2015; Christopher S. Lento (“Lento”), who was the Senior Vice President of Oncology Commercial Operations at Galena from around May 2013 through December 31, 2015; and Remy Bernarda (“Bernarda”), who was Senior Vice President of Investor Relations at Galena throughout the Class Period. (AC ¶¶ 40-44).

B. Abstral and Galena Patient Services

On October 3, 2013, Galena launched a new product—Abstral (fentanyl) sublingual tablets. (AC ¶ 47). Abstral is an opioid pain medication associated with a high risk of addiction and dependence. (AC ¶ 48). Abstral is indicated by the FDA only for “the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” (AC ¶ 51). Prescriptions written for any other purposes are deemed “off-label.” (AC ¶ 51).²

On March 3, 2014, Galena launched “Galena Patient Services” (“GPS”), a program designed to facilitate individuals obtaining prescriptions and reimbursements for Abstral. (AC ¶ 52). Mr. Ahn, President and CEO of Galena, stated that GPS’s goal was “to make prescribing and receiving Abstral as simple as possible.” (AC ¶ 52).

² Doctors are permitted to prescribe pharmaceuticals for an off-label purpose. It is illegal, however, for companies to promote the off-label use of pharmaceuticals. See *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349-50 (2001). The complaint is sometimes unclear about this distinction.

C. Dr. Ruan and Dr. Couch

Dr. Xiulu Ruan and Dr. John Patrick Couch jointly owned and operated two pain-management clinics and a pharmacy. (AC ¶¶ 65-66). These two doctors almost exclusively prescribed Abstral on an off-label basis for neck, back, and joint pain. (AC ¶ 68). Thirty percent of Galena's Abstral revenues were generated by these two doctors. (AC ¶¶ 65-66). Defendants Schwartz and Lento visited these doctors several times during the Class Period and allegedly encouraged them to prescribe Abstral off-label. (AC ¶ 65). Drs. Ruan and Couch purchased \$1.6 million worth of stock in Galena and sought to manipulate Galena's stock price by inflating Abstral's sales. (AC ¶ 69).

When Galena's stock price dropped, Drs. Ruan and Couch demanded that Galena fire the board of directors, replace the CEO, and change its leadership. (AC ¶ 87). One Galena employee claims that their demands were taken seriously because they were the highest Abstral prescribers and were "important individuals for Galena." (AC ¶ 87). Galena's then-CEO, Mr. Ahn, was fired around this time. (AC ¶ 87). Drs. Ruan and Couch have since been convicted on several criminal charges related to their practices in relation to Abstral. (AC ¶ 71).

D. Off-Label Promotion and Kickbacks

Former employees of Galena state that Galena executives "pushed" salespeople to promote Abstral off-label. (AC ¶¶ 75-77). For instance, an anonymous Galena employee was told to "visit" doctors who prescribed Abstral's competitor and "chase those prescriptions." (AC ¶ 79). These doctors were mostly primary care doctors and thus the employee perceived that he or she was "being challenged to go off-label." (AC ¶ 79).

Galena allegedly encouraged doctors, including Dr. Ruan, to enroll non-cancer patients (*i.e.*, off-label users) in Galena's RELIEF program, which tracked how patients responded to Abstral. (AC ¶ 84). The RELIEF program paid doctors \$500 for every patient that enrolled. (AC ¶ 84).

C&R Pharmacy, which was owned by Drs. Ruan and Couch, partnered with Galena on a “rebate agreement.” (AC ¶ 93). Galena would pay C&R Pharmacy a certain percentage for the Abstral prescriptions they sold. (AC ¶ 93). The patients of Drs. Ruan and Couch frequently obtained Abstral from C&R Pharmacy. (AC ¶ 94). Galena wired \$97,924 to C&R Pharmacy’s Wells Fargo bank account on February 18, 2015, likely in connection with the rebate agreement. (AC ¶ 95). According to plaintiffs, the rebate was in reality a payment to Drs. Ruan and Couch for prescribing Abstral. (AC ¶ 94).

Galena invited Drs. Ruan and Couch to attend Galena’s Advisory Board Meetings. (AC ¶ 97). Dr. Couch attended at least one meeting and was paid \$5,000, plus expenses. (AC ¶ 97). Dr. Ruan did not attend these meetings, allegedly out of concern that he might hear inside information that would prevent him from freely trading his Galena stock. (AC ¶ 97).

The Department of Justice (“DOJ”) investigated Galena regarding kickback allegations. A DOJ press release said the RELIEF program was “nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral.” (AC ¶ 84). Galena resolved the kickback allegations by paying more than \$7.55 million to the government. (AC ¶ 72).

