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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. 128

This putative securities class action was filed against Defendants Tricida, Inc. and Gerrit Klaerner (collectively, “Defendants”). On June 1, 2021, Lead Plaintiff Jeffrey Fiore filed an amended complaint alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder. *See* Dkt No. 72 at ¶ 2. The Court dismissed Fiore’s amended complaint with leave to amend. *See Pardi v. Tricida, Inc.*, No. 21-CV-00076-HSG, 2022 WL 3018144, at *1 (N.D. Cal. July 29, 2022) (“Order”). Fiore then filed a second amended complaint reasserting the same claims. *See* Dkt. No. 142¹ (“SAC”).

Pending before the Court is Klaerner’s motion to dismiss the SAC, for which briefing is complete.² *See* Dkt. Nos. 144-1 (“Mot.”), 143 (“Opp.”), 144-2 (“Reply”). The Court finds the matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). For the following reasons, the Court **GRANTS** the motion in part and **DENIES**

¹ The Court cites to redacted versions of the pleadings publicly filed on the docket pursuant to its recent sealing order. *See* Dkt. No. 141.

² Defendant Tricida, Inc. filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code, and Fiore voluntarily dismissed Tricida from the case in March 2023. *See* Dkt. No. 132. Accordingly, the only remaining defendant in this case is Klaerner. The Court refers to Klaerner and Tricida collectively as “Defendants” since both are alleged to have made statements challenged in the operative complaint, notwithstanding Tricida’s later dismissal.

1 it in part.

2 **I. BACKGROUND**

3 **A. Parties**

4 Tricida is a clinical-stage biopharmaceutical company incorporated in Delaware with
5 principal executive offices in South San Francisco, California. SAC at ¶¶ 40, 45. Klaerner was
6 Tricida’s Chief Executive Officer and President at the time the SAC was filed. *Id.* at ¶ 41. Fiore
7 alleges he was damaged by Defendants’ misrepresentations and omissions because he “purchased
8 Tricida common stock at artificially inflated prices.” *Id.* at ¶ 34.

9 **B. Factual Allegations**

10 In May 2018, Tricida completed its Phase 3 clinical trial for veverimer, a drug intended to
11 slow the progression of chronic kidney disease (“CKD”) through treatment of metabolic acidosis.
12 SAC at ¶¶ 45, 62. In a June 5, 2018 press release, Tricida announced that the Phase 3 study for
13 veverimer “was conducted at 47 sites in the United States and Europe,” and that the study “met
14 both its primary and secondary endpoints in a statistically significant manner.” *Id.* at ¶ 62.
15 Following the trial results, Tricida held its initial public offering (“IPO”) on June 28, 2018 and
16 began trading that same day on the Nasdaq Global Select Market. *Id.* at ¶¶ 7, 65. In late August
17 2019, Tricida submitted its New Drug Application (“NDA”) for veverimer to the United States
18 Food and Drug Administration (“FDA”) under the FDA’s Accelerated Approval Program. *Id.* at
19 ¶ 71. The FDA accepted Tricida’s NDA for review three months later. *Id.*

20 Beginning in May 2020, Tricida began to receive indications from the FDA that there were
21 issues with its NDA. *See, e.g., id.* at ¶¶ 24–25, 176. Early that month, Tricida executives met
22 with representatives from the FDA in which the FDA shared that it had concerns regarding:
23 (1) “the magnitude and durability of the treatment effect on the surrogate marker of serum
24 bicarbonate demonstrated in the TRCA-301 and TRCA-301E trials” and (2) “the applicability of
25 data from the TRCA-301 and TRCA-301E trials to the U.S. population.” *Id.* at ¶ 27.

26 On July 15, 2020, Tricida issued a press release stating that the FDA had notified it that the
27 Agency “ha[d] identified deficiencies that preclude discussion of labeling and postmarketing
28 requirements/commitments at this time.” *Id.* at ¶ 28. Tricida issued another press release on

1 August 24, 2020 stating that it had received a Complete Response Letter from the FDA on August
2 21, 2020 explaining that Tricida’s Phase 3 trial was inadequate on its own to demonstrate the
3 efficacy of veverimer. *Id.* at ¶¶ 29, 177, 179. The FDA further stated that it required additional
4 data regarding the magnitude and durability of veverimer’s treatment effect and on the
5 applicability of that effect to the U.S. population. *Id.* at ¶ 177. Two months later, on October 29,
6 2020, Tricida announced that the FDA had informed it that the FDA was “unlikely to rely solely
7 on serum bicarbonate data for determination of efficacy” and would “require evidence of
8 veverimer’s effect on CKD progression from a near-term interim analysis of the VALOR-CKD
9 trial for approval under the Accelerated Approval Program.” *Id.* at ¶ 180. Finally, on February
10 25, 2021, Tricida announced in a press release that the FDA had denied the appeal of its
11 application denial. *Id.* at ¶¶ 33, 185.

12 **C. Procedural Background**

13 In January 2021, Plaintiff Michael Pardi filed this lawsuit asserting violations of Sections
14 10(b) and 20(a) of the Securities Exchange Act and Rule 10b-5. *See* Dkt. No. 1 at ¶ 1. In April
15 2021, the Court appointed Fiore as Lead Plaintiff and Block & Leviton LLP as Lead Counsel.
16 Dkt. No. 65. Fiore seeks to represent “a class consisting of all purchasers of the common stock of
17 Tricida” from June 28, 2018 through February 25, 2021. SAC at ¶¶ 3, 201.

18 **II. LEGAL STANDARD**

19 **A. Rule 12(b)(6) Standard**

20 Federal Rule of Civil Procedure 8(a) requires that a complaint contain “a short and plain
21 statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). A
22 defendant may move to dismiss a complaint for failing to state a claim upon which relief can be
23 granted under Federal Rule of Civil Procedure 12(b)(6). “Dismissal under Rule 12(b)(6) is
24 appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support
25 a cognizable legal theory.” *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th
26 Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead “enough facts to state a
27 claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).
28 A claim is facially plausible when a plaintiff pleads “factual content that allows the court to draw

1 the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*,
2 556 U.S. 662, 678 (2009).

3 In reviewing the plausibility of a complaint, courts “accept factual allegations in the
4 complaint as true and construe the pleadings in the light most favorable to the nonmoving party.”
5 *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). However,
6 courts do not “accept as true allegations that are merely conclusory, unwarranted deductions of
7 fact, or unreasonable inferences.” *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir.
8 2008).

9 **B. Heightened Pleading Standard**

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

22 At the pleading stage, a complaint alleging claims under Section 10(b) and Rule 10b–5
23 must not only meet the requirements of Federal Rule of Civil Procedure 8, but also satisfy the
24 heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the Private
25 Securities Litigation Reform Act (“PSLRA”). *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869,
26 876 (9th Cir. 2012). Under Rule 9(b), claims alleging fraud are subject to a heightened pleading
27 requirement, which requires that a party “state with particularity the circumstances constituting
28 fraud or mistake.” Fed. R. Civ. P. 9(b). Additionally, all private securities fraud complaints are

1 subject to the “more exacting pleading requirements” of the PSLRA, which require that the
2 complaint plead with particularity both falsity and scienter. *Zucco Partners, LLC v. Digimarc*
3 *Corp.*, 552 F.3d 981, 990 (9th Cir. 2009).

4 **III. REQUEST FOR JUDICIAL NOTICE**

5 Klaerner asks the Court to take judicial notice of 30 exhibits. *See* Dkt. No. 129 (request
6 for judicial notice of 28 exhibits); Dkt. No. 136 (supplemental request for judicial notice of 2
7 exhibits). He argues that the exhibits are appropriately subject to the Court’s consideration under
8 the doctrines of judicial notice and incorporation by reference. Fiore filed no objection to either of
9 Klaerner’s requests for judicial notice.

10 **A. Legal Standard**

11 “Generally, district courts may not consider material outside the pleadings when assessing
12 the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure.” *In re*
13 *Eventbrite, Inc. Sec. Litig.*, No. 18-CV-02019-EJD, 2020 WL 2042078, at *7 (N.D. Cal. Apr. 28,
14 2020) (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001); *Khoja v. Orexigen*
15 *Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018)); *see also* Fed. R. Civ. P. 12(d). “This rule
16 does not apply to the incorporation by reference doctrine or judicial notice under Federal Rule of
17 Evidence 201.” *Eventbrite*, 2020 WL 2042078, at *7 (citing *Khoja*, 899 F.3d at 998).

18 A court may take judicial notice of an “adjudicative fact” pursuant to the Federal Rules of
19 Evidence, if that fact is one “that is not subject to reasonable dispute because it: (1) is generally
20 known within the trial court’s territorial jurisdiction; or (2) can be accurately and readily
21 determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b).
22 Thus, under Rule 201, courts may “take judicial notice of matters of public record, but not of facts
23 that may be subject to reasonable dispute.” *United States v. Corinthian Colls.*, 655 F.3d 984, 999
24 (9th Cir. 2011) (internal quotation marks and citation omitted).

25 In the Ninth Circuit, incorporation by reference is a doctrine that “treats certain documents
26 as though they are part of the complaint itself.” *Khoja*, 899 F.3d at 1002. A document may be
27 incorporated by reference into a complaint “if the plaintiff refers extensively to the document or
28 the document forms the basis of the plaintiff’s claim.” *United States v. Ritchie*, 342 F.3d 903, 908

1 (9th Cir. 2003). “Once a document is deemed incorporated by reference, the entire document is
2 assumed to be true for purposes of a motion to dismiss, and both parties—and the Court—are free
3 to refer to any of its contents.” *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1058 n.10 (9th Cir.
4 2014) (internal quotation marks and citation omitted).

5 **B. Analysis**

6 Exhibits 1-7 are public documents filed with the SEC. Exhibit 17 is a public decisional
7 memo from the Office of Drug Evaluation, which Klaerner offers to provide publicly available
8 information about a previous drug development program he led. Exhibit 22 is an FDA Advisory
9 Committee Calendar document publicly posted by the FDA. Exhibits 23–26 are documents
10 publicly posted by the National Institutes of Health. The Court previously granted judicial notice
11 as to Exhibits 1–6 and 22–26 without taking notice of the truth of any of the facts asserted. *See*
12 *Order* at *3. The “accuracy” of all these public documents “is not reasonably subject to dispute.”
13 *Wochos v. Tesla, Inc.*, No. 17-CV-05828-CRB, 2018 WL 4076437, at *1 (N.D. Cal. Aug. 27,
14 2018); *see Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006) (noting that SEC filings
15 are subject to judicial notice); *In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, No. 16-MD-
16 02752-LHK, 2017 WL 3727318, at *10 (N.D. Cal. Aug. 30, 2017) (“[B]oth SEC filings and
17 documents on government websites are proper subjects of judicial notice.”). Accordingly, the
18 Court **GRANTS** Klaerner’s request for judicial notice as to Exhibits 1–7, 17, and 22–26 for the
19 purpose of considering what was disclosed to the market. In doing so, the Court does not assume
20 the truth of any of the facts asserted. *Wochos*, 2018 WL 4076437, at *2.

21 Exhibits 8–14 and 28 and Reply Exhibit 2 are communications between Tricida and the
22 FDA, including meeting agendas, meeting minutes, letters, Type A meeting requests, and Type C
23 written responses. All of these exhibits except for Exhibit 13 are cited in the SAC and serve as the
24 basis for Fiore’s new allegations of falsity and scienter. Exhibits 15–16 are transcripts of earnings
25 calls cited in the SAC, which the Court found to be properly subject to judicial notice in its prior
26 order. *See Order* at *4. Reply Exhibit 1 is a transcript from an earnings call that is not cited in the
27 SAC. Exhibits 8–12, 14–16, and 28, as well as Reply Exhibit 2, are incorporated by reference
28 because the SAC explicitly and repeatedly refers to excerpts of these exhibits to support its claims.

1 See *Khoja*, 899 F.3d at 998 (“a defendant may seek to incorporate a document into the complaint
2 ‘if the plaintiff refers extensively to the document or the document forms the basis of the
3 plaintiff’s claim.’”) (quoting *Ritchie*, 342 F.3d at 907); see, e.g., *Mulquin v. Nektar Therapeutics*,
4 510 F. Supp. 3d 854, 863 (N.D. Cal. 2020) (“The Court will consider the investor presentation
5 transcripts and investor presentation slide decks that Plaintiffs allege contain false and/or
6 misleading statements for the purpose of determining what was disclosed to the market.”).
7 Finding these documents incorporated by reference, the Court **GRANTS** the motion as to Exhibits
8 8–12, 14–16, and 28 and Reply Exhibit 2. Because Exhibit 13 and Reply Exhibit 1 are not
9 specifically referenced in the complaint or relevant to the Court’s analysis because they are offered
10 to dispute the SAC’s well-pled allegations, Klaerner’s requests as to those exhibits is **DENIED**.
11 See *In re Lyft Inc. Sec. Litig.*, 484 F. Supp. 3d 758, 764 (N.D. Cal. 2020) (denying request for
12 judicial notice where exhibits were neither specifically referenced in the operative complaint nor
13 relevant to the Court’s analysis).

14 Exhibits 18–21 are four publications from the scientific journal, *The Lancet*. The Court
15 previously took judicial notice of these publications to indicate what was in the public realm at the
16 time. See Order at *4 (citing cases). For the same reasons, the Court **GRANTS** Klaerner’s
17 request for judicial notice as to Exhibits 18–21, again without taking notice of the truth of the facts
18 asserted. Finally, Klaerner seeks judicial notice of Exhibit 27, which is a public court filing
19 related to Tricida’s bankruptcy proceedings. The Court “may take judicial notice of court filings
20 and other matters of public record,” *Reyn’s Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746
21 n.6 (9th Cir. 2006), and in light of Fiore’s lack of opposition, the Court **GRANTS** Klaerner’s
22 request as to Exhibit 27.

23 **IV. MOTION TO DISMISS**

24 Fiore alleges that Klaerner³ violated Section 10(b) of the Exchange Act and Rule 10b-5 by
25 making false or misleading statements either intentionally or recklessly, starting with the June 28,
26 2018 Registration Statement and Prospectus accompanying Tricida’s IPO and ending with

27 _____
28 ³ In light of Tricida’s dismissal from this action, the Court only assesses whether Fiore’s
allegations as to statements attributable to Klaerner plausibly state a claim for securities fraud.

1 Tricida’s February 25, 2021 press release. *See, e.g.*, SAC at ¶¶ 7, 33, 65, 185, 188. Klaerner
2 moves to dismiss on two grounds: (1) the challenged statements were not materially false or
3 misleading; and (2) Fiore fails to adequately plead facts giving rise to a strong inference of
4 scienter. *See* Mot. at 6–7.⁴

5 To plead a claim under section 10(b) and Rule 10b-5, Fiore must allege: “(1) a material
6 misrepresentation or omission by [Klaerner]; (2) scienter; (3) a connection between the
7 misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the
8 misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Macomb Cty. Emps.*
9 *Ret. Sys. v. Align Tech., Inc.*, 39 F.4th 1092, 1098 (9th Cir. 2022).

10 As a preliminary matter, without seeking leave, Klaerner attempts to revisit statements that
11 the Court already found sufficiently pled. *See, e.g.*, Mot. at 6 (asserting that the new FDA
12 documents “doom[] [Fiore’s] attack on all the challenged statements, including the one statement
13 that survived the prior motion to dismiss.”); *id.* at 27 (“But information before the Court for the
14 first time now undermines [Fiore’s] allegation, and the Court may appropriately revisit the issue in
15 light of that information.”); *see generally id.* at 11–18, 27–28. This is an impermissible de facto
16 motion for reconsideration of the Court’s previous order, which Klaerner neither acknowledges
17 nor properly briefs. The Court finds that there is no basis to revisit any of its prior rulings,
18 including the statements discussing outstanding review issues with the FDA that the Court
19 previously found to be sufficiently pled. *See* Order at *12–14, 17–18. Accordingly, the Court
20 only addresses the statements that it previously found inadequately pled, along with the new
21 purported misrepresentations and allegations of scienter raised in the operative complaint.⁵

22 **A. Material Misrepresentations or Omissions**

23 **a. Legal Standard for Falsity**

24 Klaerner challenges Fiore’s claims that his statements concerning Tricida’s Phase 3
25

26 ⁴ All references to page numbers in filings are to the ECF pagination at the top of the document.

27 ⁵ Even if considered, the Court disagrees that anything in the new FDA documents “dooms” the
28 SAC when “accept[ing] factual allegations in the [SAC] as true and constru[ing] the pleadings in
the light most favorable to [Fiore],” *Manzarek*, 519 F.3d at 1031, as the Court must at this stage of
the proceedings.

1 clinical trial for verivermer were false or misleading. *See* Mot. at 11–22. “Falsity is alleged when
2 a plaintiff points to [the] defendant’s statements that directly contradict what the defendant knew
3 at that time.” *Khoja*, 899 F.3d at 1008. “In setting forth the reasons why they contend that each
4 challenged statement is misleading, securities plaintiffs may rely either on an affirmative
5 misrepresentation theory or an omission theory.” *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1188 (9th
6 Cir. 2021) (citing 17 C.F.R. § 240.10b–5(b)). “Under Rule 10b–5, an affirmative
7 misrepresentation is an ‘untrue statement of a material fact,’ and a fraudulent omission is a failure
8 to ‘state a material fact necessary in order to make the statements made, in light of the
9 circumstances under which they are made, not misleading.’” *Id.*

10 “A statement is misleading if it would give a reasonable investor the impression of a state
11 of affairs that differs in a material way from the one that actually exists.” *Retail Wholesale &*
12 *Dep’t Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir.
13 2017) (quotations and alterations omitted). “To be misleading, a statement must be ‘capable of
14 objective verification.’” *Id.* (quoting *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598,
15 606 (9th Cir. 2014)). “For example, ‘puffing’—expressing an opinion rather than a knowingly
16 false statement of fact—is not misleading.” *Id.*; *see also In re Cornerstone Propane Partners,*
17 *L.P.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) (“Generally, such statements consist of
18 forward-looking or generalized statements of optimism that are ‘not capable of objective
19 verification,’ and ‘lack[] a standard against which a reasonable investor could expect them to be
20 pegged.’”) (citations omitted). However, even “general statements of optimism, when taken in
21 context,” may be misleading “when those statements address specific aspects of a company’s
22 operation that the speaker knows to be performing poorly.” *In re Quality Sys., Inc. Sec. Litig.*, 865
23 F.3d 1130, 1143 (9th Cir. 2017).

24 “Even if a statement is not false, it may be misleading if it omits material
25 information.” *Khoja*, 899 F.3d at 1008–09. “An omission is material when there is a substantial
26 likelihood that the disclosure of the omitted fact would have been viewed by the reasonable
27 investor as having significantly altered the total mix of information available.” *Irving Firemen’s*
28 *Relief & Ret. Fund v. Uber Tech.*, 398 F. Supp. 3d 549, 556 (N.D. Cal. 2019) (citation omitted).

1 “Omissions are actionable only where they make the actual statements misleading; it is not
2 sufficient that an investor merely would consider the omitted information significant.” *Id.*
3 (internal quotation marks and citation omitted). “For the purposes of a 10b–5 claim, a
4 misrepresentation or omission is material if there is a substantial likelihood that a reasonable
5 investor would have acted differently if the misrepresentation had not been made or the truth had
6 been disclosed.” *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th Cir.
7 2005).

8 **b. The Statements at Issue**

9 **1. Opinion Statements**

10 In the SAC, Fiore challenges a number of statements made by Klaerner which were
11 allegedly misleading as to the likelihood that Tricida would achieve accelerated approval because
12 those representations omitted concerns raised by the FDA in its ongoing dialogue with Tricida
13 throughout the review and approval process. For example, Klaerner stated that the TRCA-301
14 trial “met both its primary and secondary endpoints in a highly statistically significant manner”
15 and that TRCA-301E “met its primary and all secondary endpoints.” *See, e.g.*, SAC at ¶¶ 106,
16 114, 121, 123, 125, 136, 144, 155–56. Klaerner also expressed optimism about the submission,
17 review, and approval of the NDA. *See, e.g., id.* at ¶ 104 (“Based on feedback from the FDA, we
18 believe that the data from the TRCA-101, TRCA-301 and TRCA-301E trials will provide
19 sufficient evidence of clinical safety and efficacy to support the submission and review of an NDA
20 for TRC101 pursuant to the Accelerated Approval Program.”); *id.* at ¶ 114 (Klaerner reported on
21 an earnings call that the combined results of the TRCA-301/TRCA-301E trial “far exceeded our
22 expectations,” and “we feel good about what we’ve learned in the 301E study regarding safety and
23 efficacy, increasing our confidence for a successful VALOR-CKD trial.”); *id.* at ¶ 131 (“And
24 when you fast-forward in all the work that we’ve done, from a discovery to an early development,
25 to a late stage development, agreeing with FDA, an accelerated approval path, you -- all you
26 expect to do is to show a surrogate effect, and then you have a post-marketing commitment that
27 ultimately then, you confirm that, that surrogate is going to translate.”) (emphasis omitted); *id.* at
28 ¶ 157 (“We believe that the data from the TRCA-101, TRCA-301 and TRCA-301E clinical trials

1 will provide sufficient clinical evidence of safety and efficacy to support the approval of our NDA
2 for veverimer pursuant to the Accelerated Approval Program.”). And on May 7, 2020, Klaerner
3 stated that “[o]verall, while the FDA continues its review, we remain confident that our
4 submission meets the standard for approval through the Accelerated Approval Program.” *Id.* at
5 ¶ 158.

6 Fiore contends that the representations regarding the trial’s endpoints were false and
7 misleading because Klaerner failed to disclose that the FDA had repeatedly indicated its
8 disagreement that TRCA-301’s endpoint was substantial enough to demonstrate the trial’s clinical
9 effectiveness, and the Agency had warned Defendants that simply “winning” on the primary
10 endpoint was insufficient for accelerated approval. *Id.* at ¶¶ 122–23, 126, 137, 156. Fiore also
11 claims that the optimistic statements about the NDA were false and misleading because they failed
12 to disclose significant issues and feedback communicated by the FDA. *Id.* at ¶¶ 104–105, 157;
13 *see, e.g., id.* at ¶ 115 (the FDA had “repeatedly told Defendants that it did not agree that TRCA-
14 301/301E’s endpoint was substantial enough to demonstrate clinical efficacy.”). Finally, Fiore
15 argues that the May 7, 2020 statement was false or misleading because the FDA had told Klaerner
16 at two prior meetings that “the trial results were likely inapplicable to the U.S. population because
17 TRCA-301/301E relied on foreign data primarily from a single site in Bulgaria and because the
18 size of the treatment effect was too small to be ‘reasonably likely’ to predict clinical benefit,” and
19 that study participants largely appeared to be suffering from a different condition, Balkan Endemic
20 Nephropathy (“BEN”), not CKD. *Id.* at ¶¶ 160–61.

21 The Court finds that the statements identified by Fiore are opinions, “since they inherently
22 reflect the speaker’s assessment of and judgment about the underlying circumstances.” *Markette*
23 *v. XOMA Corp.*, No. 15-CV-03425-HSG, 2017 WL 4310759, at *4 (N.D. Cal. Sept. 28, 2017).
24 “Interpretations of clinical trial data are considered opinions,” which “are only actionable under
25 the securities laws if they are not honestly believed and lacked a reasonable basis.” *City of*
26 *Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014). In pleading the falsity of
27 opinion statements such as these, Fiore “must allege both that ‘the speaker did not hold the belief
28 she professed’ and that the belief is objectively untrue.” *City of Dearborn Heights Act 345 Police*

1 & *Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017). As the Supreme Court
2 explained in *Omnicare*, “a statement of opinion is not misleading just because external facts show
3 the opinion to be incorrect.” *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension*
4 *Fund*, 575 U.S. 175, 186 (2015). “[W]hether an omission makes an expression of opinion
5 misleading always depends on context.” *Id.* at 190. Investors take into account “the customs and
6 practices of the relevant industry,” “[s]o an omission that renders misleading a statement of
7 opinion when viewed in a vacuum may not do so once that statement is considered, as appropriate,
8 in a broader frame.” *Id.*

9 While “general statements of optimism” made against a clearly pessimistic backdrop “may
10 form a basis for a securities fraud claim,” the SAC does not sufficiently plead an actionable claim
11 on this basis. *Macomb*, 39 F.4th at 1099 (quoting *Police Ret. Sys. of St. Louis v. Intuitive Surgical,*
12 *Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014)). Fiore fails to plausibly allege that Klaerner did not
13 hold the optimistic beliefs he professed, or that these beliefs are objectively untrue. For example,
14 the FDA’s expression of its view that the results likely would not be applicable to the U.S.
15 population does not show that Klaerner’s confidence in the likelihood of approval was necessarily
16 objectively false or not honestly held. *See Markette*, 2017 WL 4310759, at *5 (quoting *Dearborn*
17 *Heights*, 856 F.3d at 616); *see also Omnicare*, 575 U.S. at 186 (characterizing the inquiry as
18 focused on whether the speaker’s opinion was “honestly held”). Thus, Fiore fails to plausibly
19 plead any basis for concluding that Klaerner’s opinion statements characterizing the trial results
20 and expressing optimism about FDA approval directly contradicted what he knew at the time and
21 were therefore false. *Khoja*, 899 F.3d at 1008.

22 Moreover, the Court agrees with Klaerner that there is no general requirement under the
23 securities laws for a company to engage in a rolling, communication-by-communication disclosure
24 of every detail arising from the back-and-forth dialogue with the FDA throughout its complex
25 review and approval process, or to adopt the FDA’s position as correct and share it with the public
26 when discussing its product. *See Mot.* at 19–22; *see also Brody v. Transitional Hosps. Corp.*, 280
27 F.3d 997, 1006 (9th Cir. 2002) (rejecting argument that there is a “freestanding completeness
28 requirement” under the securities laws). The overarching flaw with Fiore’s argument is his

1 assumption that because the FDA communicated its views to Klaerner throughout the course of
2 the extensive review and approval process, it follows that his statements failing to
3 contemporaneously convey the FDA’s views and accept them as true were materially misleading.
4 But that theory does not plausibly plead falsity. Fiore does not cite, and the Court has not found,
5 controlling Ninth Circuit authority suggesting that a company’s failure to disclose the FDA’s
6 positions in real time establishes falsity under the PSLRA. To the contrary, the FDA approval
7 process necessarily involves a dialogue between companies like Tricida and the Agency, and the
8 company has “no legal obligation to loop the public into each detail of every communication with
9 the FDA.” *In re Dynavax Sec. Litig.*, No. 4:16-CV-06690-YGR, 2018 WL 2554472, at *7 (N.D.
10 Cal. June 4, 2018) (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)).

11 Post-*Omnicare*, other courts of appeal have rejected theories imposing such a disclosure
12 requirement in securities fraud cases involving the FDA approval process. For example, in
13 *Tongue v. Sanofi*, the plaintiffs “[were] sophisticated investors, no doubt aware that projections
14 provided by issuers are synthesized from a wide variety of information, and that some underlying
15 facts may be in tension with the ultimate projection set forth by the issuer.” 816 F.3d 199, 211 (2d
16 Cir. 2016). The Second Circuit explained that these investors, “well accustomed to the ‘customs
17 and practices of the relevant industry,’” would fully expect that the defendants and the FDA were
18 engaged in a continuous dialogue “about the sufficiency of various aspects of the clinical trials and
19 that inherent in the nature of [such] a dialogue are differing views.” *Id.* Thus, the Second Circuit
20 concluded the defendants’ statements about the effectiveness of their drug “[could not] be
21 misleading merely because the FDA disagreed with the conclusion—so long as Defendants
22 conducted a ‘meaningful’ inquiry and in fact held that view, the statements did not mislead in a
23 manner that [was] actionable.” *Id.* at 214.

24 Similarly, in *In re Amarin Corp. PLC Sec. Litig.*, the Third Circuit concluded that the
25 plaintiffs failed to plead falsity because the company’s announcement of the topline results of its
26 Phase 3 trial “did not lack a reasonable basis.” No. 21-2071, 2022 WL 2128560, at *3 (3d Cir.
27 June 14, 2022). The court also found the plaintiffs’ theory of omission liability unpersuasive
28 given that the company’s contemporaneous disclosures warned of the exact risk that the plaintiffs

1 argued was improperly omitted. *Id.* And the court rejected the theory that the company had a duty
2 to disclose additional information when announcing its topline results because the company had
3 put information about the trial’s placebo arm “in play.” *Id.* The court recognized that “[t]here is
4 no affirmative duty to disclose all material information, but such a duty may arise when a
5 company chooses ‘to speak about a material subject to investors.’” *Id.* (citations omitted). The
6 Third Circuit explained, however, that while the disclosures at issue described the trial results with
7 reference to the placebo group, “they did not make any affirmative characterizations regarding the
8 effectiveness” of the placebo. *Id.* (citation omitted). Accordingly, “[the company’s] disclosure of
9 the topline results did not put into play either the full trial data or additional information”
10 regarding the placebo. *Id.*

11 Here, as in *Amarin*, the SAC details several instances in which Klaerner *did* disclose
12 information that Fiore argues was improperly omitted. *See* Mot. at 20–21. For example, in both
13 the 2018 Prospectus and the Prospectus accompanying the April 2019 offering, Tricida disclosed
14 that its application relied on “an unvalidated surrogate endpoint,” and explained that “the FDA
15 may not agree that we have achieved the primary endpoint in our pivotal Phase 3 clinical trial,
16 TRCA-301, to the magnitude or to the degree of statistical significance required by the FDA.”
17 SAC at ¶ 108 (emphasis omitted).

18 Fiore claims that these disclosures were “too generalized” to actually disclaim the specific
19 risks identified by the FDA. *See, e.g.,* SAC at ¶¶ 103, 108. The Court disagrees. “Reasonable
20 investors understand that dialogue with the FDA is an integral part of the drug approval process,
21 and no sophisticated investor familiar with standard FDA practice would expect that every view []
22 taken by Defendants was shared by the FDA.” *Sanofi*, 816 F.3d at 214. Fiore does not plausibly
23 plead that the statements at issue here “lack[ed] a reasonable basis,” *Amarin*, 2022 WL 2128560,
24 at *3, or that Defendants failed to conduct a “meaningful” inquiry and did not in fact hold the
25 views expressed in their statements, *Sanofi*, 816 F.3d at 214. “In the absence of plausible
26 allegations showing a conflict between Defendants’ statements and the FDA feedback,” *Sanofi*,
27 816 F.3d at 214, the SAC fails to sufficiently plead that omitting information regarding the
28 identified topics “affirmatively led [investors like Fiore] in a wrong direction (rather than merely

1 omitted to discuss certain matters).” *In re OmniVision Tech., Inc. Sec. Litig.*, 937 F. Supp. 2d
2 1090, 1101 (N.D. Cal. 2013) (emphasis omitted); *see also Markette*, 2017 WL 4310759, at *7.
3 And as in *Sanofi*, “fatal to [Fiore’s] case is the absence of any serious conflict between the FDA’s
4 interim, albeit repeated, concerns about [the adequacy of the Phase 3 trial] and Defendants’
5 optimism about FDA approval.” *Sanofi*, 816 F.3d at 212. Ultimately, the fact that Tricida had a
6 years-long iterative dialogue with the FDA, during which the agency unsurprisingly raised issues
7 as to which there were differences of opinion, does not plausibly allege that the opinion statements
8 by Klaerner identified in the SAC were false or misleading by omission under the demanding
9 standard set by the PSLRA and cases interpreting it.

10 Nor does the Ninth Circuit’s decision in *Schueneman* support a different result. While that
11 case formally addressed scienter rather than falsity, the *Schueneman* court found that the plaintiff
12 adequately pled scienter where the company reported “favorable results on everything” in animal
13 studies and conveyed optimism about FDA approval while allegedly concealing strong indications
14 that the drug caused cancer in rats. *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 702, 708
15 (9th Cir. 2016) (emphasis omitted). The company “did more than just express its confidence in
16 [the drug’s] future”—it affirmatively represented that “all the animal studies that [had] been
17 completed” supported the company’s case for approval. *Id.* at 708. At the time these statements
18 were made, the company “knew the animal studies were *the* sticking point with the FDA.” *Id.*
19 (emphasis in original). The Ninth Circuit reasoned that these statements were representations
20 about the drug that the company could not support at the time they were made. As the court
21 explained,

[the company] was free to express confidence in FDA approval. It
might have represented that [the company] was working through
some requests from the FDA and was confident the data would
vindicate [the drug]. But what it could not do was express confidence
by claiming that all of the data was running in [the drug’s] favor. It
was not.

25 *Id.*; *see also Corban*, 868 F.3d at 40 (“That the defendants neglected to mention specific factors
26 (many of them intricate and technical) contributing to the FDA’s position, while nonetheless
27 faithfully representing that position (indeed quoting directly from FDA sources at times), strikes
28 us as more consistent with negligence than reckless or intentional concealment.”).

1 on the May 7, 2020 earnings call that an upcoming Advisory Committee meeting, also known as
2 “AdCom,” was canceled “due in part to the logistical challenges posed by COVID-19” was false
3 or misleading. *See* Order at *12; *see also* SAC at ¶¶ 25–26, 158–59. The Court explained that the
4 previous complaint contained no facts “supporting the suggestion that the FDA told Defendants it
5 canceled the AdCom meeting because of problems with the NDA.” Order at *12.

6 In the SAC, Fiore now directly alleges that “[t]he FDA did not cite logistical challenges
7 stemming from COVID-19 as even a contributing factor in canceling the AdCom meeting in its
8 communications with Tricida.” SAC at ¶ 159. Instead, citing the documents produced by the
9 FDA, he alleges that the AdCom meeting was canceled because of “the FDA’s concerns that there
10 were too many problems with the NDA to even warrant convening an Advisory Committee.” *Id.*
11 Specifically, Fiore cites documents detailing communications from the FDA to Tricida beginning
12 in January 2020 in which the Agency identified “significant issues” with the trial and their impact
13 on a potential AdCom meeting, and contends that these issues ultimately led to cancellation of that
14 meeting. *See, e.g., id.* at ¶¶ 72–77, 159. The SAC further alleges that Klaerner knew about these
15 issues because he attended meetings in January and May 2020 at which the FDA discussed them.
16 *Id.* at ¶¶ 163–65.

17 Klaerner argues that “[s]aying that the need for a meeting is ‘no longer obvious’ is a far cry
18 from saying that the meeting will not take place and even further removed from a statement that
19 the drug will not be approved,” and contends that the minutes of the mid-cycle meeting cited by
20 Fiore show that the AdCom meeting was still on the table. Mot. at 17. However, construing the
21 pleadings in the light most favorable to Fiore, the Court concludes that he has sufficiently alleged
22 that Klaerner’s May 7 statement was false or misleading given that the FDA never cited COVID-
23 19 logistics as the reason for the cancellation. *Cf. Sanofi*, 816 F.3d at 214 (finding the plaintiffs’
24 claims failed in the absence of plausible allegations showing a “direct conflict” between the
25 defendants’ statements and the FDA feedback). Fiore plausibly pleads that Klaerner misled
26 investors as to the true reasons, even “in part,” for why the AdCom meeting was canceled,
27 “affirmatively creat[ing] an impression of a state of affairs that differ[ed] in a material way from
28 the one that actually exist[ed].” *Brody*, 280 F.3d at 1006 (citation omitted). Thus, “there is a

1 substantial likelihood that the disclosure of the [allegedly] omitted fact”—namely, that the FDA
2 referenced its concerns with the NDA, and never referenced the COVID-19 pandemic, in
3 canceling the AdCom meeting—“would have been viewed by the reasonable investor as having
4 significantly altered the total mix of information available.” *Irving*, 398 F. Supp. 3d at 556.

5 Therefore, the Court denies Klaerner’s motion to dismiss on this ground.

6 **(b) Other Alleged Omissions**

7 Similarly, the SAC identifies other factual representations that Fiore contends were
8 misleading with respect to Tricida’s likelihood of achieving FDA approval. For example,
9 Klaerner stated that “[o]ne hundred ninety-six of the 208 subjects who completed the 12-week
10 treatment period in our pivotal Phase 3 trial, TRCA-301, agreed and were eligible to continue in
11 our extension trial, TRCA-301E, which we completed in March 2019.” SAC at ¶ 125. Fiore
12 argues that this statement was misleading because very few patients in the United States continued
13 on and completed the full 52-week trial, and the FDA had warned Tricida not to rely on a patient
14 population outside of the United States. *Id.* at ¶¶ 127, 138.

15 The Court finds that the SAC does not adequately plead that these omissions identified by
16 Fiore made the affirmative factual statements false or misleading. Importantly, Tricida did
17 disclose to investors that the majority of the trial participants were outside of the United States and
18 explained how that fact could affect FDA approval. *Id.* at ¶ 103 (“We conducted the TRCA-301
19 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States
20 and may, in the future, conduct clinical trials of our product candidates outside the United States.
21 The FDA may not accept such foreign clinical data”) (emphasis omitted). Viewing the
22 identified statements in context, *Omnicare*, 575 U.S. at 190, Fiore does not explain how
23 Klaerner’s omissions affected the “total mix” of information available to a reasonable investor,
24 *Irving*, 398 F. Supp. 3d at 556, or why the disclosures Klaerner did make gave reasonable
25 investors a misleading impression of the actual state of affairs, *Berson v. Applied Signal Tech.,*
26 *Inc.*, 527 F.3d 982, 987 (9th Cir. 2008), given that there is no “freestanding completeness
27 requirement” under the securities laws, *Brody*, 280 F.3d at 1006.

28 Accordingly, the Court grants Klaerner’s motion as to these factual statements.

B. Scierter

a. Legal Standard for Scierter

Klaerner also contends that Fiore’s allegations are insufficient to support a “strong inference” of scierter. Mot. at 22–30. Under the PSLRA, whenever intent is an element of a claim, the complaint must “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). “The PSLRA’s strong inference requirement has teeth,” and “is an exacting pleading obligation” that “present[s] no small hurdle for the securities fraud plaintiff.” *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020) (citing *Zucco Partners*, 552 F.3d at 990). “A complaint will only survive only if a reasonable person would deem the inference of scierter cogent and at least as compelling as any plausible opposing inference one could draw from the facts alleged.” *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 310 (2007). “In this circuit, the required state of mind is a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness.” *E. Ohman J:or Fonder AB v. NVIDIA Corp.*, 81 F.4th 918, 937 (9th Cir. 2023) (citation omitted). “[D]eliberate recklessness’ is more than ‘mere recklessness or a motive to commit fraud.’” *Nguyen*, 962 F.3d at 414 (citations omitted) (emphasis in original). “It is instead ‘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.’” *Id.* (citation omitted) (emphasis in original).

As in its prior order, the Court addresses scierter as to the statements it previously found were adequately alleged to have been material misrepresentations and omissions, as well as the one new misrepresentation it finds to be sufficiently pled.⁶

///

⁶ Fiore sets forth no new arguments regarding scierter as to the theories rejected by the Court in its last order. *See* Order at *14–15 (discussing Fiore’s allegations that Defendants were motivated to mislead the market because they otherwise would have run out of money, and that Klaerner made suspicious stock sales, as well as Fiore’s generalized claims under the “core operations” theory). Accordingly, the Court does not revisit its prior rulings on these bases, other than to again consider whether the totality of the current allegations adequately plead scierter when viewed holistically.

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

The Court previously found that Fiore did not plausibly allege scienter with respect to the statements that Tricida conducted its Phase 3 trials in “Europe.” *See* Order at *15–16. The Court reasoned that “there [were] no allegations supporting the required ‘strong inference’ that Defendants intended to mislead or were deliberately reckless in characterizing the trial location as ‘Europe’ generally.” *Id.* at *16. “Put another way, as alleged, nothing about the claimed underlying representativeness problems meets this high ‘so obvious’ standard, such that Defendants would have known that their literally true use of ‘Europe’ would be misleading.” *Id.*

Fiore now contends that the new FDA documents supply what was missing in the prior complaint. Specifically, the SAC provides additional allegations derived from the FDA documents indicating that Klaerner attended meetings at which the FDA specifically cautioned Tricida against relying on patient data from Eastern European countries. *See, e.g.*, SAC at ¶¶ 57–58, 69, 76, 98, 140, 188; *see also* Opp. at 12. Klaerner argues that these allegations are no different than those previously rejected by the Court, in that they amount to the assertion that Defendants knew “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.” Order at *16.

The Court agrees with Klaerner and finds that Fiore’s allegations again fail to raise a “strong inference” of scienter. As the Court found in its prior order, there are no allegations in the SAC plausibly pleading that the literally true characterization of the trial location as “Europe” generally amounted to “an extreme departure from the standards of ordinary care, and which present[ed] a danger of misleading buyers or sellers” that was either known to Klaerner or so obvious that Klaerner must have been aware of it. *Zucco Partners*, 552 F.3d at 991; *see also* Order at *16.

Klaerner also convincingly argues that the fact that Tricida specifically directed the market to information disclosing the location of the trials cuts against any inference of scienter. *See* Mot. at 26. For example, Tricida conveyed this information through articles published by *The Lancet*, and Klaerner later highlighted the *Lancet* publication on an earnings call. *See* Dkt. No. 128-17

1 (Ex. 15) at 7 (“I would like to highlight the publication of our Phase III TRC101 clinical trial
2 results in *The Lancet*, a leading independent general medical journal.”). Such actions further
3 negate any inference of scienter. *See, e.g., Rigel*, 697 F.3d at 885 (“if the individual defendants
4 were acting based on their belief that they had a financial motive to conceal the ‘true’ results of the
5 clinical trial, they would not have voluntarily publicly disclosed all the data and the statistical
6 methodology.”); *Nguyen*, 962 F.3d at 417 (finding the plaintiff was “hard-pressed to build a fraud
7 case” around a study when she admitted in her complaint that the defendant “acknowledged and
8 discussed this very study on an investor conference call”).

9 Accordingly, the Court again finds that Fiore fails to sufficiently allege scienter as to these
10 statements.

11 **c. Risk Disclosures About the Location of the Phase 3 TRCA-
12 301/TRCA-301E Trial Sites**

13 Similarly, in its prior order, the Court concluded that Fiore did not plausibly allege scienter
14 as to the risk disclosures regarding Tricida’s use of foreign clinical data. *See Order at *15*. The
15 Court explained that the scienter analysis for these disclosures tracked that for the “Europe”
16 statements “because both flow from the same contention that Defendants knew the FDA would be
17 less inclined to accept their NDA because it relied on clinical trial data taken from Eastern
18 European patients unlikely to be representative of the U.S. patient population and U.S. medical
19 care.” *Id.* The only difference between the risk disclosures and the “Europe” characterization was
20 that Fiore alleged Defendants misrepresented the risk that the FDA would deny Tricida’s NDA
21 because of deficiencies in the clinical trial data. *Id.*

22 For the same reasons outlined above, the Court again finds that there are no allegations in
23 the SAC plausibly pleading that the risk disclosures meet the high “so obvious” standard such that
24 Klaerner would have to know that Tricida’s disclosures would be misleading. *See Order at *16*.
25 Namely, Fiore’s allegations based on Klaerner’s participation in the FDA approval process are
26 insufficient to substantiate a plausible “strong inference” that Klaerner intended to mislead or was
27 deliberately reckless in disclosing a generalized risk that the FDA *could* reject foreign clinical data
28 submitted in the NDA. *See Order at *16*. And as discussed above, the SAC acknowledges

1 Klaerner’s statement communicating the risks associated with Tricida’s reliance on foreign
2 clinical data. *See, e.g.*, SAC at ¶ 103 (“We conducted the TRCA-301 trial and are conducting the
3 TRCA-301E trial with majority enrollment outside the United States and may, in the future,
4 conduct clinical trials of our product candidates outside the United States. The FDA may not
5 accept such foreign clinical data”) (emphasis omitted).

6 Therefore, the Court again concludes that Fiore fails to adequately plead scienter as to the
7 risk disclosures.

8 **d. Statements About the Multicenter Nature of the Phase 3 TRCA-**
9 **301/TRCA-301E Trial⁷**

10 The Court also previously found that Fiore’s scienter allegations with respect to statements
11 describing Tricida’s Phase 3 trial as “multicenter” were insufficient to survive dismissal. *See*
12 Order at *16–17. The Court found that, “as with the previous statements, there [were] no
13 allegations supporting the ‘strong inference’ that Defendants intended to mislead or were
14 deliberately reckless in labeling the trial as ‘multicenter,’ especially given that there does not
15 appear to be any dispute that the trials were in fact ‘conducted at 47 sites’ as alleged in the
16 complaint.” *Id.* at *17 (citing *Zucco Partners*, 552 F.3d at 991).

17 Here, there still appears to be no dispute that the trials were “conducted at 47 sites.” *See*,
18 *e.g.*, SAC at ¶ 95 (“most trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe”
19 and “one Bulgarian site in particular was entirely responsible for the long term treatment effects
20 seen in the study”). The SAC otherwise contains no particularized allegations in support of its
21 claim that Defendants “knew or recklessly disregarded the truth” in characterizing the trial as
22 “multicenter,” *id.*, and Fiore’s assertions about Klaerner’s participation in the FDA approval
23 process do not tip the scales. Thus, the allegations in the SAC do not alter the Court’s previous
24 finding that it “cannot conclude that the inference that [Klaerner] acted with deliberate
25 recklessness or intent to mislead investors is ‘at least as compelling’ as the inference that [he] did
26 not.” Order at *17 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 50 (2011)).

27 _____
28 ⁷ In his opposition brief, Fiore now concedes that some of these “multicenter” statements did not
mislead investors. *See Opp.* at 15 n.5.

1 As a result, the Court again finds that Fiore fails to sufficiently allege scienter as to these
2 statements and grants Klaerner’s motion on this basis.

3 **e. Statement Related to the Cancellation of the Advisory**
4 **Committee Meeting**

5 Finally, the Court concludes that Fiore has plausibly alleged scienter with respect to
6 Klaerner’s statement that the AdCom meeting was canceled in part due to “the logistical
7 challenges posed by COVID-19.” Fiore pleads that on January 24, 2020, well before the start of
8 the COVID-19 pandemic in the United States, the FDA “expressly informed Defendants” that,
9 given “significant issues” it identified with the TRCA-301 and TRCA-301E trials, it was “no
10 longer obvious” to the Agency that the AdCom meeting was needed. SAC at ¶ 159; *see also id.* at
11 ¶¶ 72–74 (detailing two of the “significant issues” identified by the FDA on January 24, 2020, and
12 alleging that “[a]s a result of these ‘significant issues[,]’ the FDA told Tricida that an advisory-
13 committee meeting was no longer needed”). The FDA allegedly reiterated these issues on several
14 occasions. For example, on April 17, 2020, the FDA sent Tricida a package ahead of the
15 upcoming late-cycle meeting, the purpose of which was to discuss any outstanding review issues,
16 and stated that it “remain[ed] concerned about the magnitude and durability of the treatment
17 effect.” *Id.* at ¶ 75. The same package reminded Tricida that, at an earlier meeting, the FDA had
18 “indicated that it was not clear that the results of TRCA-301/301E were applicable to the U.S.
19 population and practice of medicine,” and that Tricida’s decision to enroll participants at sites in
20 Eastern Europe was “particularly problematic” due to the prevalence of patients affected by BEN
21 in that region. *Id.* at ¶¶ 76–77; *see, e.g., id.* at ¶ 76 (“We are concerned that the response to
22 treatment in patients with BEN (i.e., the size of the treatment effect on blood bicarbonate) may not
23 be representative of the size of the treatment effect in patients in the U.S. with metabolic acidosis
24 associated with CKD who do not have BEN.”) (emphasis omitted). Then, at the late-cycle
25 meeting on May 1, 2020, the FDA repeated the substantive review issues it had laid out in the
26 April 17, 2020 package, and told Tricida once again that it did not believe an AdCom meeting was
27 needed. *Id.* at ¶ 77.

28 Six days later, after stating that the AdCom meeting would be canceled in part due to

1 COVID-19 “logistical issues,” Klaerner shared only one of the outstanding review issues raised by
2 the FDA at the late-cycle meeting—“the magnitude and durability of the treatment effect on the
3 surrogate markup.” *Id.* at ¶ 158. Klaerner then concluded that “[o]verall, while the FDA
4 continues its review, we remain confident that our submission meets the standard for approval
5 through the Accelerated Approval Program.” *Id.*

6 The Court finds that Fiore plausibly pleads that Klaerner intentionally or recklessly
7 misrepresented the true reasons for the cancellation of the AdCom meeting. The SAC alleges that
8 Klaerner was party to extensive communications with the FDA about its concerns and their
9 potential impact on the AdCom meeting, and that the FDA did not at any point cite COVID-19
10 logistical issues as the reason for canceling the meeting. SAC at ¶¶ 159, 162. And the SAC
11 pleads that Klaerner selectively raised only one of the FDA’s concerns in the May 7, 2020 call, but
12 not others, thereby misleading the market by omission. *Id.* at ¶ 158. Under the circumstances, it
13 was obviously relevant whether the meeting was canceled for “logistical reasons” or substantive
14 ones, and it was also relevant what the full substantive reasons were once Klaerner chose to
15 highlight some of them. *See Schueneman*, 840 F.3d at 709. It is plausible that a seasoned
16 pharmaceutical executive like Klaerner would be aware that the FDA’s reasons for canceling a
17 critical meeting would be highly significant to investors. These allegations thus plausibly plead
18 “an extreme departure from the standards of ordinary care, and which presents a danger of
19 misleading buyers or sellers” that was either known to Klaerner or so obvious that he must have
20 been aware of it. *Zucco Partners*, 552 F.3d at 991.

21 Therefore, the Court denies Klaerner’s motion on this ground.

22 **V. CONCLUSION**

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

- 24 1. The Court **DENIES** Klaerner’s motion to dismiss as to Fiore’s claim based on
25 canceling the Advisory Committee meeting in part due to COVID-19.⁸

26 _____
27 ⁸ As with its prior order, because the Court finds that at least one Section 10(b) claim has been
28 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,
the Court also **DENIES** the motion to dismiss that claim.

1 2. The Court **GRANTS** Klaerner’s motion to dismiss as to Fiore’s other claims
2 **WITHOUT LEAVE TO AMEND** due to the failure to adequately plead falsity
3 and scienter. *See Zucco Partners*, 552 F.3d at 1007 (“where the plaintiff has
4 previously been granted leave to amend and has subsequently failed to add the
5 requisite particularity to its claims, “[t]he district court’s discretion to deny leave to
6 amend is particularly broad.”) (citation omitted).

7 In sum, at this stage of the proceedings, the Court has found that two categories of
8 statements about the May 1, 2020 late-cycle meeting are actionable under the PSLRA and may
9 proceed: (1) the statements discussing outstanding review issues with the FDA that the Court
10 found in its prior order found to be sufficiently pled, *see* Order at *12–14, 17–18; and (2) the
11 statement that the AdCom meeting was canceled “due in part to the logistical challenges posed by
12 COVID-19” that the Court now finds is sufficiently pled.

13 The Court further **SETS** a telephonic case management conference for March 26, 2024 at
14 2:00 p.m. The Court further **DIRECTS** the parties to submit a joint case management statement
15 by March 19, 2024. All counsel shall use the following dial-in information to access the call:

16 Dial-in: 888-808-6929
17 Passcode: 6064255

18 For call clarity, parties shall **NOT** use speaker phone or earpieces for these calls, and where
19 at all possible, parties shall use landlines. All attorneys appearing for a telephonic case
20 management conference are required to dial in at least 15 minutes before the hearing to check in
21 with the CRD.

22 **IT IS SO ORDERED.**

23 Dated: 3/11/2024

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28


HAYWOOD S. GILLIAM, JR.
United States District Judge