UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KEVIN KENDALL, individually and on behalf of all others similarly situated,

Plaintiff,

v.

ODONATE THERAPEUTICS, INC., KEVIN C. TANG, MICHAEL HEARNE, and JOHN G. LEMKEY,

Defendants.

Case No.: 3:20-cv-01828-H-LL

ORDER DENYING DEFENDANTS' MOTION TO DISMISS

[Doc. No. 25.]

On April 13, 2021, Plaintiff Kevin Kendall filed his second amended complaint ("SAC") alleging Defendants Odonate Therapeutics, Inc. ("Odonate"), Kevin C. Tang, Michael Hearne, and John G. Lemkey ("Defendants") had violated federal securities laws. (Doc. No. 24, SAC.) On May 13, 2021, Defendants filed a motion to dismiss Plaintiff's SAC for failure to state a claim. (Doc. No. 25.) Plaintiff filed his opposition on June 26, 2021. (Doc. No. 30.) Defendants filed their reply on July 26, 2021. (Doc. No. 32.) On August 4, 2021, the Court took the matter under submission. (Doc. No. 35.) For the reasons that follow, the Court denies Defendants' motion to dismiss.

Background

The following allegations are taken from Plaintiff's SAC. This is a securities class action against Odonate Therapeutics, Inc. and three of its officers under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. (SAC ¶¶ 225–41.) The case is brought on behalf all persons and entities who purchased or otherwise acquired the stock of Odonate between December 7, 2017 and March 19, 2021 (the "Class Period"). (Id. ¶ 217.)

Founded in 2013, Odonate is a pharmaceutical company formerly focused on the development of therapeutics for the treatment of cancer. (Id. ¶¶ 2, 33.) Defendant Tang is Odonate's Chairman and Chief Executive Officer. (Id. ¶ 19.) Defendant Hearne has served as Odonate's Chief Financial Officer since November 2018. (Id. ¶ 20.) Defendant Lemkey served as Odonate's Chief Financial Officer until November 2018, when he was promoted to Chief Operating Officer. (Id. ¶ 21.) Plaintiff alleges Odonate's primary focus was developing its sole drug candidate, tesetaxel – an orally administered chemotherapy agent – to treat patients with locally advanced or metastatic breast cancer ("MBC"). (Id. ¶¶ 2, 34–35.) Odonate previously completed Phase 1 and Phase 2 clinical trials of tesetaxel in patients with MBC. (Id. ¶ 35.) In December 2017, Odonate announced it was initiating CONTESSA, a multinational, multicenter, randomized Phase 3 study of tesetaxel in combination with capecitabine (an existing approved cancer drug) in approximately 600 patients with locally advanced or MBC. (Id. ¶¶ 36, 57–59.) On December 8, 2017, Odonate filed for an Initial Public Offering ("IPO") with the Securities and Exchange Commission ("SEC") for 6,250,000 shares of common stock at a price of $24.00 per share. (Id. ¶¶ 37, 188.) Plaintiff alleges the aggregate gross proceeds from the IPO were $160.6 million, and net proceeds were $147.3 million. (Id.) Plaintiff alleges that Odonate's value proposition to investors was that tesetaxel, in combination with capecitabine or as a monotherapy, was efficacious, convenient, and safe relative to existing treatment options. (Id. ¶ 36.) Odonate's Registration Statement, filed as part of its IPO, stated: "CONTESSA is designed to evaluate whether tesetaxel plus a reduced dose of capecitabine results in improved

[progression-free survival ("PFS")] with manageable toxicity and favorable quality-of-life compared to the approved dose of capecitabine alone." (Id. ¶ 59.) The Registration Statement explained that Odonate expected to begin enrolling patients in CONTESSA in the fourth quarter of 2017, and to report top-line results from the study in 2020. (Id.)

