UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MYO THANT, et al.,

Plaintiffs,

v.

RAIN ONCOLOGY INC., et al.,

Defendants.

Case No. 5:23-cv-03518-EJD

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: ECF No. 53

When biopharmaceutical company Rain Oncology, Inc. announced negative clinical trial results for its lead drug candidate, milademetan, its stock price sank. In response, investors sued Rain and several of its officers and directors, alleging violations of federal securities law. Rain and its fellow Defendants now move to dismiss for failure to state a claim. Because Plaintiffs have sufficiently pled some, but not all, of their securities claims, the Court **GRANTS IN PART** and **DENIES IN PART** the motion to dismiss.

I. BACKGROUND[1]

Defendant Rain Oncology, Inc. is a "precision oncology company" founded in 2017. Valenzuela Decl., Ex. 1 at 11, ECF No. 53-1.[2] According to Rain, its business is to "develop[] and commercialize[] small molecule therapeutics through leveraging both an acquisition-based business model and internal research efforts." *Id.* Specifically, after another pharmaceutical company, Daiichi Sankyo Co., conducted promising Phase 1 clinical trials of a drug candidate called milademetan, Rain licensed that candidate from Daiichi with plans to conduct its own later-

[1] For purposes of this motion to dismiss, the Court accepts as true the allegations of the Amended Complaint. *Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 690 (9th Cir. 2011).

[2] Record citations are made to the ECF pagination unless otherwise indicated.

stage clinical trials. *Id.* at 9; Am. Compl. ¶ 7, ECF No. 39. Rain did so in the hopes that those planned later-stage trials would be successful and that it would eventually earn approval to market and sell milademetan. Unfortunately for Rain, events did not play out as it had hoped.

In Plaintiffs' telling, part of the reason for milademetan's eventual failure was Rain's decision not to follow the usual course for clinical trials. Typically, researchers test a drug candidate by going through three phases of clinical trials. Am. Compl. ¶ 30. At Phase 1, researchers investigate a drug candidate's safety and dose tolerance. If the Phase 1 results are favorable, researchers advance to Phase 2, where they expand the trial's patient population. This allows them to further evaluate dosage and safety, and it also allows them to begin preliminarily investigating the drug candidate's efficacy. If the Phase 2 results justify moving forward to Phase 3, researchers enroll an even larger patient population and conduct final safety and efficacy tests. In this last phase, researchers compare the drug candidate to placebos and work to determine the candidate's overall risk-benefit profile. *Id.*

Rain departed from the normal three-phase progression with milademetan. When Rain licensed milademetan in September 2020, Daiichi was just wrapping up its Phase 1 trial, the first study to test how humans responded to milademetan. *Id.* ¶¶ 7, 36. At the conclusion of that trial, Daiichi identified a potential dosing schedule that was intended to be tested further in Phase 2 trials. *Id.* ¶¶ 38, 41. Instead of conducting a Phase 2 trial, though, Rain proceeded to Phase 3 directly. *Id.* ¶¶ 7–8. Unfortunately for Rain and its investors, the Phase 3 trial did not succeed. *Id.* ¶ 47. This proved devastating for Rain's business, leading Rain's stock price to drop from $9.93 per share to $1.22 per share. *Id.* ¶ 49. The poor Phase 3 results also led Rain to suspend all further clinical development of milademeten and to implement wide-ranging layoffs in an effort to cut costs. *Id.* ¶¶ 50–52. Ultimately, Rain agreed to an acquisition by PathosAI, Inc. *Id.* ¶¶ 53–55.

According to Plaintiffs, Rain greatly increased the risk of milademetan's Phase 3 trial failing by choosing to bypass Phase 2. While such a maneuver is is not unheard of, it is rarely done for several reasons. For example, Phase 2 can reveal safety concerns that Phase 1 was unable to identify, so skipping over Phase 2 can result in Phase 3 trial participants receiving unduly dangerous therapies. Likewise, Phase 2 is a further opportunity to refine dosing schedules

identified in Phase 1, so researchers may not be able to identify the optimal dose if they advance directly from Phase 1 to Phase 3. *Id.* ¶ 32. Due to these risks, the accepted practice is for researchers to conduct Phase 2 trials unless two criteria are met: First, the drug candidate's mechanism of action (the biochemical interactions through which it works) must be well understood. Second, the drug candidate's safety profile (frequency and likelihood of adverse side effects) must also be well characterized. *Id.* ¶¶ 31, 33.

Purportedly, milademetan met neither of these criteria. Yet Rain touted its plans to bypass Phase 2 in a positive light, which Plaintiffs suggest created the misleading impression that milademetan did satisfy the criteria for skipping Phase 2. This, in turn, allegedly concealed that milademetan's Phase 3 trial faced abnormally high levels of risk and instead implied to Rain's investors that only the ordinary risks inherent in any Phase 3 trial were present. For this reason, Plaintiffs filed suit against Rain, two of its officers (the Officer Defendants),[3] and six of its directors (the Director Defendants).[4] Plaintiffs bring claims against Rain and the Director Defendants under Sections 11 and 15 of the Securities Act of 1933 for statements made in connection with Rain's initial public offering. They bring claims against Rain and the Officer Defendants under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (Exchange Act) for statements made after Rain went public. Across these claims, Plaintiffs challenge essentially six statements that Defendants repeated over the relevant time period:

1. **Validation Statements**—statements that Daiichi's Phase 1 trial "validated a rationally-designed dosing schedule" (Am. Compl. ¶¶ 66, 92, 135);
2. **Commencement Statements**—statements that Rain "anticipates commencing" or "commenced a pivotal Phase 3 trial" of milademetan "based on" the Phase 1 data (Am. Compl. ¶¶ 66, 69, 76, 83, 90, 101, 110, 119, 133, 144);

[3] The two officers are Avanish Vellanki (Chairman and CEO) and Richard Bryce (Executive VP and Chief Medical Officer).

