United States District Court
Northern District of California

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** [Re: ECF No. 96]

Before the Court is Defendants AcelRx Pharmaceuticals, Inc. (n.k.a. Talphera, Inc.), Vincent J. Angotti, and Pamela Palmer's motion to dismiss the Third Amended Complaint ("TAC") in this putative securities class action. ECF No. 96 ("Mot."); *see also* ECF No. 101 ("Reply"). Plaintiffs oppose the motion. ECF No. 100 ("Opp."). The Court held a hearing on the motion on April 4, 2024. ECF No. 104.

For the reasons stated below, the Court GRANTS Defendants' motion to dismiss WITHOUT LEAVE TO AMEND.

I. BACKGROUND

A. Factual Background

AcelRx is a pharmaceutical company that develops therapies for the treatment of acute pain. ECF No. 91 ("TAC") ¶ 38. 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.* ¶¶ 38–39. In November 2018, the U.S. Food and Drug Administration ("FDA") approved AcelRx's application for DSUVIA. *Id.* ¶ 64. 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.* ¶¶ 41, 64. 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, 147; *see* 21 U.S.C. § 331(a).

On February 11, 2021, AcelRx received a warning letter from the FDA's Office of Prescription Drug Promotion ("OPDP"). TAC ¶ 20. 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.* ¶¶ 20–21. 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.* ¶ 169. After AcelRx publicly disclosed this letter on February 16, 2021, its stock price fell $0.21 per share, or 8.37%. *Id.* ¶ 178. 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.* ¶ 175. The press release stated that the tabletop display and banner advertisement "undermine[d] 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.* ¶ 177. It went on to explain that DSUVIA "was approved with a [REMS]." *Id.*

B. Procedural History

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 a second amended complaint. ECF No. 75 ("SAC"). On July 7, 2023, the Court dismissed the second amended complaint with leave to amend in part and without leave to amend in part. *Sneed v. AcelRx Pharms., Inc.*, No. 21-CV-04353-BLF, 2023 WL 4412164 (N.D. Cal. July 7, 2023). In doing so, the Court granted Plaintiffs "one further opportunity to allege sufficient facts" in support of their Exchange Act Section 10(b) and Rule 10b-5(b) claim and Exchange Act Section 20(a) claim. *Id.* at *15. On September 5, 2023, Plaintiffs filed the operative TAC, which no longer brings claims against Asadorian. *See* TAC ¶¶ 31–37.

In the TAC, Plaintiffs allege that "Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Company engaged in the Misbranding Violations; (2) the Company was therefore subject to a foreseeable and increased risk of regulatory investigations or enforcement actions; and (3) the Company recklessly disregarded those risks. As a result, the Company's public statements were materially false and misleading throughout the Class Period." TAC ¶ 16.

Plaintiffs assert two claims: (1) violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) by all Defendants, TAC ¶¶ 192–200; and (2) violation of Section 20(a) of the Exchange Act by Defendants Angotti and Palmer, *id.* ¶¶ 201–07.

II. LEGAL STANDARD

A. Rule 12(b)(6)

"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). However, 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) (citation 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*. On a motion to dismiss, the Court's review is limited to the face of the complaint and matters judicially noticeable. *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986); *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983).

B. Rule 9(b) and the Private Securities Litigation Reform Act of 1995

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. That is, "the complaint must allege specific facts regarding the fraudulent activity, such as the time, date, place, and content of the alleged fraudulent representation, how or why the representation was false or misleading, and in some cases, the identity of the person engaged in the fraud." *In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1065 (N.D. Cal. 2010).

Similarly, under the PSLRA "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). The PSLRA further requires that "in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with

particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *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 (alteration in original) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). 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

A court generally cannot consider materials outside the pleadings on a motion to dismiss for failure to state a claim. *See* Fed. R. Civ. P. 12(b)(6). A court may, however, consider items of which it can take judicial notice without converting the motion to dismiss into one for summary judgment. *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994). A court may take judicial notice of facts "not subject to reasonable dispute" because they are either "(1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201. A court may additionally take judicial notice of "'matters of public record' without converting a Motion to Dismiss into a motion for summary judgment." *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) (quoting *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986)). Under the incorporation by reference doctrine, courts may consider 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." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (quoting *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994)) (alteration in original).

Defendants request that the Court take judicial notice of the following exhibits:

1. Exhibit 1, an AcelRx press release, issued on November 2, 2018. ECF No. 96-2.
2. Exhibit 2, DSUVIA's REMS, approved by the FDA on November 2, 2018. ECF No. 96-3.
3. Exhibit 3, DSUVIA's prescribing information, finalized and approved by the FDA on

November 2, 2018. ECF No. 96-4.

