UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOSEPH F. MARKETTE, et al.,

Plaintiffs,

v.

XOMA CORPORATION, et al.,

Defendants.

Case No. 15-cv-03425-HSG

ORDER GRANTING MOTION TO DISMISS AMENDED CLASS ACTION COMPLAINT

Re: Dkt. No. 94

This is a putative securities class action brought against Defendant XOMA Corporation ("XOMA") and other defendants pursuant to sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a). Before the Court is Defendants' motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. No 94. On June 6, 2017, the parties timely submitted supplemental briefs pursuant to the Court's order. Dkt. Nos. 110, 111. The Court **GRANTS** the motion to dismiss the Amended Class Action Complaint ("Complaint" or "Compl."), Dkt. No. 87, with **LEAVE TO AMEND**.

I. BACKGROUND AND ALLEGED FALSE OR MISLEADING STATEMENTS

A. Factual Allegations

Lead Plaintiff Joseph Tarzia ("Plaintiff") brings this putative class action "on behalf of all persons or entities who purchased XOMA common stock at artificially inflated prices" during the "Class Period" (between November 6, 2014 and July 21, 2015). Compl. ¶ 1.

i. The gevokizumab trial

XOMA is a biotechnology company. Id. ¶ 30. In 2010, XOMA partnered with Servier, a pharmaceutical research and development company, to begin work on an antibody called gevokizumab for the treatment of uveitis, a group of inflammatory eye diseases. Id. ¶¶ 6, 31-33. One form of uveitis, known as Behçet's disease posterior uveitis (BPU), is caused by a rare

autoimmune disorder. Id. ¶¶ 36-38. BPU can lead to blindness, and is characterized by a recurrence of episodes in which a patient's symptoms exacerbate (i.e., worsen). Id. at 37. As such, BPU therapy aims to both "treat the acute disease" and "prevent or at least decrease the number of" exacerbations in a patient's eye. Id. ¶ 39. The standard therapy for the condition involves a regimen of steroids and immunosuppressants, id. ¶ 7, and poses "several harmful side effects," id. ¶ 47.

In 2010, XOMA began Phase 2 studies of gevokizumab in BPU patients, id. ¶ 63, to "determine the effectiveness and safe doses of the drug," id. ¶ 63 n.11. In 2012, XOMA began the Phase 3 study that is relevant in this case, id. ¶¶ 81-82, to "provide the critical documentation of effectiveness and important additional safety data required for licensing," id. ¶ 32 n.8. This "randomized, double-blind, multi-part study," dubbed EYEGUARD-B, divided participants into two cohorts: those who received the standard therapy plus an injection of a placebo, and those who received the standard therapy plus an injection of gevokizumab. Id. ¶¶ 83-84. The trial monitored exacerbations of the participants' BPU to calculate the "primary endpoint": a comparison of the amount of time each cohort took to reach the first exacerbation. Id. ¶ 85. The trial was set to end once it reached a target number of 29 exacerbations. Id. ¶¶ 83, 86. Once the 29th exacerbation occurred, the trial would "unblind," allowing Defendants to analyze the data. Id. ¶¶ 8, 86.

ii. Reclassifications

XOMA initially told investors that the unblinding would occur in June 2014. Id. ¶ 88. On June 30, 2014, only 75 percent of the target exacerbations had occurred. Id. ¶ 89. By August 7, 2014, Defendant John Varian, XOMA's CEO, stated there were "still a few to go." Id. On November 6, 2014, Defendant Paul Rubin, XOMA's chief medical officer, disclosed on a conference call that certain previously reported exacerbations were being "reclassified" because those participants had been "rescued," or treated by doctors who did not comply with the trial's protocols. Id. ¶¶ 99. Rubin stated that "the most frequent reason" for the rescues was that the participants' "ocular symptoms worsened." Id. ¶ 90. He also stated that the reclassifications would be included in the Food and Drug Administration's "sensitivity analyses," which would treat the reclassifications "as if they [had] failed." Id. ¶ 92.

iii. The Challenged Statements

On November 6, 2014, Varian and Rubin also made the first of seven of what Plaintiff alleges were "false and misleading" statements. See id. ¶ 99 ("Challenged Statements," in block quotes below). During the same conference call where he described the reclassifications, Varian said:

> Our learnings are encouraging to our ultimate goal and should give you a good understanding of how we got from where we were back in May to where we are today."

Id. Later, referring to the exacerbations that XOMA had reclassified, Rubin stated:

> Again, while these loss per-protocol exacerbations were removed from the race to the target, they were medically validated exacerbations, in spite of a non-protocol steroid tweaking [i.e., in spite of the doctors who did not follow the trial's protocol]. Again, they directly impact the primary endpoint calculation and even more so, the sensitivity analyses.

Id. Rubin also described a slowing of exacerbations in the trial:

> Another factor that is both frustrating as well as encouraging is that the rate of exacerbations began slowing this summer. It is encouraging to see that there are still a significant number of ongoing patients in the trial, who have not experienced an exacerbation or have been rescued early.

Id. He noted that there was a "high percentage [of participants] that exacerbate fairly soon after randomization." Id. He also added the caveat that he and XOMA were "completely masked" as to which patients were in which cohort, "so nothing can really be read into this distribution." Id. Continuing his comments on the slowing of the exacerbations, Varian said:

> Now, in order to address the slowing pace of exacerbations, Servier has continued its enrollment in EYEGUARD-B, in spite of the fact that it hit target enrollment in the second quarter of this year.

