UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SUNG KIM, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

ALLAKOS INC., ROBERT ALEXANDER, LEO REDMOND, HENRIK RASMUSSEN, and ADAM TOMASI,

Defendants.

Case No. 20-cv-01720-JSW

ORDER GRANTING MOTION TO DISMISS WITH LEAVE TO AMEND

Re: Dkt. No. 33

Now before the Court is the motion to dismiss the amended class action complaint filed by lead plaintiff Sung Kim and named plaintiffs Christian Mayo and Allison Skye (collectively, "Plaintiffs"). This consolidated securities class action is brought against Defendant Allakos, Inc. ("Allakos") and Robert Alexander, Chief Executive Officer and former President, Leo Redmon, Chief Financial Officer, Henrik Rasmussen, Chief Medical Officer, and Adam Tomasi, Chief Operating Officer ("Individual Defendants" and collectively, "Defendants"). In their complaint, Plaintiffs allege two causes of action for violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 against all defendants and violation of Section 20(a) of the Exchange Act against the Individual Defendants.

The Court has considered the parties' papers, the record, and relevant legal authority and for the reasons set forth herein, the Court HEREBY GRANTS the motion to dismiss with leave to amend.

BACKGROUND

Plaintiffs bring this securities action "on behalf of all persons and entities other than Defendants who purchased the common stock of Allakos between March 14, 2019 and December 17, 2019, both dates inclusive (the 'Class Period'), and held stock until the end of the Class Period." (Amended Complaint ("AC") at ¶ 1.) The following facts are taken from the Amended Complaint, documents incorporated by reference, and judicially noticeable documents.

Allakos is a clinical stage biopharmaceutical company that is focused on a single drug, AK002, which it is developing to treat eosinophil and mast related cell diseases, including eosinophilic gastritis ("EG") and eosinophilic gastroenteritis ("EGE"). (*Id.* at ¶¶ 2, 3.) During 2018 and the first half of 2019, Allakos conducted a Phase 2 clinical trial, called the ENIGMA Trial, that tested AK002 on EG and EGE patients for safety and effectiveness. (*Id.* at ¶ 4.) On August 5, 2019, Allakos announced positive results for the ENIGMA Trial and the company's stock price went up significantly and continued to rise. (*Id.* at ¶¶ 5, 6.) Allakos simultaneously announced that it was conducting a $200 million secondary offering of common stock and the company ultimately raised $377.5 million. (*Id.* at ¶ 6.)

Also on August 5, 2019, the company hosted a conference call for analysts to discuss the result of the ENIGMA Trial ("Investor Call") and issued a Form 8-K signed by Defendant Alexander on the same date with a presentation entitled "Phase 2 Eosinophil Gastritis and Gastroenteritis Study Results." The Investor Call was transcribed. (Dkt. No. 34-2, Declaration of Stephen Blake ("Blake Decl."), Ex. O.) The speaker, Defendant Alexander and Rasmussen, used slides during the Investor Call ("Presentation"). (AC at ¶ 44; AC, Ex. 2.)

On December 18, 2019, Seligman Investments ("Seligman") published a report about the ENIGMA Trial which criticized the trial and cast doubt on the efficacy of AK002. Publication of the report, entitled "A Suspect Biotech with a Phase 2 Farce, Incredulous Trial Investigators, and Warning Signs of Potential Fraud" ("Seligman Report" or "Report"), caused Allakos' share price to decline 17% from the closing price of December 17, 2019, and over the next two days. (*Id*. at ¶¶ 7-9.) Seligman interviewed six trial investigators and also reprinted and reviewed numerous posts from trial participants and their families made in a private Facebook group. (*Id.* at ¶ 7.)