[4] The directors are Franklin Berger, Aaron Davis, Gorjan Hrustanovic, Tran Nguyen, Peter Radovich, and Stefani A. Wolff.

3. **Optimistic Statements**—statements Rain was "proud to have been able to dose the first patient in a pivotal Phase 3 trial" and "achieved a number of important clinical milestones for milademetan" (Am. Compl. ¶¶ 71, 78, 96);
4. **Late-Stage Statements**—statements that Rain was a "late-stage" oncology company (Am. Compl. ¶¶ 74, 78, 81, 85, 88, 96, 99, 105, 108, 114, 117, 123, 131, 139, 142, 148);
5. **Best-in-Class Statements**—statements that milademetan had the "potential" to become a "best-in-class" drug (Am. Compl. ¶¶ 71, 128); and
6. **Development Pipeline Diagrams**—diagrams that allegedly implied Rain had conducted both Phase 1 and Phase 2 trials for milademetan (Am. Compl. ¶¶ 94, 103, 112, 121, 126, 137, 146; *see also* representative example below, with relevant portion marked in red).

Plaintiffs challenge only the validation commencement statements under Sections 11 and 15, but they challenge all six categories of statements under Sections 10(b) and 20(a).

II. LEGAL STANDARD

Generally, the Federal Rules of Civil Procedure require plaintiffs to plead "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To satisfy this requirement, a plaintiff must plead sufficient factual matter to support a reasonable inference that the defendant is liable. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In assessing whether a plaintiff has met this standard, courts assume all factual allegations are true and construe the complaint in the light most favorable to the plaintiff. *Reese*, 643 F.3d at 690. However, courts

do not accept conclusory allegations or make unwarranted or unreasonable inferences.[5] *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (citation omitted).

When plaintiffs raise securities fraud claims under Sections 10(b) and 20(a) of the Exchange Act, they must also satisfy the heightened pleading requirements of Rule 9(b) and the Private Securities Litigation Reform Act (PSLRA). *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 604 (9th Cir. 2014). Rule 9(b) applies whenever a plaintiff alleges fraud and requires plaintiffs to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This means plaintiffs must plead the "who, what, when, where, and how" of the alleged fraud. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citation omitted). Under Rule 9(b) though, any required state of mind "may be alleged generally." Fed. R. Civ. P. 9(b). The PSLRA applies specifically to *securities* fraud, and it requires even more than Rule 9(b). Under the PSLRA, not only do plaintiffs need "to state with particularity [] the facts constituting the alleged violation," but they must also "state with particularity . . . the facts evidencing scienter." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). The particularity requirement for scienter is especially strict because it requires plaintiffs to "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *Glazer Cap. Mgmt., L.P. v. Forescout Techs., Inc.*, 63 F.4th 747, 766 (9th Cir. 2023) (quoting 15 U.S.C. § 78u-4(b)(2)(A)) (emphasis in original). This sets scienter apart from all other elements of securities fraud, for which plaintiffs need plead only a *reasonable inference*. *Id.* To meet this higher pleading standard for scienter, plaintiffs must show that the "inference of

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[5] On a motion to dismiss, courts cannot consider material outside the pleadings unless such material is judicially noticeable or incorporated by reference. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). Defendants ask the Court to consider various SEC filings and other public documents under these exceptions. Requests for Judicial Notice, ECF Nos. 54, 58. Plaintiffs largely do not object, and the Court finds those materials suitable for consideration under one or both of those exceptions. Therefore, the Court **GRANTS** judicial notice.

However, Plaintiffs take issue with how Defendants use one document—a summary of the Phase 1 clinical trial at issue in this case—because Defendants purportedly use that document to establish the truth of its contents. Objection, ECF No. 60. Courts may not use judicially noticed or incorporated documents to resolve factual disputes at the pleading stage. *Khoja*, 899 F.3d at 1003; *Lee v. City of L.A.*, 250 F.3d 668, 690 (9th Cir. 2001). As such, the Court takes notice of the Phase 1 summary to determine the information available to the public but not for the truth of the information it contains.

scienter . . . must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007).