E. Stock Manipulation

Drs. Ruan and Couch purchased more than \$1.6 million in Galena stock. (AC ¶ 99). Defendants were allegedly aware that these doctors were trading in Galena stock while trying to inflate Abstral sales by over-prescribing the medication. (AC ¶ 99). Dr. Ruan sent an email to defendant Lento confirming that he had recently purchased Galena stock. (AC ¶ 100). Emails between Drs. Ruan and Couch state that they could “play a big role” in helping Abstral’s market share grow. (AC ¶ 102).

Drs. Ruan, Couch, and Rho (a friend of Dr. Ruan) spoke with the Galena board of directors. (AC ¶ 105). Ruan told Rho that “[t]he purposes of this talk is to express our opinion to push them to replace their CEO” and “to give them

the impression that if they do not do it, we will switch to other Cos and its products altogether ...” (AC ¶ 107). Dr. Ruan implied that the board members would listen to them because “as you know very well, they know who we are....” (AC ¶ 107). “Since [we ...] are all shareholders of the [sic] and together we represent a very significant portion of their business, we have a better chance of making it if [we] team up together to get this done.” (AC ¶ 107). Dr. Ruan also emailed defendants Bernarda and Lento, stating that he agreed “with many of other share holders that the executive team and BOD need to be replaced ASAP.” (AC ¶ 108).

Ahn, Dunlap, and Bernarda were defendants in a securities-fraud action, *In re Galena Biopharma Securities Litigation*, No. 3:124-cv-367-SI (D. Or.). The plaintiffs in that action alleged that Galena and certain officers paid third-party newsletters to promote Galena stock without disclosing that those newsletters were in fact paid promotions. Galena’s stock price had nearly quadrupled and Galena investors reaped approximately \$16 million in profits when these they sold their shares. The parties reached a settlement with the SEC under which defendant Ahn disgorged \$677,250 in profits, paid prejudgment interest of \$67,181, and paid a civil penalty of \$600,000. Galena agreed to pay a civil penalty of \$200,000. (AC ¶ 111).

F. Inflated and Unsustainable Sales

According to the complaint, the defendants knew that Abstral’s sales were overwhelmingly driven by Drs. Ruan and Couch’s prescribing Abstral for off-label purposes. (AC ¶¶ 113). Defendants allegedly knew, or should have known, that “Abstral sales largely supported by two pain management doctors prescribing inordinately large amounts of Abstral to non-cancer patients could not be sustained given the government’s aggressive oversight of prescription opioids.” (AC ¶¶ 112-16, 119).

G. Statements During the Class Period

Plaintiffs propose a Class Period that begins on August 11, 2014. (AC ¶ 125). On that day, Galena issued a press release entitled “Galena Biopharma

Reports Second Quarter 2014 results.” (AC ¶ 125). For the first half of 2014, Galena reported \$4.5 million in net revenue, \$2.3 million of it earned in the second quarter. By comparison, for the first half of 2013, the company had reported no net revenue. (AC ¶ 125).

In an August 11, 2014 press release, the company noted:

“With the recent acquisition of our second approved product, Zuplenz, Galena now has two commercial products and three clinical assets in development, providing our shareholders a stratified and diversified pipeline as we look to enhance cancer care and treat its often debilitating side-effects,” said Mark J. Ahn, Ph.D., President and Chief Executive Officer. “We are excited for the second half of the year as we continue to advance all of our programs.... Commercially, we continue to gain traction with Abstral, and we have begun preparations for the launch of Zuplenz in early 2015.”

(AC ¶ 125).

On the same date, August 11, 2014, Galena filed its quarterly Form 10-Q with the SEC. The 10-Q, signed by defendants Ahn and Dunlap, confirmed Galena’s financial results for the first half of the year, as announced in the press release. (AC ¶ 126).

Plaintiffs allege that, in those August 11, 2014 statements, defendants violated their duty of disclosure. (AC ¶ 127). According to plaintiffs, defendants knew, but omitted to disclose, that it was reasonably likely that Galena’s sales could not be sustained and thus Galena’s reported financial results were likely not indicative of future performance. (AC ¶ 127).

Also on August 11, 2014, Galena held an earnings conference call for the quarter that ended June 30, 2014. (AC ¶ 128). Defendants Schwartz, Dunlap, Ahn, and Bernarda participated in the call. On this call, Schwartz stated that Galena was experiencing “continued product expansion” and had a “stable business foundation.” (AC ¶ 128). He attributed this to “first, ensuring availability, reimbursement, and insurance coverage; second, optimizing our Patient Assistance program; third, strengthening our distribution and our

wholesale partnerships; and finally, continued development of our prescriber base.” (AC ¶ 128).

Ten days later, on August 21, 2014, Galena announced that defendant Schwartz had been named CEO, replacing defendant Ahn. (AC ¶ 130). Plaintiffs claim that Ahn was “forced out” because of his involvement in the insider trading scandal. (AC ¶ 130); see subsection I.E, *supra*.