4. Exhibit 4, DSUVIA's directions for use as of November 25, 2018. ECF No. 96-5.
5. Exhibit 5, an AcelRx press release, issued on January 7, 2019. ECF No. 96-6.
6. Exhibit 6, an AcelRx press release, issued on January 31, 2019. ECF No. 96-7.
7. Exhibit 7, excerpts of AcelRx's Form 10-K, filed on March 7, 2019. ECF No. 96-8.
8. Exhibit 8, the transcript of AcelRx's presentation at the 29th Annual Oppenheimer Health Care Conference, which took place on March 20, 2019. ECF No. 96-9.
9. Exhibit 8A, an AcelRx press release, issued on May 11, 2019. ECF No. 96-10.
10. Exhibit 9, an AcelRx press release, issued on April 11, 2019. ECF No. 96-11.
11. Exhibit 10, excerpts of AcelRx's Form 10-Q, filed on May 9, 2019. ECF No. 96-12.
12. Exhibit 11, a transcript of AcelRx's Q2 2019 Earnings Call, dated August 5, 2019. ECF No. 96-13.
13. Exhibit 12, excerpts of AcelRx's Form 10-Q, filed on August 6, 2019. ECF No. 96-14.
14. Exhibit 13, a transcript of AcelRx's Q3 2019 Earnings Call, dated November 6, 2019. ECF No. 96-15.
15. Exhibit 14, excerpts of AcelRx's Form 10-Q, filed on November 7, 2019. ECF No. 96-16.
16. Exhibit 15, a transcript of AcelRx's Q4 2019 Earnings Call, dated March 16, 2020. ECF No. 96-17.
17. Exhibit 16, excerpts of AcelRx's Form 10-K, filed on March 16, 2020. ECF No. 96-18.
18. Exhibit 17, a transcript of AcelRx's Q1 2020 Earnings Call, dated May 11, 2020. ECF No. 96-19.
19. Exhibit 18, excerpts of AcelRx's Form 10-Q, filed on May 11, 2020. ECF No. 96-20.
20. Exhibit 19, excerpts of AcelRx's Form 10-Q, filed on August 10, 2020. ECF No. 96-21.
21. Exhibit 20, excerpts of AcelRx's Form 10-Q, filed on November 5, 2020. ECF No. 96-22.
22. Exhibit 21, AcelRx's Form 8-K, filed on February 16, 2021. ECF No. 96-23.
23. Exhibit 22, an analyst report published by Cantor Fitzgerald, dated February 16, 2021. ECF No. 96-24.
24. Exhibit 23, an analyst report published by H.C. Wainwright & Co., dated February 17,

2021. ECF No. 96-25.

25. Exhibit 24, an AcelRx press release, issued on May 16, 2022. ECF No. 96-26.
26. Exhibit 25, an FDA Memorandum on REMS Review, issued on November 1, 2018. ECF No. 96-27.
27. Exhibit 26, an AcelRx press release, issued on May 19, 2022. ECF No. 96-28.
28. Exhibit 27, an FDA webpage titled *Prescription Drug Advertising: Questions and Answers*. ECF No. 96-29.
29. Exhibit 28, a presentation titled "Oppenheimer 29th Annual Healthcare Conference, March 20, 2019." ECF No. 96-30.

Plaintiffs do not oppose Defendants' requests for judicial notice.

The Court finds that Exhibits 1–3, 8, 21–22, 25, and 28 are incorporated by reference into the TAC. *See, e.g.*, TAC ¶¶ 4, 64 (Ex. 1); ¶¶ 5, 22, 64 (Ex. 1); ¶ 152 (Ex. 3); ¶ 160 (Ex. 8); ¶¶20, 164–66 (Ex. 21); ¶ 179 (Ex. 22); ¶ 48 (Ex. 25); ¶ 160 (Ex. 28).

The Court takes judicial notice of Exhibits 7, 10, 12, 14, 16, and 18–20 because these documents are judicially noticeable as SEC filings, which are matters of public record not subject to reasonable dispute. *See In re Calpine Corp. Sec. Litig.*, 288 F.Supp.2d 1054, 1076 (N.D. Cal. 2003) ("[T]he Court may properly take judicial notice of SEC filings and documents expressly referenced in the [complaint]."). The Court takes judicial notice of Exhibits 11, 13, 15, and 17 because transcripts of earnings calls are publicly available documents and thus are matters of public record not subject to reasonable dispute. *See In re Facebook, Inc. Sec. Litig.*, 477 F.Supp.3d 980, 1009 (N.D. Cal. 2020) (taking judicial notice of transcripts of earnings calls). The Court takes judicial notice of Exhibits 5, 6, 8A, 9, 24, and 26 because they are press releases, which are capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. *See In re Am. Apparel, Inc. S'holder Litig.*, 855 F.Supp.2d 1043, 1062 (C.D. Cal. 2012) (taking judicial notice of press releases). The Court takes judicial notice of Exhibits 4 and 27 because they are pages from the AcelRx and FDA Websites, which are publicly available and thus proper subjects for judicial notice. *See Calhoun v. Google LLC*, 526 F.Supp.3d 605, 617 (N.D. Cal. 2021) (taking judicial notice of websites). Finally, the Court takes judicial

notice of Exhibit 23 because it is an analyst report and is not disputed by Plaintiffs. *See 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) (taking judicial notice of analyst reports). 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).

Accordingly, Defendants' request for judicial notice (ECF No. 97) is GRANTED.

IV. DISCUSSION

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

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). TAC ¶¶ 192–200. 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: falsity

and scienter. *See* Mot. at 7–23.

i. Falsity

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.").