Claims raised under Sections 11 and 15 of the Securities Act are treated differently. Unlike Exchange Act claims, these Securities Act claims are not subject to the PSLRA's heightened pleading standard. *Compare* 15 U.S.C. § 77z-1 (private litigation provision for the Securities Act), *with* 15 U.S.C. § 78u-4 (private litigation provisions for the Exchange Act); *see also Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009). And because Sections 11 and 15 do not require plaintiffs to prove any kind of fraud element, Rule 9(b) does not necessarily apply. *Hildes v. Arthur Andersen LLP*, 734 F.3d 854, 863 (9th Cir. 2013). That said, Rule 9(b) *may* apply to Sections 11 and 15; this occurs if such claims "sound[] in fraud." *Rubke*, 551 F.3d at 1161 (citation omitted). Claims sound in fraud when the complaint "alleges a unified course of fraudulent conduct and relies entirely on that course of conduct as the basis of a claim." *Id.* (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103–04 (9th Cir. 2003)) (cleaned up). Such is the case where "a complaint employs the exact same factual allegations to allege violations of section 11 as it uses to allege fraudulent conduct under section 10(b) of the Exchange Act," *id.*, or where the complaint "relies on the same alleged misrepresentations" for both its Section 11 and Section 10(b) claims. *In re Rigel*, 697 F.3d at 886.

In this instance, the Court concludes that all of Plaintiffs' claims sound in fraud. Plaintiffs rely on a uniform course of conduct—misrepresentations related to Rain's decision to bypass Phase 2 trials—to plead both their Section 10(b) and Section 11 claims. And although the statements being challenged under Section 10(b) and Section 11 technically appear in different documents, the statements that Plaintiffs challenged under Section 11 do not vary in substance from statements challenged under Section 10(b). *Compare* Am. Compl. ¶ 66 (Section 11), *with id.* ¶¶ 69, 92 (Section 10(b)). There is no disentangling the conduct giving rise to Plaintiffs' Section 10(b) claims from the conduct giving rise to Plaintiffs' Section 11 claims, so Rule 9(b) applies.

Plaintiffs' arguments to the contrary are unpersuasive. To begin, they attempt to disclaim any allegations of fraud for their Securities Act claims. *Id.* ¶¶ 207, 221. But "nominal efforts to disclaim allegations of fraud . . . are unconvincing where," as here, "the gravamen of the

complaint is fraud and no effort is made to show any other basis for the claims." *In re Rigel*, 697 F.3d at 885. Next, Plaintiffs point to the fact that they alleged their Section 10(b) and Section 11 claims against different sets of individual defendants: the Officer Defendants and Director Defendants. However, the complaint does not draw any material distinctions between the two sets of defendants. The same facts used to establish that the Officer Defendants made false statements are also used to establish that the Director Defendants made false statements. Finally, drawing again on the difference between defendants, Plaintiffs argue that they only try to plead scienter for the Officer Defendants (Section 10(b)) but not for the Director Defendants (Section 11). This is no barrier to applying Rule 9(b) either. Rule 9(b) does not impose a heightened pleading standard for state of mind and in fact expressly permits state of mind to be pled generally. Fed. R. Civ. P. 9(b). Thus, there is no tension in applying Rule 9(b) to a Section 11 claim that does not include a scienter element, and applying Rule 9(b) does not somehow require Plaintiffs to plead that the Director Defendants acted with any particular state of mind. Accordingly, Plaintiffs' Securities Act claims are subject to Rule 9(b).

III. DISCUSSION

Section 10(b) creates a cause of action for fraud in connection with the purchase or sale of any security. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 382 (1983). To plead a claim under Section 10(b) and its implementing regulation, plaintiffs must allege "(1) a material misrepresentation or omission [*i.e.*, falsity]; (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." *Or. Pub. Emps.*, 774 F.3d at 603. Section 11 applies to a narrower range of conduct but, in exchange, imposes a lower burden on plaintiffs. Specifically, plaintiffs may raise Section 11 claims only when they purchase registered securities in registered offerings. *Herman & MacLean*, 459 U.S. at 381–82. When Section 11 applies, a plaintiff need only show that the registration statement (1) contained an omission or misrepresentation (falsity), and (2) that the omission or misrepresentation was material. *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1403 (9th Cir. 1996) (citation omitted). Once the plaintiff does so, "[l]iability against the issuer of a security is virtually absolute, even for innocent misstatements." *Herman & MacLean*, 459 U.S. at

382 (footnote omitted).

Defendants move to dismiss on the grounds that Plaintiffs have failed to plead falsity (applicable to both the Section 10(b) and Section 11 claims) as well as scienter and loss causation (applicable only to the Section 10(b) claims). Because the falsity analyses for Section 10(b) and Section 11 are nearly identical when the Section 11 claims sound in fraud, *Rubke*, 551 F.3d at 1165, the Court begins by analyzing falsity together for both claims. The Court then proceeds to analyze scienter and loss causation for the Section 10(b) claims. To end, the Court addresses Plaintiffs' control person claims under Sections 20(a) and 15.

A. Falsity

1. Validation Statements

The Court begins with the statements that Daiichi's Phase 1 trials "validated a rationally-designed dosing schedule" for further testing. Am. Compl. ¶¶ 66, 92, 135. Plaintiffs offer two theories to explain why these statements were false. First, Plaintiffs contend that the statements were literally false because the data did not actually validate any dose for Phase 3 testing. Second, Plaintiffs assert that the statements create the misleading impression that Rain was justified in skipping directly to Phase 3 trials. Neither theory succeeds.

