UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

AARON SNEED JR.,

Plaintiff,

v.

ACELRX PHARMACEUTICALS, INC., et al.,

Defendants.

Case No. 21-cv-04353-BLF

ORDER GRANTING MOTION TO DISMISS SECOND AMENDED COMPLAINT WITH LEAVE TO AMEND IN PART AND WITHOUT LEAVE TO AMEND IN PART

[Re: ECF No. 78]

Now before the Court is Defendants' motion to dismiss the Second Amended Complaint in this putative securities class action. ECF No. 78 ("MTD"); *see also* ECF No. 83 ("Reply"). Plaintiffs oppose the motion. ECF No. 82 ("Opp."). For the reasons discussed at the May 30, 2023 motion hearing and further explained below, the Court GRANTS Defendants' motion to dismiss WITH LEAVE TO AMEND IN PART and WITHOUT LEAVE TO AMEND IN PART.

I. BACKGROUND

On June 8, 2021, Plaintiff Aaron Sneed Jr. filed a securities class action suit in this Court alleging violations of various securities laws by AcelRx Pharmaceuticals, Inc. ("AcelRx"), AcelRx Chief Executive Officer Vincent J. Angotti, and AcelRx Chief Financial Officer Raffi Asadorian. ECF No. 1. The Court appointed Aaron Sneed Jr. and Yaacov Musry as co-lead plaintiffs and Pomerantz LLP as lead counsel. ECF No. 47. On March 3, 2022, Plaintiffs filed an amended complaint. ECF No. 54. The amended complaint added one additional Defendant, AcelRx Chief Health Officer Pamela Palmer. *Id.* On September 28, 2022, the Court dismissed the amended complaint with leave to amend. *Sneed v. AcelRx Pharms., Inc.*, No. 21-cv-04353-BLF, 2022 WL 4544721 (N.D. Cal. Sept. 28, 2022).

On November 28, 2022, Plaintiffs filed the operative second amended complaint. ECF No.

75 ("SAC"). Plaintiffs bring suit against AcelRx, Angotti, Asadorian, and Palmer, asserting three counts under the Securities and Exchange Act of 1934 ("Exchange Act") on behalf of a class including all individuals who purchased or otherwise acquired AcelRx securities (ticker symbol ACRX) between March 20, 2019 and February 12, 2021. *Id.*

AcelRx is a pharmaceutical company that develops therapies for the treatment of acute pain. SAC ¶ 37. DSUVIA, the product at the center of this suit, is an opioid painkiller that is administered sublingually and therefore particularly useful in circumstances where patients cannot swallow oral medication and access to intravenous pain relief is not possible. *Id.* ¶¶ 37-38. In November 2018, the U.S. Food and Drug Administration ("FDA") approved AcelRx's application for DSUVIA. *Id.* ¶ 63. In so doing, the FDA also approved the DSUVIA Risk Evaluation and Mitigation Strategy ("REMS"), which is "a drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." *Id.* ¶¶ 40, 63. As an FDA-approved drug, DSUVIA is subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), which prohibits the introduction into interstate commerce of any drug that is "misbranded." *Id.* ¶ 8, 114; *see* 21 U.S.C. § 331.

On February 11, 2021, AcelRx received a warning letter from the FDA's Office of Prescription Drug Promotion ("OPDP"). SAC ¶ 18. The letter ("Warning Letter") indicated that two of AcelRx's promotional materials—a banner advertisement and a tabletop display—made "false or misleading claims and representations about the risks and efficacy of DSUVIA" and therefore violated the FDCA (the "Misbranding Violations"). *Id.* ¶¶ 18-19. The Warning Letter stated that the Misbranding Violations were "particularly concerning considering a REMS program was required for DSUVIA to ensure that the benefits of the drug outweigh the risk of respiratory depression that can result from accidental exposure." *Id.* ¶ 176. After AcelRx publicly disclosed this letter on February 16, 2021, the stock price fell $0.21 per share, or 8.37%. *Id.* ¶ 23. Also on February 16, 2021, the FDA issued a press release entitled, "FDA issues warning to AcelRx for making false and misleading claims about the risks and benefits of DSUVIA." *Id.* ¶ 182. The press release stated that the tabletop display and banner advertisement "undermine key prescribing conditions required for the safe use of this opioid product" and "dangerously

undercut[] FDA-required conditions on the proper administration of the drug, which requires particular diligence to minimize the risk of serious or even fatal adverse events." *Id.* ¶ 184. It went on to explain that DSUVIA "was approved with a [REMS]." *Id.*

Plaintiffs allege that "Defendants made false and/or misleading statements and/or failed to disclose that: (1) AcelRx failed to implement and/or maintain sufficient disclosure controls and procedures regarding the marketing of DSUVIA; (2) as a result, the Company engaged in the Misbranding Violations; and (3) the Company was therefore subject to a foreseeable and increased risk of regulatory investigations or enforcement actions. As a result, the Company's public statements were materially false and misleading throughout the Class Period." SAC ¶ 15. Plaintiffs also allege that Defendants "engaged in a scheme to illegally market DSUVIA beyond its permitted label." *Id.* ¶ 14.

Plaintiffs assert three claims: (1) violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) by all Defendants, SAC ¶¶ 199-206; (2) violation of Section 10(b) of the Exchange Act and Rule 10b-5(a), (c) by all Defendants, *id.* ¶¶ 207-16; and (3) violation of Section 20(a) of the Exchange Act by Defendants Angotti, Asadorian, and Palmer, *id.* ¶¶ 217-23.