The Seligman Report contains a number of caveats including that, as a short seller, it stood to "realize significant gains in the event that the price of its stock declines." (AC, Ex. 3 at 1.) The Report specifically acknowledges that it represents "the current opinions of Seligman Investments" and that those opinions are "subject to change at any time." (*Id.*) The Report also makes the disclaimer that it is intended "for informational purposes only and does not constitute investment advice." (*Id.*) Seligman explicitly represents that it "cannot and does not provide any representations or warranties with respect to the accuracy of" the materials cited in the Report. (*Id.*) With respect to the interviews with former employees at Allakos, Seligman concedes that the employees "that [they] spoke with have been separated from [Allakos] for at least 6 months and thus the information they have provided may be stale." (*Id.*) And lastly, Seligman explains that they "have not conducted any diligence or other verification with respect to the social media posts included in [the Report]" and the "social media posts . . . do not reflect all information the persons posting have shared on social media, including, without limitation, certain positive comments and experiences with respect to Allakos. In addition, the persons posting may have conflicts of interest or other biases with respect to Allakos, which may give them an incentive to post inaccurate, incomplete or otherwise prejudiced information on social media." (*Id.*)

Plaintiffs rely on the findings in the Seligman Report as the basis for their complaint and contend that the issues identified by Seligman regarding the ENIGMA Trial led to the decline in the value of the stock during the Class Period. The Seligman Report found that Allakos did not employ a third-party Contract Research Organization ("CRO") to conduct the ENIGMA Trial. (AC at ¶ 7.) Plaintiffs contend that as a result of not employing a CRO and otherwise having poor controls during the trial as evidenced in the Report, the blinding of the ENIGMA Trial was severely compromised. (*Id.*) Plaintiffs further contend that the use of steroids among the test subjects was inconsistent and left to the discretion of the trial investigators, creating a confounding factor of the Trial. (*Id.*) Lastly, Plaintiffs contend that there was more than one drug-related serious adverse event during the administration of the ENIGMA Trial.

Based on these findings in the Seligman Report, Plaintiffs allege that Defendants publicly misrepresented the truth about the conduct of the ENIGMA Trial. Plaintiffs allege that, contrary

to their public statements, Defendants did not employ a CRO to conduct the ENIGMA Trial. Plaintiffs further contend that the blinding of the Trial was severely compromised but this fact was not disclosed. Plaintiffs further allege that Defendants understated the number of patients who used steroids and how inconsistent usage of steroids could affect the results of the Trial. Lastly, Plaintiffs contend that Defendants misrepresented that there was only one drug-related serious adverse event during the course of the Trial when there were in fact multiple adverse reactions reported by participants in Facebook posts cited in the Seligman Report. (*Id.*) Plaintiffs contend that all of "these misstatements and/or omissions were highly material to investors because all of those issues will raise red flags with the FDA, making it less likely that Allakos will be able to use the ENIGMA Trial to gain approval of AK002 in the future." (*Id.* at ¶ 8.) Plaintiffs contend that as a result of Defendant's false and misleading statements concerning the ENIGMA Trial, the value of the price of Allakos common stock was artificially inflated and when the Seligman Report revealed the truth, the share price declined and Plaintiffs suffered significant losses. (*Id.* at ¶¶ 9, 10.)

The Court will address additional facts as necessary in its analysis.

ANALYSIS

A. Request for Judicial Notice.

Generally, when evaluating a motion to dismiss, district courts may not consider material outside the pleadings. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). There are two exceptions to this rule: the doctrine of incorporation by reference and judicial notice under Federal Rule of Evidence 201. Each mechanism permits district courts to consider materials outside a complaint, but each for different reasons. *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002-03 (9th Cir. 2018).

Under Rule 201, a court may take judicial notice of an adjudicative fact if it is "not subject to reasonable dispute." Fed. R. Evid. 201(b). A fact is "not subject to reasonable dispute" if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Id.* Although a court may take judicial notice of matters of public record and properly consider those matters when evaluating a motion to dismiss, a court

may not take judicial notice of disputed facts contained in such public records. *Lee,* 250 F.3d at 689 (quotations and citations omitted).