Id. He continued:

> We remain very hopeful that these masked results are an encouraging indication of the potential of gevokizumab in this disease and we eagerly await the opportunity to review these data in an unmasked fashion in the near future.

Id.

On March 11, 2015, XOMA held an earnings call, in which Varian responded to a question

seeking his analysis of the apparent "bifurcation" between the two groups apparent from the blinded data: those who exacerbated early and those who had not yet done so. Id. ¶ 101. Varian's first response was to provide a "big preamble," noting that "all data are blinded as it should be, right, so you truly know nothing." Id. While acknowledging that XOMA was aware of "a group of patients [in the trial] who have gone a very long time" without exacerbating, Varian ultimately concluded that "[i]t could be great news, or it could mean nothing. We won't know until the data are unblinded." Id. He then noted:

> So it's encouraging, but it doesn't mean anything until the study is unblinded.

Id. Varian asked Rubin if he "want[ed] to say any more cautionary things on that," to which Rubin replied, "Nothing cautionary." Id. Rubin continued:

> So although we don't know who's on active [gevokizumab] and who's on placebo [in the trial], if you had an active drug, this is sort of the pattern you'd expect to see.

Id.

On July 22, 2015, XOMA announced that the unblinded trial data had shown that there was "no statistical difference between" the gevokizumab and placebo cohorts, with Varian stating that the company was "stunned" at the results. Id. ¶ 104-05. Rubin noted that "this [was] really the first . . . relatively large well-controlled trial in Behçet's disease," and that as a result, their "assumptions of placebo response [were] based upon really talking to experts and their appreciation of the natural history of the disease." Id. ¶ 105. Varian added that the "final results . . . underscore[d] the paucity of actual data in the [BPU] population." Id.

iv. Alleged insider selling

Plaintiff also alleges that during the class period, Varian sold 82,630 shares of XOMA common stock for proceeds totaling $315,400. Id. ¶ 135-36. He further alleges that Rubin sold 79,530 shares of XOMA common stock, for proceeds totaling $340,464. Id. ¶ 137-38. Finally, Plaintiff alleges that Defendant Kelvin Neu, a board member at XOMA from 2012 to 2015 and the managing director of privately-owned hedge fund Baker Bros., provided Baker Bros. with insider information, which resulted in Baker Bros.' selling more than 8.3 million shares of XOMA

common stock for proceeds totaling nearly $35.8 million. Id. ¶ 139-40.[1]

B. Procedural Posture

Plaintiff filed the Complaint on July 8, 2016. Dkt. No. 87. Defendants filed this motion to dismiss on September 2, 2016. Dkt. No. 94. Plaintiff filed his opposition on October 7, 2016, Dkt. No. 102, and Defendants replied on October 21, 2016, Dkt. No. 103. On May 26, 2017, the Court ordered supplemental briefing on the impact of the Ninth Circuit's opinion in City of Dearborn Heights Act 345 Police & Retirement Sys. v. Align Tech., Inc., 856 F.3d 605 (9th Cir. 2017), Dkt. No. 109, which the parties submitted on June 9, 2017, Dkt. Nos. 110-11.

II. LEGAL STANDARD

A. Rule 12(b)(6) Standard

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" A defendant may move to dismiss a complaint for failing to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). "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). To survive a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is facially plausible when a 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).

In reviewing the plausibility of a complaint, courts "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." Manzarek v. St. Paul Fire & Marine Ins. Co., 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, courts do not "accept as true 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).

[1] Baker Bros. is not a party to this action.

B. Heightened Pleading Standards

Section 10(b) of the Securities Exchange Act of 1934 provides that it is unlawful "[t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered . . . any manipulative or deceptive device or contrivance . . . . " 15 U.S.C. § 78j(b). Under this section, the Securities and Exchange Commission promulgated Rule 10b–5, which makes it unlawful, among other things, "[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 the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5(b). "To prevail on a claim for violations of either Section 10(b) or Rule 10b–5, a plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc., 552 U.S. 148, 157 (2008).

At the pleading stage, a complaint alleging claims under section 10(b) and Rule 10b–5 must not only meet the requirements of Rule 8, but must satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 876 (9th Cir. 2012). Under Rule 9(b), claims alleging fraud are subject to a heightened pleading requirement, which requires that a party "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Additionally, all private securities fraud complaints are subject to the "more exacting pleading requirements" of the PSLRA, which require that the complaint plead with particularity both falsity and scienter. Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 990 (9th Cir. 2009).

III. DISCUSSION

A. Section 10(b) and Rule 10b–5 Claims

As a threshold matter, the parties dispute whether several of the Challenged Statements are "statements of fact," Dkt. No. 111 at 1, or "opinions," Dkt. No. 110 at 2. This distinction is

significant, because the Ninth Circuit has recently clarified the standards for pleading falsity of opinion statements under Section 10(b) and Rule 10b–5. In Dearborn, the Court of Appeals held that three different standards may apply, depending on the nature of the statement:

> First, when a plaintiff relies on a theory of material misrepresentation, the plaintiff must allege both that "the speaker did not hold the belief she professed" and that the belief is objectively untrue. Second, when a plaintiff relies on a theory that a statement of fact contained within an opinion statement is materially misleading, the plaintiff must allege that "the supporting fact the speaker supplied is untrue." Third, when a plaintiff relies on a theory of omission, the plaintiff must allege "facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement misleading to a reasonable person reading the statement fairly and in context.

856 F.3d at 615-16 (citations and internal brackets omitted). Dearborn confirmed that a plaintiff may no longer plead falsity "by alleging that 'there is no reasonable basis for the belief' under a material misrepresentation theory of liability . . . ." Id. at 616.