As a threshold matter, statements that the Phase 1 data validated a dosing schedule are opinion statements subject to a higher standard of falsity than non-opinion statements. The validation statements are an expression of how Rain and its scientists interpreted the Phase 1 data. But there is no single "correct" way to interpret data; qualified data scientists often and reasonably "disagree over how to analyze data and interpret results." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (citation omitted). As such, courts within the Ninth Circuit regularly treat interpretations of clinical data as opinions. *E.g.*, *Alger Dynamic Opportunities Fund v. Acadia Pharms. Inc.*, --- F. Supp. 3d ----, No. 24-cv-451, 2024 WL 4647297, at *11 (S.D. Cal. Oct. 31, 2024); *Pardi v. Tricida, Inc.*, No. 21-cv-00076, 2024 WL 1056013, at *7 (N.D. Cal. Mar. 11, 2024); *see also In re Rigel*, 697 F.3d at 879 (differences over the proper statistical analysis to use are differences of opinion). Other circuits agree. *E.g.*, *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) ("Interpretations of clinical trial data are considered

opinions."); *In Re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 422 (2d Cir. 2023); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016).

Since the validation statements are opinions, they can be false for purposes of Plaintiffs' claims in only three ways. *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615–16 (9th Cir. 2017). First, an opinion is false if it is (a) objectively false because it is "objectively untrue" and (b) is subjectively false because "the speaker did not hold the belief she professed." *Id.* (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 185–86 (2015)). Second, an opinion is false if it contains an embedded statement of fact that is untrue. *Id.* (quoting *Omnicare*, 575 U.S. at 186). Finally, an opinion is actionable as an omission if it creates a misleading impression about the basis for the speaker's opinion. *Id.* (quoting *Omnicare*, 575 U.S. at 194).

Plaintiffs' first theory of falsity is that the validation statements were literally false and therefore falls under the first *Dearborn Heights* category. To plead falsity under that category, Plaintiffs must demonstrate both that Daiichi's Phase 1 trial did not validate a dosing schedule (objective falsity) *and* that decisionmakers at Rain did not believe that the Phase 1 trial validated a dosing schedule (subjective falsity). Plaintiffs fail to satisfy the subjective portion of that burden for the reasons discussed in the next section. *Infra* Section III.B. But they also fail to satisfy the objective part of that burden. To plead objective falsity, Plaintiffs point to two allegations, but neither does the work that Plaintiffs need them to.

First, Plaintiffs allege that the Phase 1 trial was always intended to identify a dose for further Phase 2 testing, so Phase 1 could not have validated a dose for Phase 3 testing. Am. Compl. ¶ 36. As an initial matter, the validation statements did not purport to identify a dose for Phase 3 testing. Instead, they claimed only that Rain had identified a dose "shown to mitigate safety concerns and widen the therapeutic window" for milademetan. *Id.* ¶ 66; *see also id.* ¶¶ 92, 135 (similar). Moreover, the Court cannot infer that, just because Daiichi's Phase 1 goal was to identify a Phase 2 dose, the study necessarily could not yield data identifying a dose that would be promising in Phase 3 trials. Science is replete with examples where an experiment's results exceed researchers' initial expectations. Moreover, as Plaintiffs concede through their allegations,

it *can* be appropriate to move straight from Phase 1 to Phase 3. *Id.* ¶¶ 2, 31. Consequently, there must be situations where Phase 1 *can* identify a dose for further testing in Phase 3. Plaintiffs, though, never meaningfully discuss the data from Phase 1, nor do they explain why it is not the case here that the Phase 1 data identified a suitable Phase 3 dose.[6] The closest that Plaintiffs get to any discussion of the Phase 1 data is to briefly note that 15% of the Phase 1 trial participants received the dosing schedule that was ultimately used in Phase 3. *Id.* ¶ 6. However, the complaint does not contain allegations establishing that 15% is too small a proportion to identify a Phase 3 dose.

Next, Plaintiffs allege that Rain's Chief Scientific Officer admitted after completion of milademetan's Phase 3 trial that the dose used was too high. Am. Compl. ¶ 48. But the fact that Rain's Chief Scientific Officer reached this conclusion *after* the failure of Phase 3 trials says nothing about whether Rain was justified in further testing the dose identified in Phase 1 *before* that failure. After all, success at Phase 3 is never guaranteed. Even if researchers had done everything right to identify a dose for further testing, that dose could still ultimately prove too high or too low to be effective following Phase 3 trials. The Chief Scientific Officer's conclusion that the dose was too high is no more than fraud by hindsight—claiming fraud by "contrast[ing] a defendant's past optimism with less favorable actual results." *Knox v. Yingli Green Energy Holding Co. Ltd.*, 242 F. Supp. 3d 950, 963 (C.D. Cal. 2017) (quoting *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 62 (1st Cir. 2008)). That kind of theory cannot form the basis of a securities claim. For these reasons, Plaintiffs have failed to plead falsity under their first theory.