Incorporation by reference, on the other hand, is a judicially-created doctrine that treats certain documents as though they are part of the complaint itself. *Khoja,* 899 F.3d at 1002. This doctrine is a tool to prevent plaintiffs from highlighting only the portions of certain documents that support their claims, while omitting portions of those documents that weaken their claims. *Id.* (citations omitted). A court may incorporate a document by reference if the complaint refers extensively to the document or the document forms the basis for the plaintiff's claim. *Id.* (citations omitted). For a reference to be sufficiently "extensive," a document should be referred to "more than once." *Id.* at 1003. But "a single reference" could, in theory, satisfy the standard if the reference is "relatively lengthy." *Id.* If a document "merely creates a defense" to the complaint's allegations, the document does not necessarily "form the basis of" the complaint. *Id.* at 1002-03 ("Although the incorporation-by-reference doctrine is designed to prevent artful pleading by plaintiffs, the doctrine is not a tool for defendants to short-circuit the resolution of a well-pleaded claim."). When a court incorporates a document by reference, it may assume all contents of the document are true for the purposes of a motion to dismiss under 12(b)(6). *Id.* at 1003 (citing *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006) (quotations omitted)). Thus, courts must be cautious when drawing inferences from incorporated documents. *Id.*

Here, Plaintiffs have attached the Seligman Report and the Presentation slides to their amended complaint. They premise the majority of their conclusions on the Report and the representations made in the Presentation. The documents are both thereby properly incorporated by reference.

Defendants separately move for judicial notice of a number of documents, including their securities regulatory filings, the transcript of the Investor Call, and academic and news articles regarding the drug trial and the company. The Court concludes the documents are the types of documents that would be subject to judicial notice and Plaintiffs have filed no objection. The Court will identify portions of the documents on which it has relied in its analysis. *See Khoja*, 899 F.3d at 999-1001.

B. Legal Standard on Motion to Dismiss.

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." A motion to dismiss is proper under Federal Rule of Civil Procedure 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. The Court's "inquiry is limited to the allegations in the complaint, which are accepted as true and construed in the light most favorable to the plaintiff." *Lazy Y Ranch LTD v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Even under the liberal pleading standard of Federal Rule of Civil Procedure 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). "[D]etailed factual allegations are not required" to survive a motion to dismiss if the complaint contains sufficient factual allegations to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 570). "Labels and conclusions and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 50 U.S. at 555.

When evaluating a Rule 12(b)(6) motion to dismiss, a district court accepts as true all material facts alleged in the complaint and draws all reasonable inferences in favor of the plaintiff. *Faulkner v. ADT Servs., Inc.*, 706 F.3d 1017, 1019 (9th Cir. 2013). Nonetheless, courts do not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

A district court should grant leave to amend unless the court determines the pleading could not "possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000). If the allegations are insufficient to state a claim, a court should grant leave to amend, unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990).

C. Heightened Pleading Standard in Securities Context.

Section 10(b) of the Securities Exchange Act provides that it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national security exchange or any security not so registered . . . any manipulative or deceptive device or contrivance." 15 U.S.C. § 78j(b). Under the same section, the Securities and Exchange Commission promulgated Rule 10b-5 which makes it unlawful "[t]o 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." 17 C.F.R. § 240.10b-5(b).

A complaint alleging claims under Section 10(b) and Rule 10b-5 must meet not only the basic requirements of Civil Procedure Rule 8(a), but also satisfy the requirements of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *See Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020). Under Rule 9(b), claims alleging fraud must satisfy a heightened pleading standard which requires that the party "state with particularity the circumstances constituting fraud or mistake." In addition, all private securities fraud complaints are subject to the "more exacting pleading requirements" of the PLSRA. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). The PLSRA requires that "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omissions 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).

To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege facts that show: (1) a defendant made a material misrepresentation or omission of fact; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance on the misrepresentation or omission; (5) loss causation; and (6) economic loss. *See Halliburton Co. v. Erica P. John Fund*, 573 U.S. 258, 267 (2014).