Plaintiff alleges that significant safety concerns regarding tesetaxel arose during CONTESSA, which Defendants were aware of but did not disclose to investors or the public. (Id. ¶¶ 5, 40.) Plaintiff's allegations regarding the issues that arose during CONTESSA rely on statements from five confidential witnesses: (1) CW1, an Associate Director, Clinical Site Relationship Management at Odonate from May 2018 to December 2018; (2) CW2, a Director of Clinical Operations at Odonate from June 2017 to September 2019; (3) CW3, an Executive Assistant at Odonate from September 2017 to April 2019; (4) CW4, an Associate Director, Site Management at Odonate from December 2017 to March 2019; and (5) CW5, an Associate Director, Clinical Site Relationship Manager (May 2018 – February 2019), Regional Medical Liaison (March 2019 – April 2019), and Regional Director, Clinical Operations (May 2019 – mid-March 2021). (Id. ¶¶ 24–29.) The first doses of tesetaxel in the CONTESSA trial were allegedly administered sometime in early 2018. (Id. ¶ 41.) By at least August 2018, and potentially as early as May 2018, Plaintiff alleges that CONTESSA trial sites were reporting to Odonate that they were experiencing a higher-than-expected rate of neutropenia (abnormally low number of neutrophils, a type of white blood cell, in the blood)[1] in patients. (Id. ¶ 42.) Plaintiff alleges trial doctors expressed concerns to Odonate about the unexpectedly high rate of neutropenia, and that many patients began withdrawing from the CONTESSA trial, either voluntarily or through removal by their doctors, due to the rates of neutropenia and other adverse events ("AEs"). (Id. ¶¶ 5, 42.) CONTESSA was not a double-blind trial, meaning that Odonate knew which patients were given which dose, and had access to the raw trial data and information throughout the trial. (Id. ¶ 43.) Plaintiff alleges Odonate's company

[1] Neutropenia, Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/21058-neutropenia.

leadership, including Defendant Tang and Defendant Lemkey, received expedited reports of patients being hospitalized for neutropenia in the first few months of the CONTESSA trial. (Id.)

In August 2018, Odonate's Chief Medical Officer Joseph O'Connell ("CMO O'Connell") and Vice President of Site Management Jill Krause ("VP Krause") allegedly held a teleconference call with the clinical site management team about the higher-than-expected neutropenia rates and related patient withdrawals. (Id. ¶ 44.) During the call, CMO O'Connell and VP Krause allegedly stated that Odonate was initiating an urgent "all-hands-on-deck" program to lower the rate of patient withdrawals from CONTESSA. (Id.) Presentations would be given to clinical site investigators on how to identify early signs of neutropenia (e.g., calling patients 3–4 days after receiving a dose to inquire about fever or other neutropenia symptoms), and how to treat it in ways permitted by the trial. (Id.) The presentation was allegedly intended to provide doctors with knowledge and options to prevent patients from experiencing neutropenia within the trial, such as by lowering the tesetaxel dose for a short time or adjusting the pacing of blood draws in order to identify and treat patients more quickly. (Id. ¶¶ 44–45.) Within the following two weeks, all 100–120 trial sites allegedly received the presentation on neutropenia. (Id. ¶ 44.) Subsequently, some trial sites implemented the new recommended protocol, but approximately ten trial sites, or roughly 10% of the total number of sites, allegedly dropped out of the CONTESSA trial in the first few months. (Id. ¶ 47.) Plaintiff alleges this represented an unusually high dropout rate for clinical trials, and that Odonate had to find new sites as replacements. (Id.) Plaintiff alleges that the directive to initiate the presentation and change in protocol came from Defendant Tang, Defendant Lemkey, and CMO O'Connell, (id. ¶ 46), and that Odonate's leadership regularly received communications about the CONTESSA trial, (id. ¶¶ 49–50).

