UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, et al.,

Plaintiffs,

v.

TRICIDA, INC., et al.,

Defendants.

Case No. 21-cv-00076-HSG

ORDER GRANTING IN PART AND DENYING IN PART MOTION TO DISMISS

Re: Dkt. No. 76

This is a putative securities class action lawsuit involving allegations of material misrepresentations and omissions. Defendants move to dismiss. Dkt. No. 76. For the reasons below, the Court grants in part and denies in part the motion.[1]

I. BACKGROUND

A. Parties

Defendant Tricida, Inc. is a clinical-stage biopharmaceutical company incorporated in Delaware with principal executive offices in South San Francisco, California. Defendant Gerrit Klaerner is Tricida's Chief Executive Officer and President. Lead Plaintiff Jeffrey Fiore alleges that he was damaged by Tricida and Klaerner's misrepresentations and omissions because he "purchased Tricida common stock at artificially inflated prices." Dkt. No. 72 ("Compl.") ¶ 24.

B. Factual Allegations

In May 2018, Tricida completed its Phase 3 clinical trial for veverimer, a drug intended to slow the progression of chronic kidney disease ("CKD") through treatment of metabolic acidosis. In a June 5, 2018 press release, Tricida announced that the Phase 3 study for veverimer "was

[1] The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b).

conducted at 47 sites in the United States and Europe," and that the study "met both its primary and secondary endpoints in a statistically significant manner." *Id.* ¶ 6. Following the trial results, Tricida held its initial public offering ("IPO") on June 28, 2018 and began trading that same day on the Nasdaq Global Select Market. In August 2019, Tricida submitted its New Drug Application ("NDA") for veverimer to the United States Food and Drug Administration ("FDA") under the FDA's accelerated approval program. The FAD accepted Tricida's NDA two months later.

Beginning in May 2020, Tricida began to receive indications from the FDA that there were issues with its NDA. Early that month, Tricida executives met with representatives from the FDA who shared that the agency had concerns regarding: (1) "the magnitude and durability of the treatment effect on the surrogate marker of serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials" and (2) "the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population." *Id.* ¶ 16.

On July 15, 2020, Tricida issued a press release stating that the FDA had notified it that the agency had "identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time." *Id.* ¶ 109. Tricida issued another press release on August 24, 2020 stating that it had received a Complete Response Letter from the FDA on August 21, 2020 explaining that Tricida's Phase 3 trial alone could not demonstrate the efficacy of veverimer. The FDA further stated that it required additional data regarding the magnitude and durability of veverimer's treatment effect and on the applicability of that effect to the U.S. population. Two months later, on October 29, 2020, Tricida announced that the FDA had informed it that the FDA was "unlikely to rely solely on serum bicarbonate data for determination of efficacy" and would "require evidence of veverimer's effect on CKD progression from a near-term interim analysis of the VALOR-CKD trial for approval under the Accelerated Approval Program." *Id.* ¶ 115. Finally, on February 25, 2021, Tricida announced that the FDA had denied the appeal of its NDA denial. *Id.* ¶¶ 9, 120.

C. Procedural Background

In January 2021, Plaintiff Michael Pardi filed this lawsuit asserting violations of Sections

10(b) and 20(a) of the Securities and Exchange Act of 1934 and Rule 10b-5. *See* Dkt. No. 1 ¶ 1. In April 2021, the Court appointed Jeffrey Fiore as Lead Plaintiff and Block & Leviton LLP as Lead Counsel. Dkt. No. 65. On June 1, 2021, Fiore filed an amended complaint against Defendants Tricida and Klaerner. *See* Compl. Fiore seeks to represent "a class consisting of all purchasers of the common stock of Tricida" from June 28, 2018 through February 25, 2021. *Id.* ¶¶ 3, 136. He alleges that, starting with the June 28, 2018 registration statement and prospectus accompanying Tricida's IPO and ending with Tricida's February 25, 2021 press release, Defendants made false or misleading statements either intentionally or with deliberate recklessness.

Defendants move to dismiss. Dkt. No. 76.

II. LEGAL STANDARD

A. Federal Rule of Civil Procedure 12(b)(6)

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." Fed. R. Civ. P. 8(a)(2). 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. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir.

2008).

B. Heightened Pleading Standard

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 SEC 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 Federal Rule of Civil Procedure 8, but also 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

Fiore alleges two causes of action: (1) a violation of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants; and (2) a violation of Section 20(a) of the Exchange Act against Defendant Klaerner. *See* Compl. Defendants move to dismiss the claims on two grounds:

(1) the challenged statements were not materially false or misleading; and (2) Fiore fails to adequately plead facts giving rise to a strong inference of scienter.

A. Request for Judicial Notice

Defendants ask the Court to take judicial notice of 31 exhibits. Dkt. No. 77 (request for judicial notice of 23 exhibits)[2]; Dkt. No. 82 (supplemental request for judicial notice of 8 exhibits). Defendants argue that the exhibits are subject to the Court's consideration under the doctrines of judicial notice and incorporation by reference.

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *In re Eventbrite, Inc. Sec. Litig.*, No. 5:18-CV-02019-EJD, 2020 WL 2042078, at *7 (N.D. Cal. Apr. 28, 2020) (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001)); *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018)); *see also* Fed. R. Civ. P. 12(d). "This rule does not apply to the incorporation by reference doctrine or judicial notice under Federal Rule of Evidence 201." *Eventbrite*, 2020 WL 2042078, at *7 (citing *Khoja*, 899 F.3d at 998).

A court may take judicial notice of an "adjudicative fact" pursuant to the Federal Rules of Evidence, if that fact is one "that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Thus, under Rule 201 courts may "take judicial notice of matters of public record, but not of facts that may be subject to reasonable dispute." *United States v. Corinthian Colls.*, 655 F.3d 984, 999 (9th Cir. 2011) (internal quotation marks and citation omitted).

In the Ninth Circuit, incorporation by reference is a doctrine that "treats certain documents as though they are part of the complaint itself." *Khoja*, 899 F.3d at 1002. A document may be incorporated by reference into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). "Once a document is deemed incorporated by reference, the entire document is

[2] Defendants did not submit an Exhibit 6. *See* Dkt. No. 78 (Hemmendinger Decl.) at 2 ("Exhibit 6: [Reserved]").

assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free to refer to any of its contents." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir. 2014) (citation and quotation marks omitted).

Exhibits 1-5, 7-13, and Reply Exhibit 2 are public documents filed with the SEC. Exhibit 20 is an FDA Advisory Committee Calendar document publicly posted by the FDA. Reply Exhibits 5, 7, and 8 are guidance documents publicly posted by the FDA. Exhibits 21-24 and Reply Exhibit 6 are documents publicly posted by the National Institutes of Health. All are public documents "the accuracy of which is not reasonably subject to dispute." *Wochos v. Tesla, Inc.*, No. 17-CV-05828-CRB, 2018 WL 4076437, at *1 (N.D. Cal. Aug. 27, 2018); *see Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting that SEC filings are subject to judicial notice); *Waterford Twp. Police v. Mattel, Inc.*, 321 F. Supp. 3d 1133, 1143 (C.D. Cal. 2018) (granting judicial notice as to presentation that was "publicly available to reasonable investors at the time the defendant made the allegedly false statements" (internal quotation marks omitted)); *In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, 2017 WL 3727318, at *10 (N.D. Cal. Aug. 30, 2017) ("[B]oth SEC filings and documents on government websites are proper subjects of judicial notice."). Fiore opposes judicial notice of Exhibits 21-24 because he contends that Defendants seek judicial notice "for the purpose of demonstrating that investors knew this information contradicted or explained Defendants' misleading SEC statements on this subject." Dkt. No. 79 at 13 n.6. But the Ninth Circuit has explained that courts may take judicial notice of documents to show "that the market was aware of the information contained" in those documents. *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 (9th Cir. 1999). Accordingly, the Court takes notice of Exhibits 1-5, 7-13, 20-24, and Reply Exhibits 2, 5-8. "The Court is not taking notice of the truth of any of the facts asserted." *Wochos*, 2018 WL 4076437, at *2.