D. Misrepresentations or Omissions of Fact.

Defendants argue that the factual allegations in Plaintiffs' amended complaint are not sufficient to establish that any of the statements or purported omissions are actionable. A statement is not misleading simply because it is incomplete, but a "statement that is literally true can be misleading and thus actionable under the securities laws." *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). A statement is misleading "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1109 (9th Cir. 2010) ("*In re Cutera*") (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008)).

The false or misleading statement also must be "material," *i.e.*, "there is a 'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Bodri v. GoPro, Inc.*, 252 F. Supp. 3d 912, 922 (N.D. Cal. 2017) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). Securities laws do not require disclosure of all material information, but if a defendant touts "positive information to the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) (quoting *Berson*, 527 F.3d at 987). Ordinarily, the question of whether a statement is material should be left to the trier of fact but "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." *Reese v. Malone*, 747 F.3d 557, 568 (9th Cir. 2014), *overruled on other grounds by City of Dearborn*, 856 F.3d at 616.

Defendants contend that none of the alleged misrepresentations are actionable. The Court shall address each contested representation in turn.[1]

1. Use of an Independent CRO.

Plaintiffs contend that Allakos represented that they would hire a CRO for the ENIGMA Trial. In Allakos' SEC filings, the company represented that it generally does not "independently conduct [its] clinical trials" but instead "rel[ies] on third-parties, *such as* CROs, clinical data management organizations, medical institutions and clinical investigators" and that such "[t]hird-parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data." (AC at ¶ 94, citing 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q (emphasis added).) In these statements quoted by Plaintiffs in the complaint, Allakos explicitly represents that it typically works with various types of independent third parties in conducting its clinical studies. The Seligman Report also makes it clear that Allakos worked with a variety of independent third parties in connection with the ENIGMA Trial, including "trial investigators." (AC, Ex. 3 at 50-53.) The Report also indicated that Allakos "contracted out services as needed." (*Id.* at 53.)

Indeed, accepting as true all well-pleaded facts, the Court agrees with Allakos that no reasonable investor could conclude that Allakos' general statement that it relied on multiple third parties, such as but not limited to CROs, was false or misleading. *See In re Cutera*, 610 F.3d at 1109 (holding that a statement is misleading "if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists."). Plaintiffs' contention that Allakos' reading of their own disclosures was "hyper-literal" is unpersuasive where, as here, the statement is "quite literally true." *See Colyer v. Acelrx Pharmaceuticals, Inc.*, No. 14-CV-04416-LHK, 2015 WL 7566809, at *6 (N.D. Cal. Nov. 25, 2015) (citing *Brody*, 280 F.3d at 1006); *see also McGovney v. Aerohive Networks, Inc.*, 367 F. Supp. 3d 1038, 1059 (N.D. Cal. 2019) (citing *Brody* and finding that plaintiff had failed to plead falsity where the statement

[1] In the course of briefing the motion, Plaintiffs determined that they would not pursue a fifth claimed misrepresentation concerning incidents of Trial subjects vomiting. (*See* Opp. Br. at 10 n.1.)

was "quite literally true"). Here, Allakos' disclosure that it employed a variety of third parties to assist with its clinical trials is consistent with its employment of multiple third parties on the ENIGMA Trial rather than a single CRO.

2. ENIGMA Trial Design.

Next, Plaintiffs claim that the description of the ENIGMA Trial as a "randomized, double blind, placebo-controlled" trial was false and misleading because "the ENIGMA Trial was not well controlled and the blinding was compromised." (AC at ¶¶ 65, 96-107.) In addition to the failure to hire a CRO, which has been addressed, Plaintiffs allege that the company's representations about the study design of the Trial were misleading because "(1) adverse reactions to infusions of AK002 made patients aware of whether they were receiving AK002 or placebo, (2) trial investigators told patients whether they believed they were getting the drug instead of a placebo, (3) patients were able to see their test results during the Trial, (4) patients were told they would qualify for an extension study if they did well in the trial, encouraging them to report symptom improvement, and (5) Allakos had improper access to data and the patients during the Trial." (*Id.* at ¶ 65.)