On June 27, 2019, Odonate held an underwritten public offering of 4,750,000 shares of common stock at a price of $26.00 per share; Plaintiff alleges the aggregate gross proceeds were $142 million and net proceeds were $135.1 million. (Id. ¶¶ 38, 188.) On

October 21, 2019, Odonate announced completion of enrollment in the CONTESSA trial. (Id. ¶ 103.) On August 24, 2020, Odonate issued a press release announcing top-line results from the CONTESSA trial. (Id. ¶¶ 8, 165.) Odonate reported that the trial met its primary endpoint – improving PFS – but that Grade 3 or higher neutropenia occurred in 71.2% of patients receiving the combination treatment (tesetaxel and capecitabine) versus 8.3% of patients treated with capecitabine alone. (Id. ¶ 165.) Additionally, febrile neutropenia occurred in 12.8% of patients receiving the combination treatment versus 1.2% for capecitabine alone. (Id.) The overall treatment discontinuation rate due to any AE was 23.1% of patients treated with the combination treatment versus 11.9% of patients treated with capecitabine alone. (Id.) At this news, Odonate's stock price fell $15.21 per share, or 45.35%, to close at $18.33 per share on August 24, 2020. (Id. ¶ 166.)

On September 1, 2020, Odonate held a public offering of 6,456,000 shares at $14.25 per share; Plaintiff alleges the aggregate gross proceeds were $92 million and net proceeds were $87.4 million. (Id. ¶¶ 38, 188.) On March 22, 2021, Odonate issued a press release announcing it was discontinuing tesetaxel's development following feedback from the U.S. Food and Drug Administration ("FDA") that the clinical data package for tesetaxel was unlikely to support FDA approval. (Id. ¶ 168.) At this news, Odonate's stock price fell $15.07 per share, or 79%, to close at $3.96 per share on March 22, 2021. (Id. ¶ 169.) On March 25, 2021, Odonate filed a Form 8-K with the SEC providing more details about Odonate's discontinuation of tesetaxel's development, and the wind-down of Odonate's operations. (Id. ¶ 170.) At this news, Odonate's stock price fell $0.52, or 14.4%, to close at $3.09 per share on March 26, 2021. (Id. ¶ 171.)

On September 16, 2020, Plaintiff filed a class action complaint against Defendants. (Doc. No. 1.) On May 13, 2021, Plaintiff filed the operative SAC against Defendants. (Doc. No. 24.) Plaintiff alleges that during the Class Period, Defendants concealed material, adverse facts from investors regarding the negative results and necessary changes to protocol in the CONTESSA trial. (Id. ¶¶ 6–7.) Plaintiff alleges that throughout the Class Period, Defendants made misleading statements containing misrepresentations and

omissions regarding the CONTESSA trial, patient outcomes and experiences while using tesetaxel, and the likelihood of tesetaxel's approval by the FDA. (Id. ¶¶ 5–7.) The SAC alleges that Defendants violated Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. (Id. ¶ 13.) By the present motion, Defendants move to dismiss Plaintiff's SAC for failure to state a claim upon which relief can be granted. (Doc. No. 25.)[2]

Discussion

I. Legal Standards

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" In re Alphabet, Inc. Sec. Litig., 1 F.4th 687, 698 (9th Cir. 2021) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). "A complaint is plausible on its face 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Iqbal, 556 U.S. at 678). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Id. (quoting Iqbal, 556 U.S. at 679); see Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). Dismissal is inappropriate unless the plaintiff's complaint fails to "state a claim to relief that is plausible on its face." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 989 (9th Cir. 2009), as amended (Feb. 10, 2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

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[2] With their motion to dismiss, Defendants filed a request for judicial notice and for incorporation by reference of 22 exhibits. (Doc. No. 25-4.) On June 25, 2021, Plaintiff filed a partial opposition to Defendants' request for judicial notice of Exhibits G, I, L, M, N, O, Q, and R. (Doc. No. 28.) On July 26, 2021, Defendants requested that the Court consider an additional exhibit. (Doc. No. 34.) The Court need not resolve Plaintiff's objections, as it does not reference or rely upon any of Defendants' exhibits in its Order. The Court also notes that Defendants' request for judicial notice and for incorporation by reference, and argument relating to that request, was not made as part of their motion to dismiss or reply. (See Doc. Nos. 25-4 at 1–6; 34 at 1–3.) Additionally, Plaintiff made his objections to Defendants' exhibits in a separate filing, not as part of his opposition. (See Doc. No. 28.) This is improper; to the extent parties have requests or objections regarding exhibits, they should be raised in the applicable briefing, not in separate filings that evade the page limits for briefing.