Exhibits 14, 15, and 17, and Reply Exhibit 1 are incorporated by reference by Fiore's complaint because the complaint explicitly and repeatedly refers to excerpts of these exhibits to support its claims. *See Ritchie*, 342 F.3d at 908. Fiore does not oppose judicial notice of these documents. Accordingly, the Court takes notice of Exhibits 14, 15, and 17, and Reply Exhibit 1. Again, the Court does not need to assume the truth of any of the facts asserted.

Exhibit 16 is a January 17, 2019 Tricida press release. "Courts in the Ninth Circuit routinely take judicial notice of press releases." *In re Am. Apparel, Inc. S'holder Litig.*, 855 F. Supp. 2d 1043, 1062 (C.D. Cal. 2012) (collecting cases). Fiore does not oppose notice of this document. Accordingly, the Court takes notice of Exhibit 16 to the same extent described above.

Finally, Defendants seek judicial notice of Exhibits 18-19 and Reply Exhibits 3-4. Each exhibit is a paper from the scientific journal *The Lancet*. Defendants offer these exhibits to support the premise that certain allegedly omitted information was disclosed in the market. "[T]he Court 'may take judicial notice of publications introduced to indicate what was in the public realm at the time,' but . . . the Court may not take judicial notice as to whether the contents of those articles were in fact true." *McGovney v. Aerohive Networks, Inc.*, No. 18-CV-00435-LHK, 2019 WL 8137143, at *7 (N.D. Cal. Aug. 7, 2019) (quoting *Von Saher v. Norton Simon Museum of Art*, 592 F.3d 954, 960 (9th Cir. 2009)); *see also In re Intel Corp. Sec. Litig.*, 2019 WL 1427660, at *6 & n.9 (N.D. Cal. Mar. 29, 2019) (considering exhibit for the purpose of "showing that particular information was available to the stock market," not for "the truth of its content"). Accordingly, the Court takes notice of Exhibits 18-19 and Reply Exhibits 3-4, again without taking notice of the truth of the facts asserted.

B. Material Misrepresentations or Omissions

Defendants challenge Fiore's claims that Defendants' statements concerning Tricida's Phase 3 clinical trial for veverimer were false or misleading.

To adequately allege misleading statements and omissions, a plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). When a plaintiff alleges an omission, the omission is only material if "a reasonable investor would have viewed the nondisclosed information as having significantly altered the total mix of information made available." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (emphasis in original). Section 10(b) and Rule 10b-5(b) "do not create an affirmative duty to disclose any and all material information;" however, once a company elects to disclose that material information, it has a duty to include all facts necessary to render a statement accurate and not misleading. *Id.* at 44-45, 47; 17 C.F.R. § 240.10b-5(b).

Material information only needs to be disclosed if its omission would "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). "But 'once defendants cho[o]se to tout' 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 Pharm., Inc.*, 840 F.3d 698, 706 (9th Cir. 2016) (alterations in original) (quoting *Berson v. Applied Signal Tech. Inc.*, 527 F.3d 982, 987 (9th Cir. 2008)).

1. Statements About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

First, Defendants challenge Fiore's claim that Defendants' statements identifying the location of their Phase 3 clinical trials were misleading. Fiore's complaint identifies eleven statements made by Tricida and Klaerner between June 5, 2018 and March 2, 2020 indicating that Tricida conducted its Phase 3 TRCA-301/TRCA-301E trials "in the United States and Europe." *See* Compl. at 60-62 (Claims Chart Nos. A1-A11). Fiore alleges that these statements were misleading because they did not disclose that "all of the trial sites were in *Eastern* Europe and not a single trial was conducted in *Western* Europe." Dkt. No. 79 at 6 (emphasis in original).[3] Fiore explains that because "[d]emonstrating that a pivotal trial is adequate and well controlled under 21 C.F.R. § 314.126 requires showing that any foreign data are applicable to the U.S. population and U.S. medical practice," conducting trials in Eastern Europe "raises the risk that trial participants would not be sufficiently representative of the U.S. patient population and U.S. medical practice for the FDA to accept the trial results." Compl. ¶ 11 (citation omitted).

The Court concludes that Fiore sufficiently pleads that Defendants' statements characterizing their Phase 3 trials as conducted in "Europe" were misleading. Given that Fiore alleges differences between Eastern and Western European patient populations and that the FDA treats clinical data from those populations differently, Defendants' statements "create[d] an impression of a state of affairs that differ[ed] in a material way from the one that actually

[3] All references to page numbers in filings are to the ECF pagination at the top of the document.

exist[ed]." *Brody*, 280 F.3d at 1006.

Defendants assert that Fiore's argument fails because their statements were at most incomplete, and incomplete statements are not actionable. *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1061 (9th Cir. 2014) ("We have expressly declined to require a rule of completeness for securities disclosures"). However, the Court disagrees that the gravamen of Fiore's claim is just that Defendants could have provided more information generally. Rather, Fiore asserts that by using "Europe" (as opposed to "Eastern Europe"), Defendants omitted material information necessary to make that characterization not misleading—specifically, the fact the trials were conducted *only* in Eastern Europe, where "several aspects of CKD differ significantly" due to varying "geographic, socio-economic, infrastructure, cultural and educational features" of the "Eastern European nephrology community," as opposed to being conducted in whole or in part in Western Europe, "which is generally considered to be the most U.S.-like foreign region besides Canada." Compl. ¶ 11.

Defendants also argue that the statements were not misleading because the omitted information was "disclosed . . . in scientific journals, and amplified . . . on publicly available government websites." Dkt. No. 76 at 14. Defendants cite papers published in the medical journal *The Lancet* and studies posted to the website clinicaltrials.gov. *See, e.g.*, Dkt. No. 78-17 at 4 (March 8, 2019 paper describing a "multicentre, parallel, randomised, double blind, placebo controlled study at 37 sites (hospitals and specialty clinics) in eight countries (Bulgaria, Croatia, Georgia, Hungary, Serbia, Slovenia, Ukraine and the USA)"); Dkt. No. 78-18 at 2 (June 24, 2019 paper describing a "multicentre, randomised, blinded, placebo-controlled, 40-week extension of our 12-week parent study at 29 sites (hospitals and specialty clinics) in seven countries (Bulgaria, Georgia, Hungary, Serbia, Slovenia, Ukraine, and the USA)"); Dkt. No. 78-20 at 4-8 (study description posted on clinicaltrials.gov listing all TRCA-301 trial locations, including those in Eastern Europe); *see also* Dkt. Nos. 22, 23, 24. Defendants add that Tricida's SEC filings and statements at investor conferences referenced the disclosures in *The Lancet*. *See, e.g.*, Dkt. No. 78-2 at 12 (2018 Form 10-K stating that "[i]n May 2018, we completed our pivotal Phase 3 clinical trial, TRCA-301, and in March 2019, the results of this trial were published in *The*

Lancet").