First, the Court finds that even if the allegations regarding the alleged failures in methodology were true, these underlying allegations would merely support questioning the efficacy of the study and would not render the company's statements false or misleading. *See In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 878 (9th Cir. 2012) ("Plaintiff's allegations of 'falsity' essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study . . . . The allegations therefore concern two different judgments about the appropriate statistical methodology to be used by Defendants. The allegations are not about false statements.").

However, even if the statements were made after completion of the Trial about the methodology having been randomized, double blind, and placebo-controlled, the Court finds Plaintiffs have failed to plead sufficient facts to indicate that the professed methodology of the Trial was actually compromised thus rendering those statements misleading. Plaintiffs rely on the Seligman Report which in turn relies on the anecdotal postings in a private Facebook group. (AC

at ¶¶ 65-73; *see also* AC, Ex. 3 at 68 (sections of Report quoting social media posts by purported Trial subjects and their families stating, for example, "I really think I have the drug" and "I'm assuming I got the placebo")). However, the same social media posts indicate that test subjects were not aware of whether they received the placebo or the drug. (*See* AC, Ex. 3 at 69-70 (section of Report quoting social media posts by purported Trial subjects and their families stating, for example, "I obviously don't know if I got the placebo or not" and "We aren't sure if I have the placebo or drug. It's easier to tell if you have an infusion reaction . . . but I know not everyone reacts to infusion . . . . Wondering about this for 4 months will drive me nuts until they unblind.")) Plaintiffs' one-sided excerpts of patients' pure speculation about their status in the Trial and the company's data is not a sufficient basis for pleading falsity in the representations by Allakos that the Trial was conducted blind.

Next, Plaintiffs contend that interviews with investigators, as cited in the Seligman Report, indicated that there was some concern that possible reactions from the infusion of AK002 alerted Trial participants as to whether they were getting the drug or the placebo. (AC at ¶¶ 67, 70; Ex. 3 at 65.) As Defendants contend, however, it is "nonsensical to claim a study has been unblinded because some participants experienced a reaction to a drug. The very purpose of a drug trial is to observe the effects of a candidate drug, both positive and negative. If such reactions constituted unblinding, no trial could be considered to be blind." (Reply at 6.) Participants and investigators in the ENIGMA Trial were left to speculate whether the reactions patients had to the infusions were related to the effects of the medicine or the placebo effect. The Court does not find persuasive the contention that those who suffered side effects from the infusion could either know for certain that they had taken AK002 or that such a reaction would render the trial unblinded.

3. Patient Steroid Use.

Plaintiffs further contend that Allakos misled investors by "significantly understat[ing] the number of patients in the ENIGMA Trial who received steroids." (AC at ¶ 116.) Based on the representations contained in the Seligman Report, Plaintiffs allege that Allakos "stated only 11 of the 39 patients (28%) who received AK002 . . . also received any steroids," which they claim was "not plausible" based on the Seligman Report's anecdotal analysis of more widespread steroid use

in the patient population. (*Id*. at ¶¶ 74-75.) However, the Allakos Presentation slide that Seligman and Plaintiffs reference clearly indicates that the 28% figure related to "acute steroid use," while the study design expressly allowed for stable steroid use of "[less than or equal to] 10mg daily oral prednisone." (AC at ¶¶ 112, 114; Ex. 2 at 23.) In the disputed Investor Call, Defendant Rasmussen made it clear that

> In terms of steroid use, the protocol allowed low does chronic background steroids as long as patients were still symptomatic, as long as the patient still met the eosinophil inclusion criteria and as long as steroid had to be ke[pt] constant throughout the screening period as well as the study. Acute steroid use was allowed per site discretion as a premedication before infusion as a single dose steroid to reduce the incidence of infusion-related reactions [as] well as therapeutically to manage infusion-related reactions if they did occur.

(Blake Decl., Ex. O at 7.)