On September 25, 2014, Galena held a press conference that was attended by defendants Schwartz, Dunlap, and Bernarda. (AC ¶ 131). Defendant Schwartz stated,

“Our strategy is focused on targeting oncology patients treated by both pain medicine specialists and oncologists, thus remaining true to the overall mission of the Company. We recognize that our approach of primarily targeting oncology practices has resulted in a slow, but a consistent growth pattern that we believe will result in a viable and strategic business in the long term.”

(AC ¶ 131).

Defendants made similar statements in a November 3, 2014 press release; November 3, 2014 earnings conference call; Form 10-Q filed with the SEC on November 5, 2014; March 5, 2015 press release; March 5, 2015 earnings conference call; Form 10-K filed with the SEC on March 5, 2015; May 7, 2015 press release; May 7, 2015 Form 10-Q; and May 7, 2015 earnings conference call. (AC ¶¶ 133-45).

Under the “Risk Factors” section of the March 5, 2015 Form 10-K, Galena disclosed:

The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product’s approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject

to significant liability, including substantial monetary penalties and criminal prosecution.

... If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

(AC ¶ 140). Shortly afterward, on May 20, 2015, law enforcement raided the offices of Drs. Ruan and Couch. (AC ¶ 151). Their clinics and pharmacy were shut down. (AC ¶ 151).

On August 6, 2015, Galena issued a press release reporting “improved Abstral sales quarter over quarter resulting in our strongest net revenue quarter to date.” (AC ¶ 153). It continued, “Based on current projections, we anticipate that we will come in closer to the lower end of our guidance range, at around \$15 million for the year.” (AC ¶ 153). Galena also filed its second-quarter Form 10-Q report with the SEC on August 6, 2015. (AC ¶ 154). Under the “Risk Factors” section of the 10-Q, Galena disclosed: “We may be unable to achieve profitability with our commercial operations in a timely manner, and may have to make changes to our commercial strategy to maximize the value of our commercial assets to our shareholders.” (AC ¶ 155). The 10-Q did not disclose that the clinics and pharmacy of Drs. Ruan and Couch had been closed in May 2015—and that this represented 30% of the Abstral business. (AC ¶ 156). On August 6, 2015, Galena held an earnings conference call in which it reported that “our metrics for Abstral are trending in the right direction, although our sales growth has fluctuated quarter-over-quarter based on field demand and wholesaler inventory levels.” (AC ¶ 157).

After that earnings and reduced-revenue guidance, the Company’s stock price fell \$0.12, or 7.4%, from \$1.63 on August 6, 2015 to \$1.51 on August 7, 2015. (AC ¶ 158). Plaintiffs contend that the price of Galena’s stock would have dropped even more if “the full truth” had been revealed. (AC ¶ 159). On August 6, 2015, defendants stated that Abstral’s “underlying metrics are all trending upwards” or in the “right direction” and that “our Abstral business is growing,”

but failed to disclose that the two doctors responsible for 30% of the Company's Abstral prescriptions were arrested and their businesses were shut down. (AC ¶ 159). Defendants also allegedly attributed disappointing earnings to "ongoing market dynamics." (AC ¶ 159).

On November 9, 2015, Galena announced that it had decided to divest its commercial business, which included Abstral. (AC ¶ 160). Galena classified its commercial business activities as "discontinued operations" and stated that it anticipated exiting the commercial business by the end of the first quarter of 2016. (AC ¶ 160).

On the same day, November 9, 2015, Galena filed its third-quarter Form 10-Q with the SEC. (AC ¶ 161). The form was signed by defendants Schwartz and Dunlap. (AC ¶ 161). Galena disclosed that it had "assessed the commercial business net asset group for impairment pursuant to FASB Topic 360, ... determin[ed] that the carrying value exceeds the fair value of the assets, [and] therefore ha[ve] recorded a \$8.1 million impairment charge as of September 30, 2015." (AC ¶ 161).

The price of Galena common stock then fell \$0.19 per share, or 11%, to close at \$1.53 per share on November 10, 2015. (AC ¶ 162). Plaintiffs claim that these disclosures "revealed the severity of those risks in the sales drop off ... was so severe that Galena's entire commercial business could not be sustained." Again, however, "the price of the stock would have dropped even more if the full truth had been revealed." (AC ¶¶ 162-63).

On November 20, 2015, Galena announced that it had sold its Abstral product to a private company in a deal valued at up to \$12 million, with \$8 million cash up front and up to \$4 million in additional cash upon the achievement of certain sales milestones. (AC ¶ 164).

On December 11, 2015, Galena announced the departure of defendant Dunlap, the then-CFO, effective December 31, 2015. (AC ¶ 165). On this news, the price of Galena common stock fell \$0.07 per share, or 4.5%, to close at \$1.49 per share on December 11, 2015. (AC ¶ 165).