In the TAC, Plaintiffs point to three statements that they allege were false or misleading. *See* ECF No. 92 ("TAC App. 1"). These statements include: (1) Angotti's statement during a presentation at the March 20, 2019 Oppenheimer Health Care Conference that "You would simply remove the lock, tell the patient in the ER and post-op or the soldier [to] lift their head back, lift up their tongue, you inject it under and you're done. And it's basically as simple as that," *see id.* at 1; TAC ¶ 160; (2) the "Tongue and Done" tabletop display, *see* TAC App. 1 at 3; TAC ¶¶ 151, 162; and (3) the "Tongue and Done" banner advertisement, *see* TAC App. 1 at 4; TAC ¶¶ 151, 162. 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* TAC App. 1; TAC ¶¶ 161, 163. Plaintiffs also allege that Angotti's statement "undermined the REMS." *See* TAC App. 1 at 1; TAC ¶ 161. According to Plaintiffs, these statements created a misleading impression about the safe use of DSUVIA and subjected AcelRx to a foreseeable and increased risk of regulatory investigations or enforcement actions. *See* TAC App. 1; TAC ¶¶ 161, 163. The Court will address Statement 1 separately from Statements 2 and 3.

a. Statement 1: Angotti's Statement at the Oppenheimer Health Care Conference

Defendants argue that Angotti's statement must be considered in context, including his other statements in the same presentation and the target audience for the presentation. Mot. at 8–

9. Defendants argue that, when considered in context, no reasonable investor would understand Angotti's statement to purport to provide detailed instructions for DSUVIA's use. *Id.* Defendants also argue that information about DSUVIA's dosing, administration, and limitations of use were available in the slides accompanying Angotti's presentation and AcelRx's other public disclosures. *Id.* at 9. Plaintiffs argue that opening statements do not immunize subsequent misrepresentations. Opp. at 4. Plaintiffs further argue that Defendants' "truth on the market" defense should be rejected because investors should not be compelled to seek out external documents. *Id.* at 12–13. Finally, Plaintiffs argue that Defendants' arguments regarding what reasonable investors would know or do raise factual disputes that cannot be decided on a motion to dismiss. *Id.* at 15.[1]

The Court again determines that it is a close call whether Statement 1 is false or misleading. Defendants are correct that in determining falsity, the Court must look to the context of the total presentation. *See Huang v. Avalanche Biotechnologies, Inc.*, No. 15-CV-03185-JD, 2016 WL 6524401, at *4 (N.D. Cal. Nov. 3, 2016). To the extent that Plaintiffs argue that the Court should not consider prior opening statements in Angotti's presentation because opening statements do not immunize subsequent misrepresentations, Plaintiffs rely on inapposite case law. *See* Opp. at 4 (citing *In re Diamond Foods, Inc., Sec. Litig.*, No. C 11-05386 WHA, 2012 WL 6000923, at *5 (N.D. Cal. Nov. 30, 2012)). In *Diamond Foods*, the district court held that deliberately ambiguous statements made prior to the truth were actionable under § 10(b). *Diamond Foods*, 2012 WL 6000923, at *5. *Diamond Foods* does not, as Plaintiffs imply, support the argument that prior statements do not immunize a subsequent misrepresentation. Moreover, Plaintiffs' position is in tension with well-established law that false or misleading statements must be considered in light of all of the information available to the market, which includes contemporaneous qualifying or clarifying language. *See In re Convergent Techs. Sec. Litig.*, 948

[1] To the extent that the TAC alleged that Angotti's statement "undermined the REMS," Plaintiffs have abandoned this theory in their opposition. *See* Opp. at 12 ("The TAC does not allege misrepresentations about the REMS."). Even if the Court were to address this theory on its merits, the Court would again reject this theory because "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).

F.2d 507, 512 (9th Cir. 1991).

The context of Angotti's presentation undermines Plaintiffs' allegations of falsity, but the Court does not find that the context makes Plaintiffs' claims implausible. On a motion to dismiss, the Court must accept as true all well-pleaded factual allegations and construe them in the light most favorable to Plaintiffs. *Reese*, 643 F.3d at 690. Angotti made the allegedly false or misleading statement at an investor conference and clarified at the beginning of the same presentation that "[i]t's important if you take anything away from that, you take this away. Our interests and investments lie in acute pain, always in a medically supervised setting." ECF No. 96-9 ("Fernandes Decl. Ex. 8") at 2. He continued, "You will never find our products in a CVS, a Rite-Aid, a Walmart, or a Walgreens, but only in the institutions within which they are actually treating pain hands on." *Id.* Angotti made the allegedly false or misleading statement a few minutes later, when comparing DSUVIA to other forms of opioid administration. *See id.* at 6. However, neither the opening statement made at the beginning of the presentation nor Angotti's comparison of DSUVIA to other forms of opioid administration explicitly qualify or clarify his allegedly false or misleading statement, which omitted certain steps, dosage information, and limitations on use. *Cf. In re Intel Corp. Sec. Litig.*, No. 18-CV-00507-YGR, 2019 WL 1427660, at *10–11 (N.D. Cal. Mar. 29, 2019) (noting that contemporaneous qualify or clarifying language and information about the industry constituted context to evaluate an allegedly false or misleading statement). To the extent that Defendants suggest that reasonable investors would not expect or understand Angotti to provide complete information on DSUVIA, the Court agrees with Plaintiffs that this dispute turns on the construction of facts that is inappropriate in deciding a motion to dismiss. *See Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995) (noting that whether a public statement is misleading or whether adverse facts were adequately disclosed is a mixed question ordinarily decided by a trier of fact unless the adequacy of disclosure or materiality of the statement is so obvious that reasonable minds could not differ).