A complaint stating claims under Section 10(b) and Rule 10b-5 must additionally satisfy the dual heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Prodanova v. H.C. Wainwright & Co., LLC, 993 F.3d 1097, 1106 (9th Cir. 2021) (citing Zucco Partners, 552 F.3d at 990). Federal Rule of Civil Procedure 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). In other words, "[a]verments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." Prodanova, 993 F.3d at 1106 (quoting Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009)). While Rule 9(b) allows intent and "other conditions of a person's mind" to be averred generally, "[t]he PSLRA significantly altered pleading requirements in private securities fraud litigation by requiring that a complaint 'plead with particularity both falsity and scienter.'" Gompper v. VISX, Inc., 298 F.3d 893, 895 (9th Cir. 2002) (quoting Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001)). "PSLRA's heightened pleading requirements are meaningful ones, requiring courts carefully to evaluate securities fraud complaints to ensure compliance with the statute's elevated pleading standards." Nguyen v. Endologix, Inc., 962 F.3d 405, 413 (9th Cir. 2020).

II. Analysis

"To plead a claim under § 10(b) and Rule 10b-5, a plaintiff must allege '(1) a material misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation.'" Endologix, 962 F.3d at 413 (quoting Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc., 774 F.3d 598, 603 (9th Cir. 2014)). Defendants contend that Plaintiff has failed to allege the first two elements with sufficient particularity to satisfy the PSLRA's pleading standards. The Court addresses each in turn.

A. Whether The SAC Sufficiently Pleads Falsity

Falsity is any "untrue statement of a material fact." 15 U.S.C. § 78u–4(b)(1). It also occurs when a defendant "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading."

Id. To plead falsity under the PSLRA, a complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading and, if an allegation regarding the statement or omission is made on information and belief . . . state with particularity all facts on which that belief is formed." Id. A complaint must allege both that the statement or omission is misleading and that it is material. In re Alphabet, 1 F.4th at 699. Courts apply the "objective standard of a 'reasonable investor' to determine whether a statement is misleading." Id. (citing In re VeriFone Sec. Litig., 11 F.3d 865, 869 (9th Cir. 1993)). Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information" and instead require disclosure "only when necessary 'to make . . . statements made, in light of the circumstances under which they were made, not misleading.'" Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011) (quoting 17 C.F.R. § 240.10b-5(b)). To be misleading, a statement or omission "must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002) (citing McCormick v. The Fund American Cos., 26 F.3d 869, 880 (9th Cir. 1994))

"The materiality of the misrepresentation or an omission depends upon whether there is 'a substantial likelihood that [it] would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available' for the purpose of decisionmaking by stockholders concerning their investments." Retail Wholesale & Dep't Store Union Loc. 338 Ret. Fund v. Hewlett-Packard Co., 845 F.3d 1268, 1274 (9th Cir. 2017) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988)). The inquiry into materiality is "fact-specific," Matrixx Initiatives, 563 U.S. at 43 (quoting Basic, 485 U.S. at 236), and "requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him," Fecht v. Price Co., 70 F.3d 1078, 1080 (9th Cir. 1995) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 450 (1976)). "[T]hese assessments are peculiarly ones for the trier of fact." Id. (quoting TSC Indus., 426 U.S. at 450). As a result, resolving whether a statement or omission is misleading or material as a matter of law is generally appropriate

"only if the adequacy of the disclosure or the materiality of the statement is 'so obvious that reasonable minds [could] not differ.'" Id. at 1081 (quoting Durning v. First Bos. Corp., 815 F.2d 1265, 1268 (9th Cir. 1987)); see In re Alphabet, 1 F.4th at 700.