On December 22, 2015, Galena announced the receipt of a federal subpoena in connection with its Abstral sales. (AC ¶ 167). The price of Galena stock fell \$0.06 per share, or 3.6%, to close at \$1.57 per share on December 23, 2015. (AC ¶ 168).

On March 10, 2016, Galena filed its annual report on Form 10-K/A with the SEC. (AC ¶ 170). This form was signed by defendant Schwartz. (AC ¶ 170). It provided, in relevant part:

We are subject to U.S. federal and state health care fraud and abuse and false claims laws and regulations, and we recently have been subpoenaed in connection with marketing and promotional practices related to Abstral. Prosecutions under such laws have increased in recent years and we may become subject to such prosecutions or related litigation under these laws. If we have not fully complied with such laws, we could face substantial penalties....

A federal investigation of two of the high-prescribing physicians for Abstral has resulted in the criminal prosecution of the two physicians for alleged violations of the federal False Claims Act and other federal statutes. The criminal trial is set for some time in 2016. We have received a trial subpoena for documents in connection with that investigation....

[W]e have learned that the FDA and other governmental agencies may be investigating our Abstral promotion practices. On December 16, 2015, we received a subpoena issued by the U.S. Attorney's Office in District of New Jersey requesting the production of a broad range of documents pertaining to our marketing and promotional practices for Abstral....

(AC ¶ 170). The price of Galena common stock fell \$0.03 per share, or 3.3%, to close at \$0.86 per share on March 11, 2016. (AC ¶ 171).

On May 10, 2016, Galena filed its first-quarter Form 10-Q, which was signed by defendant Schwartz. (AC ¶ 172). It reiterated the content of the March 10, 2016 Form 10-K/A. (AC ¶ 172). It also added that the two high-prescribing physicians were subject to a new, superseding indictment that involved Galena's rebate agreement and their ownership of Galena stock. (AC

¶ 172). Galena's stock fell \$0.10, or 7.2%, to close at \$1.38 on May 11, 2016. (AC ¶ 173).

On August 6, 2016, the Company filed its second-quarter Form 10-Q, which was signed by defendant Schwartz. (AC ¶ 174). The company identified as "Risk Factors" that "We are, and in the future may be, subject to legal or administrative actions that could adversely affect our financial condition and our business." (AC ¶ 175). Galena stated that it was subject to government investigations regarding Abstral promotion practices. (AC ¶ 175).

On November 9, 2016, Galena filed its third-quarter Form 10-Q, which was signed by defendant Schwartz. (AC ¶ 176). There the company made the same disclosures regarding ongoing investigations and prosecutions. (AC ¶ 176).

On January 9, 2017, Galena filed with the SEC a Form 8-K which updated Galena's risk disclosures for the year that ended December 31, 2015. (AC ¶ 177). This 8-K disclosed that Galena was under criminal investigation by the US Department of Justice. (AC ¶ 177). Galena common stock fell \$0.04 per share, or 1.9%, to close at \$2.03 per share on January 9, 2017. (AC ¶ 178).

H. Disclosures at the End of the Class Period

January 31, 2017 is the end of the proposed Class Period. On that date, Galena announced the resignation of defendant Schwartz as President, CEO, and a member of the board. (AC ¶ 180). Several business and financial writers opined that Schwartz's resignation was connected to the Abstral investigation. (AC ¶¶ 181-82). The price of Galena common stock fell \$0.37 per share, or 22.4%, to close at \$1.28 per share on February 1, 2017. (AC 183). The stock price continued to decline, falling another \$0.16 per share, or 12.5%, to close at \$1.12 on February 2, 2017. (AC ¶ 183).

On May 26, 2017, Drs. Ruan and Couch were sentenced to 252 months and 240 months in federal prison. (AC ¶ 184).

I. Alleged Motive

Plaintiffs allege that defendants used Galena's inflated stock price to finance its operations. (AC ¶ 185). On November 18, 2014, Galena entered into a purchase agreement with Lincoln Park Capital, LLC ("LPC") that gave Galena the right to sell to LPC up to \$50 million in shares of Galena's common stock over the 36-month term of the purchase agreement. (AC ¶ 186). LPC initially purchased 2.5 million shares of Galena common stock. (AC ¶ 186). Galena received initial net proceeds of \$4.6 million. (AC ¶ 186). Galena received net proceeds of \$8.5 million from LPC's subsequent purchases of 4.6 million shares. (AC ¶ 186). During 2014 and 2015, Galena received \$2.3 million in net proceeds from the sale of 1.4 million shares of common stock through At Market Issuance Sales Agreements. (AC ¶ 187). In March 2015, Galena sold units consisting of common stock and warrants at \$1.56 per unit for proceeds of \$40.8 million. (AC ¶ 188). Plaintiffs claim that each of the financings was made possible and facilitated by the artificially inflated stock price. (AC ¶ 189).