Finally, although Defendants do not label it as such, Defendants appear to raise a "truth on the market" defense by arguing that investors would not be misled because complete and accurate information about DSUVIA's administration, use, and limitations was available in AcelRx's

public disclosures and referenced in the slides for Angotti's presentation. *See* Mot. at 9. The "truth on the market" doctrine or corollary states that "[i]f the market has become aware of the allegedly concealed information, 'the facts allegedly omitted by the defendant would already be reflected in the stock's price' and the market 'will not be misled.'" *Provenz v. Miller,* 102 F.3d 1478, 1492 (9th Cir. 1996) (alteration in original) (quoting *Convergent Techs.*, 948 F.2d at 513). "[A] 'truth-on-the-market' defense is available in principle . . . but not at the pleading stage." *In re Thoratec Corp. Sec. Litig.*, No. C-04-03168 RMW, 2006 WL 1305226, at *4 (N.D. Cal. May 11, 2006) (quoting *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 734 (7th Cir.2004)). "[B]efore the 'truth-on-the-market' doctrine can be applied, the defendants must prove that the information that was withheld or misrepresented was transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations." *Provenz*, 102 F.3d at 1492–93 (internal quotation marks omitted) (quoting *Kaplan v. Rose*, 49 F.3d 1363, 1375 (9th Cir. 1994)). Although Defendants argue that information about DSUVIA's administration, use, and limitations were transmitted to the public with a sufficient degree of intensity and credibility, determining the truth of this assertion would require the Court to engage in an intensely fact-specific analysis that is inappropriate on a motion to dismiss. *See In re Amgen Inc. Sec. Litig.*, 544 F.Supp.2d 1009, 1025 (C.D. Cal. 2008).

b. Statement 2 and 3: The Tongue and Done Tabletop Display and Banner Advertisement

Defendants argue that Plaintiffs' theory of falsity with respect to the "foreseeable and increased risk" of regulatory investigation is based on hindsight and Defendants could not have known that the FDA would view the Tongue and Done slogan as failing to present a "fair" balance of DSUVIA's risks and benefits. Mot. at 10–11. Defendants also argue that these statements must also be considered in context. *Id.* at 11–12. Finally, Defendants argue that AcelRx cannot be liable for securities fraud because it disclosed the risk of an FDA warning letter. *Id.* at 13–14. Plaintiffs respond and clarify that their theory is that AcelRx concealed that it was improperly marketing DSUVIA and that they do not have to show that an adverse regulatory response was anticipated or imminent. Opp. at 11–12. Plaintiffs further argue that Defendants cannot escape

liability by disclosing a potential for FDA investigation because they were already misbranding the drug at the time of the warnings. Opp. at 14–15.

The Court finds that it is a close call whether Plaintiffs have adequately pled that Statements 2 and 3 were false or misleading. To argue that Plaintiffs' theory is based on hindsight, Defendants primarily rely on *Immanuel Lake v. Zogenix, Inc.*, No. 19-CV-01975-RS, 2020 WL 3820424 (N.D. Cal. Jan. 27, 2020). In *Lake*, the FDA found that the defendants' New Drug Application ("NDA") was deficient for failing to include certain toxicity studies. *See id.* at *2. The securities plaintiffs theorized that the defendants' failure to inform the market that the NDA did not include such toxicity studies in certain public statements constituted a material omission. *See id.* at *2, *8. Judge Seeborg rejected this theory of falsity because it relied on an unsupported and critical assumption that, based on the FDA's reaction to the NDA, the defendants knew that the failure to include the toxicity studies in the NDA made the application facially deficient and created an "exceedingly high risk" that the FDA would reject it. *See id.* at *8. This case is distinguishable from *Lake* because Plaintiffs have pled facts showing that information about DSUVIA's proper use, limitations, and administration were known at the time the statements were made. *See* TAC ¶¶ 40–64; *cf. Lake*, 2020 WL 3820424, at *9 (distinguishing *Lake* from cases in which "defendants . . . were already in possession of information that directly contradicted their public statements when made"). Thus, Plaintiffs' theory of falsity is not entirely unsupported—Plaintiffs have included additional factual allegations that, when construed in the light most favorable to Plaintiffs, may be adequate to plead that Statements 2 and 3 were false when made.

The contexts of Statements 2 and 3 do not change this outcome. Although the Tongue and Done slogan was presented on a tablecloth and website banner advertisement, the Court cannot infer that no reasonable investor would rely on these statements. *Contra* Mtn. at 12. To do so would be contrary to the standard on motion to dismiss, which requires the Court to draw all reasonable inferences in favor of Plaintiffs, and to case law, which suggests that investors may consider public documents, such as drug advertisements targeted at medical professionals, in making investment decisions. *See, e.g., In re LifeLock, Inc. Sec. Litig.*, 690 F. App'x 947, 954

(9th Cir. 2017) (contrasting web advertisements with no potential to influence investors with "detailed drug advertisements in sophisticated medical journals," which may influence investors); *Basic Inc. v. Levinson*, 485 U.S. 224, 247 n.24 (1988) ("[M]arket professionals generally consider most publicly announced material statements about companies, thereby affecting stock market prices."). Defendants note that the tablecloth and banner advertisement refer the viewer to information about DSUVIA's safety and dosing information, *see* TAC ¶ 151, and Defendants disclosed that there was a risk of a regulatory warning letter if AcelRx failed to comply with applicable regulations, *see* ECF No. 96-12. The Court recognizes that these facts weaken Plaintiff's allegations. *See Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *10 (N.D. Cal. Sept. 27, 2012). However, the Court again declines to find that Plaintiff has failed to plead sufficient facts to show that Statements 2 and 3 were false or misleading on this basis at the motion to dismiss stage. *See* ECF No. 90 at 9; *Thoratec Corp. Sec. Litig.*, 2006 WL 1305226.

* * *

Because the Court finds it a close call whether Plaintiffs have adequately pled falsity the Court will turn to whether Plaintiffs have alleged scienter.

ii. 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. at 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) (alteration in original) (quoting *In re Read-Rite*, 335 F.3d 843, 847 (9th Cir. 2003)). "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).