Plaintiff alleges the failure to disclose that elevated rates of neutropenia in CONTESSA led to unexpectedly high rates of patient withdrawal from the trial, resulting in an emergency change to the trial protocol and presentations to all CONTESSA trial sites, was a material omission rendering many of Defendants' statements during the Class Period false and misleading. (SAC ¶¶ 40–55.) Plaintiff contends that Defendants never disclosed the August 2018 emergency program to prevent patients from experiencing neutropenia and to reduce the rate of patient discontinuation. (Doc. No. 30 at 20.) Plaintiff identifies over forty public press releases, reports, filings, presentations, and other announcements by Defendants in which they allegedly made misstatements and omissions during the Class Period. (SAC ¶¶ 57–138.) The Court need not address all of the statements pled in the SAC, as it concludes Plaintiff has sufficiently pled actionable statements by Defendants to survive a motion to dismiss.

Plaintiff alleges that Defendants stated that they were expecting "to complete enrollment of CONTESSA in the second half of 2019" and "announced the completion of enrollment in CONTESSA" in October 2019. (Id. ¶¶ 81, 86, 91–92, 97–98, 99–100, 101–02, 103–04, 105–06, 107, 108–13, 114–15, 116–17.) Plaintiff argues these statements were materially false and misleading because Defendants did not disclose that 10% of their trial sites allegedly had dropped out in the first few months of CONTESSA, which affected enrollment and necessitated finding and initiating replacement trial sites. (Id. ¶ 47.) Plaintiff also alleges that Defendants continued to make statements about the hypothesis behind CONTESSA: tesetaxel's potential to "provide significant quality-of-life advantages over other chemotherapy options," to "lengthen PFS while being well-tolerated compared to other options," to be "generally well-tolerated" by patients, to have a "favorable benefit-risk profile," and to offer "several potential therapeutic advantages over currently available taxanes." (Id. ¶¶ 81–86, 87–88, 93–94, 95–96, 108–13.) Plaintiff alleges Defendants also

continued to cite to an independent researcher's quote in describing the rationale for the CONTESSA study: "the trend toward improved efficacy with lower doses of capecitabine may result from the significantly lower proportion of patients discontinuing study therapy prematurely because of toxicity." (Id. ¶¶ 82–86, 108–13.) These statements were made in numerous forums after the alleged August 2018 emergency protocol change due to higher-than-expected rates of neutropenia and subsequent patient withdrawals in CONTESSA, including in the press releases and presentations leading up to Odonate's June 2019 public offering. (Id. ¶¶ 93–94, 95–96.) Plaintiff argues these statements were materially false and misleading in light of Odonate's value proposition to investors: that tesetaxel could be an effective, safe, and well-tolerated therapy option in comparison to existing treatment options. (Id. ¶¶ 36, 59.) Plaintiff alleges that after learning that patients were experiencing elevated levels of neutropenia and other AEs – which resulted in their voluntary or doctor-mandated withdrawals from the trial – and implementing an emergency protocol to manage and limit those outcomes, Defendants failed to disclose these events, continued to make positive statements about tesetaxel's potential, and initiated a public offering in June 2019 that raised net proceeds of $135.1 million. (Id. ¶¶ 38, 87–88, 97–98.) Plaintiff alleges Defendants' statements created an impression that CONTESSA was proceeding as expected, with no significant setbacks – especially none that would potentially undermine the central rationale behind the trial – while the undisclosed reality was materially different. (Doc. No. 30 at 16 (citing Brody, 280 F.3d at 1006).)

Additionally, Plaintiff alleges Defendants made numerous material and misleading statements and omissions in their announcement and subsequent public discussion of the CONTESSA top-line results in late 2020. In several forums, including in the filings and statements related to Odonate's September 2020 public offering, Defendants allegedly characterized CONTESSA's top-line results as "positive," and stated that "[t]esetaxel plus capecitabine was associated with what we believe are manageable side effects." (SAC ¶¶ 118–19, 120–21, 122–23, 124–25, 126–28, 129–30.) Defendants also allegedly spoke at length about the rates of neutropenia and patient treatment discontinuation in

CONTESSA during a December 2020 investor and analyst presentation, stating that "the treatment discontinuation rate due to neutropenia was low," and "[neutropenia] was generally manageable." (Id. ¶¶ 129–30.) Plaintiff argues these statements were materially false and misleading because Defendants failed to disclose that the reported AEs, like neutropenia, were managed by implementing an emergency revised trial protocol and training presentation at all of the CONTESSA trial sites. (Doc. No. 30 at 19.) Plaintiff alleges that reasonable investors would have considered the omitted information regarding the August 2018 emergency program to have materially altered the total mix of information available to them. (Id. at 20 (citing Berson v. Applied Signal Tech., Inc., 527 F.3d 982, 987 (9th Cir. 2008)).)