Plaintiffs' second theory of falsity—that the validation statements created a misleading impression—is equally unavailing. This second theory falls under the third *Dearborn Heights* category, meaning that Plaintiffs needed to plead that the validation statements created a misleading impression of the basis for Rain's opinions. But the complaint says nothing about "the

[6] Plaintiffs do allege that milademetan did not meet the criteria for skipping Phase 2. *Infra* Section III.A.2. But those criteria are not connected to any analysis of Phase 1 data. Rather, the criteria ask whether scientists understand how milademetan works and what side effects it leads to. Am. Compl. ¶¶ 31–32. Thus, eligibility for bypassing Phase 2 is separate from the question of whether the Phase 1 data identifies a dose that can be tested in Phase 3.

inquiry [Rain] did or did not conduct or the knowledge it did or did not have." *Omnicare*, 575 U.S. at 194. While Plaintiffs cite several cases where courts found misleading omissions related to clinical trial data, those cases did not involve opinions interpreting that data. Instead, they dealt with misleading disclosures of the underlying data itself, where defendants cherry-picked positive data to disclose while withholding negative data. *E.g.*, *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 707–08 (9th Cir. 2016) (finding that it was misleading to omit mention of an animal study with negative results after the defendants represented to investors that animal studies supported their drug candidate's safety). Here, there is no allegation that, when interpreting the Phase 1 trial results, Rain excluded negative data from its analysis.

Finally, to the extent Plaintiffs argue the validation statements misleadingly implied that Rain was fully justified in proceeding directly to Phase 3, that theory of omission also fails because the validation statements say nothing about whether the validated dose was appropriate for Phase 2 or Phase 3 testing. Instead, the statements only discussed the dose's effect on safety concerns and milademetan's therapeutic window. Am. Compl. ¶¶ 66, 92, 135.

Accordingly, the Court finds that Plaintiffs have failed to plead falsity for the validation statements.

2. Commencement Statements

Next, the Court turns to the challenged commencement statements. Those statements were each along the lines of: "Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021." Am. Compl. ¶¶ 66, 69, 76, 83, 90, 101, 110, 119, 133, 144.

Plaintiffs do not allege that these statements are literally false. Indeed, they concede that the Phase 3 trial commenced on July 20, 2021, *i.e.*, the second half of 2021. *Id.* ¶ 44. However, the Court finds that Plaintiffs have plausibly alleged that the commencement statements are misleading because they omitted certain risks about the decision to bypass Phase 2 trials. Namely, Rain omitted to state that milademetan did not satisfy the traditional criteria for bypassing Phase 2—a strong understanding of milademetan's mechanism of action and safety/side effect profile. *Id.* ¶¶ 31–32. According to Plaintiffs, this meant that proceeding directly to Phase 3 posed a much higher risk than the typical Phase 3 trial would, and Rain did not disclose this elevated risk.

For an omission to be misleading, "it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Here, the commencement statements purport only to say that the Phase 1 data justified moving to Phase 3. They make no representations about the traditional criteria for bypassing Phase 2 or the risks attendant to miladametan's Phase 3 trial. So, the question is whether these commencement statements affirmatively created some misimpression about the risk that miladametan's Phase 3 trial would fail.

Ultimately, it is the trier of fact who will have to determine "whether a public statement is misleading." *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995). At the pleading stage, though, courts must assess whether statements are misleading by construing the complaint in the light most favorable to the plaintiff and making all reasonable inferences in favor of the plaintiff. *Reese*, 643 F.3d at 690. Of course, plaintiffs are not entitled to implausible interpretations of a statement. *SEB Inv. Mgmt. AB v. Align Tech., Inc.*, 485 F. Supp. 3d 1113, 1126 (N.D. Cal. 2020); *see also In re Gilead Scis.*, 536 F.3d at 1055 (courts do not make unreasonable inferences at the pleading stage). But when there are multiple plausible interpretations, the obligation to draw inferences in favor of plaintiffs mean that courts must choose the interpretation most favorable to plaintiffs. *See Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 986 (9th Cir. 2008) (rejecting a "conceivable" interpretation favored by defendants for an interpretation favored by plaintiffs). The commencement statements can be reasonably interpreted in accordance with Plaintiffs' theory of a misleading omission. By representing that Rain was justified in advancing straight to Phase 3 in one respect, *i.e.*, the Phase 1 data justified doing so, the commencement statements suggest more broadly that advancement to Phase 3 was materially justified as a whole.

That leaves two remaining issues to resolve. First, what is required for it to be materially justified to bypass Phase 2? As Plaintiffs have alleged, there is a consensus within the scientific community that the criteria for doing so are (a) an established understanding of a drug candidate's mechanism of action, and (b) a well-characterized safety profile for the drug candidate. Am. Compl. ¶¶ 31–32. Plaintiffs have also supported these allegations with citations to medical research. *Id.* ¶ 33. Defendants dispute whether Plaintiffs' cited research supports this approach,

but they raise only factual issues that are not appropriate for the pleading stage. In any case, in support of their argument, Defendants cite to only 2 of the 11 articles that Plaintiffs cited in their complaint, and even then, there is disagreement about exactly what those two articles say. At this stage of litigation, Plaintiffs have sufficiently established the criteria for bypassing Phase 2.

The second issue is whether Plaintiffs sufficiently pled that it was not materially justified to advance milademetan straight to Phase 3. This latter issue is a closer call, but ultimately the Court concludes that Plaintiffs have done so. Plaintiffs' primary allegation on this point is that Daiichi's Phase 1 study was the first time milademetan was ever administered to humans. *Id.* ¶¶ 36, 58. From this, the Court can readily infer that milademetan's safety profile, *i.e.*, how likely milademetan is to cause adverse side effects, is far from well-understood. If anything, there were reasons to be especially wary about milademetan's safety because it was part of a class of drugs historically linked to severe hematologic side effects. *Id.* ¶ 57. It is harder to say if Plaintiffs' allegations are enough for the Court to infer whether milademetan's mechanism of action is well-understood. But the Court need not do so, because it is enough to find that milademetan failed the safety profile criterion. By failing that criterion, milademetan failed to meet the standard for proceeding directly to Phase 3, meaning that Rain's decision to do so exposed investors to greater than normal risk.