II. LEGAL STANDARD

"A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted 'tests the legal sufficiency of a claim.'" *Conservation Force v. Salazar*, 646 F.3d 1240, 1241–42 (9th Cir. 2011) (quoting *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)). When determining whether a claim has been stated, the Court accepts as true all well-pled factual allegations and construes them in the light most favorable to the plaintiff. *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011). But the Court need not "accept as true allegations that contradict matters properly subject to judicial notice" or "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (internal quotation marks and citations omitted). While a complaint need not contain detailed factual allegations, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*,

550 U.S. 544, 570 (2007)). A claim is facially plausible when it "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

In addition to the pleading standards discussed above, a plaintiff asserting a private securities fraud action must meet the heightened pleading requirements imposed by Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b); *see also In re VeriFone Holdings*, 704 F.3d at 701. Similarly, the PSLRA requires that "the complaint shall 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)(B). The PSLRA further requires that the complaint "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)(A). "To satisfy the requisite state of mind element, a complaint must allege that the defendant[] made false or misleading statements either intentionally or with deliberate recklessness." *In re VeriFone Holdings*, 704 F.3d at 701 (internal quotation marks and citation omitted) (alteration in original). The scienter allegations must give rise not only to a plausible inference of scienter, but to an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007).

III. REQUEST FOR JUDICIAL NOTICE

Ordinarily, a district court's inquiry on a Rule 12(b)(6) motion to dismiss is limited to the pleadings. "A court may, however, consider certain materials—documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice—without converting the motion to dismiss into a motion for summary judgment." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). Courts may take judicial notice of facts that are "not subject to reasonable dispute." Fed. R. Evid. 201(b). Indisputable facts are those that are "generally known" or that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id.*

Defendants request that the Court take judicial notice of: Exhibit 1, AcelRx Press Release,

issued on November 2, 2018; Exhibit 2, DSUVIA REMS, approved by FDA on November 2, 2018; Exhibit 3, DSUVIA Prescribing Information, approved by FDA on November 2, 2018; Exhibit 4, DSUVIA Directions for Use; Exhibit 5, AcelRx Press Release, issued on January 7, 2019; Exhibit 6, AcelRx Press Release, issued on January 31, 2019; Exhibit 7, Excerpts of AcelRx Form 10-K (FY 2018), filed with SEC on March 7, 2019; Exhibit 8, Transcript of AcelRx presentation at the 29th Annual Oppenheimer Health Care Conference, webcast live on March 20, 2019; Exhibit 9, AcelRx Press Release, issued on April 11, 2019; Exhibit 10, Excerpts of AcelRx Form 10-Q (Q1 2019), filed with SEC on May 9, 2019; Exhibit 11, Transcript of AcelRx Q2 2019 earnings call, held on August 5, 2019; Exhibit 12, Excerpts of AcelRx Form 10-Q (Q2 2019), filed with SEC on August 6, 2019; Exhibit 13, Transcript of AcelRx Q3 2019 earnings call, held on November 6, 2019; Exhibit 14, Excerpts of AcelRx Form 10-Q (Q3 2019), filed with SEC on November 7, 2019; Exhibit 15, Transcript of AcelRx Q4 2019 earnings call, held on March 16, 2020; Exhibit 16, Excerpts of AcelRx Form 10-K (FY 2019), filed with SEC on March 16, 2020; Exhibit 17, Transcript of AcelRx Q1 2020 earnings call, held on May 11, 2020; Exhibit 18, Excerpts of AcelRx Form 10-Q (Q1 2020), filed with SEC on May 11, 2020; Exhibit 19, Excerpts of AcelRx Form 10-Q (Q2 2020), filed with SEC on August 10, 2020; Exhibit 20, Excerpts of AcelRx Form 10-Q (Q3 2020), filed with SEC on November 5, 2020; Exhibit 21, AcelRx Form 8-K, filed with SEC on February 16, 2021; Exhibit 22, Analyst report published on February 16, 2021; Exhibit 23, Analyst report published on February 17, 2021; Exhibit 24, AcelRx Press Release, issued on May 16, 2022; Exhibit 25, FDA Memorandum issued on November 1, 2018; Exhibit 26, AcelRx Press Release, issued on May 19, 2022; and Exhibit 27, FDA webpage on *Prescription Drug Advertising: Questions and Answers*. ECF No. 79 ("RJN"); *see* Declaration of Janelle M. Fernandes, ECF No. 80 ("Fernandes Decl."), Exs. 1-27. Plaintiffs take no position on the request.

The incorporation by reference doctrine permits the Court to take into account documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading." *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005) (internal quotation marks and citations omitted) (alteration in original). The Court

finds that Exhibits 1-3, 8, 10, 12, 14-16, 18-22, and 25 are incorporated by reference into the SAC. *See, e.g.,* SAC ¶¶ 4, 63 (Ex. 1); ¶¶ 5, 20, 63 (Ex. 2); ¶ 119 (Ex. 3); ¶ 127 (Ex. 8); ¶¶ 131, 133 (Ex. 10); ¶¶ 135, 137 (Ex. 12); ¶¶ 139, 141 (Ex. 14); ¶¶ 150, 152 (Ex. 15); ¶¶ 143-44, 146, 148 (Ex. 16); ¶¶ 154, 156 (Ex. 18); ¶¶ 158, 160 (Ex. 19); ¶¶ 162, 164, 166, 168 (Ex. 20); ¶¶ 18, 171-73 (Ex. 21); ¶ 186 (Ex. 22); ¶ 47 (Ex. 25).

The remaining documents include an SEC filing, AcelRx Form 10-K (FY 2018) (Ex. 7); pages from the AcelRx and FDA websites (Exs. 4, 27); press releases (Exs. 5-6, 9, 24, 26); transcripts of earnings calls (Exs. 11, 13, 17); and an analyst report (Ex. 23), all of which are proper subjects of judicial notice. *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.,* 540 F.3d 1049, 1064 n.7 (SEC filings); *Calhoun v. Google LLC*, 526 F. Supp. 3d 605, 617 (N.D. Cal. 2021) (publicly available websites); *In re Am. Apparel, Inc. S'holder Litig.*, 855 F. Supp. 2d 1043, 1062 (C.D. Cal. 2012) (press releases); *In re Extreme Networks, Inc. Sec. Litig.*, No. 15-cv-04883-BLF, 2018 WL 1411129, at *10 (N.D. Cal. Mar. 21, 2018) (conference call transcripts); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, No. 12-cv-06039-WHO, 2013 WL 6441843, at *5 (N.D. Cal. Dec. 9, 2013) (analyst reports). These exhibits are all publicly available, and their accuracy is not disputed by Plaintiffs. The Court thus takes judicial notice of the existence of these exhibits. The Court does not take notice of the truth of any of the facts asserted in these documents. *See City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, No. 18-cv-04844-BLF, 2019 WL 6877195, at *23 (N.D. Cal. Dec. 17, 2019).