J. Claims and Current Motion

Plaintiffs seek to represent a class of all persons and entities that acquired Galena securities from August 11, 2014 through January 31, 2017. The Amended Complaint contains two counts. Count 1 claims that defendants violated Item 303 of SEC Regulation S-K and thus are liable under Item 303 or, alternatively, under Section 10(b) of the Exchange Act and Rule 10b-5. (AC ¶¶ 202-12). Count 2 alleges violations of Section 20(a) of the Exchange Act by defendants Ahn, Schwartz, and Dunlap. (AC ¶¶ 213-16). Plaintiffs seek compensatory damages; reasonable costs and expenses incurred in the action, including attorney's fees and expert fees; and such other relief as the court deems proper.

Now before the court are the defendants' motions to dismiss the Amended Complaint for failure to state a claim. Defendants Galena, Schwartz, Dunlap, Lento, and Bernarda filed a joint motion to dismiss. (ECF No. 46).

Defendant Ahn filed a separate motion to dismiss. (ECF No. 47). Plaintiffs oppose these motions.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In deciding a motion to dismiss under Rule 12(b)(6), a court must take all allegations in the complaint as true and view them in the light most favorable to the plaintiff. *See Warth v. Seldin*, 422 U.S. 490, 501 (1975); *see also Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008).

In place of the normal pleading standard articulated in Federal Rule of Civil Procedure 8, plaintiffs pleading securities fraud claims pursuant to Section 10(b) of the Securities Exchange Act and Rule 10b-5 must meet the heightened pleading standard of the Private Securities Litigation Reform Act (“PSLRA”). *See* 15 U.S.C. § 78u-4(b)(1). Under the PSLRA, 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,’ [*Id.*] § 78u-4(b)(2).

Rahman v. Kid Brands, Inc., 736 F.3d 237, 242 (3d Cir. 2013) (quoting *Tellabs*, 551 U.S. at 321) (internal quotations omitted; line break added). The required state of mind is “scienter,” which is defined as “a mental state embracing intent to deceive, manipulate, or defraud.” *Id.* (quoting *Tellabs*, 551 U.S. at 319).

Both provisions of the pleading standard require that facts be pled “with particularity,” echoing the requirement set forth in Federal Rule of Civil Procedure 9(b). *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009); *see* Fed. R. Civ. P. 9(b) (“[A] party must state with particularity

the circumstances constituting fraud or mistake.”). Therefore, although the PSLRA supplanted Rule 9(b) as the pleading standard governing private securities class actions, Rule 9(b)’s particularity requirement is effectively subsumed by the requirements in Section 78u-4(b)(1) of the PSLRA. *Avaya*, 564 F.3d at 253 (citing *Miss. Pub. Employees’ Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 85 n.5 (1st Cir. 2008)). This standard requires that plaintiffs plead the “who, what, when, where and how.” *Id.* Section 78u-4(b)(1) also adds an additional requirement where “an allegation regarding [a defendant’s] statement or omission is made on information or belief.” *Id.*; 15 U.S.C. § 78u-4(b)(1). In such cases, plaintiffs must also “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 conveyed by those sources. *Avaya*, 564 F.3d at 253.

The PSLRA’s approach for pleading scienter sharply deviates from the approach under Rule 9(b), which allows plaintiffs to plead the scienter element generally. *Id.* 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 account for 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.* Therefore, 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 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.” *Id.* at 254; *see* 15 U.S.C. § 78-u-5(c).

III. DISCUSSION

Plaintiffs have identified several troubling practices regarding Galena, Abstral sales, and Drs. Ruan and Couch. However, the complaint suffers from fundamental defects that prevent the court from concluding that the plaintiffs have stated a cognizable claim for securities fraud. In this opinion, I review three fundamental, interrelated issues that must be addressed: **(A)** plaintiffs do not clearly explain their reliance on Item 303 as the basis for their securities-fraud suit and how their suit is cognizable under the Third Circuit case of *Oran v. Stafford*; **(B)** plaintiffs’ theory of liability shifts and remains unclear throughout the complaint; and **(C)** plaintiffs fail to plead securities fraud on a statement-by-statement basis, as required by the PSLRA.

Plaintiffs’ nondisclosure claims rest on Item 303(a) of SEC Regulation S-K, which is alleged to be the source of a duty of disclosure. The Third Circuit case of *Oran v. Stafford*, however, precludes plaintiffs from enforcing Item 303 through an independent private right of action. And although omissions under Item 303 may independently violate Section 10(b) and Rule 10b-5, they have not been adequately alleged to do so here. Defendants’ motion to dismiss will therefore be granted, without prejudice.

