UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INCHEN HUANG, ET AL.,

Plaintiffs,

v.

ARTHUR JOSEPH HIGGINS, et al.,

Defendants.

Case No. 17-cv-04830-JST

ORDER GRANTING MOTION TO DISMISS

Re: ECF Nos. 66, 68, 70

Before the Court is the motion to dismiss Plaintiffs' amended complaint filed by Defendant Assertio Therapeutics, Inc. and Defendants Arthur Joseph Higgins, James A. Schoeneck, and August J. Moretti (collectively, the "Individual Defendants"). ECF No. 66. The Court will grant the motion.

I. BACKGROUND

This is a putative securities fraud class action brought on behalf of all persons who purchased Assertio Therapeutics[1] common stock between July 29, 2015 and August 7, 2017, against Assertio and certain current and former Assertio officers and directors. ECF No. 61, Amended Complaint for Violations of the Federal Securities Laws ("FAC") ¶ 1. The Court provides a brief overview of Plaintiffs' allegations, discussing them in greater detail as they become relevant to the Court's analysis.

Assertio is "a specialty pharmaceutical company" that "engages in the development, sale, and licensing of products, including opioids, for pain and other central nervous system

[1] At the time this action was filed, Assertio Thereaputics operated under the name Depomed, Inc., but has since changed names. See ECF No. 72. Accordingly, the Court uses Assertio Therapeutics throughout this order.

conditions." Id. ¶ 2. On April 2, 2015, Assertio acquired the U.S. rights to the NUCYNTA franchise, a line of opioids containing tapentadol, from Janssen Pharmaceuticals, Inc. and its affiliates (collectively, "Janssen"). Id. ¶ 35. Assertio sold the product in two forms: NUCYNTA ER (extended release) and NUCYNTA IR (immediate release). Id. Under Assertio's ownership, sales of NUCYNTA in the United States increased substantially, from $189.9 million in 2015 to $281.3 million in 2016. Id. ¶ 36. NUCYNTA formed an important part of Assertio's business; by August 7, 2017, the end of the Class Period, sales from the two NUCYNTA products accounted for 62 percent of Assertio's revenues. Id.

Plaintiffs allege that the growth of Assertio's NUCYNTA sales was driven by an illegal off-label marketing campaign. Id. ¶ 11. As background, the Food and Drug Administration (FDA) approves a drug or medical device for specific uses, sometimes referred to as "on-label" uses. 21 U.S.C. §§ 355(d), 360e(e)(1)(A). Once the product is approved, however, health care practitioners may also prescribe the product for "off-label" uses, meaning uses not approved by the FDA. Id. § 396; see also In re Gilead Scis. Sec. Litig. (Gilead III), 536 F.3d 1049, 1051 & n.2 (9th Cir. 2008). Nonetheless, under current FDA regulations, "pharmaceutical manufacturers are generally prohibited from promoting off-label uses of their products if the off-label marketing is false or misleading, or if it evidences that a drug is intended for such off-label use and is therefore 'misbranded.'" Polansky v. Pfizer, Inc., 822 F.3d 613, 615 (2d Cir. 2016); see also id. at 615 n.2 (citing 21 C.F.R. § 201.128).

According to Plaintiffs, Assertio "encouraged sales representatives to market NUCYNTA off-label as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label." FAC ¶ 12. Moreover, Assertio specifically targeted its off-label marketing at "family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids." Id. ¶ 11. This off-label marketing allowed Assertio to maintain positive growth in NUCYNTA sales even as sales in the rest of the opioid market were declining. Id. ¶¶ 10-11. As evidence of this off-label marketing campaign, Plaintiffs allege that Assertio's predecessor, Janssen, was accused in a separate lawsuit of marketing NUCYNTA off-label, that Assertio retained the same third-party sales force to

market NUCYNTA, and that confidential witnesses observed Assertio's off-label marketing campaign. Id. ¶¶ 69-91.

Plaintiffs reason that Defendants made material misrepresentations and omissions during the Class Period by touting the growth of the NUCYNTA franchise in earnings calls and Securities and Exchange Commission (SEC) filings without revealing that this growth was driven by off-label marketing. Id. ¶¶ 10-12. In its SEC filings, Assertio acknowledged the general risk of liability if the company was found to have marketed drugs off-label but did not indicate that it had engaged in any conduct that was likely to be considered off-label marketing. See, e.g., id. ¶¶ 101-102. Further, Plaintiffs assert, the Individual Defendants were aware of these marketing practices and the attendant risks at the time these statements were made. Id. ¶ 163.

Finally, Plaintiffs allege that the consequences of this off-label marketing manifested in a series of disclosures between November 7, 2016, and August 7, 2017. On November 7, 2016, Assertio lowered its revenue projections for the 2016 year, and on subsequent dates, outside market analysts downgraded their assessments of Assertio. Id. ¶¶ 218(a)-(b), (d)-(e). In addition, Plaintiffs attribute economic losses to Senator Claire McCaskill's March 28, 2017 announcement of "an investigation into the marketing and sales practices of the nation's top five manufacturers of prescription opioid products, including" Assertio, id. ¶ 218(c), and Assertio's August 7, 2017 announcement that the U.S. Department of Justice and Maryland Attorney General had issued subpoenas seeking similar information, id. ¶ 218(e). The day after each of these incidents, Assertio stock declined as much as $3.08 per share, falling from $22.89 to $6.15 per share over the course of these disclosures. See id. ¶ 218.

On August 18, 2017, Inchen Huang filed a putative class action complaint, alleging violations of federal securities laws. ECF No. 1. Two parties – the Depomed Investor Group ("DIG")[2] and the City of Pontiac General Employees' Retirement System[3] – filed motions seeking

[2] DIG consists of the individuals Aurelio Scarpatetti, Manuele Scarpatetti, Duy Vu, and Mark Madrack. See ECF No. 61 at 1.

[3] Three other parties filed motions seeking appointment as lead plaintiff but subsequently withdrew those motions or chose not to oppose another party's motion. See ECF No. 52 at 1.

appointment as lead plaintiff. ECF Nos. 12, 16. The Court appointed DIG as the lead plaintiff, as DIG had alleged the greatest financial stake in the outcome of the case, pleading approximately $403,000 in losses due to the decline of Assertio stock, and otherwise satisfied the requirements of Federal Rule of Civil Procedure 23. ECF No. 52 at 3-6. The Court also approved DIG's choice of lead counsel. Id. at 6-7. DIG subsequently filed an amended class action complaint. ECF No. 61. The complaint asserts two causes of action: (1) violations of Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5; and (2) violations of Section 20(a) of the Exchange Act. FAC ¶¶ 232-49.

Defendants filed a motion to dismiss on April 9, 2018. ECF No. 66.

II. LEGAL STANDARD

A. The Dual Pleading Requirements

Section 10(b) of the Securities Exchange Act of 1934 prohibits any act or omission resulting in fraud or deceit in connection with the purchase or sale of any security. To establish a violation of Section 10(b), a plaintiff must plead: (1) a material misrepresentation or omission made by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, 552 U.S. 148, 157 (2008).

On a motion to dismiss, the Court accepts the material facts alleged in the complaint, together with reasonable inferences to be drawn from those facts, as true. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). However, "the tenet that a court must accept a complaint's allegations as true is inapplicable to legal conclusions" or "threadbare recitals of a cause of action's elements, supported by mere conclusory statements." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Moreover, while a plaintiff generally need only plead "enough facts to state a claim to relief that is plausible on its face" to survive a motion to dismiss, Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007), "[s]ecurities fraud class actions must meet the higher, exacting pleading standards of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ('PSLRA')," Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc., 774 F.3d 598, 604 (9th Cir. 2014).

Under the PSLRA and Rule 9(b), a complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" with respect to each alleged false statement or omission, and "a party must state with particularity the circumstances constituting fraud or mistake." 15 U.S.C. § 78u-4(b)(2)(A); Fed. R. Civ. P. 9(b); see also Or. Pub. Emps. Ret. Fund, 774 F.3d at 605. "In order to show a strong inference of deliberate recklessness, plaintiffs must state facts that come closer to demonstrating intent, as opposed to mere motive and opportunity." In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 974 (9th Cir. 1999), abrogated on other grounds by S. Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 784 (9th Cir. 2008). If the complaint does not satisfy the PSLRA's pleading requirements, the Court must grant a motion to dismiss the complaint. 15 U.S.C. § 78u-4(b)(3)(A).