Defendants' request for judicial notice is GRANTED.

IV. DISCUSSION

Defendants move to dismiss the complaint for failure to meet the pleading requirements for all claims. *See* MTD.

A. Claim 1: Section 10(b) and Rule 10b-5(b)

Plaintiffs bring a claim under Section 10(b) of the Exchange Act and the associated Rule 10b-5(b). SAC ¶¶ 199-206. Section 10(b) makes it unlawful "for any person . . . [t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may

prescribe[.]" 15 U.S.C. § 78j(b). Rule 10b-5, promulgated by the Securities and Exchange Commission under the authority of § 10(b), in turn makes it unlawful for any person,

> (a) To employ any device, scheme or artifice to defraud,
>
> (b) To 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 light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. To state a securities fraud claim, a plaintiff must plead: "(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; (5) economic loss; and (6) loss causation." *Dearborn Heights*, 856 F.3d at 613. Defendants' motion is predicated on requirements one and two. *See* MTD at 8-22.

1. Falsity

Defendants argue that the SAC should be dismissed because Plaintiffs have not adequately alleged any false statements. MTD at 8-17.

To plead falsity, a plaintiff must plead "specific facts indicating why" the statements at issue were false. *Metzler*, 540 F.3d at 1070. "[T]o meet the requirements of Rule 9(b), Plaintiffs must, for each allegedly false or misleading statement, clearly allege with particularity *why* the statement was false or misleading *at the time it was made*." *Norfolk Cnty. Ret. Sys. v. Solazyme, Inc.*, No. 15-cv-02938-HSG, 2016 WL 7475555, at *3 (N.D. Cal. Dec. 29, 2016); *see also In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1404 (9th Cir. 1996) ("[S]tatement or omission must be shown to have been false or misleading when made.").

Plaintiffs point to 23 statements that they allege were false or misleading. *See* ECF No. 76 ("SAC App. 1"). Defendants argue that none are false. MTD at 8-17. The Court will address each category of statement in turn.

Statements About DSUVIA's Use and Administration

Statements 1, 2, and 3 are all statements about DSUVIA's administration. *See* SAC App.

1; SAC ¶¶ 118, 127, 129. Statement 2 is the tabletop display, and Statement 3 is the banner advertisement. SAC App. 1; SAC ¶¶ 118, 129. These two advertisements were the subject of the FDA warning letter, and both include the "Tongue and Done" slogan that the FDA ultimately determined was "misleading because [it] impl[ies] that the administration of DSUVIA consists of a simple, one-step process, when this is not the case." *See* SAC App. 1; SAC ¶¶ 118, 175. And Statement 1 is a statement made by Defendant Angotti at the AcelRx presentation at the Oppenheim Health Care Conference about how to administer DSUVIA: "You would simply remove the lock, tell the patient in the ER and post-op or the soldier [to] tilt their head back, lift up their tongue, you inject it under and you're done. And it's basically as simple as that." SAC App. 1; SAC ¶¶ 127. Plaintiffs allege that these statements about the administration of DSUVIA were misleading because they omitted material information, including information about dosing, administration, and limitations of use. *See* SAC App. 1; SAC ¶¶ 118, 127, 129. They also allege falsity on the basis that AcelRx failed to implement or maintain sufficient controls and procedures regarding the marketing of DSUVIA, and therefore the company was subject to a foreseeable and increased risk of regulatory investigations or enforcement actions. *See* SAC App. 1; SAC ¶¶ 128, 130.

Defendants argue that these statements were not false or misleading for several reasons. First, they argue that Plaintiffs have not alleged that the statements were false when made, as Plaintiffs allegations of falsity are based on the Warning Letter, which was issued after the statements were made. MTD at 9-10. Defendants next assert that the allegedly omitted "material information" *was* disclosed to investors, as Defendants disclosed safety information and limitations of use, and that "no reasonable investor would have viewed these statements as providing comprehensive instructions for use." *Id.* at 12-13. Defendants then assert that Plaintiffs did not plead how Defendants' failures regarding internal controls resulted in an increased risk of regulatory investigations or enforcement actions. *Id.* at 13. And Defendants argue that these statements are not actionable because Plaintiffs do not plead that any of the three Individual Defendants was a "maker" of any of the statements. *Id.* at 13-14.

The Court determines that it is a close call as to whether these statements were false or

misleading. Defendants argue that the statements could not have been false when made because the Warning Letter did not come out until months after the statements were made. MTD at 9-10. In *Norfolk County Retirement System v. Solazyme, Inc.*, the court dismissed the plaintiffs' Section 10 claim. *See* 2016 WL 7475555. It explained that "[t]hroughout the complaint, Plaintiffs reference facts they claim establish that key representations were false or misleading when made, but they consistently fail to allege that the facts existed and were known to Defendants *at the time the statements were made*." *Id.* at *3. The Court thinks that the current situation is distinguishable. Here, facts about DSUVIA's proper use, limitations, and administration were known at the time that the statements were made, as can be gleaned from Plaintiffs' allegations about the extensive and iterative FDA process that AcelRx went through to obtain approval for DSUVIA. *See* SAC ¶¶ 39-63. The timing of the Warning Letter in relation to the statements is more indicative of scienter, which the Court will address below.