Plaintiffs' scienter allegations are primarily based on statements from 12 former employees ("FEs")[2] of AcelRx. Defendants argue that most of the FEs are not credible and should be disregarded and that even if credible, the FEs do not adequately support allegations of scienter. Mot. at 16–21. "To rely on statements of [an FE] to plead scienter, the allegations 'must pass two hurdles': (1) the sources 'must be described with sufficient particularity to establish their reliability and personal knowledge'; and (2) the reported statements 'must themselves be indicative of scienter.'" *Sakkal v. Anaplan Inc.*, 557 F.Supp.3d 988, 998–99 (N.D. Cal. 2021) (quoting *Zucco Partners*, 552 F.3d at 995).

a. Whether the FE Allegations Are Credible

Defendants argue that the Court should disregard statements by FEs 1, 2, 3, 5, 6, 8, 9, 10, and 12 because they are not alleged to have had any contact with either Angotti or Palmer. Mot. at 16. Defendants also argue that the court should disregard FEs 2, 3, 5, 6, 8, 10, 11, and 12 because they held non-marketing and non-regulatory roles and thus were not able to opine about the materials that used the Tongue and Done slogan. *Id.* at 16–17. Plaintiffs respond that FE5 is alleged to have had direct contact with Angotti and Palmer and that allegations of direct contact are not required for the Court to consider FE statements. Opp. at 17–18. Plaintiffs also argue that they have adequately alleged the title, supervisor, and work performed by each FE and how the FE's statement relates to fraud. *See id.* at 17.

The Court finds that Plaintiffs have provided an adequate basis for determining that the FEs have personal knowledge of the events about which they report. The Ninth Circuit has held that the first prong of the two-part test for confidential witnesses "analyzes whether a complaint has provided sufficient detail about a confidential witness' position within the defendant company to provide a basis for attributing the facts reported by that witness to the witness' personal knowledge." *Zucco Partners*, 552 F.3d at 995. The Ninth Circuit does not require that every

[2] The Court will use the phrase FEs because the parties use it in their briefing. However, the Court observes that the applicable law for FEs is the same as that for confidential witnesses.

confidential witness must have had direct contact with the Defendants. Instead, all that is required is sufficient detail to establish that a witness has personal knowledge about the facts that they reported. *See Washtenaw Cnty. Emps. Ret. Sys. v. Celera Corp.*, No. 5:10-CV-02604 EJD, 2012 WL 3835078, at *3 (N.D. Cal. Sept. 4, 2012) ("The Plaintiffs' failure to recruit a confidential witness with personal knowledge of the Defendants' mental state does not mean the allegations must be disregarded altogether. The court considers them only for what they say about the company's operations at the relevant times."). Thus, direct contact might be required if a witness reports facts that would require direct contact to establish personal knowledge. However, FEs 1, 2, 3, 5, 6, 8, 9, 10, and 12 have not reported any facts that require direct contact. In fact, each of these FEs has reported facts about which the FE has personal knowledge based on the FE's former role at AcelRx and the work performed. *See, e.g.*, TAC at ¶¶ 72–81 (FE1, a former contract marketing manger, reporting on the process for marketing DSUVIA); TAC ¶¶ 102–09 (FE5, a former account manager, reporting on the formulation and use of Tongue and Done); TAC ¶¶ 125–33 (FE10, a former hospital account manager, reporting on Angotti's decisions regarding the marketing scope of DSUVIA based on FE10's close work with AcelRx senior executives regarding marketing development). For similar reasons, the fact that FEs 2, 3, 5, 6, 8, 10, 11, and 12 held non-marketing and non-regulatory roles does not require the Court to disregard their reports. These FEs report facts based in their personal knowledge, which the Court can determine from Plaintiffs' allegations regarding the position of each FE and the work that the FE performed. Finally, the Court observes that Defendants' challenges to the FEs' lack of direct contact and lack of marketing or regulatory roles are best considered when determining the adequacy of the FE reports as indicative of scienter. *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1063 (9th Cir. 2014) (crediting statements that lacked foundation and critical information regarding the context and content of reports relevant to the misstatements but finding that the allegations did not establish scienter); *Anaplan Inc.*, 557 F.Supp.3d at 999 (noting that "none of the CWs had any significant contact with [the defendants]" but crediting the limited factual allegations and finding that they were insufficient to establish scienter).

b. Whether the FE Allegations Are Indicative of Scienter

Defendants argue that Plaintiffs' additional FE allegations, including new allegations from FEs 4, 5 and 7 and the addition of FEs 8 through 12, do not adequately support an inference of scienter. Mot. at 17–21. Defendants correctly note that the allegations pertaining to FEs 1, 2, 3, and 6 remain substantively unchanged. *See id.* at 17; ECF No. 93 ("TAC App. 2") (a redline identifying changes between the SAC and TAC). Defendants also argue that AcelRx's interactions with the FDA regarding the REMS, Angotti's motives, the core operations theory, warning letters to other companies, Angotti's attendance at conferences where the Tongue and Done slogan was used, and Angotti's experience and background are individually and holistically inadequate to support a theory of scienter. *See* Mot. at 21–23. Plaintiffs respond that Defendants had multiple interactions with the FDA regarding DSUVIA generally, DSUVIA's REMS, and the multiple amendments to DSUVIA's REMS and that this information put Defendants on notice that AcelRx would be subject to FDA scrutiny if it failed to adhere to the REMS and compliance was its responsibility. Opp. at 18.