B. Falsity and Materiality

The PSLRA provides that "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." 15 U.S.C. § 78u-4(b)(1)(B). For statements to be actionable under the PSLRA, they must be both false or misleading and material. A statement or omission is misleading under the PSLRA and Section 10(b) of the Exchange Act "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 985 (9th Cir. 2008) (internal quotation marks and citation omitted).

A false or misleading statement or omission is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). To plead materiality, a complaint's allegations must "suffice to raise a reasonable expectation that discovery will reveal evidence satisfying the materiality requirement, and to allow the court to draw the reasonable inference that the defendant is liable." In re Atossa Genetics Inc Sec. Litig., 868 F.3d 784, 794 (9th Cir. 2017) (citation omitted). "Although determining materiality in securities fraud cases should ordinarily be left to

the trier of fact, conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." In re Cutera Sec. Litig., 610 F.3d 1103, 1108 (9th Cir. 2010) (internal quotation marks and citations omitted).

C. Scienter

The required state of mind under the PSLRA is a "mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193–94 n.12 (1976). In order to adequately establish scienter, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A).

The "strong inference" required by the PSLRA "must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007). "A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009). In evaluating whether a complaint satisfies the "strong inference" requirement, courts must undertake a two-step inquiry by first considering "whether any of the allegations, standing alone, are sufficient to create a strong inference of scienter," and "if no individual allegation is sufficient, . . . conduct[ing] a 'holistic' review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness." Curry v. Yelp Inc., 875 F.3d 1219, 1226 (9th Cir. 2017) (citation omitted).

In the Ninth Circuit, scienter is a "mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc., 856 F.3d 605, 619 (9th Cir. 2017) (quoting Schueneman v. Arena Pharm., Inc., 840 F.3d 698, 705 (9th Cir. 2016)). "Deliberate recklessness is an extreme departure from the standards of ordinary care[,] 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." Webb v. Solarcity Corp., 884 F.3d 844, 851 (9th Cir. 2018) (alteration and emphasis in original) (quoting City of Dearborn Heights, 856 F.3d at 619). Stated differently, deliberate recklessness requires that an actor "had reasonable grounds to believe material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose such facts although [the actor] could have done so without extraordinary effort." Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., 759 F.3d 1051, 1063 (9th Cir. 2014) (citation omitted). "Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness." In re Verifone Holdings, Inc. Sec. Litig., 704 F.3d 694, 701 (9th Cir. 2012).

D. Loss Causation

Loss causation, "i.e., a causal connection between the material misrepresentation and the loss" experienced by the plaintiff, is a necessary element of pleading a securities fraud claim under Section 10(b) of the Exchange Act. Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 342 (2005). The plaintiff "must demonstrate that an economic loss was caused by the defendant's misrepresentations, rather than some other intervening event." Lloyd v. CVB Fin. Corp., 811 F.3d 1200, 1209 (9th Cir. 2016). In other words, plaintiffs alleging that they suffered a loss because they resold shares at a lower price must show that the price reflects "the earlier misrepresentation" rather than "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price." Dura Pharm., 544 U.S. at 343. The Ninth Circuit has held that, as with other elements of a securities fraud claim, plaintiffs must plead loss causation with the particularity required by Federal Rule of Civil Procedure 9(b). See Or. Pub. Emps. Ret. Fund, 774 F.3d at 605.

"The burden of pleading loss causation is typically satisfied by allegations that the defendant revealed the truth through 'corrective disclosures' which 'caused the company's stock price to drop and investors to lose money.'" Lloyd, 811 F.3d at 1209 (quoting Halliburton Co. v. Erica P. John Fund, Inc., 134 S. Ct. 2398, 2406 (2014)); see also Nuveen Mun. High Income

Opportunity Fund v. City of Alameda, 730 F.3d 1111, 1119 (9th Cir. 2013) ("Typically, 'to satisfy the loss causation requirement, the plaintiff must show that the revelation of that misrepresentation or omission was a substantial factor in causing a decline in the security's price, thus creating an actual economic loss for the plaintiff.'" (quoting McCage v. Ernst & Young, LLP, 494 F.3d 418, 425-26 (3d. Cir. 2007)). However, "[d]isclosure of the fraud is not a sine qua non of loss causation, which may be shown even where the alleged fraud is not necessarily revealed prior to the economic loss." Nuveen, 730 F.3d at 1120. "The fundamental inquiry before the Court remains whether there is 'a causal connection between the material misrepresentation and the loss.'" Thomas v. Magnachip Semiconductor Corp., 167 F. Supp. 3d 1029, 1046 (N.D. Cal. 2016) (quoting Dura Pharm., 544 U.S. at 342).

III. DISCUSSION

Defendants move to dismiss the complaint, arguing that Plaintiffs do not adequately plead (1) a material misrepresentation or omission, (2) scienter, or (3) loss causation. ECF No. 66 at 7-8.

A. Falsity and Materiality

Plaintiffs allege numerous false or misleading Class Period statements made during earnings calls or in SEC filings. These statements generally fall into two categories. First, Plaintiffs cite statements in which Defendants "described [Assertio's] recent marketing achievements as successes, but at the same time did not disclose that these supposed successes were obtained in part through an illicit off-label marketing campaign." FAC ¶ 108; see also, e.g., id. ¶¶ 99, 104, 110. Second, Plaintiffs highlight SEC filings where Assertio acknowledged the possibility that "[w]e may incur significant liability if it is determined that we are promoting or have in the past promoted the 'off-label' use of drugs." Id. ¶¶ 101, 105, 111, 115, 121. Plaintiffs contend that these risk statements were misleading because they did not provide the necessary context that Assertio "had already been deliberately engaged in off-label marketing," making "the potential exposure arising therefrom . . . a far more likely event." Id. ¶ 102. The foundational premise of Plaintiffs' claims, therefore, is that Assertio engaged in off-label marketing. Defendants contend that Plaintiffs' allegations are insufficient to plead that such off-label

marketing occurred, and that Plaintiffs consequently fail to plead material misrepresentations or omissions. ECF No. 66 at 11. The Court first considers the extent of off-label marketing plausibly alleged, then turns to whether each category of statements is material and misleading.

1. Extent of Off-label Marketing

Plaintiffs rely on three general types of allegations of off-label marketing: (1) allegations of off-label marketing by Janssen between 2009 and 2012; (2) confidential witness allegations regarding off-label marketing by Assertio; and (3) a website maintained by Assertio.

First, Plaintiffs allege that Janssen engaged in off-label marketing of NUCYNTA prior to April 2015, when Janssen sold the NUCYNTA franchise to Assertio. FAC ¶¶ 69-80. Plaintiffs point out that the City of Chicago filed a complaint against Janssen, in which the City alleged that "between 2009 and 2012, NUCYNTA and NUCYNTA ER sales representatives repeatedly promoted these drugs as less addictive than other opioids." Id. ¶ 73. In August 2015, after Assertio acquired NUCYNTA from Janssen, the City of Chicago amended its complaint to name Assertio as an additional defendant, but the court subsequently dismissed Assertio from the litigation in November 2015. Id. ¶ 57. Plaintiffs allege that despite knowledge of the accusations in this litigation, Assertio hired the same third-party sales force that promoted NUCYNTA under Janssen's ownership (Quintiles) to promote NUCYNTA on Assertio's behalf. Id. ¶ 83.