Plaintiffs' theory about an increased risk of regulatory scrutiny is less convincing. *See* SAC ¶¶ 128, 130. As to Defendant Angotti's statement, Plaintiffs allege that Angotti "undermined the REMS" and, "as a result, the Company was therefore subject to a foreseeable and increased risk of regulatory investigations or enforcement actions." *Id.* ¶ 128. As to the banner advertisement and tabletop display, Plaintiffs allege that "AcelRx failed to implement and/or maintain sufficient internal controls and procedures regarding the marketing of DSUVIA" and, "as a result, the Company was therefore subject to a foreseeable and increased risk of regulatory investigations or enforcement actions." *Id.* ¶ 130. This is an instance where "the reasons . . . why . . . the statements are false or misleading bear no connection to the substance of the statements." *See Veal v. LendingClub Corp.*, 423 F. Supp. 3d 785, 807 (N.D. Cal. 2019).

Defendants argue that the allegedly omitted material information was actually disclosed to investors and that no reasonable investor would have viewed the statements as providing comprehensive instructions for use. MTD at 12-13. Plaintiffs counter that this "truth on the market" defense by Defendants lacks merit. Opp. at 16-18. The Court recognizes that full information about the use and administration of DSUVIA was publicly available. Such a consideration weakens Plaintiffs' allegations. *See Kovtun v. VIVUS, Inc.*, No. C 10-4957 PJH,

2012 WL 4477647, at *8 (N.D. Cal. Sept. 27, 2012) (considering statements "in the context" of information that was "well-known and understood by the FDA . . . and by the markets"). But the Court declines to find that the statements were not false or misleading on this basis at the motion to dismiss stage. *See In re Turnstone Sys. Sec. Litig.*, No. C 01-1256 SBA, 2003 U.S. Dist. LEXIS 26709, at *127-28 (N.D. Cal. Feb. 4, 2003) (recognizing the truth-on-the-market defense is "generally inappropriate" at the motion to dismiss stage "because it raises distinctly factual issues").

Finally, Defendants also argue that the Individual Defendants were not "makers" of these statements. MTD at 13-14. "For purposes of Rule 10b–5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011). The Court notes that Defendant Angotti was clearly the "maker" of Statement 1, but there are no allegations that the other two Individual Defendants were "makers" of this Statement. *See* SAC ¶ 127. As to the other two statements, in arguing that the Individual Defendants were "makers" of the statements, Plaintiffs point the Court to two paragraphs of the SAC, both of which allege that the Individual Defendants had the "power and authority" or "control and authority" to control the contents of the statements. *See* Opp. at 13 (citing SAC ¶¶ 35, 203). While these allegations are fairly conclusory, Plaintiffs do provide some additional allegations that Defendants Angotti and Palmer had some degree of control over Statements 2 and 3. *See* SAC ¶¶ 102 (alleging Angotti "weighed in on" marketing materials), 110 (alleging Angotti and Palmer were present at a meeting in which the "Tongue and Done" slogan was discussed and provided input as to use of the slogan). The Court determines that the allegations are sufficient for purposes of the motion to dismiss. *See In re Rocket Fuel, Inc. Sec. Litig.*, No. 14-cv-3998-PJH, 2015 WL 9311921, at *10 (N.D. Cal. Dec. 23, 2015) (determining the plaintiffs had alleged the defendants were "makers" of the statements for purposes of the motion to dismiss where the "complaint does indeed allege that the three Insider defendants 'possessed the power and authority to control the contents of the Company's press releases [and] investor and media presentations'" (citation omitted)).

Risk Factors

Statements 4, 6, 8, 22, and 23 are all related to risk factors. *See* SAC App. 1; SAC ¶¶ 131, 135, 139, 166, 168. Statements 4, 6, and 8 provide that "[t]he success of DSUVIA will depend on numerous factors, including . . . effective management of and compliance with the DSUVIA Risk Evaluation and Mitigation Strategies, or REMS program [and] continued demonstration of an acceptable safety profile of DSUVIA following approval." SAC App. 1; SAC ¶¶ 131, 135, 139. Statement 22 identifies several risks, including that (1) guidelines and recommendations from government agencies and non-governmental organizations, as well as existing laws and regulations, can reduce the use of DSUVIA; (2) AcelRx may be unable to generate sufficient revenue if unable to maintain or grow its sales and marketing capabilities or enter into agreements with third parties to market and sell products; and (3) a key part of the business strategy is to establish relationships to commercialize and fund development and approval of the products, and AcelRx may not succeed in doing so. SAC App. 1; SAC ¶¶ 166. Statement 23 reiterates the portion of Statement 22 about generating sufficient revenue, and it also provides that AcelRx must maintain or grow internal sales, marketing, distribution, managerial and other capabilities or make arrangements with third parties to do so in order to commercialize DSUVIA. SAC App. 1; SAC ¶¶ 168. Defendants argue that Plaintiffs have not alleged falsity as to these statements about risk factors. MTD at 14-15. Plaintiffs argue that Statements 4, 6, and 8 were false because AcelRx was engaging in the Misbranding Violations, which they assert undermined the REMS. Opp. at 15; *see also* SAC App. 1; SAC ¶¶ 171-84.

"The Ninth Circuit has noted that 'risk factors' are not actionable without further factual allegations indicating that the risks had already 'come to fruition.'" *In re Pivotal Sec. Litig.*, No. No. 3:19-cv-03589-CRB, 2020 WL 4193384, at *6 (N.D. Cal. July 21, 2020) (quoting *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009)); *see also Flynn v. Sientra, Inc.*, No. CV 15-07548 SJO (RAOx), 2016 WL 3360676, at *11 (C.D. Cal. June 9, 2016) (holding that statements about risks were " more than plausibly misleading when viewed in conjunction with Plaintiffs' allegations that serious regulatory issues had already transpired by the time these statements were made and [defendants] knew or recklessly disregarded the existence of these

issues"). As Defendants argue, Plaintiffs here had not alleged that any of the risks being warned of had already come to fruition at the time the statements were made. *See* MTD at 14-15. For example, as to Statements 4, 6, and 8, Plaintiffs have not alleged that AcelRx had not effectively managed or complied with the REMS nor that DSUVIA no longer demonstrated an acceptable safety profile. *See* SAC. The same is true of the risks identified in Statements 22 and 23. Plaintiffs have not alleged falsity as to the risk statements.