Defendants' challenge amounts to a "truth-on-the-market" affirmative defense. Defendants claim that the market was not misled because the allegedly omitted information – the fact that the trials were conducted in Eastern Europe – was already publicly disclosed in *The Lancet* and on public government websites. *See Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996). This fits the Ninth Circuit's definition of the defense: "if the market has become aware of the allegedly concealed information, the facts allegedly omitted by the defendant would already be reflected in the stock's price and the market will not be misled." *Id.* (internal quotations omitted). Courts regularly conclude that this defense "is not available at the motion to dismiss stage . . . because, 'as the Supreme Court and Ninth Circuit have explained, the truth-on-the-market defense is a method of refuting an alleged misrepresentation's materiality.'" *Bos. Ret. Sys. v. Uber Techs., Inc.*, No. 19-CV-06361-RS, 2020 WL 4569846, at *6 (N.D. Cal. Aug. 7, 2020) (quoting *Connecticut Ret. Plans & Tr. Funds v. Amgen Inc.*, 660 F.3d 1170, 1177 (9th Cir. 2011), *aff'd*, 568 U.S. 455 (2013)); *id.* ("Materiality is a mixed question of law and fact, and [p]roof of that sort is a matter for trial[.]" (internal quotation marks and citations omitted)). To the extent that the defense is available at the Rule 12(b)(6) stage, "Defendants bear a 'heavy burden' of proving that information withheld or misrepresented was transmitted to the public with a degree of intensity and credibility to effectively counterbalance the misleading impressions created by insider one-sided representations." *In re Iso Ray, Inc. Sec. Litig.*, 189 F. Supp. 3d 1057, 1073 (E.D. Wash. 2016) (quoting *Provenz*, 102 F.3d at 1492-93); *see also Nguyen v. Radient Pharm. Corp.*, 2011 WL 5041959 at *7 (C.D. Cal. 2011) ("Any conflicting interpretation of the false or misleading statements . . . will likely lead to consideration of facts that are inappropriate at the 12(b)(6) stage of the litigation."). Because Defendants do not meet, or even address, their burden of "proving that information withheld or misrepresented was transmitted to the public with a degree of intensity and credibility to effectively counterbalance the misleading impressions created by insider one-sided representations," *Iso Ray*, 189 F. Supp. 3d at 1073, Defendants' "truth-on-the-market" defense cannot be a proper basis for dismissal at this stage.

Defendants dispute Fiore's "truth-on-the-market" characterization. They claim that they

simply "argue that they disclosed all required information, not that they failed to make required disclosures but should be excused because other sources have already made the same information available." Dkt. No. 80 at 8 (quoting *City of Royal Oak Ret. Sys. v. Juniper Networks*, 880 F. Supp. 2d 1045, 1066 n.6 (N.D. Cal. 2012)). However, to the extent that Defendants simply assert that they "disclosed all required information," that contention collapses into the "incompleteness" argument the Court has already rejected. *See Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 887 (9th Cir. 2008) ("[I]nvestors are not generally required to look beyond a given document to discover what is true and what is not.").[4]

Accordingly, the Court denies Defendants' motion as to this ground.

2. Risk Disclosures About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

Next, Defendants challenge Fiore's claim that their risk disclosures were misleading. In the prospectus filed in connection with its IPO, Tricida stated that "the FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States." Compl. ¶ 60. It represented that:

> Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for TRC101, this is subject to certain conditions. For example, such foreign clinical trials should be conducted in accordance with GCPs, including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. *The foreign clinical data should also be applicable to the U.S. population and U.S. medical practice.* Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.
>
> We conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. *The FDA may not accept such foreign clinical data,* and in such event, we may be required to re-conduct the relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse

[4] Defendants also suggest that the truth-on-the-market theory only applies in cases involving "concededly false or misleading statements." Dkt. No. 80 at 7-8. But the Court finds no support for this contention in any legal authority cited by Defendants (or otherwise).

effect on our ability to carry out our business plans.

Id.[5] (emphases added). Fiore claims that these risk disclosures regarding (1) the applicability of the foreign clinical data to the U.S. population and medical practice; and (2) the likelihood that the FDA "may not accept such foreign clinical data" were false and misleading. *Id.*

Fiore alleges that because Defendants knew that their NDA would "rely[] upon a study with majority enrollment of Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care," they misrepresented the risk investors should have been aware of with respect to the likelihood of FDA approval. Dkt. No. 79 at 15. Fiore claims that the disclosures were misleading because they "created the impression that this generalized risk—that the FDA could, in theory, reject foreign data used in TRCA-301/TRCA-301E—was the risk investors should be aware of," instead of the "actual" more "specific, concrete, and severe" risk that "the[ir] study results were heavily dependent on patients from Eastern Europe," "a patient population that the FDA does not consider to be representative of the U.S. population when it comes to CKD." *Id.* at 16. In other words, because Defendants "[were] aware of the risk posed by [their studies'] majority enrollment in Eastern European sites," once Defendants made statements about the applicability of foreign data to NDA consideration, they were obligated to disclose that their European data came from Eastern Europe.

Construing the pleadings in the light most favorable to Fiore, the Court concludes that Fiore has sufficiently alleged that Defendants' risk disclosures were misleading. Fiore plausibly alleges that, more than simply being "incomplete," Defendants' risk disclosures, which identified only the generalized risk that the FDA *could* reject foreign clinical data submitted in an NDA, were misleading due to their omission of the Eastern European trial locations. While a reasonable investor reading the challenged risk disclosures in a vacuum may not have viewed them as misleading, because Defendants' omission of the Eastern European origins of the clinical data allegedly obscured a known and concrete risk, Defendants' risk disclosures – which acknowledge only a generic risk that "the FDA may not accept such foreign clinical data" – were similarly

[5] According to the complaint, Defendants made identical comments in their 2Q and 3Q 2018, 1Q, 2Q, and 3Q 2019, and 1Q 2020 Form 10-Q filings, and 2018 and 2019 Form 10-K filings. *See* Compl. at 63-67 (Claims Chart Nos. B1-B10).

misleading. *See Junge v. Geron Corp.*, No. 20-CV-00547 WHA, 2021 WL 1375960, at *6 (N.D. Cal. Apr. 12, 2021) (risk disclosure that "complete and partial remission may not be seen" in clinical trial results "was misleading" where "defendants knew the final study results"). Thus, there is "a substantial likelihood that the disclosure of the omitted fact," namely the study's heavy reliance on Eastern European clinical data, "would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1413 (9th Cir. 1994) (quoting *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (emphasis added))).

Defendants counter that "the allegedly concealed information was in fact disclosed and widely available." Dkt. No. 80 at 8. This is the same "truth-on-the-market" defense the Court rejected above. *See supra* Section III.B.1. The Court reaches the same conclusion here.

Accordingly, the Court denies Defendants' motion as to this ground.