Defendants argue that the Court should not consider the allegations against Janssen, citing cases holding that "paragraphs in a complaint that are either based on, or rely on, complaints in other actions that have been dismissed, settled, or otherwise not resolved, are, as a matter of law, immaterial" for the purposes of a motion to strike.[4] In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig., 934 F. Supp. 2d 1219, 1226 (C.D. Cal. 2013) (quoting RSM Prod. Corp. v. Fridman, 643 F. Supp. 2d 382, 403 (S.D.N.Y. 2009)); see also In re Connectics Corp. Sec. Litig., 542 F. Supp. 2d. 996, 1005-06 (N.D. Cal. 2008) (granting motion to strike allegations based solely on SEC complaint with no "independent, reasonable investigation as required by Rule 11(b)"). But here, Defendants have not filed a motion or otherwise asked the Court to strike allegations related

[4] Federal Rule of Civil Procedure 12(f) provides that "[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter," either sua sponte or upon a motion by either party.

to Janssen's practices, nor explained why the Court should disregard those allegations in the absence of such a motion. Moreover, In re Connectics Corp. Securities Litigation specifically emphasized that the plaintiff there sought to "rely entirely on another complaint as the sole basis for his or her allegations." 542 F. Supp. 2d at 1005. The In re Connectics court distinguished cases such as In re Cylink Securities Litigation, which permitted "a complaint filed by the SEC may come into the mix of the materials considered by the court on a motion to dismiss." 542 F. Supp. 2d at 1005 (citing In re Cylink Sec. Litig., 178 F. Supp. 2d 1077, 1080, 1083 (N.D. Cal. 2001)). Ultimately, however, the Court need not decide whether the City of Chicago allegations are immaterial as a matter of law because they contribute at most a weak inference of off-label marketing by Assertio.

The Court agrees with Defendants that the alleged conduct of a different company three years prior to the Class Period, without more, provides an insufficient basis to infer that Assertio engaged in those same practices. See Cats v. Prot. One, Inc., No. CV99-3755DT(RCX), 2001 WL 34070630, at *15 (C.D. Cal. June 4, 2001) ("Alleged [misconduct] occurring prior to the Class Period cannot meet the heightened pleading standards of the PSLRA in the absence of specific facts showing that the practice continued during the Class Period."). Here, Plaintiffs also note that Assertio retained the same outside sales contractor as Janssen. FAC ¶ 83. This might provide some support for Plaintiffs' theory that Assertio continued Janssen's sales practices, had those practices not already come under scrutiny. But, as Plaintiffs stress, Defendants were aware of the substance of the ongoing City of Chicago litigation at the time Assertio acquired NUCYNTA, id. ¶¶ 81, 172, and acknowledged the litigation in their SEC filings, id. ¶¶ 172-173. The Court finds that it is not reasonable to infer that in the face of this ongoing litigation, Assertio continued the same disputed off-label marketing, absent the pleading of specific facts related to *Assertio's* practices.[5]

[5] Plaintiffs' citation to Webb v. Solarcity Corp., 884 F.3d 844 (9th Cir. 2018), is not to the contrary. In Webb, the Ninth Circuit stated that the district court did not err in concluding that confidential witness allegations from before the Class Period provided "little reliable insight into what occurred during the class period." Id. at 851 n.1. But the Webb court pointed out that "[i]nformation from before the class period is relevant because it can 'confirm what a defendant should have known during the class period.'" Id. (quoting In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 72 (2d Cir. 2001)). Here, there is no dispute that the Defendants were aware of the alleged Janssen off-label marketing. Rather, the parties contest whether any off-label marketing

Next, Plaintiffs attempt to plead those facts in the form of allegations from confidential witnesses, whom Plaintiffs designate as Former Employees ("FE") 1 through 4. FAC ¶¶ 85-91. To satisfy the PSLRA's pleading requirements, the FEs' statements must satisfy two tests. First, the FEs must be "described with sufficient particularity to establish their reliability and personal knowledge." Zucco Partners, 552 F.3d at 995. Second, the FEs' statements must "themselves be indicative of" the elements in question; here, falsity and materiality. Id.

Plaintiffs have described the FEs with sufficient particularity by providing "each witness's job description and responsibilities." In re Quality Sys., 865 F.3d at 1145. Because each FE was a sales representative for Assertio during at least part of the Class Period, see FAC ¶¶ 85, 87-88, 90, these descriptions "support the probability that a person in the position occupied by the source would possess the information alleged," In re Quality Sys., 865 F.3d at 1145 (quoting In re Daou Sys., Inc., 411 F.3d 1006, 1015 (9th Cir. 2005)).

Defendants argue, though, that the FEs' allegations are too vague to establish personal knowledge that any off-label marketing took place. In particular, Defendants note – and Plaintiffs do not dispute – that companies may permissibly communicate some off-label information, such as in response to "unsolicited requests." ECF No. 66 at 14. Accordingly, allegations that the FEs were told by their superiors that NUCYNTA was a safer opioid, even if taken as true, do not necessarily establish that any sales representatives were instructed to, or actually made, prohibited off-label statements to prescribing practitioners. See In re InterMune, Inc., No. C 03-2954 SI, 2004 WL 1737264, at *6 (N.D. Cal. July 30, 2004) ("Plaintiffs fail to allege facts with the necessary particularity to suggest that InterMune's promotion of Actimmune went beyond what is the acceptable practice of providing doctors[] with informational material to the actual promotion of the drug for its off-label use."). Many statements provided by the FEs are deficient for this reason. See FAC ¶¶ 86 ("FE1 stated that the [sales] manager was very vocal about NUCYNTA being a 'safer opioid.'"), 87 ("FE 2 stated 'We were being convinced it was a safer opioid' that was 'the overall consensus being told to us.'"), 89 ("When asked where FE3 heard NUCYNTA was safer and less euphoric, FE3 stated that they were told during sales training that NUCYNTA

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by Assertio "occurred during the class period." Id.

did not provide the same euphoria as other street-level opioids."). None of the FEs alleges that they themselves marketed NUCYNTA off-label.

With this distinction in mind, the Court concludes that FE3's and FE4's statements do not allege any off-label marketing. FE3 stated that if doctors had "specific questions about abuse, we did talk abuse." Id. ¶ 89. This statement does not support an inference that FE3 and other sales personnel promoted off-label use, rather than permissibly responding to unsolicited requests for further information. FE4 alleges that "'there may have been some perception' that NUCYNTA was a safer painkiller" and that FE4's trainer "expressed that there was a 'gray area' when it comes to selling opioids," but these statements do not indicate that FE4 had any personal knowledge that off-label marketing occurred. Id. ¶ 90.

Construed in their most favorable light, FE2's allegations raise an inference that some unnamed Assertio supervisors tacitly encouraged off-label marketing. FE2 alleges that "when the sales team complained about selling to neurologists, FE2's superiors would say that 'this is a great opportunity to introduce them to the safer opioid.'" Id. ¶ 87. At most, the Court can infer that FE2's superiors suggested that sales personnel should rely on this talking point in selling to neurologists.

FE1 is the only confidential witness who alleges observing any instances of off-label marketing. FE1 states that a manager, David Sims, trained FE1 "to pushback against prescribers who cited concerns writing an opioid prescription," and that FE1 "heard Sims call NUCYNTA a safer opioid to physicians." Id. ¶ 86. FE1 further reports observing another "former Quintiles sales representative who actively told physicians that NUCYNTA was a safer opioid." Id.

"Taken collectively," In re Quality Sys., 865 F.3d at 1145 (citation omitted), the FEs' statements suggest that Assertio emphasized to its sales representatives that NUCYNTA was a safer opioid, but establish little direct evidence of any off-label marketing. Any inference of off-label marketing is further undermined by two considerations. First, the extent of off-label marketing that can be inferred is limited by the fact that many of the FEs did not work at Assertio for the entire Class Period. See id. ¶¶ 85 (FE1 ended March 2016), 87 (FE2 ended July 2017), 88

(FE3 ended August 2016), 90 (FE4 ended late November/early December 2016).[6] See Brodsky v. Yahoo! Inc., 630 F. Supp. 2d 1104, 1115 (N.D. Cal. 2009) ("[B]ecause CW 3 and CW 5 were not Yahoo! employees for most of the Class Period, the Court cannot rely on their statements to support claims of false revenue reporting for the entire Class Period.").