The Seligman Report focuses on whether the use of steroids may have impacted or undermined the Trial's results, but the disclosures cited in the Report and the Complaint as well as the record of the Investor Call indicate that the company did in fact disclose the use of steroids, both acute use and stable daily use. Plaintiffs' contention that the ENIGMA Trial's outcome may have been affected negatively by the patients' use of steroids is a critique of the design of the study rather than proof of any actionable misrepresentation or omission. *See, e.g., Abely v. Aeterna Zentaris Inc.*, No. 12-CV-4711, 2013 WL 2399869, at *10 (S.D.N.Y. May 29, 2013) ("[P]laintiff's critiques all go toward the design of the study and not to the existence of actionable misrepresentations or omissions . . . . Thus, his allegations . . . merely amount to a competing view of how the trial should have been designed, not an allegation of material misstatement or omission.") The "court does not judge the methodology of a drug trial, but whether a defendant's statement about that study were false and misleading." *Id.* at *7.

For the first time in opposition to the pending motion, Plaintiffs now argue that Defendant Alexander's representation during the Investor Call on August 5, 2019, that steroids "had absolutely 0 effect on the results, and that was shown in the [ENIGMA] study" was false and misleading. (*Id.* at ¶ 113.) Plaintiffs contend that "based on what we know about the haphazard administration of steroids during the ENIGMA Trial, there is no way that the study could have

shown steroids had '0 effect on the results.'" (Opp. Br. at 17.) First, there is no similar contention made by Plaintiffs in the operative complaint. Second, to the extent the Trial allowed for haphazard administration of steroids and allowed the trial investigators to determine whether and how to administrate acute dosages to study patients, this is again a critique of the design of the Trial and not a misrepresentation which could form the basis for a securities fraud claim. Lastly, it is unclear to the Court on what basis the Plaintiffs' contention is premised or why the representations made in the company's slide presentation and by Defendant Rasmussen were false or misleading. According to Allakos' representations, the company tracked the steroid infusions and "demonstrated that they had no statistically significant impact on the relative efficacy of AK002 compared to a placebo." (Reply at 7.) In the course of the trial, the company analyzed the whole cohort of patients as well as conducted a separate analysis excluding the patients with acute dosages of steroids, and found highly similar results in the efficacy of the drug regardless whether the patients receiving steroids were excluded. (AC, Ex. 2 at 25.) Accordingly, Plaintiffs have failed to allege that the statement made by Defendant Alexander during the Investor Call regarding the effect of steroids during the drug trial was false or misleading.

4. Incidents of Serious Adverse Effects.

In their final allegation of false statements, Plaintiffs allege that Allakos falsely indicated that there was only "one drug-related serious adverse event" during the ENIGMA Trial. (AC at ¶ 81.) Plaintiffs allege that multiple social media posts indicated that, in the course of the Trial, patients suffered from a variety of adverse effects, thus rendering the claim of only one serious adverse event false and misleading. (*Id.* at ¶¶ 82, 83.)

Federal regulations define the term "adverse event" as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 312.32(a). A "serious adverse event" is an adverse event that results in "[d]eath, a life-threatening adverse event, inpatient hospitalization . . ., [or] a persistent or significant incapacity or substantial duration of the ability to conduct normal life functions." *Id.* An adverse event is considered "treatment emergent" if it "emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state." (Blake Decl., Ex. P at 35.) A treatment related adverse event

or serious adverse event will not be considered drug-related in the absence of "evidence to suggest a causal relationship between the drug and the adverse event." 21 C.F.R. § 312.32(c)(1)(i). It is the responsibility of each trial investigator, not the company sponsoring the drug trial, to report any serious adverse event and assess whether that event is drug-related. 21 C.F.R. § 312.64(b).