The Court will first summarize the accounts of FEs 8–12, who were added for the first time in the TAC, and it will then summarize the accounts of FEs 1–7.

FE8 was a hospital account director from September 2019 to March 2020 and was based in Milwaukee, Wisconsin. TAC ¶ 119. FE8 noted that the Tongue and Done slogan was featured prominently in sales training for hospital account managers and could not "recall any internal controls or processes set up by AcelRx to reduce the risk of negative consequences for the improper marketing of DSUVIA." *Id.* ¶¶ 120–21. FE8 stated that AcelRx viewed FDA warning letters as "an acceptable risk" and "a cost of doing business." *Id.* ¶ 122.

FE9 was a regional director for scientific affairs from June 2019 to February 2020 and was based in Pasadena, California. TAC ¶ 123. FE9 noted "widespread awareness of the possibility of receiving FDA warning letters at AcelRx, which was matched by a reckless lack of concern about the fallout from such letters." *Id.* ¶ 124.

FE10 was a hospital account manager from March 2019 to September 2019 and was based in Phoenix, Arizona. TAC ¶ 125. FE10 was responsible for commercially launching DSUVIA

and stated that it was difficult to "get buy-in" from medical users regarding DSUVIA because of the REMS. *Id.* ¶¶ 126, 129. FE10 alleged that Angotti sought to expand DSUVIA's target market from hospitals and the battlefield to ambulatory service centers. *Id.* ¶ 130. FE10 also alleged that Angotti was motivated to oversimply DSUVIA's application to facilitate the expansion into ambulatory surgical centers and demonstrate success to AcelRx's investors. *Id.* ¶ 132. FE10 believed that DSUVIA was not appropriate for ambulatory surgical centers. *Id.* ¶ 133.

FE11 was a hospital account manager from May 2019 to March 2020 and was based in Columbus, Ohio. TAC ¶ 134. FE11 represented AcelRx at the 2019 ASA national meeting, where the Tongue and Done slogan was used. *Id.* ¶ 136. FE11 reported that the Tongue and Done slogan was featured prominently in AcelRx's curriculum for hospital account managers and in marketing to physicians. *Id.* ¶ 138. FE11 believed that Tongue and Done was already approved by the FDA and that such slogans were generally subject to FDA approval prior to use. *Id.* ¶ 139.

FE12 was a hospital account manager from May 2019 to March 2020 and was based in the northeast. TAC ¶ 140. FE12 reported that the Tongue and Done slogan "was unusual to the point of being inappropriate, and most of the sales force was uncomfortable with it." *Id.* ¶ 142. FE12's sales team would flip the tabletop display over at events such that it would not be seen. *Id.* ¶ 144. FE12 voiced grievances to Regional Business Director Albert Socha, who raised them to a DSUVIA product manager, who would then decide whether to raise the grievances with Angotti or other C-suite leaders. *Id.* ¶ 145. FE12 also confirmed that Tongue and Done and other materials were required to go through an internal compliance review before being approved for use. *Id.* ¶ 146.

FE1 worked as a contract marketing manager from June 2017 through March 2020 and as a marketing specialist from January 2016 through June 2017, and FE1 reported to the senior director of marketing. TAC ¶¶ 72–73. FE1 stated that DSUVIA's brand identity required regular sign-off from AcelRx's regulatory and compliance staff, and FE1 confirmed FE6's account that the Company's promotional review committee ("PRC") approved marketing messages to ensure that content was FDA-compliant and that the PRC was in direct communication with the FDA. *Id.* ¶¶ 77–79.

FE2 was a contract HR Consultant from June 2019 through August 2021. TAC ¶ 82. FE2 stated that Angotti provided final approval and would have reviewed and signed off on marketing materials. *Id.* ¶ 86.

FE3 was a medical editor for Publicis Groupe ("Publicis") from March 2018 to September 2018. TAC ¶ 87. Publicis' Health division worked with AcelRx on the marketing materials for DSUVIA, with the Senior Director of Marketing (FE4) as the primary contact. *Id.* ¶¶ 87–88. FE3 confirmed that DSUVIA was marketed to health care professionals in ambulatory surgical centers and hospitals. *Id.* ¶ 89.

FE4 was the Senior Director of Marketing from May 2017 to June 2022, reported directly to Angotti, and personally created the Tongue and Done campaign. TAC ¶¶ 91–93. FE4 said Angotti was aware of the Tongue and Done slogan and explicitly supported the slogan's approval. *Id.* ¶ 93. FE4 also reported that Palmer and other senior officers participated in PRC meetings where the Tongue and Done slogan was considered an approved. *Id.* ¶ 95. FE4 explained that AcelRx used the Tongue and Done slogan at certain identified medical conferences. *Id.* ¶¶ 96–101.

FE5 was an account manager from September 2018 to March 2020, and was the first sales representative AcelRx hired to promote DSUVIA. TAC ¶ 102. FE5 confirmed that FE4 developed the Tongue and Done campaign and that Palmer and Angotti weighed in on marketing materials. *Id.* ¶¶ 104–05. FE5 stated that Angotti attended conferences in which AcelRx touted the Tongue and Done campaign to medical professionals. *Id.* ¶ 106. FE5 also stated that, based on FE5's 30 years of experience in the pharmaceutical sector, the FDA's reaction to Tongue and Done was predictable because the industry is tightly regulated and brief taglines carry an inherent risk of omitting required information. *Id.* ¶ 108. FE5 also reported that numerous colleagues found the Tongue and Done slogan to be inappropriate. *Id.* ¶ 109.