Second, the FEs' accounts lack the "specific[ity] in time, context, and details" that courts have frequently required as indicia of reliability. Lloyd, 811 F.3d at 1208; see also Costabile v. Natus Med. Inc., 293 F. Supp. 3d 994, 1010 (N.D. Cal. 2018) (reasoning that the court could not determine the reliability of a witness account that did not "provide[] any context surrounding when, why, or how" the witness learned of information); Schaffer v. Horizon Pharma PLC, No. 16-CV-1763 (JMF), 2018 WL 481883, at *8 (S.D.N.Y. Jan. 18, 2018) (holding that where no "source indicates who, when, or how he or she was directed to market drugs in this manner, the statements fall short of establishing, with the requisite degree of particularity, a company-wide practice"). The FEs' statements are not entirely devoid of such details, as they identify some of the individuals who supervised the FEs. See, e.g., FAC ¶¶ 86, 88. Yet they provide no details as to the critical conversations that would establish personal knowledge of off-label marketing. FE1, for instance, states that Sims and an unnamed Quintiles representative promoted NUCYNTA for off-label uses to physicians, but does not cite any specific conversation, let alone details such as when and with whom a conversation took place, or what was said. Id. ¶ 86.

The parties cite a litany of cases in support of their respective positions, but the most on-point cases support Defendants' view. In Gilead, for instance, confidential witnesses alleged that "specific instructions were given to sales and marketing personnel to utilize off-label information to push sales of" the drug in question. In re Gilead Sci. Sec. Litig. (Gilead I), No. C03-4999-MJJ, 2005 WL 181885, at *8 (N.D. Cal. Jan. 26, 2005). Moreover, the confidential witnesses identified the particular meetings at which they received these instructions. Id. Even so, the court reasoned that the confidential witnesses "only allege that [the company's] representatives were instructed to

[6] Defendants argue that FE1's statements should be discounted because "it is unclear whether FE1 purports to be recounting events at Janssen or at [Assertio]," ECF No. 66 at 15, given that FE1's employment began in October 2011, FAC ¶ 85. But FE1 is described as an employee of Assertio, with no indication that FE1 ever worked for Janssen. See id. The Court can reasonably infer that FE1's allegations regarding the marketing of NUCYNTA pertain to events after April 2015, when Assertio acquired NUCYNTA. See id. ¶ 35.

engage in such activity, not that such activity actually took place." Id. The court concluded that off-label marketing occurred only because the confidential witness allegations were corroborated by FDA letters specifically citing instances of off-label marketing by the company's sales representatives. Id.

Here, the FEs do not provide the details of any individual meetings, nor allege that they received specific instructions to market NUCYNTA for off-label uses. Further, Plaintiffs do not allege corroborating evidence akin to the FDA warning letters in Gilead. As discussed in greater detail below, the investigation and subpoenas on which Plaintiffs rely were directed at the marketing practices of five opioid manufacturers generally, rather than detailing specific instances of off-label marketing by Assertio personnel. See FAC ¶¶ 138, 157.

In re Amgen Inc. Securities Litigation (Amgen I), 544 F. Supp. 2d 1009 (C.D. Cal. 2008), likewise cuts against Plaintiffs' position. There, a confidential witness described in detail a "sales aid" provided by the company's regional manager containing specific questions to ask prescribers related to off-label promotion. Id. at 1033. Other confidential witnesses also identified specific training materials and a speaker program that the company used to support off-label marketing. Id.

By contrast, Plaintiffs acknowledge that Assertio omitted the alleged off-label facts "from their printed training materials." FAC ¶ 89. Contrary to Plaintiffs' suggestion, id., the Court cannot infer that improper verbal instructions were given from the absence of such instructions on printed materials.

The Court need not determine whether these flaws render the FEs' statements entirely unreliable for the purposes of this motion because, even accepting the statements as true, Plaintiffs fail to adequately plead materiality. The Court therefore assumes the truth of the FEs' statements for the purposes of this motion but declines to infer a broader company-wide practice.

Finally, Plaintiffs allege that Assertio operated a website "promoting the prescribing of NUCYNTA based upon the premise that it was a safer, more tolerable, and less abused opioid than Oxycodone," even though those claims were not on NUCYNTA's label. ECF No. 68 at 18; see also FAC ¶ 84. Although this allegation is sparse in detail, the Court takes it as true at the motion to dismiss stage.

In sum, the most generous reading of Plaintiffs' complaint is that Defendants maintained a website that contained some off-label claims, and one Assertio sales representative observed two other representatives make unsolicited off-label claims to prescribers. The Court can infer a slightly broader practice of off-label marketing from confidential witness allegations that NUCYNTA's potential for off-label uses was a point of emphasis during sales representatives' training and that Assertio retained the same sales force that had been accused of off-label marketing under Janssen's watch.

2. Statements Regarding NUCYNTA Sales

The Court next considers whether this off-label marketing renders the challenged statements materially misleading. In their first category of actionable misrepresentations, Plaintiffs cite Defendants' "misleading statements about [Assertio's] strengthening sales in spite of worsening negative 'headwinds' and/or market conditions affecting the opioid industry." ECF No. 68 at 14-15. Plaintiffs do not dispute that these statements conveyed factually accurate information about the status of NUCYNTA sales. See, e.g., FAC ¶ 117 ("During the first full year after our relaunch, we delivered $274 million of total NUCYNTA net sales, an increase of 59% over the final year of sales under the previous owner."). Plaintiffs' claim, therefore, turns on an omissions theory, i.e., that Defendants were required to disclose their off-label marketing campaign along with NUCYNTA sales figures.

The Ninth Circuit has "expressly declined to require a rule of completeness for securities disclosures because '[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not.'" Police Ret. Sys. of St. Louis, 759 F.3d at 1061 (alteration in original) (quoting Brody v. Transitional Hosp. Corp., 280 F.3d 997, 1006 (9th Cir. 2002)). Accordingly, "[t]o be actionable under the securities laws, an omission must . . . affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." Brody, 280 F.3d at 1006.

Plaintiffs' failure to plead a widespread off-label marketing campaign dooms their omissions claim. In considering a similar claim, the First Circuit has cogently explained the "long chain of inferences" necessary to make the failure to discuss off-label marketing material:

> First, we would have to infer that, of the 85% of Abiomed revenue due to sales of Impella products, a substantial portion is due to sales of the Impella 2.5. . . . Second, we would have to infer that, of the revenues from the Impella 2.5, a substantial portion was due to purchases for off-label use by health care professionals. . . . Third, we would have to infer that, of the revenues from off-label use, a substantial portion of that use was due to off-label marketing of the device, and, further, that the portion was so significant as to undercut the company's projected growth figures. And fourth, we would have to infer that the resulting undercutting of the growth figures was substantial enough to have a material effect on the stock price.

*Fire & Police Pension Ass'*n of Colo. v. Abiomed, Inc., 778 F.3d 228, 242-43 (1st Cir. 2015).

Here, Plaintiffs have adequately pleaded facts necessary to support the first inference because they allege that NUCYNTA comprised 62 percent of Assertio's revenue during the Class Period. FAC ¶ 10. But Plaintiffs' theory falters at the second required inference. Plaintiffs have not alleged any facts related to what portion of NUCYNTA sales "was due to purchases for off-label use by health care professionals." Abiomed, Inc., 778 F.3d at 242-43. Nor are Plaintiffs' allegations, which support an inference only that some limited amount of off-label marketing occurred, enough for the Court to infer that "a substantial portion of [off-label] use was due to off-label marketing." Id.; see also Schaffer, 2018 WL 481883, at *8 ("[T]he mere fact that prescriptions were written for off-label purposes . . . does not necessarily imply that Horizon was actively marketing its drugs as such."). Similarly, "[u]nder the heightened pleading standard required in PSLRA cases, the Court cannot simply assume that [any] off-label marketing of [NUCYNTA] necessarily resulted in increased sales of that drug." Gilead I, 2005 WL 181885, at *9 (N.D. Cal. Jan. 26, 2005). As in Gilead I, Plaintiffs have failed to "identify a single prescription written for [NUCYNTA] that was allegedly generated by off-label marketing activity," and so have not "allege[d] facts to bridge this logical gap." Id.[7]

Accordingly, the Court holds that this category of statements was not materially

[7] In Gilead II, plaintiffs subsequently amended their complaint to include confidential witness allegations as to the percentage of sales that resulted from off-label marketing, facts regarding the proportion of off-label use, and specific examples of doctors prescribing off-label uses after "receiv[ing] unsolicited data from Defendants." In re Gilead Scis. (Gilead II), No. C 03-4999 MJJ, 2005 WL 2649200, at *7 (N.D. Cal. Oct. 11, 2005). Nonetheless, the court concluded that these far more detailed allegations raised a "close question" as to materiality, which it ultimately did not decide because plaintiffs had failed to satisfy loss causation. Id.

misleading.