Earnings Call Statement

Statement 15 was made by Defendant Palmer during a quarterly earnings call on March 16, 2020:

> AcelRx ensures proper use of DSUVIA via physician education and the DSUVIA risk evaluation and mitigation strategies or REMS program. DSUVIA is only available to facilities that are part of the DSUVIA REMS program. Facilities that administer DSUVIA must be able to . . . ensure the appropriate administration of DSUVIA. All safety information and the black box warning for DSUVIA can be found at dsuvia.com.

SAC App. 1; SAC ¶ 152.

Defendants argue that Plaintiffs have not alleged the falsity of this statement. MTD at 10-11. Plaintiffs do not argue otherwise. *See* Opp. The Court agrees that Plaintiffs have not alleged the falsity of the statement, as Plaintiffs have not alleged that AcelRx was not complying with the REMS. *See* SAC.

Sales and Marketing Efforts

Statement 10 addresses AcelRx's sales and marketing practices for DSUVIA. *See* SAC App. 1; SAC ¶ 143. It provides that Defendants were using a scientific support team to understand hospital needs to present DSUVIA effectively; had increased awareness of sublingual administration of sufentanil by publishing data; had engaged Advisory Boards that included various medical professionals and other experts to provide input on commercial positioning for DSUVIA; had developed a sales and marketing organization; and had deployed a team to explain the benefits of DSUVIA at medical centers. *Id.* As Defendants point out, the SAC does not allege that these activities did not occur. *See* Opp. at 14. Plaintiffs have not alleged falsity as to this statement.

SOX Certifications and Controls

Statements 5, 7, 9, 13, 17, 19, and 21 are all SOX certifications. *See* SAC App. 1; SAC ¶¶ 133, 137, 141, 148, 156, 160, 164. These SOX certifications "are wholly untethered to Plaintiffs' described reasons for falsity." *See Veal*, 423 F. Supp. 3d at 808. These statements provide that certain SEC filings complied with the Exchange Act and "fairly present[], in all material respects, the financial condition and results of operations of the Company." *See* SAC App. 1. The SAC does not include allegations about the financial condition or results of operations at AcelRx. "Absent any allegations of financial wrongdoing, the SOX certifications have no nexus to Plaintiffs' reasons for falsity." *Veal*, 423 F. Supp. 3d at 808; *see In re Banco Bradesco S.A. Sec. Litig.*, 277 F. Supp. 3d 600, 654 (S.D.N.Y. 2017) ("Plaintiff has failed to plead that [the SOX] certification was false or misleading because . . . the amended complaint does not adequately allege a nexus between the alleged [wrongful act] and [the company's] financial condition or results of operations, or that the Company's *financial reports* contained inaccuracies." (emphasis in original)). Plaintiffs have not alleged falsity as to the SOX certifications.

Statements 12, 16, 18, and 20 are all SOX controls and procedure verification statements. *See* SAC App. 1; SAC ¶¶ 146, 154, 158, 162. These statements provided that AcelRx's "disclosure controls and procedures were effective." *See* SAC App. 1. Again, these SOX statements "are wholly untethered to Plaintiffs' described reasons for falsity." *See Veal*, 423 F. Supp. 3d at 808. The term "disclosure controls and procedures" means "controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act (15 U.S.C. 78a *et seq.*) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms." 17 C.F.R. § 240.13a-15(e). Plaintiffs make no allegations that Defendants' disclosure controls and procedures were not actually effective. *See* SAC. Plaintiffs have not alleged falsity as to these statements.

Forward-Looking Statements

Statement 11 provides that AcelRx "may adjust [its] commercialization plan" by, among other things, "continuing to build and progressively deploy a high-quality, customer focused and

experienced sales organization in the United States dedicated to bringing innovative, highly valued healthcare solutions to patients, payers and healthcare providers," as needed, and by "continuing to establish DSUVIA as a suitable choice for moderate-to-severe acute pain in certified medically supervised settings." *See* SAC App. 1; SAC ¶ 144. Defendants argue that this statement is not actionable because it is forward-looking. MTD at 16-17.

The PSLRA safe harbor precludes liability for forward-looking statements in either of two circumstances: (1) "if they were identified as forward-looking statements and accompanied by meaningful cautionary language," or (2) "if the investors fail to prove the projections were made with actual knowledge that they were materially false or misleading." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111-12 (9th Cir. 2010); *see* 15 U.S.C. § 78u-5(c)(1). A forward-looking statement is "any statement regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions 'underlying or related to' any of these issues." *No. 84 Emp.-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003) (citing 15 U.S.C. § 78u-5(i)).

Statement 11 is located in the Form 10-K filed with the SEC dated March 16, 2020. *See* SAC App. 1; Fernandes Decl., Ex. 16. The Form 10-K identifies the statement as forward-looking. Fernandes Decl., Ex. 16 at 3. The statement provides that AcelRx *may* change its commercialization plan. Any such change would necessarily be in the future. The statement falls under the category of "plans and objectives of management for future operations." Further, the statement is accompanied by meaningful cautionary language. *See id.* Therefore, this statement is protected by the PSLRA safe harbor. Plaintiffs have not alleged that Statement 11 is actionable.

Corporate Optimism

Statement 14 is that the DSUVIA launch was "progressing well with [the] healthcare providers." *See* SAC App. 1; SAC ¶ 150. Defendants argue that the statement is puffery, *see* MTD at 17, and the Court agrees. "In the Ninth Circuit, 'vague, generalized assertions of corporate optimism or statements of mere puffing are not actionable material misrepresentations under federal securities laws' because no reasonable investor would rely on such statements." *In re Facebook, Inc. Sec. Litig.*, 405 F. Supp. 3d 809, 835 (N.D. Cal. Sept. 25, 2019) (quoting *In re*

Fusion-io, Inc. Sec. Litig., No. 13-CV-05368-LHK, 2015 WL 661869, at *14 (N.D. Cal. Feb. 12, 2015)). "Statements like '[w]e are very pleased with the learning from our pilot launch,' 'so far we're getting really great feedback,' and 'we are very pleased with our progress to date,' are inactionable puffery." *Id.* (quoting *Wozniak v. Align Tech., Inc.*, 850 F. Supp. 2d 1029, 1036 (N.D. Cal. 2012)). Similarly, "statements projecting 'excellent results,' a 'blowout winner' product, 'significant sales gains,' and '10% to 30% growth rate over the next several years'" were held to be puffery, and therefore not actionable. *In re Fusion-io*, 2015 WL 661869, at *14 (citing *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005)). The statement here—that the launch is "progressing well"—is similarly nonactionable puffery. Further, as Defendants note, Plaintiffs do not allege that the launch was not "progressing well." *See* MTD at 17. This statement is not actionable.