FE6 was a federal account director from July 2019 to November 2021. TAC ¶ 110. He stated that the PRC approved marketing messages. *Id.* ¶ 111. As the TAC alleges, the medical department, run by Palmer, served on this committee. *Id.* ¶¶ 34, 78, 111. FE6 had to inform healthcare professionals that due to the Warning Letter, the Company would no longer be using

the Tongue and Done slogan. *Id.* ¶ 112. FE6 said the Warning Letter harmed the Company's reputation. *Id.*

FE7 was a regional medical director from September 2018 to March 2019. TAC ¶ 113. FE7 expressed concerns regarding the Tongue and Done slogan to Angotti, Palmer, and FE7's supervisor, Gail Spahn. *Id.* ¶ 114. Specifically, FE7 raised concerns that the Tongue and Done campaign oversimplified the use of a powerful opioid, contained sexual overtones that could be misinterpreted, and that the slogan put the company at risk of an FDA warning letter. *Id.* FE7 raised these concerns at a meeting with senior management, including Angotti and Palmer, but Palmer told FE7 that Tongue and Done was a marketing decision and thus the medical affairs team should not get involved. *Id.* ¶ 115. 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 FE7 was not supporting leadership's decisions and she did not feel confident in him supporting an opioid product. *Id.* ¶¶ 116–17. FE7 said that the Tongue and Done materials were used at meetings, national sales meetings, medical affairs meetings, and strategic development meetings. *Id.* ¶ 118. 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.*

The Court again finds that these allegations are insufficient. For the most part, the FEs demonstrate that Angotti and Palmer were aware of the Tongue and Done slogan in promotional materials and their use at conferences. *See, e.g.*, TAC ¶ 86 (FE2); *id.* ¶ 89 (FE3); *id.* ¶¶ 93, 95 (FE4); *id.* ¶¶ 104–05 (FE5); *id.* ¶ 111 (FE6); *id.* ¶¶ 114–16 (FE7). FEs 8–12 confirm that the Tongue and Done slogan was used and displayed prominently while marketing DSUVIA and training sales personnel. *See, e.g., id.* ¶¶ 120–21 (FE8); *id.* ¶¶ 136, 138 (FE11); *see also id.* ¶ 146 (FE12 confirming that the Tongue and Done slogan went through internal compliance review before deployment). But the fact that Angotti and Palmer were aware of or even signed off on the use of the Tongue and Done slogan in marketing DSUVIA is not enough to raise a strong inference that either Defendant intended to deceive investors or to engage in Misbranding Violations through the use of those materials. Similarly, the FEs and Plaintiffs' allegations more

broadly show that Defendants were aware of FDA regulations and worked with the FDA in developing the REMS. *See, e.g.*, *id.* ¶¶ 45–64 (summarizing AcelRx's communications with the FDA leading to the approval of DSUVIA with a REMS); *id.* ¶¶ 77–79 (FE1 noting that the PRC ensured marketing messages were FDA-compliant and was in direct communication with the FDA); *id.* ¶ 95 (FE4 noting that Palmer and other AcelRx executives were charged with ensuring regulatory compliance and/or interacting with the FDA). 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 do not allege that Defendants failed to comply with the REMS. *See* TAC. In addition, 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.

Although FE7 expressed concern to Angotti and Palmer that the Tongue and Done slogan put AcelRx at risk of an FDA warning letter, this fact is not sufficient to raise an inference that Angotti and Palmer intended to deceive investors. *See 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). Indeed, the mere fact that an employee raised concerns absent facts that Defendants ever accepted the views on which those concerns were based is not sufficient to show that Defendants knew their statements were false. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1194 (9th Cir. 2021) (finding that the plaintiffs failed to plead that the defendants had knowledge that statements were false based on allegations that two employees raised concerns because there were no facts indicating that Defendants adopted or agreed with the concerns); *see also In re Pivotal Sec. Litig.*, No. 3:19-CV-03589-CRB, 2020 WL 4193384, at *17 (N.D. Cal. July 21, 2020) (finding confidential witness allegations were not indicative of scienter because disagreements within the company over its approach to selling a product did not support allegations of deliberate recklessness).

Nor do Plaintiffs' additional FE allegations change this outcome. First, FE5 alleges that

based on FE5's experience, the FDA's reaction to the Tongue and Done slogan was predictable. TAC ¶ 108. FE5 and FE12 reported that employees found the Tongue and Done slogan inappropriate. *Id.* ¶¶ 109, 142. However, these facts say nothing about Angotti's or Palmer's opinions or even that Angotti and Palmer were apprised of the employees' opinions. *See Yellen v. Hak*e, 437 F.Supp.2d 941, 957 (S.D. Iowa 2006) (finding allegations of an employee's opinion inadequate to establish scienter because it did not show whether the defendants shared the view). Second, FE8 and FE9 report that AcelRx considered warning letters an acceptable risk and that AcelRx was not concerned about the fallout from warning letters. *See* TAC ¶¶ 109, 122, 124. However, these allegations of general corporate awareness are inadequate because they fail to state with particularity the facts on which this belief is formed, and they do not establish facts relevant to Defendants' mental state. *See Zucco Partners*, 552 F.3d at 998 (finding "generalized claims about corporate knowledge . . . not sufficient to create a strong inference of scienter" because reporting witnesses did not have "reliable personal knowledge of the defendants' mental state"); *Veal*, 423 F.Supp.3d at 814 (finding that "scienter cannot be established based on 'general awareness' and 'hand-on management style' or by lumping 'management' and 'executives' together"). Put differently, general awareness of the risk of regulatory activity is omnipresent in heavily regulated activities, and such allegations do not give rise to a strong inference of scienter, especially where Plaintiffs have alleged no facts that would support an inference that Defendants knew that the Tongue and Done slogan would produce an FDA warning letter. Third, FE10 discussed how Angotti was motivated to demonstrate DSUVIA's success to investors. TAC ¶ 132. However, it is well established that "allegations of routine corporate objectives such as the desire to obtain good financing and expand 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." *Rigel Pharms.*, 697 F.3d at 884; *see also Webb v. Solarcity Corp.*, 884 F.3d 844, 856 (9th Cir. 2018) (same); *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002) (same). To the extent that FE10 criticized Angotti's decision to market to ambulatory surgical centers as inappropriate, this criticism does not show that Angotti knew or recklessly disregarded that the Tongue and Done slogan was false or that it would trigger an FDA warning