3. Risk Statements

Plaintiffs' second category of statements covers SEC filings that disclosed the general risk of liability from off-label marketing but did not indicate that Assertio was engaged in activities that, as Plaintiffs contend, were likely to be deemed to violate FDA rules.

A risk statement may be materially misleading if it "speaks about the risks . . . in the abstract, with no indication that the risk 'may already have come to fruition.'" Siracusano v. Matrixx Initiatives, Inc., 585 F.3d 1167, 1181 (9th Cir. 2009), *aff'*d, 563 U.S. 27 (2011) (quoting Berson, 527 F.3d at 986). For instance, Siracusano concluded that a drug manufacturer's statement that "[w]e may incur significant costs resulting from product liability claims" was materially misleading where the statement "failed to disclose that a lawsuit alleging that [the product] caused anosmia had already been filed and, given the finding of [university] researchers . . . it was highly likely that additional suits would be filed in the future." Id. at 1172.

Similarly, in Atossa Genetics, Atossa received an FDA warning letter expressing a variety of concerns, including that one of Atossa's products was misbranded, another product lacked FDA clearance, and Attosa's marketing materials were false and misleading. 868 F.3d at 791. In a subsequent SEC filing, Atossa reported receiving the letter but omitted "the balance of the FDA's alleged serious concerns" regarding the need for FDA approval and misleading marketing materials. Id. at 797. The court reasoned that Atossa "hid the ball" because "the omissions gave the reasonable inference that the FDA had raised no concerns related" to the omitted matters, even though "the FDA had raised precisely that concern." Id. Moreover, given these specific concerns, "Atossa's general disclaimer that it could be subject to future regulatory action from 'other matters'" did not prevent the risk statement from being materially misleading. Id.

Here, because Plaintiffs do not adequately plead a widespread off-label marketing scheme, Assertio did not materially misstate the likelihood or extent of regulatory risks. See Lloyd, 811 F.3d at 1207 (rejecting a similar argument that the "risk had already come to fruition" where the statements gave adequate and accurate context as to the facts relevant to the risk). Plaintiffs do not offer any arguments on this point independent of their widespread off-label allegations. Further,

cases such as Siracusano and Atossa Genetics involved specific manifestations of a precise risk not present here.

The Court holds that this category of statements was also not materially misleading.[8]

B. Scienter

Plaintiffs' complaint also fails to raise a strong inference of scienter. Plaintiffs rely on a variety of allegations to demonstrate scienter for the Individual Defendants (Higgins, Schoeneck, and Moretti). If the scienter requirement is met as to any of the Individual Defendants, it is met as to Assertio because Defendants do not argue that the Individual Defendants were acting outside the scope of their apparent authority. In re ChinaCast Educ. Corp. Sec. Litig., 809 F.3d 471, 476 (9th Cir. 2015) ("The scienter of the senior controlling officers of a corporation may be attributed to the corporation itself to establish liability as a primary violator of § 10(b) and Rule 10b–5 when those senior officials were acting within the scope of their apparent authority.").[9]

The Court addresses each argument individually, then considers all of the relevant allegations holistically. See Curry, 875 F.3d at 1226.

1. Actual Awareness

First, Plaintiffs contend that Higgins, Schoeneck, and Moretti were actually "aware that

[8] To the extent that Defendants argue that they are not liable because off-label marketing is protected by the First Amendment, ECF No. 66 at 19-21, their cited authority does not support that proposition. Plaintiffs do not assert that the off-label marketing itself was materially misleading and therefore the basis for liability, but rather that the Defendants' statements and omissions related to NUCYNTA sales were false and material because they did not disclose that off-label marketing was taking place. Moreover, even under the Second Circuit's holding in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), off-label marketing exposes a company to regulatory risks because "Caronia left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label," Polansky, 822 F.3d at 615 n.2 (citing Caronia, 703 F.3d at 162). Under a different set of facts, the omission of such risks could well be material.

[9] The Ninth Circuit has suggested that, in some cases, it may be "possible to raise the inference of scienter without doing so for a specific individual," such as where "a company's public statements were so important and so dramatically false that they would create a strong inference that at least some corporate officials knew of the falsity upon publication." In re NVIDIA Corp. Sec. Litig., 768 F.3d 1046, 1063 (9th Cir. 2014) (second quoting Glazer Capital Mgmt., LP v. Magistri, 549 F.3d 736, 743 (9th Cir. 2008)). To the extent that Plaintiffs' complaint suggests reliance on such a "collective scienter" theory, see FAC ¶ 215, Plaintiffs' opposition focuses exclusively on the Individual Defendants' scienter, making clear that Plaintiffs are not relying on collective scienter, see ECF No. 68 at 22-27.

[Assertio] was instructing its employees to market NUCYNTA 'off-label,'" and thus knew that omitting this information rendered their challenged statements misleading. ECF No. 68 at 18. Plaintiffs' complaint provides examples of the Individual Defendants discussing NUCYNTA as a safer opioid with investors, accompanied by the caveat that Defendants could not make such claims for marketing purposes. See FAC ¶¶ 177 (Schoeneck stating "I can't make a claim around that because we don't actually have that in the label"); 179 (Higgins stating that Assertio was "looking to strengthen our label"), 186 (Moretti stating that "I think that physicians feel that [NUCYNTA has less potential for abuse]; however, those claims are not on the label"). These statements demonstrate that Defendants were aware that off-label marketing was improper, but not that such marketing occurred. Allegations related to Defendants' "vast experience in the pharmaceutical industry," id. ¶¶ 197-200, are to the same effect.

Plaintiffs also rely on the same confidential witness allegations discussed above. As an initial matter, Plaintiffs must "allege scienter with respect to each of the individual defendants." Or. Pub. Emps. Ret. Fund, 774 F.3d at 607. The FEs' allegations do not mention Higgins or Moretti, and so "do not permit the Court to conclude that any [FE] had personal knowledge of [their] state of mind." Shenwick v. Twitter, Inc., 282 F. Supp. 3d 1115, 1149 (N.D. Cal. 2017) (finding CW allegations insufficient where "[c]ritically, none of the CWs report communicating directly with" the individual defendants).

The complaint does contain one FE allegation related to Schoeneck. FE3, a pain sales specialist at Assertio, stated that, "I heard Jim Schoeneck talk a lot. The perception of opioids? You're selling a molecule that's not supposed to cause euphoria. You're kind of talking out both sides of your mouth. I'm selling a painkiller, but not the same as (the ones) on the street." FAC ¶ 192. It is unclear which portions of this statement are attributable to Schoeneck, rather than FE3. Further, as discussed above, this confidential witness allegation lacks the "specific[ity] in time, context, and details" to support its reliability. Lloyd, 811 F.3d at 1208; see also Or. Pub. Emps. Ret. Fund, 774 F.3d at 607 (discounting anonymous accounts of meetings that purportedly demonstrated scienter where "Plaintiffs do not provide specificity about the[] meetings"). Accordingly, this allegation raises only a weak inference of scienter; nonetheless, the Court

considers this statement in its holistic analysis.

2. Core Operations Doctrine

Plaintiffs' other arguments in support of Individual Defendants' awareness are premised on the core operations doctrine. Under the core operations doctrine, "[a]llegations regarding management's role may help satisfy the PSLRA scienter requirement in three circumstances:"

> First, the allegations may be viewed holistically, along with other allegations in the complaint, to raise a strong inference of scienter under the Tellabs standard. Second, the allegations "may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information," as in Daou and Oracle. Third, in rare circumstances, such allegations may be sufficient, without accompanying particularized allegations, where the nature of the relevant fact is of such prominence that it would be "absurd" to suggest that management was without knowledge of the matter.

Reese, 747 F.3d 557, 575–76 (9th Cir. 2014), overruled on other grounds by City of Dearborn Heights, 856 F.3d at 616.