The Court agrees with Defendants that five of the seven Challenged Statements are statements of opinion subject to Dearborn's pleading standard:

No.[2]	Statement of Opinion
1	"Our learnings are encouraging to our ultimate goal . . . ." Compl. ¶ 99.
2	"Another factor that is both frustrating as well as encouraging is that the rate of exacerbations began slowing this summer. It is encouraging to see that there are still a significant number of ongoing patients in the trial, who have not experienced an exacerbation or have been rescued early." Compl. ¶ 99.
3	"We remain very hopeful that these masked results are an encouraging indication of the potential of gevokizumab in this disease and we eagerly await the opportunity to review these data in an unmasked fashion in the near future." Compl. ¶ 99.
4	"So it's encouraging, but it doesn't mean anything until the study is unblinded." Compl. ¶ 101.
5	"So although we don't know who's on active and who's on placebo, if you had an active drug, this is sort of the pattern you'd expect to see." Compl. ¶ 101.

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[2] Unfortunately, in their supplemental briefs, the parties number the Challenged Statements differently. Compare Dkt. No. 110 at 2 with Dkt. No. 111 at 6. For clarity and consistency, the Court adopts Defendants' numbering.

Four of these statements on their face convey the speaker's opinion that certain developments are "encouraging," in one instance adding that the speaker is "hopeful." The Court finds it clear that these are opinion statements, since they inherently reflect the speaker's assessment of and judgment about the underlying circumstances. See Dearborn, 895 F.3d at 613 (citing Fait v. Regions Fin. Corp., 655 F.3d 105, 110 (2d Cir. 2011)) (affirming district court's finding that goodwill valuations were opinion statements because they were "inherently subjective" and "involve[d] management's opinion regarding fair value"); City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014) ("Interpretations of clinical trial data are considered opinions."). Similarly, the fifth statement expresses the speaker's "expect[ation]" as to "the sort of pattern" that an active drug would create. See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1325 (holding that a statement of opinion does not "express[] certainty about a thing"); Tongue v. Sanofi, 816 F.3d 199, 211-12 (2d Cir. 2016) (finding that pharmaceutical company's expression of "even exceptional optimism" about a drug's approval was not misleading and thus not actionable, even in light of FDA's repeated concerns about the company's methodology).

The Court rejects Plaintiff's argument that these statements are "statements of fact" not subject to the Dearborn pleading requirements. Dkt. No. 111 at 1, 6. There is no reasonable basis to read a statement of hopefulness, encouragement, or expectation as anything other than an opinion, and the Court disagrees that the statements were "phrased as certainties, not beliefs." Dkt. No. 111 at 2. The case upon which Plaintiff relies in his supplemental brief, Bridges v. Geringer, No. 5:13-cv-01290-EJD, 2015 WL 2438227 at * 7 (N.D. Cal. 2015), is plainly distinguishable: there, the defendant made obviously factual representations, such as "the majority of the funds were invested in large cap U.S. public equities" and "[defendant] was generating consistent, long-term returns for his clients." Nor is the Court persuaded by Plaintiff's argument that the statements "had specific factual connotations," Dkt. No. 111 at 2, as Plaintiff fails to explain why this characterization, even if accepted as true, transforms a statement that facially reflects the speaker's beliefs into a statement of fact, see Omnicare, 135 S. Ct. at 1328 (explaining that "a statement of opinion is not misleading just because external facts show the opinion to be

incorrect"); Dearborn, 856 F.3d at 613 (affirming district court's finding that statements regarding goodwill valuations are opinion statements).

Having determined that five of the seven Challenged Statements are statements of opinion, the Court applies the standards set out in Dearborn to determine whether Plaintiff has adequately pled the falsity of those statements. The Court then applies general Supreme Court and Ninth Circuit principles regarding material omissions to determine whether Plaintiff has adequately pled the falsity of the remaining two statements.

i. Plaintiff Has Not Sufficiently Alleged Falsity of the Statements of Opinion Under Dearborn (Statements 1-5)

a. No Sufficient Allegation of Falsity as to the Pure Statements of Opinion (Statements 1, 3, and 4)

Because Statements 1, 3, and 4 are pure opinion statements, Dearborn's material misrepresentation prong applies. Under a theory of material misrepresentation, Plaintiff's burden at this stage of the litigation is to allege, with sufficient particularity, that Defendants "did not hold the belief [they] professed and that the belief is objectively untrue." See Dearborn, 856 F.3d at 616 (citation and internal quotation marks omitted); see also Omnicare, 135 S. Ct. at 1327 (characterizing the inquiry as whether one's opinion was "honestly held").

Far from satisfying that standard, Plaintiff attempts to conflate the accuracy of Defendants' predictions and expectations with the sincerity with which Defendants held them. See, e.g., Dkt. No. 102 at 8 ("Varian/Xoma's statements that their 'learnings' regarding the Delay and Rescues were '**encouraging towards our ultimate goal**' [citation omitted] was materially false when made because the large number of Rescues . . . was necessarily negative . . . and therefore **not** supportive of Xoma's goal of FDA approval . . . .") (emphasis in original); 9 ("By Defendants' own logic, if a large number of longterm Survivors is encouraging, then conversely a large number of early Rescues must be **discouraging**.") (emphasis in original); 10 (arguing Rubin's statement that "if you had an active drug, this is the sort of pattern you'd expect to see" was false because an effective drug could show "vastly different" patterns). Plaintiff, in other words, makes no effort to allege that Defendants "did not hold the belief they professed," see Dearborn, 856 F.3d at 616 (citation omitted), opting instead to argue that their beliefs and expectations were ultimately not

borne out. When Plaintiff does set forth the argument that Defendants' beliefs were insincere, it is in a purely conclusory fashion. See Dkt. No. 102 at 10 ("Defendants did not sincerely believe their statements about the [exacerbation pattern] because, as they now concede, '**XOMA had no idea what the blinded exacerbation pattern meant or how rescues might impact results** . . . .') (emphasis in original); see also Compl. ¶¶ 100, 102 (alleging knowing or reckless disregard of the falsity of the Challenged Statements by Defendants).