letter. In fact, FE10's criticism appears misplaced—the FDA-approved DSUVIA label expressly includes use in surgical centers. *See* ECF No. 96-4 ("Fernandes Decl. Ex. 3") at 1. Fourth, FE11's allegations merely confirm that the Tongue and Done slogan was used, and thus do not raise a strong inference of scienter. *See* TAC ¶¶ 134–39. Finally, for similar reasons as FE7, the fact that FE12 raised grievances does not support a strong inference of scienter, especially where there are no allegations that FE12's grievances ever reached Angotti or Palmer. *See Pivotal*, 2020 WL 4193384, at *17.

Thus, the Court again finds that 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.

c. Non-FE Allegations

The Court briefly addresses Plaintiffs' theories that are not directly addressed in the Court's discussion of the FE allegations above. For example, Plaintiffs again appear to invoke the core operations theory, arguing that based on the regulatory obligations surrounding DSUVIA and Defendants' participation in the marketing of the product, Defendants were aware of or recklessly disregarded the danger of misleading marketing. *See* Opp. at 18–19 (quoting cases discussing the core operations theory); TAC ¶¶ 84, 107, and 111 (alleging that DSUVIA is a small company). 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*, 552 F.3d at 1000 (quoting *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 786 (9th Cir. 2008)). However, as the Court concluded previously, Plaintiffs' allegations that AcelRx was a small company and that it only had 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"). Nor is this case one of the "rare circumstances" when scienter is

adequately alleged through the core operations theory. *See Mulligan v. Impax Lab'ys, Inc.*, 36 F.Supp.3d 942, 969 (N.D. Cal. 2014).

In addition, although Plaintiffs do not raise this argument in their opposition brief, the TAC again raises allegations about two other FDA warning letters, sent in 2008 and 2009, over drugs that were also subject to a REMS. *See* TAC ¶ 44. The Court again concludes that the fact that the FDA sent warning letters to other companies adds nothing to the scienter analysis.

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. 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.

* * *

Thus, the Court GRANTS the motion to dismiss the § 10(b) and Rule 10b-5(b) claim against all Defendants.

B. Claim 2: Section 20(a)

Plaintiffs bring a claim against Defendants Angotti and Palmer for violation of Section 20(a) of the Exchange Act. TAC ¶¶ 201–07. Defendants move to dismiss this claim. *See* Mot. at 24.

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.

Thus, the Court GRANTS the motion to dismiss the § 20(a) claim against Defendants Angotti and Palmer.

C. Leave to Amend

Defendants argue that leave to amend should be denied because Plaintiffs have repeatedly

failed to cure deficiencies. *See* Mot. at 24. Plaintiffs do not request further leave to amend. *See* Opp.; ECF No. 106 (transcript of proceedings).

District courts have discretion to deny leave to amend. In doing so, the Court must consider the factors set forth by the Supreme Court in *Foman v. Davis*, 371 U.S. 178 (1962), and discussed at length by the Ninth Circuit in *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048 (9th Cir. 2003). A district court ordinarily must grant leave to amend unless one or more of the *Foman* factors is present: (1) undue delay, (2) bad faith or dilatory motive, (3) repeated failure to cure deficiencies by amendment, (4) undue prejudice to the opposing party, or (5) futility of amendment. *Eminence Capital*, 316 F.3d at 1052. "[W]here the plaintiff has previously been granted leave to amend and has subsequently failed to add the requisite particularity to its claims, '[t]he district court's discretion to deny leave to amend is particularly broad.'" *Zucco Partners*, 552 F.3d at 1009 (quoting *In re Read-Rite*, 335 F.3d at 845).

In this case, the Court finds that Plaintiffs have repeatedly failed to cure the deficiencies identified by the Court and that further opportunities to amend would be futile. It is clear upon the Court's review of the TAC that Plaintiffs have made their best case, and it has been found wanting. *See Zucco Partners*, 552 F.3d at 1009 (affirming a district court's dismissal of a second amended complaint without leave to amend where a district court found that the plaintiffs' repeated failure to cure deficiencies indicated that the plaintiffs had no additional facts to plead). Accordingly, the Court will dismiss Plaintiffs' claims WITHOUT LEAVE TO AMEND.

V. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that Defendants AcelRx Pharmaceuticals, Inc. (n.k.a. Talphera, Inc.), Vincent J. Angotti, and Pamela Palmer's Motion to Dismiss is GRANTED WITHOUT LEAVE TO AMEND.

Dated: May 7, 2024

BETH LABSON FREEMAN
United States District Judge