The SAC's allegations are sufficient to state a claim under Section 10(b) and Rule 10b-5. Plaintiff has identified several allegedly material misstatements and omissions and alleged the reasons why a reasonable investor would consider these statements and omissions to be misleading with particularity. See 15 U.S.C. § 78u–4(b)(1). It is plausible that a reasonable investor would have considered the omitted information regarding the alleged August 2018 emergency program to be material, given that the unexpectedly high rates of neutropenia and patient withdrawals were at odds with the value proposition and hypothesis of CONTESSA. See Matrixx, 563 U.S. at 44. Defendants allegedly did not disclose the adjustment to the trial protocol at any point during CONTESSA, nor during the reporting and discussion of CONTESSA's top-line results; it is plausible that a reasonable investor would find the omission misleading. See Basic, 485 U.S. at 231–32. The Court cannot determine at this time – as a matter of law – that the omitted information did not make the statements made by Defendants during the Class Period misleading to a reasonable investor. See In re Rigel Pharms., Inc. Sec. Litig., 697 F.3d 869, 880 n.8 (9th Cir. 2012).

Defendants argue that there is no affirmative duty to disclose information under securities laws, and contend In re Rigel Pharmaceuticals, Inc. Securities Litigation is controlling. (Doc. No. 25-1 at 13.) Securities laws "do not create an affirmative duty to

disclose any and all material information," rather, "companies can control what they have to disclose under these provisions by controlling what they say to the market." Matrixx, 563 U.S. at 44–45. But once Defendants chose to speak on certain topics, such as about the completion of enrollment in CONTESSA or the top-line results from CONTESSA, "they were bound to do so in a manner that wouldn't mislead investors." Schueneman v. Arena Pharms., Inc., 840 F.3d 698, 707 (9th Cir. 2016) (quoting Berson, 527 F.3d at 987). The Court disagrees that Rigel is factually analogous at this stage of litigation. The plaintiff in Rigel alleged that Defendants' initial disclosure of results was incomplete, and that later-reported information should have been included in the initial reporting. 697 F.3d at 881. The Ninth Circuit concluded that "the subsequent release of more extensive information . . . was not inconsistent with the results that originally were reported," id., and that "the omitted information did not contradict, or render misleading, the original reports of the top-line results." Id. at 881 n.10. Here, Plaintiff alleges that Defendants never disclosed the August 2018 emergency change in protocol resulting from elevated rates of neutropenia and patient withdrawals, but rather continued to make public statements regarding CONTESSA's enrollment, value proposition, and top-line results. Plaintiff has sufficiently alleged that the omitted information about the August 2018 program may have rendered Defendants' public statements misleading.

Defendants also contend that each of the statements alleged in the SAC are either true or an opinion and therefore are not actionable. (Doc. No. 25-1 at 2.) But "a statement that is literally true can be misleading and thus actionable under the securities laws." Brody, 280 F.3d at 1006. Thus, while Defendants' statements that they were completing enrollment in CONTESSA in late 2019 may have been true, it is plausible that a reasonable investor would consider the omission that enrollment had been affected by 10% of sites withdrawing from the trial to be material and misleading. "For an opinion to be misleading by omission, (1) the "statement must omit material facts about the defendant's inquiry into or knowledge concerning a statement of opinion," and (2) "those facts must conflict with what a reasonable investor would take from the statement itself." In re Atossa Genetics Inc