3. Statements about the Multicenter Nature of the Phase 3 TRCA-301/TRCA-301E Trial

Fiore alleges that Defendants' SEC filings, beginning with their IPO documents and ending with their 1Q 2020 Form 10-Q, made misleading statements indicating that the Phase 3 trial was a "multicenter" study. Compl. ¶¶ 58, 63, 106. Fiore further alleges that because only a single study supported Defendants' NDA, Defendants misled investors by portraying that single study as a "multicenter" study, when in reality the study's "multicenter" aspect was diminished because "data from one high-enrolling clinical site had a disproportionate impact on the trial's results." *Id.* ¶ 57.

According to Fiore's complaint, FDA guidance states that "[a] conclusion based on two persuasive studies will always be more secure than a conclusion based on a single, comparably persuasive study." *Id.* (quoting FDA, *Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 13 (May 1998), https://www.fda.gov/media/71655/ download). To the extent that the FDA does accept an NDA based upon a single study, "[o]ne of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is 'a large multicenter study in which (1) no single study site

provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen.'" *Id.* (quoting FDA, *Providing Clinical Evidence of Effectiveness* 13). Fiore alleges that Defendants' use of the term "multicenter" was misleading because Defendants "knew that data from one high-enrolling clinical site [from their study] had a disproportionate impact on the trial's results" and thus "that the credibility of [their] multicenter study [was] diminished." *Id.* at 20-21.

Defendants respond that their "multicenter" statements are "demonstrably true" because "37 sites enrolled patients in TRCA-301 and 29 sites enrolled patients in TRCA-301E." Dkt. No. 76 at 18. They claim that they "did not have a duty to go further and disclose the precise enrollment figures for each site." *Id.*

Fiore plausibly alleges that Defendants' use of the term "multicenter" was misleading because it "would give a reasonable investor the impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1109 (9th Cir. 2010); *see also Khoja*, 899 F.3d at 1009 ("[O]nce defendants choose to tout positive information to the market, they are bound to do so in a manner that won't mislead investors, including disclosing adverse information that cuts against the positive information." (alterations omitted)). Fiore alleges that "multicenter" is effectively a term of art under the FDA's guidance, which refers to a study across multiple trial sites "in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen." Compl. ¶ 57. He further alleges that by labeling their trials as "multicenter," Defendants gave the misleading impression that the FDA would find them credible because no single study site would be responsible for a disproportionate share of either the trial subjects or the favorable effect seen. But in reality, according to the complaint, "the TRCA-301/TRCA-301E trial results were 'strongly influenced by a single site.'" *Id.* ¶120.

Defendants claim that Fiore makes an inappropriate "fraud-by-hindsight" argument by relying on "later regulatory determinations . . . to show that Tricida's statements about its clinical trials were false when made." Dkt. No. 76 at 19. For support, they cite *Immanuel Lake v. Zogenix, Inc.*, 2020 WL 3820424 (N.D. Cal. Jan. 27, 2020), a case in which the FDA issued a

refuse-to-file letter noting that Zogenix had not discussed certain toxicity studies in its NDA. *Id.* at *8. Afterward, plaintiffs sued Zogenix claiming that it had deceived investors by failing to disclose the studies in question in its NDA. The *Zogenix* court rejected the claim as employing "fraud-by-hindsight reasoning" and warned:

> [W]ere plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a NDA rejection from the FDA. Potential plaintiffs could merely parrot any deficiency identified by the FDA . . . and then claim the company concealed from the market that it failed to include this "necessary" piece of information in its application.

Id. at *9. But plaintiff's claim there is distinguishable from Fiore's claim here: while the plaintiff in *Zogenix* alleged that the defendant failed to disclose a study only later identified by the FDA, Fiore alleges that Defendants *affirmatively touted* a feature of their trial – its "multicenter" nature – to investors, which implied that the FDA would find it more credible.

Accordingly, the Court denies Defendants' motion as to this ground.

4. Statements About Veverimer's Prospects for FDA Accelerated Approval During a June 12, 2019 Presentation

Fiore alleges that Klaerner made two misleading statements concerning veverimer's prospects for FDA approval at a June 12, 2019 Goldman Sachs Global Healthcare Conference. Compl. ¶¶ 34, 78, 79.

a. "All You Expect To Do Is Show a Surrogate Effect"

Presenting to investors at the conference, Klaerner stated:

> And when you fast-forward in all the work that we've done, from a discovery to an early development, to a late stage development, agreeing with FDA, an accelerated approval path, you -- *all you expect to do is to show a surrogate effect, and then you have a post-marketing commitment that ultimately then, you confirm that, that surrogate is going to translate.*
>
> *Now we found ourselves with 1-year safety extension data that showed clinical benefit*. And I think that excitement, you can feel now, I think, in the company, both from interacting with payers, interacting with physicians, interacting with regulators, I think that is a good thing to have.

Dkt. No. 78-13 at 8 (emphases added).

Fiore argues that Klaerner's reference to accelerated approval was misleading because it

"suggested that FDA approval through the [Accelerated Drug Application program]—at least given the state of developments for veverimer—was easier or more likely than if the veverimer NDA had proceeded along the standard approval path." Dkt. No. 79 at 18.

Defendants contend that Klaerner's statements about the accelerated approval program were not misleading because such information "was available not only through Tricida's many unchallenged descriptions but also from the FDA." Dkt. No. 76 at 20. As Defendants point out, Fiore acknowledges this information in his complaint:

> Drug candidates evaluated via the [Accelerated Drug Application program] must still meet the same statutory standards for safety and efficacy: substantial evidence based on adequate and well-controlled clinically investigations. And Drugs granted accelerated approval must promptly conduct post-marketing confirmatory trials to verify clinical benefit, all of which dictates a more rapid pace of development.

Compl. ¶ 80 (citing Richard Moscicki, M.D., *FDA's Breakthrough Therapy Designation and Expedited Review Programs: Part II, FDA* (Apr. 21, 2016), https://www.fda.gov/drugs/newsevents-human-drugs/fdas-breakthrough-therapy-designation-and-expedited-review-programspart-ii; 21 U.S.C. § 355(d); 21 C.F.R. § 314.126).

To be sure, "some statements literally true on their face may nonetheless be misleading when considered in context . . . [and] can become, through their context and manner of presentation, devices which mislead investors." *Miller*, 519 F.3d at 886 (citations and internal quotation marks omitted). However, that is not the case here. On their face, Klaerner's statements accurately explained that (1) the accelerated approval process required both a showing of a surrogate effect and a post-marketing commitment, and (2) Tricida had "1-year safety extension data that showed clinical benefit" – in other words, that Tricida had data showing a surrogate effect. Given that the FDA's guidance makes clear what the terms of the accelerated approval process are, Klaerner's statements about one step of the process were not misleading.

Accordingly, the Court grants Defendants' motion as to this ground.

b. "We Have The Ability To Submit Our NDA With Just One Pivotal Trial That Shows A Surrogate Effect"

Later in the same June 12, 2019 presentation, Klaerner was asked about the role of the confirmatory trial VALOR-CKD with regards to veverimer. Compl. ¶ 78. Klaerner responded:

> It's a study that is now a post-marketing commitment with FDA following the accelerated approval path. That's something that is quite common for oncology or orphan diseases. It's not very common for cardiorenal.
>
> *We have the ability to submit our NDA with just one pivotal trial that shows a surrogate effect, and we've completed that.* The pivotal portion of that trial actually just got published in the Lancet in March, and we submitted the extension study to another major medical journal and hope to see that published soon, too.