A. Securities Disclosure Requirements and Item 303

i. 10(b) and Item 303 disclosure requirements

Plaintiffs argue that defendants are liable because they failed to disclose certain trends, uncertainties, and facts—for example, Galena’s over-reliance on Drs. Ruan and Couch’s sales, Galena’s litigation risks, the unsustainability of Abstral sales, and so on. *See* (ECF No. 51, pp. 16-31).

Federal law imposes disclosure requirements in connection with securities. 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 extracted an implied private right of action under Rule 10b-5 from the text and purposes of Section 10(b). *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011).

To state a claim for securities fraud 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. *Id.* at 37-38; *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014).

To be actionable, a misstatement or omission must be material. The issue of materiality is a mixed question of law and fact, involving the application of a legal standard to a specific set of facts. *See TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976); *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 641 (3d Cir. 1989). “Only when the disclosures or omissions are so clearly unimportant that reasonable minds could not differ should the ultimate

issue of materiality be decided as a matter of law.” *Craftmatic*, 890 F.2d at 641; see *Basic v. Levinson*, 485 U.S. 224, 239 (1988). “[W]here there is room for differing opinions on the issue of materiality, the question should be left for jury determination.” *Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 599 (3d Cir. 2000) (citing *Ballan v. Wilfred Am. Educ. Corp.*, 720 F. Supp. 241, 249 (E.D.N.Y. 1989)).

The Supreme Court has instructed that “[s]ilence, absent a duty to disclose, is not misleading under Rule 10b-5.” *Basic v. Levinson*, 485 U.S. 224, 239 n.17 (1988); see also *Chiarella v. United States*, 445 U.S. 222, 230-31 (1980). A duty to disclose may arise, however, when there is “a corporate insider trad[ing] on confidential information,” a “statute or regulation requiring disclosure,” or a corporate statement that, absent disclosure, would be “inaccurate, incomplete, or misleading.” *Glazer v. Formica Corp.*, 964 F.2d 149, 157 (2d Cir. 1992); accord *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000).

Item 303 of SEC Regulation S-K independently mandates the disclosure of certain information. For full fiscal years, Item 303(a) requires the registrant to, among other things:

- (ii) Describe 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.

(AC ¶¶ 120-21). For interim periods (e.g., quarterly reports), Item 303(b) requires disclosure of material changes in those items listed in Item 303(a), including known trends and uncertainties. (AC ¶ 121). Instruction 3 to paragraph 303(a) provides that “[t]he discussion and analysis shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.” 17 C.F.R. § 229.303(a), Instruction 3. SEC’s interpretive release regarding the Regulation imposes a disclosure duty “where a trend, demand, commitment, event or

uncertainty is both [1] presently known to management and [2] reasonably likely to have material effects on the registrant's financial condition or results of operations." Management's Discussion and Analysis of Financial Condition and Results of Operations, Securities Act Release No. 6835, Exchange Act Release No. 26,831, Investment Company Act Release No. 16,961, 43 SEC Docket 1330 (May 18, 1989). (AC ¶ 123).

ii. No Private Right of Action Under Item 303

The first question, then, is whether there is a private right of action based solely on a violation of the disclosure requirements of Item 303. There is not.

Item 303 is enforced by the SEC through enforcement actions, not by private plaintiffs through civil lawsuits. *See Interpretation: Commission Guidance Regarding Management's Discussion and Analysis of Financial Condition and Results of Operations*, Securities and Exchange Commission, 17 C.F.R. §§ 211, 231, 241 (Dec. 19, 2003), www.sec.gov/rules/interp/33-8350.htm#P18_1728. The Third Circuit has held squarely in *Oran v. Stafford*, 226 F.3d 275, 285-86 (3d Cir. 2000), that there is no independent private right of action under Item 303. "Neither the language of [Item 303] nor the SEC's interpretive releases construing it suggest that it was intended to establish a private right of action" *Id.* I of course follow this controlling precedent. Plaintiffs do not possess an independent right of action under Item 303.³

iii. Material omissions or misstatements in Item 303 that independently violate 10b-5

A direct private right of action under Item 303 is not the only potential route to liability, however. In this subsection, I consider the alternative theory

³ The Supreme Court granted certiorari to address a disagreement among the Second, Third, and Ninth Circuits regarding the existence or scope of an independent private right of action (or actionable disclosure mandate) under Item 303. *Leidos, Inc. v. Indiana Public Retirement System*, 137 S. Ct. 1395 (2017). That case, however, was voluntarily dismissed. 138 S. Ct. 2670 (2018).

that defendants' alleged omissions in the Item 303 disclosures could independently run afoul of Rule 10b-5 and therefore support a claim.