Moreover, the facts alleged suggest that Defendants actually believed the statements when they made them. Varian and Rubin made Statements 1 and 3, respectively, in reference to the reclassifications, particularly with regard to the slowing rate of exacerbations. Compl. ¶ 99. A slowdown in exacerbations meant the unblinding would have to be delayed, but it could also mean that gevokizumab was working. See id. ("It is encouraging to see that there are still a significant number of ongoing patients in the trial, who have not experienced an exacerbation or have been rescued early."). It is entirely plausible that Defendants would be encouraged by the prospect of a group of participants who had "been in the trial for over six months without issues . . . ." See id. Notably, Defendants still provided plenty of cautionary language. See id. ("And we are completely masked whether these early exacerbating patients, rescued or controlled patients are in drug or placebo, so nothing can really be read into this distribution."); id. ("[W]e eagerly await the opportunity to review these data in an unmasked fashion in the near future.").

As to Statement 4, Varian made that statement in reference to the exacerbation pattern over the first 90 days of the trial, when "[there was] a group of patients who [got] past a certain point, and they [had] not exacerbated." Id. ¶ 101. He described that as "encouraging," with the caveat that "it [didn't] mean anything until the study [was] unblinded." Id. Again, it is plausible that Varian sincerely held this belief—particularly given that the blinded data showed that, "if patients [got] to a certain point in time [in the trial], the rate of exacerbation goes to virtually nothing." Id. In light of Servier's prediction that "every patient would exacerbate at some point in time . . . including gevokizumab patients," id., the facts as alleged provide no support for the notion that Defendants' optimism was not "honestly held," see Omnicare, 135 S. Ct. at 1327.

Because Plaintiff's allegations focus on the fact that Defendants' beliefs regarding the

potential outcomes of the trial later proved to be misplaced, rather than alleging that those beliefs were insincere, he fails to sufficiently allege falsity with regard to Statements 1, 3, and 4.

b. No Sufficient Allegation of Falsity as to the Opinions With Embedded Facts (Statements 2 and 5)

Statements 2 and 5 are statements of opinion with embedded facts. To sufficiently plead that such a statement is false, Plaintiff "must allege that the supporting fact [the speaker] supplied [is] untrue." Dearborn, 856 F.3d at 616 (citation and internal quotation marks omitted). Plaintiff's allegations again are insufficient, focusing on the fact that Defendants' optimism turned out to be misplaced rather than on showing that Defendants' supporting facts are untrue.

1. Statement 2

There are two facts embedded in Statement 2, which Varian made in a call with analysts: (1) "that the rate of exacerbations began slowing this summer," and (2) "that there [were] still a significant number of ongoing patients in the trial, who have not experienced an exacerbation or have been rescued early." Compl. ¶ 99. Plaintiff simply makes no allegation as to the falsity of these facts, instead disputing the conclusions that Defendants drew from those facts. Moreover, as discussed above, there is no sufficient allegation that Varian did not believe his characterization of the trial's prospects when he described it as "encouraging." Thus, Plaintiff has failed to sufficiently allege falsity as to Statement 2.

2. Statement 5

For the same reason, Plaintiff fails to sufficiently allege falsity as to Statement 5. In that statement, made by Varian in an update to investors, the embedded fact is that Defendants "[didn't] know who's on active [i.e., gevokizumab] and who's on placebo." Id. ¶ 101. The closest Plaintiff comes to alleging that fact to be false is to assert that effective "drugs could have exacerbation patterns vastly different than" the one to which Rubin referred in Statement 5. See id. In support of that assertion, Plaintiff cites In re Immune Response Sec. Litig., 375 F. Supp. 2d 983, 1020 (S.D. Cal. 2005), for the proposition that "allegations of specific problems undermining a defendant's optimistic claims suffice to explain how the claims are false." Dkt. No. 102 at 10. Immune Response, in turn, cites as support a Ninth Circuit case that characterizes that rule as a

way to satisfy Rule 9(b)'s particularity requirements. See Fecht v. Price Co., 70 F.3d 1078, 1083 (9th Cir. 1995). Nowhere, however, does Plaintiff himself actually allege specific problems with Statement 5, instead arguing that Varian might have interpreted the trial patterns differently. See Dkt. No. 102 at 10 (opposition); Dkt. No. 111 at 4 (supplemental brief). Indeed, Immune Response and Fecht both seem to call for something similar to the Dearborn standard: a particularized allegation that the embedded fact is untrue. Plaintiff makes no such allegation here. Nor is there any sufficient allegation that Varian did not believe his statement that Defendants did not know which trial participants were in what cohort, for the reasons described above. Thus, Plaintiff has failed to sufficiently allege falsity as to Statement 5.

ii. Plaintiff Has Not Sufficiently Alleged that Any of Defendants' Statements Were Materially False or Misleading Based on Alleged Omissions (Statements 1-7)