Defendants counter that any reasonable investor would know that there is risk with Phase 3 trials—it is common knowledge that such trials are never guaranteed to succeed. And in any event, Defendants say, Rain repeatedly and emphatically disclosed that its Phase 3 trial might fail. *E.g.*, Valenzuela Decl., Ex. 1 at 12 ("[O]ur anticipated clinical trials of [milademetan] may not be successful."); Ex. 2 at 101; Ex. 6 at 134; Ex. 11 at 184 (similar). The problem is that Rain disclosed only the *general* risk attendant to any Phase 3 trial, whether Phase 2 was skipped or not. What Rain allegedly failed to disclose is that, by proceeding directly to Phase 3 when milademetan did not meet the criteria for doing so, the milademetan Phase 3 trial was subject to *atypically* high risks unknown to investors. At this early stage, that is enough.

Therefore, the Court finds Plaintiffs have adequately pled that the commencement statements are misleading for omitting milademetan's failure to satisfy the Phase 2 bypass criteria.

3. Optimistic Statements

Plaintiffs also challenge two sets of statements that Rain was "proud to have advanced milademetan into a pivotal [Phase 3] study less than 12 months after acquiring the program," Am. Compl. ¶¶ 71, 78, and that "Rain has achieved a number of important clinical milestones for milademetan." *Id.* ¶¶ 96. Again, there is no suggestion that either of these statements are literally false. Rain acquired rights to milademetan in September 2020 and began its Phase 3 trial in July 2021, less than 12 months later. *Id.* ¶¶ 7, 44. Rain also achieved "clinical milestones" as it defined them in its statement, which included beginning its Phase 3 trial. *Id.* ¶ 96.

With literal falsity off the table, Plaintiffs instead argue that the optimism of these statements misleadingly downplayed the risks of milademetan's Phase 3 trial. Generally, though, "vague statements of optimism," known as puffery in the case law, "are not actionable because professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014) (quoting *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010)) (internal quotations omitted). Such statements of puffery are only actionable when they "address specific aspects of a company's operation that the speaker knows to be performing poorly" and "affirmatively create" a misimpression about those operations. *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1143–44 (9th Cir. 2017) (quoting *Brody*, 280 F.3d at 1006). Rain's optimistic statements here do not create an affirmative misimpression like Rain's commencement statements did. The optimistic statements make no claims about the basis for proceeding directly to Phase 3 trials, unlike the commencement statements. Consequently, the Court finds these optimistic statements to be inactionable puffery.

4. Late-Stage Statements

The fourth category of challenged statements consists of statements where Rain describes itself as a "late-stage" company. Am. Compl. ¶¶ 74, 78, 81, 85, 88, 96, 99, 105, 108, 114, 117, 123, 131, 139, 142, 148. As alleged, this is literally true. By the time Rain first used the "late-stage" label on August 10, 2021, *id.* ¶¶ 73–74, it had already begun its late-stage (Phase 3) clinical trial for milademetan. *Id.* ¶ 44.

Insofar as Plaintiffs argue the late-stage statements are actionable omissions because they created a misleading impression about the extent of Rain's clinical trial experience, that argument fails as well. Statements must be read in context. "In other words, a duty to provide information exists only where statements were made which were misleading in light of the context surrounding the statements." *Retail Wholesale & Dep't Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1278 (9th Cir. 2017). In this instance, Rain disclosed its lack of experience from the very beginning, dispelling any suggestion that Rain was more seasoned than it really was. For example, in its prospectus, Rain explained, "We have a limited operating history [and] have not initiated, conducted or completed any clinical trials." Valenzuela Decl., Ex. 1 at 12; *see also id.* at 18 (same). Rain then repeated the same or similar disclosures multiple times throughout the proposed class period in its other SEC filings. Valenzuela Decl., Ex. 2 at 101–02; Ex. 6 at 134–35; Ex. 11 at 184–85. Plaintiffs have not pled that these late-stage statements are false.

5. Best-in-Class Statements

The fifth category of challenged statements—that milademetan had "the potential to be the best-in-class" for its category of drugs, Am. Compl. ¶¶ 71, 128—fails as puffery. Claims that a product is "best-in-class" are classic statements of puffery and corporate hyperbole that are not actionable under federal securities law. *In re Pivotal Sec. Litig.*, No. 3:19-cv-03589, 2020 WL 4193384, at *14 (N.D. Cal. July 21, 2020); *3226701 Can., Inc. v. Qualcomm, Inc.*, No. 15-cv-2678, 2017 WL 971846, at *10 (S.D. Cal. Jan. 27, 2017); *see also Hadian v. Fate Therapeutics, Inc.*, No. 3:23-cv-00111, 2024 WL 4246083, at *20 (S.D. Cal. Sept. 19, 2024) (hyperbolic language is typically inactionable puffery). Nor do these statements suggest that milademetan was performing better than it was. For one, these statements address only miladematan's "potential" to be best-in-class. There is no claim that milademetan had already been established as a best-in-class drug. In any case, Rain repeatedly disclosed to investors that milademetan was still in the middle of clinical trials, so investors understood that it had not yet been determined whether milademetan was best-in-class. Thus, Plaintiffs also fail to plead falsity for these statements.