Dkt. No. 78-13 at 8 (emphasis added). Fiore alleges that Klaerner's statement was misleading because he "presented the single phase 3 efficacy trial as a strength—something increasing the likelihood that the FDA would approve veverimer— when in fact it was a significant risk to FDA approval of the NDA." Compl. ¶ 83. In particular, Fiore argues that Klaerner's use of the phrase "we have the ability" implies "something unique to Tricida" and his use of the phrase "to submit our NDA with just one pivotal trial" implies "fewer trials than others need to submit with their NDAs." Dkt. No. 79 at 19.

Taken on its face, Klaerner's statement accurately noted that Tricida had the option to – and did – submit an NDA based on a single surrogate endpoint trial under the accelerated approval program. Given that the FDA's own guidance makes clear the terms of the accelerated approval program, *see supra* Section III.B.4.a, the Court concludes that Fiore has not adequately alleged that Klaerner's characterization of the program was misleading.

Accordingly, the Court grants Defendants' motion as to this ground.

5. Statements About the VALOR-CKD Trial Design

Next, Fiore challenges Defendants' statements regarding their VALOR-CKD trial protocol as false and misleading. *See* Compl. at 70-73 (Claims Chart Nos. D1-D6). Fiore identifies six statements Defendants made in their SEC filings and during the June 12, 2019 Goldman Sachs Global Healthcare Conference representing that Defendants "had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial" and "initiated the trial . . . with an

anticipated sample size of approximately 1,600 subjects." Dkt. No. 78-2 at 62.

Fiore's theory of liability is that Defendants' statements were false because they "lied to investors about the true anticipated number of randomized patients necessary for the VALOR-CKD trial to adequately confirm clinical efficacy." Dkt. No. 79 at 21. Fiore alleges that while Defendants disclosed to investors that they anticipated including a certain number (1,600) of randomized patients in the VALOR-CKD trial, in reality, according to a confidential witness ("CW1"), "by March 2019 Tricida had set a target internally of enrolling 4,000 patients in the VALOR-CKD trial." Compl. ¶ 72. Referencing representations in Tricida's June 28, 2018 IPO Prospectus, Fiore argues that "[i]f enrolling 1,900 to 2,100 patients corresponds to randomizing 1,400 to 1,600 subjects, then enrolling 4,000 patients corresponds to randomizing roughly double the 1,600 subjects Tricida publicly stated." Dkt. No. 79 at 21 (citing Dkt. No. 78-1 (Tricida IPO Prospectus) at 66 (explaining "that the VALOR-CKD trial will enroll approximately 1,900 to 2,100 subjects in the run-in portion of the trial to randomize 1,400 to 1,600 subjects")). Thus, Fiore concludes, Defendants disclosed that they were anticipating a trial sample size requiring half the number of patients Defendants were actually seeking to enroll. *Id.*

Even assuming CW1's "reliability and personal knowledge," *Zucco*, 552 F.2d at 995, the Court concludes that Fiore has not sufficiently pled that Defendants' statements were false or misleading.

First, Fiore has not plausibly alleged that Defendants' statements were false at the time they were made. Fiore does not explain why the difference between a trial protocol anticipating 1,600 patients and "the true anticipated number of randomized patients" necessarily suggests that Defendants' representation was false. *See Rigel*, 697 F.3d at 877 ("In order to allege falsity, a plaintiff must set forth facts explaining why the difference between two statements 'is not merely the difference between two permissible judgments, but rather the result of a falsehood.'" (quoting *In re GlenFed, Inc. Securities Litigation*, 42 F.3d 1541, 1549 (9th Cir. 1994) (en banc))).

Fiore argues that Defendants' statements indicated that they "had determined 1,600 subjects to be the *necessary* number of patients for the VALOR-CKD confirmatory trial." Compl. ¶ 72 (emphasis added). But even as alleged, Defendants never stated that 1,600 randomized

patients (or any number of patients) were necessary for their trial. Rather, Defendants' statements noted that they had "had multiple interactions with the FDA to finalize the protocol for the VALOR-CKD trial" and "initiated the trial . . . with an anticipated sample size of approximately 1,600 subjects." Dkt. No. 78-2 (Tricida 2018 Form 10-K) at 62. The fact that CW1 alleges that Defendants set an internal target of 4,000 patients to enroll does not imply that Defendants' statements that they anticipated proceeding with 1,600 patients was false. Rather, the Court agrees with Defendants that it is equally (or more) plausible that "a recruitment goal of 4,000 patients at the top of the funnel is consistent with an enrollment goal of 1,900 to 2,100 patients and a randomization target of 1,600—the figures Tricida reported to investors." Dkt. No. 80 at 12.

Fiore interprets Defendants' June 28, 2018 IPO Prospectus statement that Defendants would "obtain the FDA's agreement" regarding the VALOR-CKD trial protocol and enrollment before submitting the NDA to mean that Defendants actually did agree to a specific trial protocol with the FDA regarding the trial. *See* Dkt. No. 79 at 21. He concludes that "[i]f the FDA had approved the trial, then Tricida failed to live up to the agreement; or, no agreement was ever reached, which is why the FDA found that the VALOR-CKD trial was 'underpowered.'" *Id.* But there are no allegations indicating that Defendants had agreed to a trial protocol with the FDA at the time it made the statements at issue; the statements were made months before the NDA was submitted and only discuss an *anticipated* sample size.[6]

Second, Fiore has not plausibly alleged that Defendants' statements were misleading at the time they were made. There are no allegations in the complaint supporting the inference that Defendants' disclosure of their anticipated trial sample size would give "a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exist[ed].'"

[6] Fiore now argues in his opposition that Defendants' statements demonstrate that "Tricida prematurely submitted the NDA and misled investors that the VALOR-CKD trial was adequately enrolled as of August 2019." Dkt. No. 79 at 20. But the challenged statements do not support that inference because all statements were made months before the NDA was submitted, and none ever stated that the VALOR-CKD trial was adequately enrolled. Similarly, Fiore argues in the opposition that at the time Defendants made the challenged statements, they "knew that [they] needed to recruit 4,000 patients to achieve the necessary randomization for the VALOR-CKD trials." Dkt. No. 79 at 21 n.9. But this conclusion is likewise unsupported by the facts set out in the complaint.

Berson, 527 F.3d at 985 (quotation omitted)). Fiore assumes that a reasonable investor would have taken Defendants' disclosure anticipating a 1,600-patient sample size to mean that Defendants' trial would yield successful results or that the FDA was likely to accept Defendants' NDA, but there are no allegations in Fiore's complaint to support this. *See Matrixx Initiatives*, 563 U.S. at 44 (an omitted fact is material "when there is a substantial likelihood that [its disclosure] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available"). Put another way, Fiore argues that Defendants should have disclosed the "true anticipated number of randomized patients" for the trial, *e.g.*, 3,200, using Fiore's reasoning derived from the Tricida IPO Prospectus. But Fiore does not explain how disclosing this different number instead would have affected the "total mix" of information available to a reasonable investor, *id.*, or why the disclosure Defendants actually made gave reasonable investors any misleading impression of the actual state of affairs, *Berson*, 527 F.3d at 985 (quotation omitted).