Plaintiff's allegations also fail under an omissions theory. A defendant is liable under Rule 10b–5 if it omits "material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." Matrixx Initiatives v. Siracusano, 563 U.S. 27, 47 (2011) (citing 17 C.F.R § 240.10b–5(b) (internal quotation marks omitted). An omission is material "when 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 available." Id. at 38 (citations and internal quotation marks omitted). "[A]s long as the omissions do not make the actual statements misleading, a company is not required to disclose every . . . result from a clinical trial, even if the company discloses some . . . results and even if investors would consider the omitted information significant." Rigel, 697 F.3d at 880 n.8.

a. Statements 1-5

Even if Statements 1, 2, 3, 4, and 5 were not subject to the Dearborn standard, and the Court instead analyzed them under an omissions theory, Plaintiff's allegations are still insufficient.

1. Statements 1, 2, and 3

Plaintiff alleges that, in making Statements 1, 2, and 3, Defendants "omitted and/or misrepresented" certain "adverse facts that then existed and were known or recklessly disregarded by the speaker at the time of each statement": (1) that a large number of rescues "rendered the

Trial less likely to succeed given that [they] were due to medically relevant exacerbations"; (2) that Defendants did not know which patients were in which cohort; (3) that Defendants had a "paucity of data" about the BPU population, "especially as it relates to therapy"; (4) that patients in the control group were on the standard therapy, which often led to significant periods of remission; and (5) that the standard therapy could "cause or contribute to" the exacerbation pattern, and that XOMA's Phase 2 data showed "significant periods of remission" for patients on the standard therapy. Compl. ¶ 100. The Court considers each allegedly omitted fact in turn.

First, Plaintiff alleges that in making Statements 1, 2, and 3, Defendants failed to mention that the rescues and subsequent reclassifications "rendered the Trial less likely to succeed," id., given Rubin's statement that the rescues would "directly impact the primary endpoint calculation and even more so, the sensitivity analyses," id. ¶ 99. Plaintiff argues that given Rubin's statement, Defendants had an obligation to disclose the number of rescues to investors, as that number put Defendants on notice of the trial's potentially negative outcome. See Dkt. No. 102 at 7. Considering the statements in context, however, this alleged omission fails to meet the pleading standard. Most importantly, Rubin did in fact tell investors that the rescues "were medically validated exacerbations," and that they would "directly impact the primary endpoint calculation and, even more so, the sensitivity analyses." Compl. ¶ 99. Perhaps Rubin couched the fact of a potential adverse effect on the trial's outcome in optimistic language, but he still disclosed the underlying fact. Thus, no actionable omission has been sufficiently alleged.

Second, Plaintiff alleges that Defendants did not know which patients were in which cohort, rendering baseless their enthusiasm in Statements 1, 2, and 3. See id. ¶¶ 99-100. The key here is that Defendants were clear that the actual data was masked to them. See id. ¶ 99 ("And we are completely masked whether these early exacerbating patients, rescued or controlled patients are in drug or placebo . . . ."); id. ("[W]e eagerly await the opportunity to review these data in an unmasked fashion in the near future."). Thus, again, no omission has been alleged. Moreover, in this context, it would have been clear to investors that Defendants had incomplete information (i.e., due to the double-blind nature of the study) and were making reasoned predictions based on what they did know. See In re Vical Inc. Sec. Litig., Nos. 13-cv-2628 and 13-cv-2653 BAS

(RBB), 2015 WL 1013827, at *5 (S.D. Cal. Mar. 9, 2015) (finding no false or misleading statement where drug developer "used faulty assumptions to make overly optimistic projections" about the results of a blinded drug trial because those assumptions "were characterized as such to investors").

Third, Plaintiff argues that Varian's statement regarding the "paucity of data" in the BPU population, made after the trial was unblinded, evinces an omission that Defendants ought to have disclosed. See id. ¶ 105; Dkt. No. 102 at 11-12. Because Defendants did not mention this "paucity of data" in the same call during which they made Statements 1, 2, and 3, the Court considers the context of the call, and whether "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 available," see Matrixx, 563 U.S. at 38 (citations and internal quotation marks omitted), and concludes that such likelihood is negligible based on the facts alleged. Rather, investors had to have been aware that EYEGUARD-B was intended to treat a rare disease, see Compl. ¶¶ 36-38, for which there was no FDA-approved treatment in the United States, id. ¶ 40. For that reason, any investor must have also been aware that there was likely to be a "paucity of data," whether with regard to BPU the disease or to BPU's response to therapy.

Finally, Plaintiff alleges that Defendants failed to mention the possibility that standard therapies were responsible for the encouraging exacerbation pattern, as evidenced by Defendants' Phase 2 studies. See Compl. ¶ 100. But Rubin addressed this by implication, when he said that Defendants were "completely masked" as to whether gevokizumab or the placebo (i.e., the standard therapy) were responsible for the exacerbation pattern. Id. ¶ 99. Still, even if Defendants had omitted mention of this possibility altogether, based on the allegations the Court finds no "substantial likelihood" that a reasonable investor would find such an omission to be material. Any reasonable investor would have been aware that Defendants were not trying to find the treatment plan for BPU—they were trying to find a better treatment plan that lacked the "serious side effects" of the existing standard therapy. See id. ¶ 47. It follows that the standard therapy would be at least somewhat effective, and that investors would have known that.

Thus, Plaintiff's allegations as to Statements 1, 2, and 3 fail under an omissions theory.