In *Oran*, the Third Circuit stated that Item 303's disclosure requirements surpass those of Rule 10b-5, particularly as to materiality. It follows that not all failures to disclose under Item 303 would give rise to a Rule 10b-5 claim. 226 F.3d at 288. *Oran* suggested, however, that some such omissions might be actionable:

[The Item 303] test varies considerably from the general test for securities fraud materiality set out by the Supreme Court in *Basic Inc. v. Levinson*, which premised forward-looking disclosure “upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity.” As the SEC specifically noted, “[t]he probability/magnitude test for materiality approved by the Supreme Court in *Basic* ... is inapposite to Item 303 disclosure”; rather, [Item] 303's disclosure obligations extend considerably beyond those required by Rule 10b-5.

Because the materiality standards for Rule 10b-5 and [Item] 303 differ significantly, the “demonstration of a violation of the disclosure requirements of Item 303 does not lead inevitably to the conclusion that such disclosure would be required under Rule 10b-5. Such a duty to disclose must be separately shown.” [Thus ...] a violation of [Item] 303's reporting requirements does not automatically give rise to a material omission under Rule 10b-5.

Id. (internal citations omitted). Under *Oran*, then, “a violation of 303's reporting requirements does not *automatically* give rise” to a private right of action, but omissions from Item 303 disclosures could form the basis of a private securities suit if “[s]uch a duty to disclose [is] separately shown.” *Id.* (emphasis added).

Two Courts of Appeals—both citing *Oran*—have reached differing conclusions as to what is required to state a Rule 10b-5 claim based on Item 303 omissions.

The Ninth Circuit agrees that a material misrepresentation or omission in an Item 303 disclosure may be actionable. It is not a defense to a Rule 10b-5 claim, for example, that the misrepresentation or omission occurred in the context of an Item 303 disclosure. Item 303 does not, however, create an *independent* duty to disclose. *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014). To be actionable, an omitted fact under Item 303 must meet the materiality requirements of Rule 10b-5: *i.e.*, its disclosure must be necessary in order to make the company’s statements, in the light of the circumstances under which they were made, not misleading.

The Second Circuit’s interpretation is slightly more plaintiff-friendly. In *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 103 (2d Cir. 2015), it held that Item 303 creates an enforceable duty to disclose trends and uncertainties. The omission of *material* information from an Item 303 form can therefore be the basis of a securities action under Rule 10b-5. *Id.* It is not required that such an omission render other corporate statements misleading. *Id.*

To my mind, the Ninth Circuit’s interpretation is truer to the Third Circuit’s holding in *Oran* that “a duty to disclose,” beyond Item 303’s requirements, “must be separately shown.” 226 F.3d at 288. Under *Oran*, 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*.

This amended complaint does not clearly, factually allege that defendants have made material omissions under Item 303 that render other disclosures, such as the earnings and revenue statements, materially misleading. It follows that the Complaint fails to state a Rule 10b-5 claim with the requisite specificity. Now that the Court has stated the governing standard, it may be possible to do so, but I will not undertake to refine the allegations.

Defendants assert that the complaint suffers from two related defects that stem, in large part, from the same lack of clarity: **(B)** The complaint posits unclear and shifting theories of liability; and **(C)** The complaint does not delineate a statement-by-statement analysis of disclosures that are allegedly

material misrepresentations because of Item 303 omissions. These defects, discussed in the following sections, need to be rectified before the court can evaluate whether the plaintiffs have sufficiently pled a securities-fraud claim.

B. Unclear and Shifting Theories of Liability

Plaintiffs claim that defendants are liable based on their failure to disclose “trends or uncertainties” as required by Item 303. Plaintiffs do not present clearly defined theories of liability and do not clearly connect each allegedly false statement to each theory. Nonetheless, I can extract four theories from the allegations of the complaint:

- **Theory One:** (a) Defendants violated federal statutes by promoting the off-label use of Abstral, paying kickbacks to prescribers, knowingly working with prescribers who were trying to manipulate Galena stock, and failing to disclose the prescribers’ stock ownership; (b) Galena was exposed to civil and criminal liability because of these actions; and (c) defendants failed to disclose these “trends or uncertainties” per Item 303. (d) Thus, (some or all of) defendants’ statements about earnings and revenue were materially false or misleading. (AC ¶¶ 26-28).
- **Theory Two:** (a) Defendants knew that the government had taken an increasingly strict and active stance against the over-prescription and off-label prescription of powerful opioids such as Abstral; (b) defendants knew that Dr. Ruan and Dr. Couch, who were responsible for 30% of all Abstral sales, were over-prescribing Abstral on an off-label basis; (c) defendants knew that Abstral’s success was thus unsustainable; (d) defendants failed to disclose this “trend or uncertainty” in Item 303 and thus (some or all of) defendants’ statements about earnings and revenue were materially false or misleading. (AC ¶¶ 112-19).
- **Theory Three:** (a) Dr. Ruan and Dr. Couch were over-prescribing Abstral to manipulate Galena stock and personally profit; (b) defendants knew about their stock manipulation and conspired with them; and (c) defendants failed to disclose this conspiracy, and the associated risks regarding litigation and revenue per Item 303. (AC ¶¶ 129-44). (d) Thus, (some or all of) defendants’ statements about earnings and revenue were materially false or misleading.