Plaintiffs appear to argue that Schoeneck had "actual access" based on his role overseeing "the sales, marketing, and managed care functions" of Assertio, dating back to at least November 7, 2016. ECF No. 68 at 23 (quoting FAC ¶ 196). "As [the Ninth Circuit] has noted on more than one occasion, corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter – at least absent some additional allegation of specific information conveyed to management and related to the fraud." Metzler Inv. GMBH v. Corinthian Colleges, Inc., 540 F.3d 1049, 1068 (9th Cir. 2008). The vague allegation that the sales and marketing functions "report[ed] directly" to Schoeneck, FAC ¶ 196, does not provide the "what, where, when, and how regarding [Schoeneck's] access to the relevant information that belies fraudulent intent," Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc., No. 10-CV-03451-LHK, 2012 WL 1868874, at *19 (N.D. Cal. May 22, 2012), *aff'*d, 759 F.3d 1051 (9th Cir. 2014); see also In re Daou Sys., 411 F.3d at 1022 ("General allegations of defendants' 'hands-on' management style, their interaction with other officers and employees, their attendance at meetings, and their receipt of unspecified weekly or monthly reports are insufficient [to establish scienter]."). This flaw is further compounded by the defects in Plaintiffs' allegations regarding

instances of off-label marketing. In other words, the Court cannot infer from Schoeneck's role that he had "actual access" to information that off-label marketing was occurring when Plaintiffs have not provided enough detail as to what information existed.

Next, Plaintiffs invoke the third use of the core operations doctrine, arguing that it would be "absurd to suggest" that the Individual Defendants "were unaware of how the company managed to increase prescriptions and sales" of NUCYNTA because the drug franchise comprised over 60 percent of Assertio's revenue. ECF No. 68 at 23-24. Had Plaintiffs adequately alleged that the basis for NUCYNTA's growth in sales was a systematic, widespread off-label marketing claim, this argument might have merit. Cf. Berson, 527 F.3d at 988 n.5 (holding that absurdity inference applied to stop-work order "on the company's largest contract with one of its most important customers"). Similarly, if the complaint supported an inference of a widespread marketing campaign under Assertio's watch, then allegations related to Defendants' knowledge of the allegations regarding Janssen and Quintiles' prior practices, see ECF No. 68 at 22, would be relevant to show that Defendants either knew of, or were willfully blind to, Assertio's own off-label marketing. But given that Plaintiffs have alleged primarily that Assertio emphasized NUCYNTA's off-label properties to its sales representatives, but only provide one vague account of two representatives actually marketing off-label, it is not "absurd to suggest" that the Individual Defendants were unaware that such misconduct had occurred. See Curry v. Yelp Inc., No. 14-CV-03547-JST, 2015 WL 1849037, at *12 (N.D. Cal. Apr. 21, 2015).

Therefore, the Court concludes that Plaintiffs have not adequately alleged that Schoeneck had "actual access" or that it would be absurd for the Individual Defendants not to know of the alleged off-label marketing.

3. Financial Motives

Plaintiffs contend that Defendants had financial motives to mislead investors, citing compensation tied to corporate objectives and stock options. FAC ¶¶ 205-208.

"A strong correlation between financial results and stock options or cash bonuses for individual defendants may occasionally be compelling enough to support an inference of scienter." Zucco Partners, 552 F.3d at 1004. However, because "it is common for executive compensation,

including stock options and bonuses, to be based partly on the executive's success in achieving key corporate goals," the Ninth Circuit has cautioned that "allegations of [such] routine corporate objectives . . . are not, without more, sufficient to allege scienter; to hold otherwise would support a finding of scienter for any company that seeks to enhance its business prospects." In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 884 (9th Cir. 2012).

Here, Plaintiffs argue that the "more" is that "Defendants were complicit in an overarching scheme" involving multiple major opioid manufacturers, citing findings in a report from Senator McCaskill's investigation. ECF No. 68 at 24-25. These scienter allegations are not in Plaintiffs' complaint, cf. FAC ¶¶ 205-208, and therefore the Court may not consider them, see Schneider v. *Cal. Dep't* of Corr., 151 F.3d 1194, 1197 (9th Cir. 1998) ("In determining the propriety of a Rule 12(b)(6) dismissal, a court may not look beyond the complaint to a plaintiff's moving papers, such as a memorandum in opposition to a defendant's motion to dismiss."). Nonetheless, because the FAC adequately alleges a link between Defendants' compensation and specific corporate objectives, the Court will consider Defendants' potential financial motivations as part of the holistic scienter analysis below. See In re Rigel Pharm., 697 F.3d at 884.

4. Stock Sales

Plaintiffs assert that "while in possession of material, nonpublic information concerning [Assertio's] true business health, Moretti also sold 30,000 shares of his stock for $572,797.49." FAC ¶ 209.

"Although 'unusual' or 'suspicious' stock sales by corporate insiders may constitute circumstantial evidence of scienter, insider trading is suspicious only when it is 'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information.'" Zucco Partners, 552 F.3d at 1005 (quoting Silicon Graphics, 183 F.3d at 986). Whether a stock sale meets this standard turns on three factors: "(1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history." City of Dearborn Heights, 856 F.3d at 621 (quoting Zucco Partners, 552 F.3d at 1005).

Plaintiffs' bald allegation of Moretti's stock sale (or sales), without any specifics as to the

percentage of shares, the timing of the sale, or Moretti's prior trading history, does not contribute to an inference of scienter. As this court said in Curry, it "has no basis on which to conclude that there exists a strong inference that these sales were out of line with prior trading practices because the Complaint does not allege any information regarding the insider's prior trading practices." 2015 WL 1849037 at *13; see also City of Dearborn Heights, 856 F.3d at 622 (rejecting stock sale allegations that did not allege "the timing of these sales, and the prior trading history" for the defendants).

5. Resignation

Plaintiffs further point to Schoeneck's resignation on March 28, 2017, as evidence of scienter. FAC ¶ 211-214.[10]

"[A]n employee's resignation supports an inference of scienter only when 'the resignation at issue was uncharacteristic when compared to the defendant's typical hiring and termination patterns or was accompanied by suspicious circumstances.'" City of Dearborn Heights, 856 F.3d at 622 (quoting Zucco Partners, 552 F.3d at 1002).

Here, Plaintiffs primarily assert that Schoeneck's departure was suspicious because he resigned on the same day that Senator McCaskill first announced her investigation. ECF No. 68 at 26; FAC ¶¶ 213-214.[11] Shenwick v. Twitter, on which Plaintiffs rely, is distinguishable because that case involved additional evidence, beyond temporal proximity, that the alleged fraud was the reason for the departures. 282 F. Supp. 3d at 1148; see also Middlesex Ret. Sys. v. Quest Software Inc., 527 F. Supp. 2d 1164, 1188 (C.D. Cal. 2007) (finding a resignation suspicious where the defendant "did not resign because of internal pressure, but instead resigned specifically to avoid

[10] Plaintiffs' complaint also cites the resignations and compensation packages of two non-Defendant Assertio officers between November 2016 and June 2017 as evidence of scienter. FAC ¶ 211. Because Plaintiffs do not rely on these two resignations in their opposition, cf. ECF No. 68 at 26-27, the Court does not consider them.

[11] Plaintiffs also claim that Schoeneck's departure was unusual because he received a severance package not authorized by his employment agreement and his resignation announcement "did not contain any of the typical salutary words often found in corporate statements announcing high-level resignations." FAC ¶¶ 211, 213. Without specific allegations as to Assertio's "typical" practices, the Court cannot infer that these practices were "uncharacteristic." City of Dearborn Heights, 856 F.3d at 622 (citation omitted).

cooperating with the Special Committee – a body created to investigate potential impropriety"). Moreover, Plaintiffs have not alleged that Assertio was aware of Senator McCaskill's investigation when Schoeneck made the decision to resign, nor even that Senator McCaskill's announcement preceded Schoeneck's resignation. Cf. FAC ¶ 211. By contrast, in In re Banc of California Securities Litigation, the company itself announced the SEC investigation on the same day as the Defendant's resignation, demonstrating its awareness of that investigation. No. SACV1700118AGDFMX, 2017 WL 3972456, at *8 (C.D. Cal. Sept. 6, 2017).