Sec. Litig., 868 F.3d 784, 802 (9th Cir. 2017) (citing City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc., 856 F.3d 605, 615 (9th Cir. 2017)). Defendants argue that because they disclosed the exact percentages of CONTESSA patients that experienced side effects in their top-line results, their opinion that the side effects were "manageable" is not actionable. (Doc. Nos. 25-1 at 18; 32 at 6–7.) But Plaintiff has alleged that Defendants never disclosed the August 2018 emergency change in protocol that was specifically implemented to manage side effects and patient withdrawals. (Doc. No. 30 at 20.) Plaintiff has sufficiently alleged that Defendants' "omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." City of Dearborn Heights, 856 F.3d at 615–16 (quoting Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 575 U.S. 175, 194 (2015)).

In sum, Plaintiff has sufficiently pled that Defendants made public statements and omissions during the Class Period that reasonable jurors could find to be material and misleading. See In re Alphabet, 1 F.4th at 699. Given the fact-intensive nature of these inquiries, Defendants' arguments regarding the falsity of the alleged statements are better suited to a motion for summary judgment or opposition to class certification when the record is more fully developed. See Fecht, 70 F.3d at 1080–81.

B. Whether The SAC Sufficiently Pleads Scienter

To adequately plead scienter under the PSLRA, the complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). To allege the requisite scienter, a complaint must "allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." Endologix, 962 F.3d at 414 (quoting Zucco Partners, 552 F.3d at 991). "[D]eliberate recklessness" is more than "mere recklessness or a motive to commit fraud." Schueneman, 840 F.3d at 705 (quoting Zucco Partners, 552 F.3d at 991). It exists when a statement represents "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. (quoting Zucco

Partners, 552 F.3d at 991). Plaintiffs alleging deliberate recklessness need not prove that a defendant "actually knew" their statements were false or misleading, just that they "recklessly turn[ed] a blind eye" to the falsity. In re VeriFone Holdings, Inc. Secs. Litig., 704 F.3d 694, 708 (9th Cir. 2012). When "determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." Zucco Partners, 552 F.3d at 991 (quoting Tellabs, 551 U.S. at 323). A strong inference of scienter exists "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, 551 U.S. at 324. The inference "need not be irrefutable, i.e., of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" Id. For a motion to dismiss, "if two possible inferences—one fraudulent and the other nonfraudulent—are equally compelling, a plaintiff has demonstrated a strong inference of scienter." ESG Cap. Partners, LP v. Stratos, 828 F.3d 1023, 1033 (9th Cir. 2016).

As an initial matter, Defendants contend that the Court should disregard Plaintiff's allegations relying on the statements of five confidential witnesses. (Doc. No. 25-1 at 19–21.) "[A] complaint relying on statements from confidential witnesses must pass two hurdles to satisfy the PSLRA pleading requirements." Zucco Partners, 552 F.3d at 995. "First, the confidential witnesses whose statements are introduced to establish scienter must be described with sufficient particularity to establish their reliability and personal knowledge." Id. "Second, those statements which are reported by confidential witnesses with sufficient reliability and personal knowledge must themselves be indicative of scienter." Id. In assessing allegations based on confidential witness statements, courts look to "the level of detail provided by the confidential sources, the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia." Id. (quoting In re Daou Sys., Inc., 411 F.3d 1006, 1015 (9th Cir. 2005)). The SAC identifies the job title, tenure, supervisors, and responsibilities for each of the five confidential witnesses. (SAC ¶¶ 24–29.) The confidential witnesses are described with sufficient

particularity to support the probability that someone in a position occupied by the sources would possess the information alleged, see Daou, 411 F.3d at 1015, their statements are cross-corroborating, and they were employed at Odonate during relevant time periods. Defendants' arguments as to why the accounts of the confidential witnesses should be disregarded are unpersuasive. The Court concludes the allegations regarding the five confidential witnesses are sufficient to satisfy the PSLRA pleading requirements and will credit them in its analysis of Defendants' scienter.