Conclusion

The Court concludes that Plaintiffs have not pled falsity as to Statements 4-27, but it is a close call as to Statements 1-3. The Court therefore turns to whether Plaintiffs have alleged scienter.

2. Scienter

Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). To plead 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). Scienter is adequately pled when "all of the facts alleged, taken collectively, give rise to a strong inference of scienter." *Tellabs*, 551 U.S. 323. This means that "[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.* at 324. The facts alleged "must not only be particular, but also must 'strongly imply [the defendant's] *contemporaneous* knowledge that the statement was false when made.'" *In re Infonet Servs. Corp. Sec. Litig.*, 310 F. Supp. 2d 1080, 1102 (C.D. Cal. 2003) (quoting *In re Read-Rite*, 335 F.3d 843, 847 (9th Cir. 2003)) (alteration in original). "Where, as here, the Plaintiffs seek to hold individuals and a company liable on a securities fraud theory, we

require that the Plaintiffs allege scienter with respect to each of the individual defendants." *Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 607 (9th Cir. 2014).

In their opposition to the motion to dismiss, Plaintiffs assert that scienter can be inferred when holistically considering the following: (1) access to information and (2) core operations. Opp. at 18-24. The Court finds that these bases do not give rise to a strong inference of scienter.

a. Access to Information

First, Plaintiffs assert that Defendants' access to information undermining their public statements supports scienter. Opp. at 18-23. Plaintiffs first point to the fact that Defendants had multiple interactions with the FDA regarding DSUVIA, specifically the REMS, and these negotiations put Defendants on notice that AcelRx would be subject to FDA scrutiny if it failed to adhere to the REMS and that REMS compliance was its responsibility. Opp. at 18-19. But Defendants' awareness of FDA regulations and their work with the FDA in developing the REMS do not strongly imply that they knew any specific statement identified above was false at the time it was made. Further, Plaintiffs have not alleged that Defendants failed to comply with the REMS. *See* SAC. Plaintiffs also assert that AcelRx submitted its tabletop display for DSUVIA to OPDP prior to Defendant Angotti's March 16, 2020 statement. Opp. at 19. But the fact that the tabletop display was submitted to OPDP again does not indicate that Defendant Angotti knew that any statement identified above was untrue. The fact that Defendants were aware that the FDA was regulating its marketing does not give rise to an inference that Defendants would be aware that any particular marketing material was misleading or otherwise not in compliance with the FDCA.

Plaintiffs also rely on the statements of seven former employees ("FEs"). Opp. at 19-23; *see* SAC ¶¶ 71-113. The Court will first summarize the accounts of FEs 4-7, who were added for the first time in the SAC, and it will then summarize the accounts of FEs 1-3.

The SAC alleges that FE4 was the Senior Director of Marketing, reported directly to Angotti, and personally created the Tongue and Done campaign. SAC ¶¶ 90-92. FE4 said Angotti was aware of the Tongue and Done slogan and that Defendant Palmer and other senior officers weighed in on the slogan before it was deployed. *Id.* ¶¶ 93. FE4 explained that the Company used

the Tongue and Done slogan at certain identified medical conferences. *Id.* ¶¶ 94–99.

FE5 was the first sales representative the Company hired to promote DSUVIA. SAC ¶ 100. He confirmed that FE4 developed the Tongue and Done campaign and that Palmer and Angotti weighed in on marketing materials. *Id.* ¶¶ 100–02. FE5 stated that Angotti attended conferences in which the Company touted the Tongue and Done campaign to medical professionals. *Id.* ¶¶ 103–04.

FE6 was a federal account director for the Company from July 2019 to November 2021. SAC ¶ 105. He stated that the Company's promotional review committee ("PRC") approved marking messages. *Id.* ¶ 106. As the SAC alleges, the medical department, run by Palmer, served on this committee. *Id.* ¶¶ 33, 77, 106. FE6 explained that he had to inform healthcare professionals that due to the Warning Letter, the Company would no longer be using the Tongue and Done slogan. *Id.* ¶ 107. FE6 said the Warning Letter harmed the Company's reputation. *Id.* ¶ 107.

FE7 was a regional medical director at the Company. SAC ¶ 108. He stated that he expressed concerns about the Tongue and Done slogan to Angotti, Palmer, and his supervisor, Gail Spahn. *Id.* ¶ 109. Specifically, FE7 raised concerns that the Tongue and Done campaign oversimplified the use of a powerful opioid and contained sexual overtones that could be misinterpreted. *Id.* He raised these concerns at a meeting with senior management, including Angotti and Palmer, but Palmer told him that Tongue and Done was a marketing decision and thus the medical affairs team should not get involved. *Id.* ¶ 110. FE7 stated that at the meeting, Angotti responded to FE7's concerns by saying that he trusted his marketing team. *Id.* Three months later, FE7 again expressed his concerns to Spahn, and Spahn fired him shortly thereafter on the basis that he was not supporting leadership's decisions and she did not feel confident in him supporting an opioid product. *Id.* ¶¶ 111-12. FE7 said that the Tongue and Done materials were used at meetings, national sales meetings, medical affairs meetings, and strategic development meetings. *Id.* ¶ 113. FE7 also recalled that Angotti attended a pain management conference where AcelRx marketed DSUVIA using the "Tongue and Done" table drape and sales handouts. *Id.*

FE1 worked as a contract marketing manager for AcelRx from June 2017 through March 2020 and as a marketing specialist from January 2016 through June 2017, and he reported to the senior director of marketing. SAC ¶¶ 71-72. He stated that DSUVIA's brand identity required regular sign-off from AcelRx's regulatory and compliance staff, and he confirmed FE6's account that the Company's promotional review committee ("PRC") approved marking messages to ensure that content was FDA-compliant and that the PRC was in direct communication with the FDA. *Id.* ¶¶ 76-78.

FE2 was a contract HR Consultant from June 2019 through August 2021. SAC ¶ 81. He stated that Angotti provided final approval and would have reviewed and signed off on marketing materials. *Id.* ¶ 85.

FE3 was a medical editor for Publicis Groupe ("Publicis") from March 2018 to September 2018. SAC ¶ 86. Publicis' Health division worked with AcelRx on the marketing materials for DSUVIA, with the Senior Director of Marketing (FE4) as the primary contact. *Id.* ¶¶ 86-87. He confirmed that DSUVIA was marketed to health care professionals in ambulatory surgical centers and hospitals. *Id.* ¶ 88.

Defendants argue that these allegations are insufficient to support scienter. MTD at 19-21. They argue that the allegations show nothing more than that certain individual Defendants were aware of the promotional materials, not that Defendants intended to deceive investors. *Id.* at 20.

The Court agrees. The fact that Defendants Angotti and Palmer were aware of the promotional materials and their use at conferences is not enough to raise a strong inference that they intended to deceive investors or to engage in the Misbranding Violations through the use of those materials. Further, the fact that the FE7 expressed concern about the Tongue and Done slogan to Defendants Palmer and Angotti is not sufficient to raise an inference that they intended to deceive investors. *Cf. In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 883 (9th Cir. 2012) (stating that allegations that a defendant was aware of a fact was not sufficient to show the defendant believed they made false or misleading statements about that fact). The FE allegations do not give rise to a strong inference that the Defendants had a "mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst*, 425 U.S. at 193.

b. Core Operations

Plaintiffs also argue that the core operations theory supports scienter. Opp. at 23. Under the core operations theory, "scienter may be imputed based on the inference that key officers have knowledge of the core operations of the company." *Mulligan v. Impax Lab'ys, Inc.*, 36 F. Supp. 3d 942, 969 (N.D. Cal. 2014) (internal quotation marks and citation omitted). If a plaintiff provides "'allegations regarding a management's role in the company' that are 'particular and suggest that the defendant had actual access to the disputed information,' and 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,'" then falsity itself can support scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1000 (9th Cir. 2009) (quoting *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008)). Plaintiffs argue that the core operations theory applies here because AcelRx is a small company with minimal marketing staff, DSUVIA was the only approved product, and the FE statements establish that the individual Defendants were involved with the marketing campaign for DSUVIA. Opp. at 23.

Allegations that a company is small or that it has only one product are not sufficient to raise a strong inference of scienter. *See In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1064 (9th Cir. 2014) (allegations of "flagship product" insufficient); *Glazer Cap. Mgmt., LP v. Magistri*, 549 F.3d 736, 747 (9th Cir. 2008) (holding "the mere size and nature of [the] business are not sufficient to create a strong inference of scienter"). This case is not one of the "rare circumstances" when scienter is adequately alleged through the core operations theory. *See Mulligan*, 36 F. Supp. 3d at 969.

c. Other Warning Letters

While not discussed in the Scienter portion of their opposition brief, *see* Opp. at 18-24, Plaintiffs do add to the SAC allegations about two other FDA warning letters, sent in 2008 and 2009, over drugs that were also subject to REMS, *see* SAC ¶¶ 43. To the extent that Plaintiffs allege that these letters support scienter, the Court disagrees. The fact that the FDA sent warning letters to other companies adds nothing to the scienter analysis. Defendants were clearly aware that the marketing materials were subject to FDA regulation, as indicated by the fact that they

submitted the marketing materials to the FDA for review. The existence of these letters does not give rise to an inference of scienter.

d. Holistic Review

After having determined that none of Plaintiffs' allegations, standing alone, is sufficient to create a strong inference of scienter, the Court now considers the allegations holistically. *See Zucco*, 552 F.3d at 992. Plaintiffs also argue that the totality of the allegations are sufficient to support scienter. Opp. at 23-24. The Court finds that taken together, the facts do not evince such fraudulent intent or deliberate recklessness as to make the inference of scienter cogent. *Tellabs*, 551 U.S. at 323.

3. Conclusion

The Court GRANTS the motion to dismiss the Rule 10b-5(b) claim WITH LEAVE TO AMEND.

B. Claim 2: Section 10(b) and Rule 10b-5(a) and (c)

Plaintiffs also bring a claim under subsections (a) and (c) of Rule 10b-5, quoted above. SAC ¶¶ 207-16. Defendants move to dismiss this claim. MTD at 22-25.

"To state a scheme liability claim, a plaintiff must show: '(1) that the defendant committed a deceptive or manipulative act, (2) in furtherance of the alleged scheme to defraud, (3) with scienter, and (4) reliance.'" *Plumber & Steamfitters Loc. 773 Pension Fund v. Danske Bank A/S*, 11 F.4th 90, 105 (2d Cir. 2021) (quoting *In re Mindbody, Inc. Sec. Litig.*, 489 F. Supp. 3d 188, 216 (S.D.N.Y. 2020)). "And, of course, the deceptive or fraudulent scheme or activity must have occurred 'in connection with the purchase or sale of a[ ] security.'" *Id.* (alteration in original) (quoting 17 C.F.R. § 240.10b-5).

Plaintiffs explain that the claim is based on an alleged "scheme to illegally market DSUVIA beyond its permitted label through misleading advertisements to doctors who would prescribe and oversee the administration of the drug to 'enhance sales of DSUVIA.'" Opp. at 24 (quoting SAC ¶ 208). Plaintiffs argue that "[o]n the basis of that falsified marketing scheme, Defendants 'deceive[d] investors into believing the prospects and addressable market for DSUVIA was larger than it actually was.'" *Id.* (quoting SAC ¶ 208).