2. Statements 4 and 5

Plaintiff further alleges that Statements 4 and 5 "were materially false and/or misleading because they omitted and/or misrepresented" certain "adverse facts that then existed and were known or recklessly disregarded by the speaker at the time of each statement": (1) Defendants did not know which patients were in which cohort; (2) effective drugs "could have exacerbation patterns vastly different" than the one seen in EYEGUARD-B; (3) Defendants had a "paucity of data" about the BPU population, "especially as it relates to therapy"; (4) that patients in the control group were on the standard therapy that often led to significant periods of remission; (5) that the standard therapy could "cause or contribute to" the exacerbation pattern, and that XOMA's Phase 2 data showed "significant periods of remission" for patients on the standard therapy; and (6) a large number of rescues "rendered the trial less likely to succeed given that [they] were due to medically relevant exacerbations . . . ." Id. ¶ 102.

For reasons similar to those for Statements 1, 2, and 3, Plaintiff's allegations with regard to Statements 4 and 5 fail under an omissions theory. Here, not only did Defendants not omit the fact that they were masked from the data—Varian provided "a big preamble," the purpose of which was to make clear to investors that the exacerbation pattern Defendants were seeing "could be great news, or it could mean nothing. We won't know until the data are unblinded." Id. ¶ 101. Nor did Defendants render their statements misleading by failing to mention the fact that effective drugs could have different exacerbation patterns: while the Court takes that allegation to be true at this stage of the litigation, Plaintiff makes no allegation that identical or similar exacerbation patterns were a requisite to success. And, as discussed above, the alleged omissions regarding the "paucity of data," the efficacy of the standard therapy, and the number of rescues are inactionable as pled because there is no "substantial likelihood" that a "reasonable investor" would view such omissions as "having significantly altered the total mix of information available." Matrixx, 563 U.S. at 38 (internal quotation marks omitted).

Thus, Plaintiff's allegations as to Statements 4 and 5 fail under an omissions theory.

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b. Statements 6 and 7

It is undisputed that the two Challenged Statements remaining are not opinion statements:

No.	Statement
6	"Again, while these loss per-protocol exacerbations were removed from the race to the target, they were medically validated exacerbations, in spite of a non-protocol steroid tweaking. Again, they directly impact the primary endpoint calculation and even more so, the sensitivity analyses." Compl. ¶ 99.
7	"Now, in order to address the slowing pace of exacerbations, Servier has continued its enrollment in EYEGUARD-B, in spite of the fact that it hit target enrollment in the second quarter of this year." Compl. ¶ 99.

Thus, they are subject to general Supreme Court and Ninth Circuit principles regarding material omissions.

1. Statement 6

Plaintiff alleges that Defendants made an actionable omission when Varian explained the effect the rescues would have on the trial. See Compl. ¶ 99. Here, Plaintiff must make particularized allegations that Defendants omitted material facts such that Statement 6 was misleading "in light of the circumstances under which [it was] made." See Matrixx, 563 U.S. at 47.

As with his allegations regarding the other Challenged Statements, Plaintiff is unclear as to what exactly he is alleging Defendants omitted from Statement 6. See Compl. ¶ 100 (alleging that Statement 6 "omitted and/or misrepresented" certain adverse facts without further specifying) (emphasis added). Based on the Complaint, however, Plaintiff seems to be alleging that Rubin failed to mention that "[a] large number of Rescues occurred that rendered the Trial less likely to succeed given that the Rescues were due to medically relevant exacerbations that would weigh against gevokizumab's efficacy . . . ." Id. Looking to the circumstances under which Rubin made Statement 6, the Court concludes that the Complaint does not sufficiently allege that Defendants' statements were misleading. As discussed above, Rubin was frank in stating that the rescues "were medically validated exacerbations" that would "directly impact the primary endpoint calculation and even more so, the sensitivity analyses." See id. ¶ 99. During that same call, however, Rubin also stated that Defendants were "completely masked" as to whether the rescued patients were "in drug or placebo," id., meaning he did not know enough about the rescues to

know whether the trial was indeed "less likely to succeed," see id. ¶ 100. Defendants' trial was double-blind, making it entirely plausible that Rubin would choose not to speculate as to whether the rescues did, in fact, "render the Trial less likely to succeed." See id.

Given the double-blind nature of the trial, the number of rescues is not information that a reasonable investor would view as "having significantly altered the total mix of information available." Matrixx, 563 U.S. at 38. Even if Defendants had provided investors with that number, it would have required several inferential leaps to arrive at Plaintiff's conclusions, as the Complaint well demonstrates. See Compl. ¶ 94 (calculating 12 rescues, "upon information and belief"). Thus, as alleged, the number of rescues had no material effect on the "total mix of information available" to investors, and Plaintiff's allegations as to Statement 6 fail under an omissions theory.

2. Statement 7

Finally, Plaintiff alleges that Defendants made an actionable omission in Statement 7, when Rubin stated that "in order to address the slowing pace of exacerbations, Servier has continued its enrollment in EYEGUARD-B, in spite of the fact that it hit target enrollment in the second quarter of this year." Compl. ¶ 99. Plaintiff alleges that Statement 7 is "materially false and/or misleading" because it "omitted and/or misrepresented" the fact that "Servier enrolled new patients in material part because a large number of Rescues occurred, which fact itself reduced the Trial's prospects." Id. ¶ 100.