The proximity between Schoeneck's resignation and Senator McCaskill's announcement raises some possibility that the two events were connected, but this is not enough to support an inference of Schoeneck's scienter. Even assuming that the investigation was related to the alleged off-label marketing and that Assertio forced Schoeneck to resign as a result, Plaintiffs "point to no particularized allegation refuting the reasonable assumption" that Schoeneck was forced out "simply because the errors . . . occurred on his watch or because he failed adequately to supervise his [employees]." Zucco Partners, 552 F.3d at 1002 (quoting In re U.S. Aggregates, Inc. Sec. Litig., 235 F. Supp. 2d 1063, 1074 (N.D. Cal. 2002)). Without such allegations, Schoeneck's resignation does not contribute to a finding of scienter. See Webb, 884 F.3d at 857.

6. Holistic Review

To recap, Plaintiffs allege no direct evidence that Moretti or Higgins knew of off-label marketing. Moreover, the core operations doctrine contributes little to the analysis, given the limited scope of off-label marketing that can be inferred and Plaintiffs' boilerplate allegations of Moretti's and Higgins's "general awareness of the day-to-day workings of the company's business." Metzler Inv. GMBH, 540 F.3d at 1068. Considering these factors, combined with Plaintiffs' "allegations of routine corporate objectives" linked to Moretti's and Higgins's compensation, In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d at 884, the Court concludes that Plaintiffs have failed to raise a "cogent and compelling" inference of scienter as to those two Defendants, Tellabs, 551 U.S. at 324.

The case for Schoeneck's scienter is not meaningfully stronger. In addition to similar allegations of Schoeneck's management role and compensation motivations, Plaintiffs offer one

FE's ambiguous allegation that Schoeneck discussed NUCYNTA's off-label uses to sales representatives, and perhaps encouraged off-label promotion. Further, Schoeneck resigned on the same day as the McCaskill investigation was announced, although Plaintiffs have not alleged facts supporting a causal relationship between the two events.

Viewing these allegations holistically, the Court finds that they do not overcome the competing inference that the Individual Defendants were unaware that in some instances NUCYNTA sales representatives crossed the line into promoting off-label uses, so as to render Defendants' statements regarding NUCYNTA sales and regulatory risk materially misleading. Simply put, "Plaintiffs' allegations reveal isolated instances of [off-label marketing], rather than widespread deception, which is necessary to establish fraudulent intent or reckless ignorance based on a holistic analysis." Or. Pub. Emps. Ret. Fund, 774 F.3d at 608.

C. Loss Causation

Finally, Plaintiffs also fail to allege loss causation. The complaint identifies two categories of events that Plaintiffs contend establish loss causation: (1) lowered revenue projections and (2) announcements of investigatory actions by outside entities. The Court examines each in turn.

1. Lowered Revenue Projections

Plaintiffs cite a series of negative disclosures regarding Assertio's financial health, each of which was followed by a drop in Assertio's stock price. First, on November 7, 2016, Assertio lowered its projected total revenue for 2016 from $480-505 million to $455-465 million, citing, among other things, "worsening conditions in the opioid market." FAC ¶ 123, 218(a). Neither the press release or earnings call on that day mentioned off-label marketing; in fact, Assertio cited growth in both NUCYNTA IR and NUCYNTA ER prescriptions, although shipments to wholesalers declined. Id. ¶ 123-124. Next, on December 11, 2016, a market analyst firm (Piper Jaffray) downgraded its projections for Assertio, stating, "it has become clear to us that management, based in part on its own commentary, does not really have a new strategy in place to wring significant further volume growth out of NUCYNTA ER in the face of more challenging market dynamics." Id. ¶¶ 129, 218(b). On May 17, 2017, another market analyst (Roth Capital Partners) reduced its price target for Assertio stock, "based largely on a deteriorating macro

environment for opioid pain treatments." Id. ¶ 218(d). Finally, on August 7, 2017, Assertio lowered its estimates for its 2017 total revenue from $405-425 million to $395-410 million, and added language to its SEC filings "to discuss worsening market conditions resulting from regulatory actions, government investigations, and heightened public attention on opioid abuse." Id. ¶ 218(e); see also id. ¶ 157.

Plaintiffs argue that the disclosures on November 7, 2016, December 11, 2016, and May 17, 2017, "signaled to investors that Defendants' prior statements about Depomed's ability to weather negative headwinds in the opioid industry were misleading." ECF No. 68 at 28. Defendants respond that these announcements "do not mention improper sales practices or imply that they occurred," and instead relate to "the general worsening market conditions for opioid products and the consequent effect on [Assertio's] financial performance." ECF No. 66 at 34. Plaintiffs counter that the announcements need not directly disclose the off-label marketing, because the off-label marketing proximately caused the worsening sales outlook for NUCYNTA. ECF No. 68 at 27. Plaintiffs attribute these lowered revenue projections to greater "regulatory scrutiny," which they contend made prescribers "less inclined to write 'off-label' prescriptions." Id. at 30. Plaintiffs reasons that this sequence of events constitutes a "materialization of risk," a theory of loss causation that has been accepted by district courts within this Circuit. Id. at 28 (citing In re Amgen Inc. Sec. Litig. (Amgen II), No. CV072536PSGPLAX, 2014 WL 12585809, at *20 (C.D. Cal. Aug. 4, 2014) (collecting cases)).

The Ninth Circuit has been clear that "[d]isclosure of the fraud is not a sine qua non of loss causation, which may be shown even where the alleged fraud is not necessarily revealed prior to the economic loss." *Mineworkers'* Pension Scheme v. First Solar Inc., 881 F.3d 750, 753 (9th Cir. 2018) (quoting Nuveen, 730 F.3d at 1120). Accordingly, there are an "'infinite variety' of causation theories a plaintiff might allege to satisfy proximate cause," id. (quoting Lloyd, 811 F.3d at 1210), including that "that the stock price fell upon the revelation of an earnings miss," where the alleged fraud bears a sufficient relationship to the earnings miss, id. In Nuveen, the Ninth Circuit acknowledged that other circuits had "recognize[d] loss causation where a plaintiff shows that 'misstatements and omissions concealed the price-volatility risk (or some other risk) that

materialized and played some part in diminishing the market value' of a security," but found it unnecessary to adopt that theory in order to resolve the case. 730 F.3d at 1120 (quoting Lentell v. Merrill Lynch & Co., 396 F.3d 161, 176 (2d Cir. 2005)).

Here, the Court likewise need not determine whether "materialization of risk" is sufficient to establish loss causation, because even assuming the viability of such a theory, Plaintiffs have not sufficiently alleged "a causal connection" between the risks of the alleged off-label marketing and the negative financial news announced on the identified disclosure dates. Dura Pharm., 544 U.S. at 342. The cases that Plaintiffs cite in support of their theory provide a helpful contrast.

In Gilead, the plaintiffs alleged that Gilead's off-label marketing "led to higher demand for [the drug] Viread, which in turn inflated Gilead's stock price." Gilead III, 536 F.3d at 1057. The FDA had publicly issued a Warning Letter condemning Gilead's off-label marketing and ordering Gilead to make corrective disclosures. Id. at 1053. Critically, the plaintiffs there alleged that the Warning Letter led to a drop in sales because "[p]hysicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients" and that "[c]ompetitors invoked the letter in efforts to persuade physicians to switch from Viread to their products." Id. The Ninth Circuit held that "the complaint sufficiently alleges a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter's effect on Viread orders, and (3) the Warning Letter's effect on Gilead's stock price." Id. at 1057.

Similarly, in Amgen, plaintiffs alleged an extensive off-label marketing campaign and "that the risk of decreased off-label sales materialized . . . when the FDA imposed a black box warning on all [of the relevant drugs'] labeling, cautioning against the use of [the drugs] in certain off-label settings." Amgen II, 2014 WL 12585809, at *21. Noting that the complaint "states that the black box warning 'had the economic effect of curtailing Amgen's off-label marketing,'" the court reasoned that it adequately pleaded "a causal connection between Defendants' misrepresentations that Amgen [did not engage in off-label marketing] and the harm investors ultimately suffered as a result of the FDA's restrictions on off-label use." Id.