Fiore relies on the FDA's February 25, 2021 Appeal Denied Letter explaining that Defendants' VALOR-CKD trial results were "underpowered" to argue that Defendants' 1,600-patient figure was material. Fiore claims that because Defendants explained in their challenged statements that they had chosen the 1,600-randomized-patient figure "in order to show a 30% to 35% reduction in renal events" at a "90% power level," Dkt. No. 78-1 (Tricida IPO Prospectus) at 6, Defendants knew that their VALOR-CKD trial would be unsuccessful. But this argument employs "the very sort of fraud-by-hindsight reasoning that the PSLRA was enacted to avoid." *Zogenix*, 2020 WL 3820424, at *8; *see also Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 693 (9th Cir. 2011) (expressing the "general principle" that "to be actionable, a statement or omission must have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events" (internal quotations omitted)). "[A] plaintiff must set forth, as part of the circumstances constituting fraud, an explanation as to why the disputed statement was untrue or misleading *when made.*" *See GlenFed*, 42 F.3d at 1549 (emphasis in original). Here, there are no allegations supporting the inference that a trial with 1,600 randomized patients necessarily would be unable to reach the intended power level so as to make Defendants' statements false or

misleading.

Accordingly, the Court grants Defendants' motion as to this ground.

6. Statements About the May 1, 2020 Late-Cycle Meeting

Fiore next claims that Klaerner made false or misleading statements during Tricida's May 7, 2020 earnings call. *See* Compl. at 77-79 (Claims Chart No. E3).

a. Cancelling the Advisory Committee Meeting Due to COVID-19

During the May 7, 2020 call, Klaerner explained that the FDA had informed Tricida at a May 2020 late-cycle meeting that a scheduled upcoming advisory committee meeting, also known as "AdCom," would be canceled "in part due to the logistical challenges posed by COVID-19." *Id.* ¶ 17.

Fiore alleges that Klaerner's statement was misleading because "the reason why the FDA 'indicated it currently does not plan to hold an AdCom to discuss veverimer' was not, primarily, due to the logistical challenges posed by COVID-19, but instead due to the FDA's concerns that there were too many problems with the NDA to even warrant convening an Advisory Committee." *Id.* ¶ 101. But the complaint nowhere pleads facts supporting the suggestion that the FDA told Defendants it canceled the AdCom meeting because of problems with the NDA.

Accordingly, the Court finds that Fiore's complaint does not sufficiently plead that Klaerner's statement referencing COVID-19 and the AdCom meeting was false or misleading. Defendants' motion is granted as to this ground.

b. Discussing Outstanding Review Issues with the FDA

Fiore also alleges that a later statement Klaerner made during the same May 7, 2020 call was misleading because Defendants disclosed only some of the issues they discussed with the FDA at the May 2020 late-cycle meeting. Klaerner said:

> In our late-cycle meeting with [sic] FDA, we took the opportunity to address outstanding review issues. We presented our data and rationale as to why we think we very much satisfied the requirements for initial approval under the Accelerated Approval Program including the magnitude and durability of the treatment effect on the surrogate markup serum bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials.
>
> Under the initial approval, we have to ensure that US patients who

> would be prescribed veverimer get clinically significant benefit that outweighs the risk of treatment. Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program.

Id. ¶ 101.

Fiore alleges that Klaerner's statement misled investors because while it revealed that Defendants had discussed outstanding review issues with the FDA, he omitted the FDA's "concerns regarding the trial data supporting TRCA-301, that the majority of participants were from Eastern Europe and the high concentration in one trial site." Dkt. No. 79 at 24. Fiore argues that Defendants' 2Q 2020 Form 10-Q, filed three months later, confirmed the materiality of this omission when it revealed that at the May 2020 meeting the FDA shared concerns about "the magnitude and durability of the treatment effect on the surrogate marker" and the "*applicability of data* from the TRCA-301 and TRCA-301E trials to the U.S. population." *Id.* ¶ 102 (emphasis added). Defendants ultimately acknowledged in their 2Q 2020 Form 10-Q that the FDA would likely decline to approve the NDA. *See* Dkt. No. 78-6 at 4 (2Q 2020 Form 10-Q stating, "We believe we are likely to receive [] clarification [from the FDA how to address its concerns] in the form of a Complete Response Letter, or CRL. Consequently, at this time we do not believe we will receive approval to market veverimer in the United States by our . . . goal date of August 22, 2020, if at all.").

The Court concludes that Fiore has sufficiently alleged that Klaerner's May 7 statement was misleading. The Court recognizes that a company does not have a "legal obligation to loop the public into each detail of every communication with the FDA." *In re Dynavax Sec. Litig.*, No. 4:16-CV-06690-YGR, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)). Here, however, Klaerner disclosed the fact that Defendants had discussed "outstanding review issues" with the FDA at the May 2020 late-cycle meeting and shared one of those issues: "the magnitude and durability of the treatment effect on the surrogate marker." Compl. ¶ 101. Fiore plausibly alleges that by disclosing this key detail, Klaerner was obligated to share the other significant review issue – "applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population" – discussed with the FDA. And contrary to Defendants' argument, Dkt. No. 76 at 25, this fact was not disclosed by

Klaerner's challenged May 7 statement that Defendants were looking into the "clinical benefit that the U.S. patients get." This generic reference to addressing the trial's clinical benefit did not disclose to a reasonable investor that the FDA was concerned with whether the data from that trial was applicable to the U.S. population. Further, Fiore's allegations that the August 6, 2020 2Q 2020 Form 10-Q indicated Defendants did discuss the applicability concern with the FDA at the May 2020 meeting suggest that, at the time Klaerner made the statement at issue, Defendants knew the nature of the FDA's concerns with their clinical data, and that those concerns affected veverimer's chances for FDA approval. Put another way, Fiore's allegations support a plausible inference that Klaerner informed investors of the good news – the discussion of "review issues" with the FDA – without including the bad news from the same meeting – the discussion of the FDA's concerns with the "applicability" of Defendants' clinical data. *See Schueneman*, 840 F.3d at 706 ("[O]nce defendants choose to tout 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." (simplified) (quotation omitted)).

Defendants argue that a deficiency notice issued by the FDA on July 14, 2020 changed Defendants' "belief about the FDA's likely course of action" and only then caused them to believe that the FDA would not approve their NDA. The notice "informed Tricida that deficiencies in the NDA precluded completion of the steps remaining in the approval process." Dkt. No. 76 at 25. However, Defendants' alternate explanation does not bear on the Court's inquiry at the pleading stage: whether, "construing the pleadings in the light most favorable to the nonmoving party," *Manzarek*, 519 F.3d at 1031, the complaint pleads facts that "would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *Cutera*, 610 F.3d at 1109. The complaint here does so.

Accordingly, the Court denies Defendants' motion as to this ground.

C. Scienter

The Court next considers whether Fiore has sufficiently alleged scienter. The Court only addresses scienter as to the statements that Fiore has adequately alleged to have been material misrepresentations or omissions.

The PSLRA requires that the complaint specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading, and show that the allegations "give rise to a strong inference that the defendant acted with the required state of mind." *See Schueneman*, 840 F.3d at 705. Thus, a plaintiff's burden "is to allege sufficiently particular facts to demonstrate a strong inference of scienter—a mental state that not only covers 'intent to deceive, manipulate, or defraud,' but also 'deliberate recklessness.'" *Id.* (internal citations marks omitted). The Ninth Circuit has defined "deliberate recklessness" as more than "mere recklessness or a motive to commit fraud." *Zucco*, 552 F.3d at 991. "[D]eliberate recklessness is 'an extreme departure from the standards of ordinary care . . . 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.'" *Schueneman*, 840 F.3d at 705 (quoting *Zucco*, 552 F.3d at 991 (internal quotation marks omitted)).

"A complaint will survive," the Supreme Court has instructed, "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). "All in all, though not impossible, this 'is not an easy standard to comply with—it was not intended to be—and plaintiffs must be held to it.'" *Schueneman*, 840 F.3d at 705 (quoting *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (per curiam)).

As a threshold matter, the Court finds inadequate a number of Fiore's alleged bases for inferring scienter. First, the Court rejects Fiore's assertion that he has pled scienter because Defendants were motivated to mislead the market into believing that the FDA would approve veverimer because Defendants otherwise would have run out of money. *See* Dkt. No. 79 at 28 n.14 ("The Company's entire future hung on the success of bringing veverimer to market. (citing Compl. ¶ 124)). Courts routinely conclude that such theories do not give rise to an inference of scienter. *See Zogenix*, 2020 WL 3820424, at *11 (finding scienter insufficiently pled where "Plaintiffs have no answer to defendants' benign explanation . . . that 'Zogenix had every incentive to get it right the first time, and to put [its drug] on the path to approval'"); *see also Jun*

Shi v. Ampio Pharms., Inc., No. 2:18-CV-07476-RGKRAO, 2020 WL 5092910, at *5 (C.D. Cal. June 19, 2020) ("[t]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason[.]" (alterations in original)); *In re Axonyx Sec. Litig.*, No. 05-CV-02307 (TPG), 2009 WL 812244, at *3 (S.D.N.Y. Mar. 27, 2009) (dismissing plaintiffs' complaint and concluding that "[a]ny inference of scienter suggested by the complaint is, to say the least, significantly less compelling than the opposing inference—that Axonyx did its best to design and carry out a successful clinical trial, but that despite these best efforts, Phenserine was not an effective drug to treat Alzheimer's disease").

Fiore further relies on the fact that throughout the class period, "Klaerner sold nearly $10 million in shares of Tricida stock" while making only a "single purchase of Tricida stock" of 15,790 shares for $300,010. Compl. ¶122. But Defendants respond that each of Klaerner's stock sales were made under a Rule 10b5-1 trading plan. Dkt. No. 76 at 28 (citing Dkt. No. 78-12 (Klaerner's SEC Form 4 filings submitted during the class period)).

"[T]he weight of authority in the Ninth Circuit" holds that courts can consider 10b5-1 trading plans when evaluating allegations concerning scienter. *See Azar v. Yelp, Inc.*, No. 18-CV-00400-EMC, 2018 WL 6182756, at *4 (N.D. Cal. Nov. 27, 2018) (citing *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008) (stock sales made "according to pre-determined plans may rebut an inference of scienter")); *see also In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1146 (9th Cir. 2017) ("'Unusual' or 'suspicious' stock sales by corporate insiders may constitute circumstantial evidence of scienter . . . ." (quotation omitted)). "To evaluate suspiciousness of stock sales, we consider, inter alia, three factors: (1) the amount and percentage of shares sold; (2) timing of the sales; and (3) consistency with prior trading history." *Id.* (quoting *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1232 (9th Cir. 2004)).

The Court concludes that Fiore has not shown that the timing of Klaerner's stock sales was unusual or suspicious. Fiore alleges that the timeline of Klaerner's sales was "aggressive" because Klaerner made 34 sales and only 1 purchase of Tricida stock over the class period. Compl. ¶ 122.

But an allegation that someone sells more shares than they buy does not by itself support the inference that they sold in "suspicious amounts" warranting an inference of scienter. Moreover, because the trading plan was only implemented at the start of the class period (when Tricida held its IPO), there is no prior trading history to evaluate Klaerner's sales against.

Second, Fiore claims that he has plausibly alleged an inference of scienter because "the day-to-day operations at [Tricida] leading up and throughout the Class Period focused solely on shepherding veverimer through clinical trials and FDA approval to commercialization," and that "Tricida was entirely Klaerner's project." Compl. ¶ 124. However, courts have found that generalized "core operations" allegations like these do not create an inference of scienter. *See NVIDIA*, 768 F.3d at 1064 (denying application of the core operations theory even when "the problem concerned [NVIDIA's] flagship product and was cause for concern to [NVIDIA's] two largest customers"); *Iron Workers Loc. 580 Joint Funds v. Nvidia Corp.*, No. 18-CV-07669-HSG, 2020 WL 1244936, at *12 (N.D. Cal. Mar. 16, 2020) ("Simply alleging that gaming is NVIDIA's core business does not give rise to an inference of scienter."); *Norfolk Cnty. Ret. Sys. v. Solazyme, Inc.*, No. 15-CV-02938-HSG, 2018 WL 3126393, at *9 (N.D. Cal. June 26, 2018) (finding that plaintiffs failed to allege "specific involvement of the [d]efendants in the details of the purported misrepresentations" even where the alleged misrepresentations concerned the "central cornerstone" of defendants' strategy).

1. Statements About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

The Court concludes that Fiore does not plausibly allege scienter with respect to Defendants' statements between June 5, 2018 and March 2, 2020 that Tricida conducted its Phase 3 trials in "Europe."

Fiore alleges that Defendants knew that: (1) FDA guidance states that in evaluating a drug application, the FDA considers the representativeness of the drug's Phase 3 clinical trial data to the U.S. population; (2) their Phase 3 studies relied on clinical trial data taken from Eastern Europe population; and (3) clinical trial data taken from Eastern Europe populations is less representative to the U.S. population than Western Europe populations. Fiore argues that these

allegations establish that Defendants knew that the FDA would be less likely to accept their NDA because it relied on clinical trial data from Eastern European patients who are unlikely to be representative of the U.S. patient population and U.S. medical care. Dkt. No. 79 at 26.

But there are no allegations supporting the required "strong inference" that Defendants intended to mislead or were deliberately reckless in characterizing the trial location as "Europe" generally. *See Zucco*, 552 F.3d at 991 ("[A]lthough facts showing mere recklessness or a motive to commit fraud and opportunity to do so may provide some reasonable inference of intent, they are not sufficient to establish a strong inference of deliberate recklessness." (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 974 (9th Cir. 1999)). And there are no allegations establishing that the characterization represented "an extreme departure from the standards of ordinary care [presenting] 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.* Put another way, as alleged, nothing about the claimed underlying representativeness problems meets this high "so obvious" standard, such that Defendants would had to have known that their literally true use of "Europe" would be misleading.

Accordingly, Fiore fails to sufficiently allege scienter.

2. Risk Disclosures About the Location of the Phase 3 TRCA-301/TRCA-301E Trial Sites

The Court concludes that Fiore does not plausibly allege scienter with respect to Defendants' risk disclosures about their study's use of foreign clinical data.

The scienter analysis for these disclosures follows the analysis regarding the "Europe" statement above, *see supra* Section III.C.1, because both flow from the same contention that Defendants knew that the FDA would be less inclined to accept their NDA because it relied on clinical trial data taken from Eastern European patients unlikely to be representative of the U.S. patient population and U.S. medical care. The only difference here is rather than misrepresent the deficiencies in the clinical trial data itself, as he claims Defendants did with respect to their "Europe" characterization, Fiore alleges that Defendants misrepresented the risk that the FDA would deny their NDA because of those deficiencies.

Fiore fails to sufficiently allege scienter because, like the statements above, there are no allegations supporting the "strong inference" that Defendants intended to mislead or were deliberately reckless in disclosing a generalized risk that the FDA *could* reject foreign clinical data submitted in an NDA. *Zucco*, 552 F.3d at 991. And there are no allegations indicating that Defendants' risk disclosures met the high "so obvious" standard such that Defendants would had to have known that their disclosures would be misleading.

3. Statements about the Multicenter Nature of the Phase 3 TRCA-301/TRCA-301E Trial

The Court concludes that Fiore does not plausibly allege scienter with respect to Defendants' statements describing their Phase 3 trial as "multicenter."

Fiore alleges that Defendants knew that: (1) FDA guidance states that when a conclusion relies on a single study, "[o]ne of the characteristics the FDA looks for in a single study capable of supporting an effectiveness claim is 'a large multicenter study in which (1) no single study site provided an unusually large fraction of the patients and (2) no single investigator or site was disproportionately responsible for the favorable effect seen,'" Compl. ¶ 57; and (2) "data from one high-enrolling clinical site [from Defendants' study] had a disproportionate impact on the trial's results." *Id.* ¶ 13. Thus, because the study relied on data from one site with a disproportionate impact, the study would not fit the FDA's stated criteria about multicenter studies. Fiore concludes that Defendants knew of this problem and thus also knew that the FDA would be less likely to accepted the clinical data. Dkt. No. 79 at 26.

But as with the previous statements, there are no allegations supporting the "strong inference" that Defendants intended to mislead or were deliberately reckless in labeling the trial as "multicenter," especially given that there does not appear to be any dispute that the trials were in fact "conducted at 47 sites" as alleged in the complaint. *See Zucco*, 552 F.3d at 991. Based upon the allegations in the complaint, the Court cannot conclude that the inference that Defendants acted with deliberate recklessness or intent to mislead investors is "at least as compelling" as the inference that they did not. *Matrixx Initiatives*, 563 U.S. at 50.

4. Statements About Discussing Outstanding Review Issues with the FDA at the May 1, 2020 Late-Cycle Meeting

The Court concludes that Fiore has plausibly alleged scienter with respect to Klaerner's statements regarding the May 1, 2020 late-cycle meeting. Defendants met with the FDA at a May 1, 2020 late-cycle meeting and discussed the FDA's concerns with Defendants' clinical data. Six days later, on May 7, 2020, Klaerner disclosed this meeting during an earnings call. However, he only shared one issue discussed at that meeting – "the magnitude and durability of the treatment effect on the surrogate marker." He did not share the other issue that was discussed – the FDA's concerns with the applicability of Defendants' foreign clinical data to the U.S. population. Klaerner only said that Defendants were "looking at . . . the clinical benefit that the U.S. patients get." Dkt. No. 78-14 (May 7, 2020 Tricida Earnings Call) at 11. Klaerner concluded his statement by assuring investors that, "Overall, while the FDA continues its review, we remain confident that our submission meets the standard for approval through the Accelerated Approval Program." *Id.* at 6.

The facts here are similar to those in *Schueneman*. 840 F.3d at 702. There, the defendant (a bio-pharmaceutical company that was testing and developing a new drug) affirmatively told investors that the company was "confident" about the drug's approval, which was based on the testing data including "all the animal studies that have been completed." *Id.* The company made that statement despite the allegation that it knew, and had indeed reported to the FDA, the result of a rat study that indicated that the drug was causing tumors and various types of cancer in rats. *Id.* at 701. Based on those allegations, the Ninth Circuit held that while the company "may not have had a duty to disclose the Rat Study had they not been representing that animal studies supported [the drug]'s safety and therefore its likelihood of being approved . . . once [the company] chose to tout [the drug]'s likely approval by referencing allegedly positive animal and preclinical studies, they were bound to do so in a manner that wouldn't mislead investors." *Id.* at 707-708.

Like the company in *Schueneman*, Defendants "may not have had a duty to disclose" the FDA's concern regarding the applicability of their data had they not also partially disclosed the conversation with the FDA and discussed their chances for approval. 840 F.3d at 707. But "once defendants chose to tout [allegedly positive discussions with the FDA], they were bound to do so

in a manner that wouldn't mislead investors as to [potentially negative issues from that same discussion within their possession]." *Berson*, 527 F.3d at 987. Here, Defendants' failure to inform the market about the FDA's applicability concerns is plausibly alleged to be "an extreme departure from the standards of ordinary care . . . [that] present[ed] a danger of misleading buyers or sellers that [was] either known to [Defendants] or [was] so obvious that [Defendants] must have been aware of it." *Zucco*, 552 F.3d at 991 (internal quotation marks omitted).

Further, Tricida's 2Q 2020 Form 10-Q at least supports an inference at this stage that Defendants knew that the omitted applicability concern was an issue. The form, filed three months after Klaerner's statement, described the discussions from the same May 2020 late-cycle meeting Klaerner referenced on May 7. As Klaerner had done in May, the Form 10-Q recited the review issue regarding "the magnitude and durability of the treatment effect on the surrogate marker." Dkt. No. 78-6 at 3. However, it also revealed to the public for the first time the other issue discussed at that meeting – the FDA's concerns with "the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population." *Id.* And the Form 10-Q concluded that Defendants "do not believe we will receive approval to market veverimer in the United States by our [] goal date of August 22, 2020, if at all." *Id.*

Defendants could have remained altogether silent about the review issues they discussed with the FDA. But they could not disclose only one review issue discussed with the FDA and conclude that they were thus confident about their chances for approval, while omitting the other review issue they knew the FDA was concerned about. The Court concludes that Fiore's allegations viewed *in toto* create a "strong inference" of scienter. *Zucco*, 552 F.3d at 992.

Accordingly, the Court denies Defendants' motion as to this ground.

CONCLUSION

For the reasons stated above, the Court rules as follows:

1. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to Fiore's claim based on statements about the location of the Phase 3 TRCA-301/TRCA-301E trial sites, based on failure to adequately plead scienter.
2. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to

Fiore's claim based on risk disclosures about the location of the Phase 3 TRCA-301/TRCA-301E trial sites, based on failure to adequately plead scienter.

3. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to Fiore's claim based on statements about the multicenter nature of the Phase 3 TRCA-301/TRCA-301E trial, based on failure to adequately plead scienter.

4. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to Fiore's claim based on statements about veverimer's prospects for FDA Accelerated Approval during a June 12, 2019 presentation, based on failure to plead falsity.

5. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to Fiore's claim based on statements about the VALOR-CKD trial design, based on failure to plead falsity.

6. The Court **GRANTS** Defendants' motion **WITH LEAVE TO AMEND** as to Fiore's claim based on a statement about cancelling an advisory committee meeting with the FDA due to COVID-19, based on failure to plead falsity.

7. The Court **DENIES** Defendants' motion as to Fiore's claim based on statements about the May 1, 2020 late-cycle meeting.[7]

Any amended complaint must be filed within twenty-one (21) days of the date of this order.

IT IS SO ORDERED.

Dated: 7/29/2022

HAYWOOD S. GILLIAM, JR.
United States District Judge

[7] Because the Court finds that at least one Section 10(b) claim has been adequately pled, and because neither party substantively addressed the Section 20(a) control person claim other than to note that it depends on a showing of a primary Section 10(b) violation, *see* Dkt. No. 76 at 31, the Court also **DENIES** the motion to dismiss that claim.