A slide from the company's Presentation on August 5, 2019, summarizes the safety precautions taken during the Trial and indeed indicates one drug-related serious adverse event. (AC, Ex. 2 at 31.) Plaintiffs allege that "Defendants also stated the 9% of the AK002 patients and 14% of the placebo patients had 'treatment emergent serious adverse event[s]' during the ENIGMA Trial." (AC at ¶ 81.) Plaintiffs allege in the amended complaint that Defendant Rasmussen represented in the Investor Call that the cohort of patients suitable for the drug trial were a "sick patient population who have a lot of problems. Many of them have concomitant diseases. So typically, the serious adverse events were basically defined by a patient being hospitalized, in most cases, because of GI problems. And that's probably why the incidence was slightly higher on placebo as compared to on active." (*Id.*)

The uncorroborated reports from third parties in the Facebook group do not provide support for a finding that the company's representations, based on the reporting of its investigators, was false and misleading. The Court is not persuaded that it can replace the judgment of the investigators with the anecdotal reports by test subjects and their families. It is the responsibility of the investigators to report and assess the circumstances relating to adverse events in test subjects as well as to determine whether those events are drug-related or treatment emergent. *See* 21 C.F.R. § 312.64(b). A dispute over whether any particular incident during a drug trial should be classified as a drug-related severe adverse event cannot form the basis for a securities claim. *See, e.g., City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (holding that "[i]nterpretations of clinical trial data are considered opinions . . . only actionable under the securities laws if they are not honestly believed and lack a reasonable basis.") Accordingly, the social media reports and assessments cited in the complaint do not form the basis of a claim for securities fraud. *See Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013) (finding that there was "no false statement" where "defendant's competing analysis or

interpretation of data is itself reasonable."); *see also Philco Investments, Ltd. v. Martin*, No. C-10-02785-CRB, 2011 WL 500694, at *8 (N.D. Cal. Feb. 9, 2011) (requiring more than "the difference between two permissible judgments").

E. Scienter.

Because Plaintiffs have failed to plead falsity, the Court need not reach the issue of scienter. *See Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 694 (9th Cir. 2011); *Royal Oak*, 880 F. Supp. 2d 1045, 1068 (N.D. Cal. 2012) (no scienter where plaintiffs failed to adequately plead the alleged statements were false or misleading).

F. Section 20(a) Claim.

Plaintiffs also allege the Individual Defendants violated Section 20(a) of the Exchange Act, which creates joint and several liability for a "control person" who "directly or indirectly, controls any person liable under any provision of [the Exchange Act] or any rule or regulation thereunder . . . to the same extent as such controlled person to any person to whom such controlled personal is liable[.]" 15 U.S.C. § 78t(a); *see also City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 623 (9th Cir. 2017) (stating that "without 'a primary violation of federal securities law,' Plaintiff cannot establish control person liability").

Under Section 20(a), "certain 'controlling' individuals [are] also liable for violations of section 10(b) and underlying regulations." *Zucco*, 552 F.3d at 990 (citing 15 U.S.C. § 78t(a)). Because a Section 20(a) claim is derivative, "a defendant employee of a corporation who has violated the securities laws will be jointly and severally liable to the plaintiff, as long as the plaintiff demonstrates 'a primary violation of federal securities law' and that 'the defendant exercised actual power or control over the primary violator." *Id.* (citation omitted).

As addressed above, because Plaintiffs have not alleged a primary violation of Section 10(b) or Rule 10b-5 by any defendant, their claims under Section 20(a) fail.

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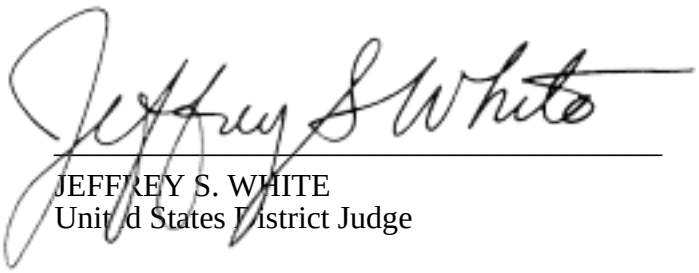
CONCLUSION

For the foregoing reasons, the Court GRANTS Defendants' motion to dismiss with leave to amend. Any amended complaint shall be due by no later than April 29, 2022.

IT IS SO ORDERED.

Dated: March 31, 2022



JEFFREY S. WHITE
United States District Judge

United States District Court
Northern District of California