6. Development Pipeline Diagrams

Finally, Plaintiffs challenge various diagrams showing milademetan's "development

pipeline" as misleadingly suggesting that Rain had conducted both Phase 1 and Phase 2 clinical trials when it was Daiichi who conducted the Phase 1 trial and no Phase 2 trial was conducted. Am. Compl. ¶¶ 94, 103, 112, 121, 126, 137, 146. Again, there is nothing misleading about these diagrams because Rain repeatedly disclosed in its SEC filings exactly what it allegedly omitted. Rain disclosed that Daiichi conducted the Phase 1 trial. *E.g.*, Valenzuela Decl., Ex. 1 at 18, 22, 58, 62, 65–70; Ex. 2 at 97, 100, 102, 105; Ex. 4 at 116; Ex. 5 at 124; Ex. 6 at 131, 135, 138; Ex. 7 at 148; Ex. 8 at 154, 156; Ex. 9 at 163, 166; Ex. 11 at 177, 180, 185. And Rain disclosed that it skipped directly from Phase 1 to Phase 3.[7] *E.g.*, Valenzuela Decl., Ex. 1 at 9–10, 55, 57, 59, 62, 69–70; Ex. 2 at 98, 100; Ex. 4 at 116; Ex. 6 at 132; Ex. 7 at 148; Ex. 8 at 156; Ex. 9 at 167; Ex. 11 at 181. Accordingly, Plaintiffs fail to plead falsity for this last category of challenged statements.

B. Scienter

Because Plaintiffs have successfully pled falsity for only the commencement statements, the Court focuses its scienter analysis on those statements. Plaintiffs' theory is that the commencement statements created a misleading impression about the risk of moving directly from Phase 1 to Phase 3 for milademetan. So, to establish scienter, Plaintiffs had to plead facts showing that the Officer Defendants—the individual defendants against whom the Section 10(b) claims are raised—knew (or disregarded with deliberate recklessness) facts showing that it was ill-advised and risky to skip Phase 2. *See In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701–02 (9th Cir. 2012). Plaintiffs have not done so.

Here, the primary scienter argument boils down to this: Milademetan was so important to Rain that the Officer Defendants must have known about milademetan's Phase 1 data. Then, because both Officer Defendants have so much experience in the biopharmaceutical industry, they must have realized that the Phase 1 data did not support skipping Phase 2. *See* Am. Compl. ¶¶ 19–20. Even assuming the first half of that argument is correct under some type of core operations

[7] Although not grounds for dismissal, the Court notes that Plaintiffs' theory about the pipeline diagrams misleadingly suggesting that Rain had conducted a Phase 2 trial is inconsistent with Plaintiffs' theory that Rain misled investors into thinking that skipping Phase 2 was justified—the latter necessarily implies that investors knew Rain did not conduct a Phase 2 trial. *See* Fed. R. Civ. P. 8(d)(3).

inference, *see S. Ferry LP, No.2 v. Killinger*, 542 F.3d 776, 783–86 (9th Cir. 2008), the second half does not follow. While the Officer Defendants' industry experience may give them the ability to interpret clinical trial data—and even this much is not clear for Mr. Vellanki, whose background is in the financial and business side of the biopharmaceutical industry rather than the scientific or medical side, Am. Compl. ¶ 19—the fact of their experience says nothing about how they actually interpreted the Phase 1 data. And there are no other allegations speaking to how the Officer Defendants actually interpreted the data. For instance, Plaintiffs do not allege that, after reviewing the Phase 1 data, the Officer Defendants thought that the data did not support advancing to Phase 3 trials. Nor are there allegations that the Officer Defendants decided to move to Phase 3 in a deliberately reckless way, such as by deciding to bypass Phase 2 without reviewing the Phase 1 data at all. In these circumstances, rather than infer scienter, it is far more compelling to infer that the Officer Defendants believed sincerely, even if mistakenly, that the Phase 1 data was promising enough to proceed directly to Phase 3.

In a similar vein, while Plaintiffs allege it is established in the literature that Phase 2 should not be skipped unless a drug candidate's mechanism of action and safety profile are well characterized, *id.* ¶ 4, the Court cannot infer that the Officer Defendants knew this fact merely from general allegations about their backgrounds. Experience does not equate with omniscience, and nothing in the complaint suggests that this information about bypassing Phase 2 is such common knowledge that virtually all industry participants should know of it.