- **Theory Four:** (a) Dr. Ruan and Dr. Couch’s practices, clinics, and pharmacy were shut down in May 2015; (b) these operations were responsible for 30% of Abstral sales; (c) the closure of these operations were reasonably likely to have a negative effect on Galena’s earnings and revenue; (d) defendants released a disappointing earnings and revenue guidance; (e) but also said that sales were “fluctuat[ing]” and did not explicitly disclose what happened with Dr. Ruan and Dr. Couch. (f) Defendants should have fully disclosed these risks and uncertainties per Item 303. (AC ¶¶ 153-59). (g) As a result of this omission, (some or all of) defendants’ statements about earnings and revenue were materially false or misleading.

Plaintiffs do not clearly articulate these theories or explicitly explain how the failure to disclose any particular piece of information under Item 303 made another specifically identified disclosure materially misleading. It is not the court’s role to match these theories of omission with alleged material misstatements in the complaint, and I will not do so.

C. Statement-by-Statement Analysis

Relatedly, the complaint fails to conduct a statement-by-statement analysis of alleged material misstatements. Under the PSLRA, a complaint must clearly identify the reason or reasons why each flagged statement is false or misleading—or how an omission makes another disclosure false or misleading. The PSLRA provides, in pertinent part:

(1) Misleading statements and omissions

In any private action arising under this chapter in which the plaintiff alleges that the defendant—

(A) made an untrue statement of a material fact; or

(B) omitted to state a material fact necessary in order to make the statement made, in the light of the circumstances in which they were made, not misleading;

the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

15 U.S.C. § 78u-4(b)(1),(2) (emphasis added). The PSLRA further requires dismissal of any action that fails to meet any of the above statutory pleading requirements:

In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of paragraphs (1) and (2) are not met.

15 U.S.C. § 78u-4(b)(3).

Under the PSLRA, plaintiffs must address how each individual statement is false or misleading. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 259-60 & n.30 (3d Cir. 2009); *see also In re Wilmington Tr. Sec. Litig.*, 852 F. Supp. 2d 477, 490-91 (D. Del. 2012). “Shareholders must specify each allegedly misleading statement [and] the reason or reasons why the statement is misleading.” *Avaya*, 564 F.3d at 259 (citing *Tellabs*, 551 U.S. at 320-21). Congress instituted this requirement “[a]s a check against abusive litigation by private parties....” *Tellabs*, 551 U.S. at 313; *see also In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277-78 (3d Cir. 2010). As stated by the District of Delaware in a PSLRA case:

While the Amended Complaint does specify each statement that was allegedly misleading, it falls short of describing the reason or reasons why each statement was misleading.... It is Plaintiffs’ burden to plead fraud on a statement-by-statement basis, and they may not evade that requirement by requiring the Court to try to match the allegedly fraudulent statements to the allegations of wrongdoing that are scattered throughout the ... Amended Complaint.

In re Wilmington Tr. Sec. Litig., 852 F. Supp. 2d at 490 (quoting *In re The Goodyear Tire & Rubber Co. Sec. Litig.*, 436 F.Supp.2d 873, 904 (N.D. Ohio 2006)).

Like the *Wilmington* court, I find that the plaintiffs here have left too much to the Court's imagination. To prevail on this motion, they must match statements with alleged omissions and state reasons why those omissions made statements materially misleading or false. "Until plaintiffs specifically identify the statements on which they would like to proceed and the reasons why these statements are false or misleading, neither the defendants nor the court can address these allegations with the degree of particularity required by the PSLRA." *In re Wilmington Tr. Sec. Litig.*, 852 F. Supp. 2d at 490-91.

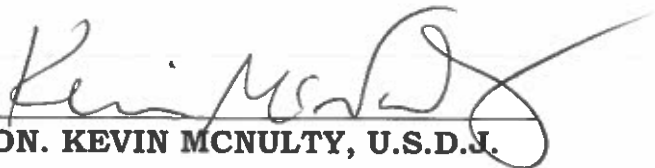
In sum, plaintiffs have generally identified troubling practices regarding Galena. I dismiss the complaint without prejudice, however, for failure to articulate clear theories of securities liability and failure to plead fraud on a statement-by-statement basis.

IV. CONCLUSION

For the foregoing reasons, defendants' motions to dismiss are granted, without prejudice to the filing of a second amended complaint within 30 days.

An appropriate order accompanies this opinion.

Dated: August 21, 2018


HON. KEVIN MCNULTY, U.S.D.J.