The Court has already addressed part of these allegations above. Defendants' mentioning the possibility that the rescues would "reduce the Trial's prospects" would amount to little more than baseless speculation, given the double-blind nature of the trial. As for Rubin's attribution of Servier's continued enrollment in EYEGUARD-B to the "slowing pace of exacerbations," it appears to boil down to a question of semantics. Rubin stated that the number of rescues "[was] almost identical to the newly occurred per-protocol exacerbations." Id. ¶ 99. Because those rescues "were removed from the race to the target"—that is, the 29 exacerbations needed to close and unblind the trial—it makes sense that the rescues would slow down the exacerbation rate. At bottom, Rubin attributed Servier's continued enrollment in the trial to the "slowing pace of

exacerbations" in the same call during which he described how the rescues were slowing the exacerbation rate. Thus, Rubin's wording in Statement 7, "in light of the circumstances under which [it] was made," see Matrixx, 563 U.S. at 47, is not misleading, regardless of whether he expressly attributed Servier's continued enrollment to a slowdown in exacerbations caused by the rescues.

As such, Plaintiff's allegations regarding Statement 7 fail under an omissions theory.

iii. Plaintiff Fails to Adequately Plead Scienter

Even if Plaintiff had adequately pled a material misrepresentation or omission by Defendants, he has still failed to adequately plead another element of a Section 10(b) or Rule 10b–5 violation: scienter. See Stoneridge Inv. Partners, 552 U.S. at 157. "To adequately plead scienter under the PSLRA, the complaint must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Rigel, 697 F.3d at 877 (quoting 15 U.S.C. § 78u-4(b)(2)(A)). In this Circuit, "scienter requires 'a strong inference of, at a minimum, deliberate recklessness.'" In re NVIDIA Corp. Sec. Litig., 768 F.3d 1046, 1053 (9th Cir. 2014) (quoting In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 977 (9th Cir. 1999)) (emphasis in original). Deliberate recklessness, in turn, must "reflect[] some degree of intentional or conscious misconduct," id. (quoting Silicon Graphics, 183 F.3d at 977), and involves "a highly unreasonable omission, involving . . . an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it," id. (quoting Hollinger v. Titan Capital Corp., 914 F.2d 1564, 1569 (9th Cir. 1990) (en banc)).

A plaintiff can meet his pleading burden for scienter by alleging "specific contemporaneous statements or conditions." Ronconi v. Larkin, 253 F.3d 423, 432 (9th Cir. 2001) (citing In re GlenFed, Inc. Sec. Litig., 42 F.3d 1541, 1549 (9th Cir. 1994)). In this context, "[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." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007).

a. The "Core Operations" Inference Does Not Apply

Plaintiff alleges that "[b]ecause the fraud alleged herein relates to the core business of XOMA, knowledge of the facts underlying the fraudulent scheme may be imputed to the Individual Defendants." Compl. ¶ 113. This application of the core operations inference fails:

> [A]llegations regarding management's role in a company may be relevant and help to satisfy the PSLRA scienter requirement in three circumstances. First, the allegations may be used in any form along with other allegations that, when read together, raise an inference of scienter that is "cogent and compelling, thus strong in light of other explanations." . . . Second, such allegations may independently satisfy the PSLRA where they are particular and suggest that defendants had actual access to the disputed information . . . Finally, such allegations may conceivably satisfy the PSLRA standard in a more bare form, without accompanying particularized allegations, in rare circumstances 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.

South Ferry LP, No. 2 v. Killinger, 542 F.3d 776, 785-86 (9th Cir. 2008) (citations omitted).

In support of his core operations allegation, see Comp. ¶ 113, Plaintiff alleges that XOMA "had a contractual right to Servier's EYEGUARD-B records," which provided that each party would "make available to the other Party all data and results generated," in addition to providing each other with "regular reports detailing [their] Development activities . . . ." Id. ¶ 114. He also alleges that Varian, Rubin, and Neu "had actual access to the Trial's protocols and procedures because they discussed the relevant data in detail before and throughout the Class Period." Id. ¶ 115. Moreover, Plaintiff alleges that the individual defendants "repeatedly confirmed that they received interim patient rescue data" from EYEGUARD-B, and that "[e]ven prior to the Unblinding Event, the Individual Defendants would have had access to the ongoing results given that XOMA collaborated with Servier in developing and conducing the trial." Id. ¶ 117. Plaintiff alleges that Rubin and Varian could not have made statements regarding the number of participants who were reclassified, or the number of patients who had not exacerbated, "without access to and knowledge of the underlying data the statements purport to represent." Id.

One allegation is notably absent from Plaintiff's complaint: that Defendants had actual knowledge of the unblinded data. Plaintiff's allegations do not support such an inference, and in fact, seem to operate on the conclusory assumption that because Defendants were managing the

double-blinded drug trial, they necessarily were not masked from the unblinded data. Indeed, Plaintiff alleges facts that tend to show otherwise. For example, he alleges that Varian and Rubin could not have made general statements regarding the blinded data while EYEGUARD-B was in progress without access to the unblinded data, while simultaneously reproducing transcripts from phone calls in which those defendants do exactly that. Plaintiff's allegations do not amount to a "cogent or compelling" inference of scienter, nor do they suffice to "suggest that defendants had actual access to the disputed information." See South Ferry, 542 F.3d at 785-86. Nor is this a "rare circumstance[]" where it would be "absurd" to suggest that Varian and Rubin did not have knowledge of the blinded data—to the contrary, that seems the most plausible explanation. See Vical, 2015 WL 1013827, at *5; Anderson v. Peregrine Pharm., Inc., No. SACV 12-1647 PSG (FMOx), 2013 WL 4780059, at *12 (C.D. Cal. Aug. 23, 2013) (finding "it would be 'absurd to suggest'" that defendants "had knowledge that the data in [a] double-blind study was unverified").

Plaintiff's allegations thus do not sufficiently plead scienter on a core operations theory.

b. None of Plaintiff's Other Allegations Support an Inference of Deliberate or Reckless Falsification

In support of his scienter argument, Plaintiff also alleges that Defendants (1) attempted to conceal their fraud by providing a "bogus" explanation for their optimism during the trial, see Compl. ¶¶ 118-22; (2) knew that the standard therapy "could control and delay BPU Exacerbations for months," id. ¶¶ 123-25; and (3) sold, along with Baker Bros., "a combined total of 8,524,932 shares of XOMA common stock, for combined proceeds of over $36,438,480 . . . with the heaviest trading (98.44% of shares sold) occurring within the 70 days after the start of the Class Period," id. ¶ 141. None of these allegations create an inference of scienter that is "cogent," nor one that is "as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324.

Here, the most compelling inference is not that Defendants engaged in any "extreme departure from the standards of ordinary care." NVIDIA, 768 F.3d at 1053 (citation omitted). Indeed, if anything, the totality of the allegations and record before the Court more compellingly supports the inference that Defendants believed in good faith the Challenged Statements when

made. For example, Plaintiff does not challenge that Defendants relied on Servier in "assum[ing] every patient would exacerbate at some point in time," Compl. ¶ 101, and on experts in "making assumptions" about the response of the placebo cohort, id. ¶ 105. Moreover, as described above, Defendants were transparent regarding the limitations of the data they possessed, and offered plenty of cautionary language to put investors and analysts on notice that their statements were based on blinded data and thus necessarily predictive in nature. See id. ¶¶ 99 (noting that Defendants were "completely masked whether these early exacerbating patients, rescued or controlled patients are in drug or placebo," and were "eagerly await[ing] the opportunity to review these data in an unmasked fashion in the near future"); 101 (noting that Defendants' conclusions were "based on the blinded data," providing a "big preamble" about how Defendants would not know what the exacerbation patterns meant "until the data are unblinded," and stating that the exacerbation pattern "doesn't mean anything until the study is unblinded").

Plaintiff thus fails to adequately allege that Defendants acted with the requisite "deliberate recklessness." See NVIDIA, 768 F.3d at 1053. Nor does he purport to offer any "specific contemporaneous statements or conditions" that would allow him to do so. See Ronconi, 253 F.3d at 432. Instead, his argument essentially amounts to an assertion that, because Defendants coordinated the study and had access to high-level logistical data, they must have also had access to the unblinded data. This is far from sufficient, and the Court finds that a reasonable person would not, on the basis of Plaintiff's allegations, "deem the inference of scienter cogent and at least as compelling as any opposing inference . . . ." See Tellabs, 551 U.S. at 324.

iv. Plaintiff's Claims Against Neu Must be Dismissed, Because Plaintiff Does Not Plead That Neu Made Any False or Misleading Statement or Had "Ultimate Authority" Over Such a Statement

"For purposes of Rule 10b–5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." Janus Capital Grp., Inc. v. First Derivative Traders, 564 U.S. 135, 142 (2011). But despite Plaintiff's argument in his opposition that Neu, as a board member of XOMA, "had 'ultimate authority' over the false and misleading statements at issue," Dkt. No. 102 at 16, Plaintiff failed to make any factual allegations in his Complaint in support of that argument. Indeed, he fails to

allege that Neu made—or even knew about—any of the seven Challenged Statements. Thus, Plaintiff has failed to carry his pleading burden, and his claims against Neu must be dismissed.

v. Because Plaintiff's Fraud Claims Fail, So Does His "Scheme Liability" Claim Pursuant to Rule 10b–5(a) and 10b–5(c)

Plaintiff further alleges that Defendants violated Rules 10b–5(a) and (c), Compl. ¶ 172, by engaging in a "Fraudulent Scheme To Pump The Blinded EYEGUARD-B Data," id. at 36 (heading of section J). "A defendant may only be liable as part of a fraud claim based upon misrepresentations and omissions under Rules 10b–5(a) or (c) when the scheme also encompasses conduct beyond those misrepresentations or omissions." WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc., 655 F.3d 1039, 1057 (9th Cir. 2011). Like the plaintiffs in Spot Runner, Plaintiff here "does not allege any facts that are separate from those already in [his] Rule 10b–5(b) omission claims," meaning his scheme liability claim is "fundamentally" his omission claim by another name. See id. at 1058. For that reason, the Court dismisses the claim.

B. Plaintiff's Section 20(a) Claim also Fails Based on the Failure of His Section 10(b) Claims

Plaintiff also alleges Section 20(a) claims against Varian, Rubin, and Neu under a "control person" theory of liability. See Compl. ¶¶ 158-60; 182-91. As Plaintiff has not adequately alleged a primary violation of 10b–5, his claims for control person liability under section 20 are **DISMISSED** with leave to amend. See Howard v. Everex Sys., Inc., 228 F.3d 1057, 1065 (9th Cir. 2000) ("In order to prove a prima facie case under § 20(a), plaintiff must prove: (1) a primary violation of federal securities laws . . . and (2) that the defendant exercised actual power or control over the primary violator . . . .").

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IV. CONCLUSION

For the foregoing reasons, the Court **DISMISSES** the Complaint with **LEAVE TO AMEND**. Any amended complaint must be filed within 28 days of the date of this Order.

IT IS SO ORDERED.

Dated: 9/28/2017

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California