Plaintiffs' confidential witness, referred to as FE 1 in the complaint, is no more helpful to establishing scienter, either on her own or in conjunction with the arguments above. Although Plaintiffs have "provided sufficient detail about [FE 1's] position within the defendant company" for the Court to credit her allegations, *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009); Am. Compl. ¶ 60, those allegations are ultimately not "indicative of scienter." *Zucco*, 552 F.3d at 995. Other than a conclusory assertion that the Officer Defendants must have known about the limitations of Phase 1 data, FE 1 mostly offers her own thoughts about whether it was appropriate to skip past Phase 2 trials. Am. Compl. ¶¶ 61–63, 162. FE 1 never indicates that she conveyed those thoughts to either Officer Defendant, so her personal thoughts do not support

any inference of scienter. *See In re Intel Corp. Sec. Litig.*, No. 5:20-cv-05194, 2023 WL 2767779, at *23 (N.D. Cal. Mar. 31, 2023) (information from former employees that does not "ma[k]e its way to any Individual Defendant" does not support scienter). And while FE 1 did directly "advise Vellanki that he was focusing too heavily and allocating too many resources on miladametan's manufacturing instead of focusing on miladametan's clinical operations," Am. Compl. ¶ 162, the accusations of falsity in this case have nothing to do with manufacturing. Finally, FE 1's vague allegation that "various" unnamed employees told Vellanki to not make "certain" unspecified statements, *id.*, are too nebulous to support scienter.

The only remaining scienter argument to address is Plaintiffs' claim that Rain faced "all-but-certain failure" if it conducted Phase 2 trials instead of skipping them. Opp'n 23, ECF No. 56. From Plaintiffs' perspective, this gave the Officer Defendants a motive to misrepresent the risks associated with bypassing Phase 2. *Id.* at 23–24. The problem is that Plaintiffs have not pled that Rain's failure was all but certain. In asserting inevitable failure, Plaintiffs appear to be referring to allegations that Rain did not have sufficient funding to conduct both Phase 2 and Phase 3 trials. Am. Compl. ¶¶ 163–64. However, those allegations only show that, because Rain planned to move directly to Phase 3, Rain raised just enough money to carry out its plan of bypassing Phase 2. The allegations do not show that Rain would be unable to raise funds to conduct Phase 2 trials if Rain had needed to. Since Plaintiffs have not pled imminent failure, the best they can do is to argue that the Officer Defendants were trying to save money where they could. That is a routine corporate objective and is not enough to establish scienter. *In re Rigel*, 697 F.3d at 884.

Consequently, Plaintiffs have failed to plead scienter for the commencement statements.[8]

C. Loss Causation

In the securities context, "loss causation is simply a variant of proximate cause" that asks

[8] Plaintiffs do make one other scienter argument based on certain SEC comment letters. But those comment letters only relate to the late-stage statements, for which Plaintiffs did not plead falsity. And even for those statements, the comment letters do not show scienter because the letters were sent before Rain made any such statements and before Rain began the Phase 3 trials that made it a "late stage company." Am. Compl. ¶¶ 154–160 (exchanges with SEC occurred in the first half of 2021); *id.* ¶¶ 73–74 (first "late stage" statement on August 10, 2021); *id.* ¶ 44 (Phase 3 trial began on July 20, 2021).

"whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1210 (9th Cir. 2016). There are any number of ways that a plaintiff can show loss causation. *Id.* In this case, Plaintiffs try to show loss causation using a "materialization of the risk" theory. Under this theory, Plaintiffs can demonstrate loss causation by pleading that a "loss was within the zone of risk *concealed* by the misrepresentations and omissions alleged by a disappointed investor." *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013) (quoting *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 173 (2d Cir. 2005)); *see also In re Splunk Inc. Sec. Litig.*, 592 F. Supp. 3d 919, 950 (N.D. Cal. 2022) (finding loss causation where a stock drop was caused by an earnings miss that, in turn, "was caused by the undisclosed actions regarding which Defendants allegedly misled investors").

The gravamen of Plaintiffs' allegations is that, in one way or another, Rain downplayed the level of risk that skipping directly to Phase 3 entailed. Put differently, Plaintiffs claim that skipping straight to Phase 3 increased the risk that Phase 3 would fail in ways that investors could not appreciate. When the Phase 3 trial failed, that risk materialized. Am. Compl. ¶¶ 47–49. Phase 3's failure also caused Rain's stock price to decline. *Id.* These allegations fit precisely into a "materialization of the risk" theory, so Plaintiffs have pled loss causation.

D. Control Person Claims

Sections 20(a) and 15 allow plaintiffs to raise "control person" claims that derive from primary violations of Sections 10(b) and 11 respectively. *In re Rigel*, 697 F.3d at 886. Because Plaintiffs have successfully pled falsity of the commencement statements, they have stated a claim under Section 11 for those statements. Therefore, the Section 15 claims based on those statements may proceed. However, Plaintiffs have not pled the falsity of any other statements and have also not pled scienter as to any statement. Therefore, Plaintiffs have not stated a claim as to the remainder of their Section 11 claims or any of their Section 10(b) claims. Accordingly, the Court dismisses the Section 15 claims as to statements other than the commencement statements and also dismisses all Section 20(a) claims.

IV. CONCLUSION

The Court **GRANTS IN PART** and **DENIES IN PART** Defendants' motion to dismiss. Plaintiff's Section 11 claim based on the commencement statements, and the corresponding Section 15 claim, may proceed. All other claims are **DISMISSED**. Plaintiffs may file an amended complaint within **thirty (30) days** of this Order. The parties shall meet and confer and file a stipulated schedule for the next steps in this matter within **fourteen (14) days** of this Order.

IT IS SO ORDERED.

Dated: February 24, 2025

EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California