The claim fails. Plaintiffs argue that Defendants were reassuring investors that they were in compliance with REMS and were marketing according to law while they were instead promoting DSUVIA with the "Tongue and Done" slogan. Opp. at 24-25. Again, Plaintiffs have not alleged a failure to comply with REMS. *See* SAC. And for the same reasons that Plaintiffs have not alleged scienter as to the Misbranding Violations, they have also not alleged scienter as to a scheme to defraud investors. There are no allegations that the Defendants had an intent to engage in a scheme to defraud investors about the market size of DSUVIA. The Court already determined there was no scienter as to the Misbranding Violations. And as Defendants point out, Plaintiffs do not allege any inflated sales figures or enhanced market size. *See* Reply at 14-15.

This situation is distinguishable from the cases that Plaintiffs cite. *See* Opp. at 24. Plaintiffs point to *Klein v. Altria Group, Inc.*, in which the court determined that the plaintiffs had adequately pled scheme liability where they alleged "that Defendants acted in concert to deceive the FDA into not regulating mint [tobacco products] so that they could continue to target youth with the mint product, including submitting falsified data and studies." 525 F. Supp. 3d 638, 665 (E.D. Va. 2021). Further, Plaintiffs alleged "that [defendant] JUUL embarked on a years-long effort to increase youth addiction and [defendant] Altria knew about this effort. Still, rather than apprising investors of the risks associated with the effort, Defendants continued to publicly deny JUUL's intention of targeting youths in an effort to avoid further litigation or regulation that could curb their values." *Id.* Defendants here did not submit falsified data or studies to the FDA to avoid regulation. Instead, Defendants complied with FDA regulations, submitting its advertisements to the FDA for approval.

Plaintiffs also point to *Mart v. Tactile Systems Technology, Inc.*, which centered on the sale of one of the defendant's devices—the Flexitouch—for at-home treatment of certain diseases. 595 F. Supp. 3d 788, 799 (D. Minn. 2022). The court explained that "[i]n furtherance of the scheme, Defendants allegedly exaggerated and distorted clinical study results and claims data analyses to convey that Flexitouch's market size was three to four times greater than it actually was, and paid illegal kickbacks to induce doctors and hospital staff to prescribe the Flexitouch." *Id.* at 823 (internal quotation marks and citation omitted). The court went on to state that the defendants had

"allegedly issued false and misleading statements in furtherance of the scheme which was intended to, and did, drive Flexitouch sales, and with it, [the defendant's] revenues and share price." *Id.* (internal quotation marks and citation omitted). Defendants in this case did not exaggerate any study results or data analyses. Further, there are no allegations as to either the actual market size, or what Plaintiffs claim was an inflated market size.

Finally, Plaintiffs cite to *West Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 57 F. Supp. 3d 950 (D. Minn. 2014). In that case, the plaintiffs alleged that the defendants engaged in a scheme to deceive investors and artificially inflate the stock price. *Id.* at 964-65. The plaintiffs alleged that the defendant's clinical studies revealed safety risks with its product, so the defendant engaged in a scheme to conceal these safety risks. *Id.* at 965. The defendant did so by "forg[ing] relationships, including financial relationships, with physician authors who published research articles in respected medical journals and knowingly concealed in those original articles, or omitted altogether, known facts regarding [the product's] adverse side effects observed in clinical trials," and these articles "overstated apparent disadvantages of alternate . . . procedures . . . as opposed to treatment with [the product]." *Id.* The defendant paid the physician authors, and the defendant's employees edited the articles to remove information that could have informed the public and doctors about the harmful side effects of the product. *Id.* No such behavior was present here.

The Court determines that Plaintiff has not alleged a scheme liability claim. The Court GRANTS the motion to dismiss the Rule 10b-5(a) and (c) claim WITHOUT LEAVE TO AMEND.

C. Claim 3: Section 20(a)

Plaintiffs bring a claim against Defendants Angotti, Asadorian, and Palmer for violation of Section 20(a) of the Exchange Act. SAC ¶¶ 217-23. Defendants move to dismiss this claim. MTD at 25 n.5.

Section 20(a) of the Exchange Act extends liability for § 10(b) violations to those who are "controlling persons" of the alleged violations. *Hollinger v. Titan Cap. Corp.*, 914 F.2d 1564, 1572 (9th Cir. 1990); *see* 15 U.S.C. § 78t(a). To prevail on their claim for violations of § 20(a),

Plaintiffs must first allege a violation of § 10(b). *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002). They have failed to do so here.

The Court GRANTS the motion to dismiss the § 20(a) claim against Defendants Angotti, Asadorian, and Palmer WITH LEAVE TO AMEND.

V. ORDER

The Court GRANTS Defendants' motion to dismiss the SAC WITH LEAVE TO AMEND all claims except Claim 2. Although the Court is granting leave to amend all of the falsity allegations, it seems unlikely that Plaintiffs will do better on the risk factors, earnings call statement, sales and marketing efforts, SOX certifications and controls, or forward-looking statements. However, Plaintiffs requested one further opportunity to allege sufficient facts, which is allowed. Amendment of allegations related to scienter is allowed. Scheme liability, alleged in Claim 2, is dismissed WITHOUT LEAVE TO AMEND. Plaintiffs have never provided any plausible factual allegations to support that claim. Plaintiffs SHALL file a third amended complaint ("TAC"), if they are able to rectify the defects discussed above, no later than sixty days from the date of this Order. No parties or claims may be added without leave of Court. Plaintiffs SHALL provide a chart with the TAC including a numbered list of the false and misleading statements, and for each statement: (1) a citation to the pleading; (2) the identity of the speaker; (3) the date of the statement; (4) the location of the statement; (5) evidence the statement was false when made; and (6) evidence of scienter with respect to that statement. Plaintiffs SHALL provide a redline of the TAC against the SAC.

IT IS SO ORDERED.

Dated: July 7, 2023

BETH LABSON FREEMAN
United States District Judge