Here, the flaw in Plaintiffs' materialization of risk theory is that they fail to connect the

risks of the alleged off-label marketing to a subsequent stagnation or decrease in off-label prescriptions underlying the negative financial news released on Plaintiffs' loss causation dates. Plaintiffs offer only a conclusory allegation that "prescribing physicians began to scale back their 'off-label' use of NUCYNTA due to the growing 'opioid epidemic.'" ECF No. 68 at 28. As noted with respect to materiality, Plaintiffs fail to plead any specific facts related to the scale of off-label marketing of NUCYNTA, its off-label prescriptions, or the curtailment of those prescriptions. Nor does the content of the disclosures support Plaintiffs' theory. Indeed, Assertio's November 7, 2016 announcement touted an "all-time monthly high of over 30,000 prescriptions" for NUCYNTA ER in August 2016 and stated that "[w]e continue to see NUCYNTA IR prescription showing signs of growth." FAC ¶ 124. Assertio instead attributed the earnings miss for third quarter revenues to "several factors, including a disconnect between prescription demand and wholesaler shipments." Id. ¶ 123. Moreover, Plaintiffs' cursory descriptions of the subsequent downgrades by Piper Jaffray and Roth Capital Partners do not provide details that would link Assertio's lowered revenue projections to prescribers cutting back off-label NUCYNTA prescriptions. Id. ¶ 129, 218(d).

In Gilead, by contrast, the complaint alleged "that 75% to 95% percent of sales were caused by off-label marketing" and an "analyst report show[ed] that Viread prescriptions experienced a 'sharp drop'" following the publication of the FDA Warning Letter. 536 F.3d at 1053, 1058. Here, Plaintiffs' allegations do not give the Court a basis to infer that a reduction in off-label sales was responsible for the reduced revenue guidance, rather than the negative conditions in the opioid market generally, which were cited by the announcements at issue. See FAC ¶¶ 123-124, 129, 218(a)-(b), (d). Plaintiffs' theory of loss causation thus lacks the particularity required by the PSLRA and Rule 9(b). See Or. Pub. Emps. Ret. Fund, 774 F.3d at 608.

Accordingly, Plaintiffs fail to adequately allege loss causation based on a materialization of risk theory.

2. Investigation Announcements

Plaintiffs cite two separate investigation announcements as establishing loss causation.

First, Plaintiffs point to the March 28, 2017 announcement that Senator McCaskill was launching an investigation into the marketing practices of the five largest opioid manufacturers, including Assertio. FAC ¶¶ 138-139, 218(c). Second, Plaintiffs highlight Assertio's August 7, 2017 announcement that the Maryland Attorney General and the U.S. Department of Justice had issued "subpoenas related to opioid sales and marketing" to Assertio and other opioid manufacturers. Id. ¶¶ 157, 217(e).

"[T]he announcement of an investigation, standing alone and without any subsequent disclosure of actual wrongdoing, does not reveal to the market the pertinent truth of anything, and therefore does not qualify as a corrective disclosure." Lloyd, 811 F.3d at 1209-10 (quoting Loos v. Immersion Corp., 762 F.3d 880, 890 n.3 (9th Cir. 2014)). In other words, an investigation's revelation of "a mere 'risk' or 'potential' for fraud is insufficient to establish loss causation." Loos, 762 F.3d at 889. In Lloyd, however, the Ninth Circuit held that a plaintiff could plead loss causation if the investigation announcement was accompanied by "a subsequent corrective disclosure by the defendant." 811 F.3d at 1210. The Lloyd court concluded that the following sequence of events adequately pleaded loss causation: "(1) [the bank] CVB's disclosure of [an SEC] subpoena caused its stock price to drop precipitously; (2) the market and various analysts perceived the subpoena to be related to CVB's alleged misstatements about [its largest borrower] Garrett's ability to repay; (3) the market's fears about the subpoena were confirmed by CVB's September 9 disclosure that it was writing off $34 million in Garrett loans and categorizing the remainder as non-performing; and (4) the September 9 disclosure's minimal effect on CVB's stock price indicate[d] that the earlier 22% drop reflected, at least in part, the market's concerns about the Garrett loans." Id. at 1210-11.

Here, Plaintiffs first argue that the announcements of investigations are themselves sufficient because they "were not isolated incidents" but involved "three investigations announced over a period of five months . . . by external government agencies." ECF No. 68 at 31. But Ninth Circuit precedent rejects this approach. Loos, for instance, cautioned that "at the moment an investigation is announced, the market cannot possibly know what the investigation will ultimately reveal." 762 F.3d at 890. And in Curry, the Ninth Circuit explained that "the element of loss

causation cannot be adequately made out merely by resting on a number of customer complaints and asserting that where there is smoke, there must be fire." 875 F.3d at 1225. More investigations might mean more smoke, but that does not authorize the Court to speculate as to the likelihood of fire, absent "an express disclosure of actual wrongdoing" within the announcement of the investigation, Loos, 762 F.3d at 890 n.3, or "a subsequent corrective disclosure," Lloyd, 811 F.3d at 1210. Further, as Defendants point out, the inference of fraudulent conduct raised by these announcements is weakened by the fact that the investigations were directed at the opioid industry generally, rather than Assertio in particular. See Or. Pub. Emps. Ret. Fund, 774 F.3d at 608 (declining to find loss causation based on government report that "revealed a systemic practice of manipulative and deceptive recruitment practices" because it "focused on the for-profit education industry as a whole, rather than" the defendants).

Second, Plaintiffs analogize to Lloyd, arguing that additional events "gave Plaintiffs reason to believe that wrongdoing on the part of Defendants had occurred." ECF No. 68 at 32. Plaintiffs cite the additional risk warnings contained in Assertio's August 7, 2017 Form 10-Q, but nothing in the potential for "negative publicity" or "increased regulation" disclosed in that document indicates that Assertio engaged in the off-label marketing that Plaintiffs alleged. ECF No. 68 at 31 (citing FAC ¶¶ 157-158). The form references industry-wide scrutiny and "greater public awareness of the problem of opioid abuse," but does not specifically reference Assertio's practices. See FAC ¶ 157.[12] This falls far short of the subsequent corrective disclosure in Lloyd, where the defendant bank announced that it was writing off $34 million in loans from its largest borrower, directly confirming the market's fears that the earlier subpoena into the bank's loan underwriting guidelines reflected "misstatements about [that particular borrower's] ability to repay." 811 F.3d at 1210-11. Here, additional disclosures as to the general state of affairs in the opioid industry do not confirm any speculation as to whether Assertio's marketing practices were, in fact, improper.

[12] The disclosures also reveal additional lawsuits and investigations, FAC ¶ 157, but as noted above, the fact of these actions alone cannot establish loss causation. The same is true for the post-August 7, 2017 investigations cited in Plaintiffs' opposition. ECF No. 68 at 32 n.5.

Plaintiffs also assert that President Trump's October 26, 2017 announcement of a public health emergency regarding the opioid epidemic "validate[d] investor suspicions," ECF No. 68 at 32 n.5, but declaring a state of emergency as to the extent of opioid abuse does not reveal any information about investigations into opioid manufacturers' marketing practices.

Therefore, the Court finds that Plaintiffs also fail to allege loss causation based on the announcement of investigations.

D. Section 20(a) Control Person Liability

Section 20(a) of the Exchange Act, which forms the basis of Plaintiffs' second cause of action, extends liability to persons who directly or indirectly control a violation of the securities laws. 15 U.S.C. § 78t(a). Under Section 20(a), "a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates a primary violation of federal securities law and that the defendant exercised actual power or control over the primary violator." City of Dearborn Heights, 856 F.3d at 623 (quoting Zucco Partners, 552 F.3d at 990).

A claim under Section 20(a) can survive only if the underlying predicate Exchange Act violation also survives. See City of Dearborn Heights, 856 F.3d at 623. Because the Court dismisses Plaintiffs' Exchange Act claim, Plaintiffs' second cause of action must also be dismissed.

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion to dismiss without prejudice. Plaintiffs may file an amended complaint within 21 days.

IT IS SO ORDERED.

Dated: March 18, 2019

JON S. TIGAR
United States District Judge