Plaintiff alleges that Defendants knew that their public misrepresentations and omissions would mislead investors, and/or were deliberately reckless as to the danger of misleading investors. (SAC ¶¶ 174–81.) Defendants allegedly were informed of the elevated rates of neutropenia and patient withdrawals as early as May 2018, and as late as August 2018. (Id. ¶¶ 176–77.) Plaintiff alleges Defendants held an urgent teleconference in August 2018 regarding the AEs in the CONTESSA trial, and initiated an emergency program to decrease the number of patient discontinuations due to neutropenia. (Id.) Members of Odonate's leadership allegedly gave the directive to initiate the emergency protocol change, received the presentation that was given to all of the CONTESSA trial sites, and received regular updates on AEs, including expedited reports if patients were hospitalized for neutropenia. (Id. ¶¶ 43–44, 46, 49–40, 176–79.) Plaintiff alleges that Defendants held a secondary public offering in June 2019 – after the emergency change in protocol and presentations to all of the CONTESSA trial sites – in which they raised gross proceeds of $142 million and net proceeds of $135.1 million. (Id. ¶ 188.) After the top-line results from CONTESSA were released – allegedly without mention of the change in protocol – Defendants held an additional public offering in September 2020, in which they raised gross proceeds of $92 million and net proceeds of $87.4 million. (Id.)

These allegations are sufficient to plead a strong inference that Defendants made materially misleading statements intentionally or with deliberate recklessness. It is plausible that the omitted information presented a danger of misleading buyers or sellers that was either known to Defendants or was so obvious that they must have been aware of

it. See Schueneman, 840 F.3d at 705. Plaintiff has adequately pled "a narrative of fraud—facts which, if true, substantiate an explanation at least as plausible as a nonfraudulent alternative." ESG Capital Partners, 828 F.3d at 1035. Defendants contend that a more compelling opposing inference is that by initiating the change in study protocol, Odonate was working to protect the health of patients in CONTESSA by ensuring study sites could respond effectively to observe neutropenia. (Doc. No. 25-1 at 22). The Court does not consider this to be an opposing inference to Plaintiff's alleged theory of fraud. See Zucco Partners, 552 F.3d at 991. It is plausible that Defendants were ensuring the health of their CONTESSA trial patients while simultaneously misleading their investors by failing to disclose that material information. As Plaintiff notes, that the CONTESSA trial patients experienced elevated rates of neutropenia is not the sole basis for his allegations of scienter; rather, it is that Defendants allegedly significantly altered the CONTESSA trial protocol to address the neutropenia and patient withdrawals, without ever disclosing that fact to investors. (Doc. No. 30 at 26.) In sum, after considering all of these allegations, the Court concludes that Plaintiff has met his burden in creating a "cogent inference" that Defendants acted at least deliberately recklessly. See Tellabs, Inc., 551 U.S. at 314. Accordingly, it denies Defendants' motion to dismiss Plaintiff's Section 10(b) claim.[3]

C. Whether The SAC Satisfies Federal Pleading Requirements

Finally, Defendants contend that Plaintiff's SAC fails to meet federal pleading standards. (Doc. No. 25-1 at 9–12.) The Court disagrees. Defendants' arguments are better suited to a motion for summary judgment or opposition to class certification when the record is more fully developed.

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[3] Defendants also seek to dismiss Plaintiff's Section 20(a) claim on the sole ground that Plaintiff failed to plead a primary violation of Section 10(b). (Doc. No. 25-1 at 25.) Because the Court concludes Plaintiff has sufficiently pled a violation of Section 10(b), the Court denies Defendants' motion to dismiss Plaintiff's Section 20(a) claim. See In re Vical Inc. Sec. Litig., No. 13-CV-2628 BAS RBB, 2015 WL 1013827, at *6 (S.D. Cal. Mar. 9, 2015) ("In order to succeed on a section 20(a) claim, a plaintiff must properly plead an underlying section 10(b) violation.").

Conclusion

For the reasons above, the Court denies Defendants' motion to dismiss Plaintiff's SAC in its entirety. Defendants must file an answer to the SAC within thirty (30) days of the date of this Order.

IT IS SO ORDERED.

DATED: August 4, 2021

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT