UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JONNIE HOMYK, et al.,

Plaintiffs,

v.

CHEMOCENTRYX, INC., et al.,

Defendants.

Case No. 21-cv-03343-JST

ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Re: ECF Nos. 267, 279

Before the Court are Lead Plaintiff Indiana Public Retirement System's motion for partial summary judgment and Defendants ChemoCentryx Inc. ("ChemoCentryx) and Dr. Thomas J. Schall's (together, "Defendants") cross motion for summary judgment. ECF Nos. 267, 279. The Court will grant Defendants' motion and deny Lead Plaintiff's motion as moot.

I. BACKGROUND

Because the facts are well-known to the parties and the Court has summarized the background of this action in detail in its prior orders, ECF Nos. 61, 131, 275, the Court will not repeat them in full here. In sum, Lead Plaintiff Indiana Public Retirement System brings this action individually and on behalf of all persons who purchased or otherwise acquired ChemoCentryx common stock between November 26, 2019, and May 6, 2021, inclusive ("Class Period"). Plaintiff alleges that ChemoCentryx and Dr. Thomas Schall, its President and Chief Executive Officer, violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements and omissions about the safety, efficacy, and application for Food and Drug Administration ("FDA") approval of a proprietary vasculitis drug called avacopan, thereby artificially inflating the price of ChemoCentryx stock during the Class Period.

ChemoCentryx developed and marketed avacopan as a breakthrough therapy for the treatment of ANCA-associated vasculitis ("AAV"), a rare autoimmune disease, that could potentially replace the existing standard of care involving steroids and immunosuppressants. ECF. No. 47 ¶¶ 1, 5, 48. At the start of the Class Period, Defendants announced the results of a study called ADVOCATE, the Phase III trial of avacopan for the treatment of AAV. *Id.* ¶ 10. In that announcement and throughout the Class Period, Defendants stated that trial safety results showed that avacopan was safer than standard-of-care steroid therapy; that, in the trial, avacopan had demonstrated non-inferiority versus prednisone with respect to the primary endpoint of Birmingham Vasculitis Activity Score ("BVAS") remission at week 26 and superiority at week 52; that the study demonstrated that chronic steroids were not needed to achieve remission; and that communications with the FDA regarding the avacopan New Drug Application ("NDA") had been straightforward. *Id.*

However, Plaintiff alleges that Defendants knowingly withheld adverse facts from investors during the Class Period that undermined their public statements. For example, in private communications with Defendants in 2016 and 2020, the FDA had expressed concerns about the reliability of the trial's design and results. Specifically, the FDA told Defendants that statistical non-inferiority would be inadequate to demonstrate that avacopan could replace the steroid-based standard of care, casting doubt on the sufficiency of ADVOCATE's key week 26 results. *Id.* ¶¶ 96–100. Plaintiff also alleges that Defendants knew that steroid use was significant and widespread among avacopan patients enrolled in the trial, which undermined Defendants' claims about avacopan's efficacy as a "monotherapy." *See id.* ¶¶ 138–46. Plaintiff alleges that Defendants knew of and failed to disclose serious adverse liver events, including an event meeting Hy's Law criteria[1] and one occurring after rechallenge, that occurred during the trial. *Id.* ¶ 128. Further, Plaintiff alleges that ChemoCentryx did not disclose its failure to follow trial protocol in

[1] "A Hy's Law case involves significant elevations in both a patient's serum levels of aminotransferase (enzyme leaked by injured cells) and increases in bilirubin, indicating the liver injury is significant enough to impair liver function. . . . [T]he occurrence of even one case meeting Hy's Law criteria in a clinical trial is enough to raise red flags, as these cases often predict severe post[-]marketing liver toxicity." ECF No. 202-29 at 22-23 (footnote omitted).

calculating remission results. When these results were later calculated in accordance with trial protocol, avacopan failed to achieve superiority to standard-of-care steroid therapy at week 52 by a statistically significant margin. *Id.* ¶¶ 130–37.

On February 18, 2021, ChemoCentryx published the ADVOCATE results in a *New England Journal of Medicine* ("*NEJM*") article. *Id.* ¶ 144. The peer-reviewed article included a table that detailed the "other than protocol-specified" glucocorticoid use by patients in both the avacopan and prednisone treatment arms in ADVOCATE. *Id.* However, the *NEJM* article did not explicitly disclose that 64% of avacopan patients were prescribed steroids for the specific purpose of helping control their AAV. *Id.*

On May 4, 2021, the FDA published the Briefing Book and other materials (together, "Advisory Committee Materials") in advance of its Advisory Committee meeting. The concerns reflected in these documents mirrored many of the concerns the FDA had privately expressed to ChemoCentryx in 2016 and 2020. *Id.* ¶ 17. These materials further revealed, among other things, the extent of steroid use among avacopan patients in the trial. *Id.* In response to the release of the Advisory Committee Materials, ChemoCentryx's common stock dropped more than 45% in a single day. *Id.* ¶ 18.

On May 6, 2021, the Advisory Committee held a public meeting to discuss avacopan. This meeting, Plaintiff alleges, allowed investors to appreciate the significance of the previously concealed facts discussed in the FDA Briefing Book, including the clinical import of the ADVOCATE results. *Id.* Advisory Committee members were evenly split on the question of whether the drug should be approved, and those who voted in favor of approval argued its label should be limited—that is, that it should only be approved for use by a limited set of patients. The next day, ChemoCentryx common stock fell by approximately 62%. *Id.*

On October 8, 2021, however, approximately five months after the end of the Class Period, the FDA approved avacopan for the market under the trade name of TAVNEOS. *Id.* ¶ 191. Plaintiff alleges that the FDA ultimately approved avacopan for use only in conjunction with steroids and only by adult patients with severe active AAV. *Id.* ¶¶ 21–23. The FDA also required ChemoCentryx to include warnings for liver toxicity on the avacopan label and ordered

ChemoCentryx to conduct three post-marketing studies to evaluate liver toxicity. *Id.*

II. JURISDICTION

The Court has jurisdiction under 28 U.S.C. § 1331.

III. LEGAL STANDARD

Summary judgment is proper where the pleadings, discovery and affidavits show that there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *See* Fed. R. Civ. P. 56(a). Material facts are those that may affect the outcome of the case. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute as to a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *See id.*

A court shall grant summary judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial [,] . . . since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The moving party bears the initial burden of identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. *Id.* at 323. The burden then shifts to the nonmoving party to "go beyond the pleadings and by [his] own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *See id.* at 324 (citing Fed. R. Civ. P. 56(e)).

For purposes of summary judgment, the court must view the evidence in the light most favorable to the non-moving party, drawing all justifiable inferences in that party's favor. *AXIS Reinsurance Co. v. Northrop Grumman Corp.*, 975 F.3d 840, 844 (9th Cir. 2020). If, as to any given material fact, evidence produced by the moving party conflicts with evidence produced by the nonmoving party, the Court must assume the truth of the evidence set forth by the nonmoving party with respect to that material fact. *Furnace v. Sullivan*, 705 F.3d 1021, 1026 (9th Cir. 2013). However, facts must be viewed in the light most favorable to the nonmoving party only if there is a "genuine" dispute as to those facts. *Scott v. Harris*, 550 U.S. 372, 380 (2007). The court's

function on a summary judgment motion is not to make credibility determinations or weigh conflicting evidence. *Manley v. Rowley*, 847 F.3d 705, 711 (9th Cir. 2017).

The court is not required "to scour the record in search of a genuine issue of triable fact," *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996) (citations omitted), and it may limit its review to the documents submitted for purposes of summary judgment and those parts of the record specifically referenced therein. *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1030 (9th Cir. 2001). "A mere scintilla of evidence will not be sufficient to defeat a properly supported motion for summary judgment; rather, the non-moving party must introduce some significant probative evidence tending to support the complaint." *Summers v. Teichert & Son, Inc.*, 127 F.3d 1150, 1152 (9th Cir. 1997) (citation and internal quotation marks omitted).

IV. REQUEST FOR JUDICIAL NOTICE

"Judicial notice under Rule 201 permits a court to notice an adjudicative fact if it is 'not subject to reasonable dispute,'" i.e., the fact "is 'generally known,' or 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'" *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018) (quoting Fed. R. Evid. 201(b)).

Defendants request that the Court take judicial notice of twelve documents. ECF No. 283. The documents can be categorized into (1) ChemoCentryx's SEC filings (Exhibits 28, 38, 59, and 86); and (2) FDA documents (Exhibits 8, 20, 21, 43, 53, 57, 58, and 76). *See generally id.* Plaintiff opposes the request for judicial notice of Exhibits 8, 57, 58, 59, and 76. ECF No. 302. Plaintiff opposes judicial notice because it argues that Defendants improperly seek judicial notice of "disputed facts" and the challenged documents are not relevant. *See id.* at 4–11.

The Court first addresses whether these types of documents are generally subject to judicial notice and then respond to Plaintiff's arguments. Beginning with ChemoCentryx's SEC filings, courts regularly take judicial notice of these kinds of "publicly available financial documents." *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008); *see also Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 n. 2 (9th Cir. 2006); *Strezsak v. Ardelyx Inc.*, 2024 WL 1160900, at *4 (N.D. Cal. Mar. 18, 2024) (taking judicial notice of SEC filings "for the purpose of considering what was disclosed to the market" and not for "the truth of

any of the facts asserted"). Similarly, courts also routinely take judicial notice of FDA documents like those at issue here. *See, e.g., Sneed v. Procter & Gamble Co.*, No. 23-CV-05443-JST, 2025 WL 1017933, at *3 (N.D. Cal. Apr. 4, 2025) (taking judicial notice of FDA approval letters); *Kettner v. Cadista Holdings, Inc.*, No. 2:19-CV-02123-TLP-CGC, 2019 WL 11583314, at *2 (W.D. Tenn. Aug. 12, 2019) (taking judicial notice of FDA documents approving an abbreviated new drug application); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1126, n.1 (N.D. Cal. 2013) (taking judicial notice of an FDA guidance document); *Wilson v. Frito-Lay N. Am., Inc.*, 260 F. Supp. 3d 1202, 1207 (N.D. Cal. 2017) (taking judicial notice of FDA labeling guidance).

Next, the Court agrees with Plaintiff that the Court cannot take judicial notice of disputed facts stated in public records. *See Insight Psychology & Addiction, Inc. v. City of Costa Mesa*, 724 F. Supp. 3d 1067, 1080 (C.D. Cal. 2024) (citing *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001)). However, the Court finds that it can take judicial notice of the existence of these documents without accepting the truth of any disputed content. More specifically, the Court can take judicial notice of undisputed facts such as when avacopan was approved, what was being approved, and what the label for avacopan stated. *See Wilson v. Amneal Pharms., L.L.C.*, No. 1:13-CV-00333-CWD, 2013 WL 6909930, at *7 (D. Idaho Dec. 31, 2013) (taking judicial notice of "when certain approvals occurred, and what was being approved——whether it was the transfer of the ANDA for Generic Bactrim, or the labels for Brand Name Bactrim and what those labels stated"—and not "the entirety of the [approval] letters' contents"). Similarly, the Court may take judicial notice of the RITUXAN ("RTX") labels for what those labels said on certain dates, without accepting any disputed facts about what the general standard of care relating to RTX was. And the Court may take judicial notice of the SEC filings for the fact "that the market was aware of the information contained in" those filings without accepting that that underlying information was actually true. *Heliotrope Gen. Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n. 118 (9th Cir.1999); *see also Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954, 960 (9th Cir. 2010). As to relevance, Plaintiff repeats legal arguments about why FDA approval is not significant or was not based on sufficient data that it made in its opposition to Defendants' motion

for summary judgment, and these arguments do not affect the *fact* of approval on a certain date noticeable from the FDA documents.

Accordingly, the Court grants Defendants' request for judicial notice of the twelve documents.

V. DEFENDANTS' CROSS MOTION

A. Section 10(b) and Rule 10-b5 Claim

Section 10(b) of the Securities Exchange Act of 1934 declares it unlawful to "use or employ, in connection with the purchase or sale of any security . . . , any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary." 15 U.S.C. § 78j(b). There is an "implied [ ] private cause of action" in Section 10(b). *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011).

"SEC Rule 10b-5 implements [Section 10(b)] by making it unlawful to . . . 'make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b–5).

"Thus, to prevail on a claim for violations of either Section 10(b) or Rule 10b-5, a plaintiff must prove six elements: '(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1051–52 (9th Cir. 2014) (quoting *Matrixx Initiatives*, 563 U.S. at 37-38).

Defendants move for summary judgment, arguing that there is no triable issue of fact as to whether Plaintiff can establish the first two elements. After carefully reviewing the evidence cited by the parties, the Court concludes that Plaintiff cannot establish a material misrepresentation or omission and that summary judgment must be entered in Defendants' favor on that basis.[2]

1. Statements of Opinion

Defendants move for summary judgment on the basis that their challenged statements are

[2] Because the Court grants Defendants' motion for summary judgment on this basis, it does not reach Defendants' remaining arguments or Plaintiff's motion for partial summary judgment.

inactionable opinions. As a preliminary matter, the Court must determine whether the statements at issue in this case are facts or opinions. "In the context of the securities laws, '[a] fact is a thing done or existing or an actual happening,'" while "'[a]n opinion is a belief, a view, or a sentiment which the mind forms of persons or things.'" *In re QuantumScape Sec. Class Action Litig.*, 580 F. Supp. 3d at 738 (N.D. Cal. 2022) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 183 (2015)). "A statement of fact ('the coffee is hot') expresses certainty about a thing, whereas a statement of opinion ('I think the coffee is hot') does not." *Id.* (quoting *Omnicare*, 575 U.S. at 183).

The parties have grouped the challenged statements in this case into five general categories: (1) statements about ADVOCATE's safety results; (2) statements about ADVOCATE's secondary endpoints; (3) statements about ADVOCATE's primary endpoints; (4) statements about avacopan's ability to replace steroid therapy; and (5) statements about the NDA and ChemoCentryx's interactions with the FDA.

The Court finds that all of the challenged statements are opinions largely dealing with Defendants' interpretations of trial data or scientific methodology—some of which contain embedded facts, and all of which are subject to the standard established in *Omnicare* for proving falsity. In cases alleging that a drug manufacturer has misled investors in its presentation of clinical trial data, courts consistently find that those statements are opinions because "there is no single 'correct' way to interpret data [, and] qualified data scientists often and reasonably 'disagree over how to analyze data and interpret results.'" *Thant v. Rain Oncology Inc.*, No. 5:23-CV-03518-EJD, 2025 WL 588994, at *4 (N.D. Cal. Feb. 24, 2025) (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *see also, e.g., Alger Dynamic Opportunities Fund v. Acadia Pharms. Inc.*, 756 F. Supp. 3d 852, 872 (S.D. Cal. 2024) ("Defendants' interpretation of the data and results of the studies were plainly expressions of opinion."); *Pardi v. Tricida, Inc.*, No. 21-cv-00076, 2024 WL 1056013, at *7 (N.D. Cal. Mar. 11, 2024) (representations that a clinical trial met its primary and second endpoints, that the defendant was optimistic about its NDA approval, and that its clinical trial data would provide sufficient evidence of safety and efficacy for FDA approval were all opinions); *In*

re Rigel Pharms., Inc. Sec. Litig., 697 F.3d 869, 879 (9th Cir. 2012) (challenges to statements concerning statistical results of a clinical trial represent differences of opinion when the criticisms relate to the reliability of the underlying methodology); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) ("Interpretations of clinical trial data are considered opinions."); *In Re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 422 (2d Cir. 2023) (statements about the proper interpretation of data are opinions); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (statements summarizing the efficacy results from a clinical trial are opinions reflecting the speaker's interpretation of data).

Here, Defendants' statements about the acceptability of avacopan's safety profile reflect their own assessment of the drug's safety based on trial data, and those statements sometimes contain the embedded fact that avacopan "had fewer adverse events and fewer serious adverse events." *See, e.g.*, ECF No. 47 ¶ 268; ECF No. 268-26 at 5. Their statements about ADVOCATE meeting its primary and secondary endpoints and that avacopan operated as a "monotherapy" that could replace steroids in the trial similarly embody Defendants' interpretation of ADVOCATE trial data. *See, e.g.*, ECF No. 47 ¶ 317; ECF No. 268-23 at 5 ("[A]vacopan was *essentially* a monotherapy since the standard concomitant background therapies such as cyclophosphamide or rituximab have ceased. *The data suggests* that avacopan alone may suffice in controlling ANCA vasculitis over time . . . ." (emphasis added)). And Defendants' statements about their interactions with the FDA express their own perspective and judgment on prior FDA communications. *See, e.g.*, ECF No. 47 ¶ 425; ECF No. 268-31 at 8 ("FDA has not highlighted any particular issues that would have to be discussed at AdCom.").

2. Falsity[3]

Under *Omnicare*, a plaintiff can plead falsity for opinion statements in three ways: "First,

[3] The Court notes that there is some overlap in its current discussion and its prior order resolving Defendants' motion to dismiss. *See generally* ECF No. 61. To the extent the Court previously found that Plaintiff had adequately pleaded falsity as to these categories of statements, the Court notes that Defendants had made only a limited challenge to a small subset of the statements as inactionable opinions in its motion to dismiss. *See id.* Moreover, the undisputed evidence now available in the record as well as the new legal authority cited by Defendants inform the Court's current analysis.

when a plaintiff relies on a theory of material misrepresentation, the plaintiff must allege both that 'the speaker did not hold the belief she professed' and that the belief is objectively untrue." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615–16 (9th Cir. 2017) (quoting *Omnicare*, 575 U.S. at 186). "Second, when a plaintiff relies on a theory that a statement of fact contained within an opinion statement is materially misleading, the plaintiff must allege that 'the supporting fact [the speaker] supplied [is] untrue."' *Id.* at 616 (quoting *Omnicare*, 575 U.S. at 186). "Third, when a plaintiff relies on a theory of omission, the plaintiff must allege 'facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.'" *Id.* (quoting *Omnicare*, 575 U.S. at 194).

When examining a theory of omission, "the court must ask whether the alleged omission rendered [the] opinions misleading . . . because the excluded fact shows that [the speaker] lacked the basis for making those statements that a reasonable investor would expect." *Omnicare*, 575 U.S. at 196. "A statement of opinion is not misleading just because external facts show the opinion to be incorrect" or the "issuer knows, but fails to disclose, some fact cutting the other way." *Id.* at 188–89. However, a reasonable investor expects that the issuer's opinion "fairly aligns with the information in the issuer's possession at the time." *Id.* at 189.

Because "whether an omission makes an expression of opinion misleading always depends on context," the "court must take account of whatever facts [the defendant] *did* provide about [the subject of its opinion], as well as any other hedges, disclaimers, or qualifications it included," and consider an investor who "takes into account the customs and practices of the relevant industry." *Id.* at 190, 196 (emphasis in original). Therefore, "an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as appropriate, in a broader frame." *Id.* at 190.

At the outset, the Court notes the heightened standard that courts have applied post-*Omnicare* to determine when a defendant's failure to disclose FDA feedback or other scientific criticism—even when repeating serious concerns—constitutes a material omission rendering an opinion misleading and actionable. Another court in this district has recently summarized the

approach taken by other courts of appeal and adopted their logic as follows:

> For example, in *Tongue v. Sanofi*, the plaintiffs "[were] sophisticated investors, no doubt aware that projections provided by issuers are synthesized from a wide variety of information, and that some underlying facts may be in tension with the ultimate projection set forth by the issuer." 816 F.3d 199, 211 (2d Cir. 2016). The Second Circuit explained that these investors, "well accustomed to the 'customs and practices of the relevant industry,'" would fully expect that the defendants and the FDA were engaged in a continuous dialogue "about the sufficiency of various aspects of the clinical trials and that inherent in the nature of [such] a dialogue are differing views." *Id.* Thus, the Second Circuit concluded the defendants' statements about the effectiveness of their drug "[could not] be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact held that view, the statements did not mislead in a manner that [was] actionable." *Id.* at 214.
>
> Similarly, in *In re Amarin Corp. PLC Sec. Litig.*, the Third Circuit concluded that the plaintiffs failed to plead falsity because the company's announcement of the topline results of its Phase 3 trial "did not lack a reasonable basis." No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022). The court also found the plaintiffs' theory of omission liability unpersuasive given that the company's contemporaneous disclosures warned of the exact risk that the plaintiffs argued was improperly omitted. *Id.* And the court rejected the theory that the company had a duty to disclose additional information when announcing its topline results because the company had put information about the trial's placebo arm "in play." *Id.* The court recognized that "[t]here is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses 'to speak about a material subject to investors.'" *Id.* (citations omitted). The Third Circuit explained, however, that while the disclosures at issue described the trial results with reference to the placebo group, "they did not make any affirmative characterizations regarding the effectiveness" of the placebo. *Id.* (citation omitted). Accordingly, "[the company's] disclosure of the topline results did not put into play either the full trial data or additional information" regarding the placebo. *Id.*

Pardi v. Tricida, Inc., No. 21-CV-00076-HSG, 2024 WL 1056013, at *8 (N.D. Cal. Mar. 11, 2024), *opinion clarified*, No. 21-CV-00076-HSG, 2024 WL 3262615 (N.D. Cal. July 1, 2024); *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 541–42 ("Furthermore, in a series of cases, courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review.") (collecting cases); *Strezsak v. Ardelyx Inc.*, No. 21-CV-05868-HSG, 2024 WL 1160900, at *6 (N.D. Cal. Mar. 18, 2024) ("Defendants had 'no legal obligation to loop

the public into each detail of every communication with the FDA.'" (quoting *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018)).

The cases cited by Plaintiff do not hold otherwise. In *Schueneman v. Arena Pharmaceuticals, Inc.*, the defendant stated that "'all the animal studies that [had] been completed' supported [defendant's] case for approval," even though it was aware of a study in which rats receiving its drug were getting cancer and knew that this study was "*the* sticking point with the FDA," such that the FDA had made "highly unusual" and "out-of-process" bi-monthly demands for information regarding the study. 840 F.3d 698, 700, 707, 708 (9th Cir. 2016).[4] Rather than dealing with the falsity of an opinion statement—and nowhere addressing *Omnicare*—*Schueneman* thus involved a direct contradiction between the defendant's representation of the information in claimed to have in its possession and the information it actually had.

Similarly, in *Khoja v. Orexigen Therapeutics, Inc.*, the defendant purposefully leaked the positive interim results it received from a study overseen by an Executive Steering Committee ("ESC") despite the FDA requiring those results to remain confidential. 899 F.3d 988, 994 (9th Cir. 2018). The FDA then reprimanded the defendant and forbade it from disclosing the interim results again, reiterating that the interim results had "a high degree of uncertainty and were likely to change with the accumulation of additional data." *Id.* at 995. Despite the FDA's instructions, however, the defendant included the interim results in its provisional patent application one month later, requested that its application be published, and then included the results in its Form 8-K with the Securities and Exchange Commission—thereby boosting its stock prices. *Id.* The Ninth Circuit in *Khoja* found that the defendant's failure to disclose that the interim results were likely unreliable could constitute a material omission. *Id.* at 1009–10. Critically, the Ninth Circuit did not apply *Omnicare*, as the ESC's results did not represent the defendant's own interpretations, but rather the confidential and tentative interpretations of the ESC.[5]

[4] The Court also notes that *Schueneman* formally addressed scienter rather than falsity. *Id.* at 707.
[5] For similar reasons, Plaintiff's remaining citations fare no better, as they were decided prior to *Omnicare* and also did not address whether the defendant had a reasonable basis for their opinions in the face of omitted scientific criticism. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27 (2011); *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597 (4th Cir. 2015).

a. ADVOCATE's Safety Results

Plaintiff argues that Defendants misrepresented ADVOCATE's safety results, primarily focusing on the following statement made by Defendants: "We had fewer adverse events and fewer serious adverse events, a very acceptable safety profile to go forward we believe and apply for approval in this indication." ECF No. 47 ¶ 268; *see also id.* ¶¶ 10, 70, 207.

The challenged statements contain the embedded fact that patients in the avacopan treatment arm of ADVOCATE "had fewer adverse events and fewer serious adverse events" than patients in the prednisone arm. Plaintiff does not argue that this fact is literally false.[6] Instead, Plaintiff argues that Defendants' safety statements were misleading because they knowingly omitted information from ADVOCATE showing that avacopan caused higher incidents of drug-induced liver injury, including cases meeting the standard for Hy's Law. More specifically, Plaintiff argues that Defendants were well aware of concerns relating to avacopan's hepatotoxicity risk because they were repeatedly raised by the ADVOCATE Data Monitoring Committee ("DMC") and purportedly shared by one of ChemoCentryx's senior medical executives.

Defendants argue that the safety statements at issue are non-actionable opinions whose bases are supported by ultimate FDA approval and disclosure of the underlying safety statistics during the Class Period. The Court agrees with Defendants.

First, there is no genuine dispute that the FDA approved avacopan (under the name TAVNEOS) for use in the United States based on a review of the ADVOCATE data in October 2021.[7] *See* ECF No. 282-59 at 4; ECF No. 282-57. The FDA thus found that ADVOCATE's results provided clinically meaningful evidence that avacopan had an acceptable safety profile—even despite the serious liver safety risks that the FDA itself had flagged in its Briefing Book. *See*

[6] Indeed, the FDA reported in its Briefing Book the following comparisons of adverse events ("AEs") between the avacopan and prednisone treatment groups respectively: "severe AEs (23.5% vs. 25.0%), AEs leading to discontinuation of study medication (16.3% vs. 17.1%) and [serious] AEs (42.2% vs. 45.1%)." ECF No. 282-2 at 13.

[7] The Court notes that Plaintiff now argues that the FDA would not have approved avacopan at all if ChemoCentryx had not "manipulated" the trial data in its unblinding and readjudication process. ECF No. 303-3 at 12–13, 19. As Plaintiff has contended only that Defendants "manipulated" the ADVOCATE data regarding efficacy (whether avacopan was superior to the standard of care), Plaintiff's "data manipulation" allegations do not affect the significance of the FDA's approval as to *safety* based on ADVOCATE's data.

21 U.S.C. § 355(d) (providing that the Secretary of the FDA shall refuse to approve the new drug application for any drug where the Secretary finds that "the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions"); 21 C.F.R. § 314.105(a) ("FDA will approve an NDA and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the NDA applies," which includes when the results of the tests show that the drug is unsafe for use.). Defendants' statement that they "believe[d]" that avacopan had "a very acceptable safety profile to go forward" based on there being "fewer adverse events and fewer serious adverse events" in the avacopan group over the prednisone group was thus per se reasonable. *See Philip Morris*, 89 F.4th at 422. In other words, Plaintiff cannot show that Defendants "lacked the basis for making" the statements regarding their interpretation of avacopan's safety profile "that a reasonable investor would expect," when the FDA ultimately agreed that avacopan had an acceptable safety profile. *Omnicare*, 575 U.S. at 196. And while Plaintiff claims that *Philip Morris* is distinguishable because the FDA approved avacopan for use only with warnings of "serious cases of hepatic injury," ECF No. 303-3 at 28 (quoting ECF No. 303-39 at 10), there is no "serious conflict" between the label's warning about certain risks and Defendants' statements—adopted by the FDA—that avacopan had an overall "acceptable safety profile." *See Tongue*, 816 F.3d at 212.

Moreover, it is undisputed that Defendants published the ADVOCATE safety statistics on which they based their safety statements. In both the October 2019 that Defendants published in the Journal of Medical Internet Research ("JMIR Article") and the February 2021 *NEJM* article, Defendants publicly disclosed statistics indicating that there were more adverse events, serious adverse events, and deaths in the control group than the avacopan group, but also that there were more serious adverse events related to liver safety in the avacopan group compared to the control group. ECF No. 282-31 at 13; ECF No. 282-17 at 9–10. While Defendants did not disclose these statistics in exactly the form that the DMC or Plaintiff believe they should have—highlighting the cases that met Hy's Law or avacopan's specific hepatotoxicity risks—there is no obligation under federal securities law for Defendants "to disclose alternative methods of interpreting the data" from their clinical trial. *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d at 879. Where Defendants'

own interpretation of data is itself reasonable, Defendants are not required to disclose the DMC's "contrary views" to their interpretation of the ADVOCATE trial data even if that feedback "cast[s] doubt on the trial data." *See Strezsak*, 2024 WL 1160900, at *6; *Philip Morris*, 89 F.4th at 420. For similar reasons, that one of ChemoCentryx's senior medical executives advised Schall to publicly discuss cases of liver injury does not compel a different result. *See Omnicare*, 575 U.S. at 190 ("A reasonable investor does not expect that *every* fact known to an issuer supports its opinion statement."). "At bottom, Plaintiff['s] allegations regarding Defendants' stated opinion about the [ADVOCATE safety] results are little more than a dispute about the proper interpretation of data," and "Defendants' statements were not misleading simply because the FDA [or the DMC] disagreed with Defendants' interpretation of the data; an issuer is not liable merely because it 'knows, but fails to disclose, some fact cutting the other way.'" *Tongue*, 816 F.3d at 214 (quoting *Omnicare*, 575 U.S. at 188–89).

b. ADVOCATE's "Validated" Secondary Endpoints

Plaintiff contends that Defendants touted the results from the ADVOCATE trial's "validated" secondary endpoints—primarily the use of the glucocorticoid toxicity index ("GTI")—as "definitive evidence statistically that [avacopan was] superior in reducing glucocorticoid-related toxicities." ECF No. 303-3 at 18 (quoting ECF No. 47 ¶¶ 218–90). Plaintiff argues that these statements were misleading because the FDA had consistently told Defendants that it would not accept results from the GTI for regulatory purposes and individuals at ChemoCentryx had expressed internally that the GTI may not be considered "validated."

Reading the challenged statements in the context of the "hedges, disclaimers, [and] qualifications [Defendants] included" about their usage of the GTI, however, the Court finds that Plaintiff has not demonstrated that there was any omission that rendered Defendants' opinion statements about their secondary endpoints misleading. *Omnicare*, 575 U.S. at 196. For example, during Defendants' November 25, 2019 Investor Call, Schall described the novel use of GTI as what "we believe now [is], at least, [a] semi-validated instrument." ECF No. 282-26 at 8. Indeed, on that same call, an actual investor demonstrated their understanding about the "novel" nature of GTI—inquiring "how familiar are physicians and payers to this metric . . . [a]nd how easily is this

going to be receptive amongst the community there?" *Id.* at 17. To this, Schall acknowledged that "GTI, as good as it is, is brand new," and that there would need to be much "education to be done on GTI" but that he believed "that people are going to understand its power." *Id.* at 18. And even the example statement cited by Plaintiff expresses that the GTI was "newly-validated"—not that it was validated by the FDA or other regulatory authorities. ECF No. 268-10 at 3. A reasonable investor would thus not have been misled by the statement as to GTI's validity because the context of Defendants' disclosures revealed the extent to which Defendants were expressing their own opinion on the novel application of GTI. *See Omnicare, Inc.*, 575 U.S. at 190 ("A reasonable investor does not expect that *every* fact known to an issuer supports its opinion statement.").

Moreover, Defendants' statements about GTI being "validated" "cannot be misleading merely because the FDA disagreed with the conclusion—so long as Defendants conducted a 'meaningful' inquiry and in fact held that view, the statements did not mislead in a manner that is actionable." *Tongue*, 816 F.3d at 214. Here, Defendants conducted a "meaningful" inquiry, as Defendants cited multiple academic papers supporting Schall's view that GTI was "newly-validated" or "at least, semi-validated." *See* ECF No. 282-17 at 12 nn. 24, 25 (*NEJM* article citing a 2017 paper and 2020 paper establishing the use of GTI to measure glucocorticoid-associated morbidity); ECF No. 282-4 at 21 n.34 (JMIR Article citing the same 2017 paper). And while Plaintiff cites internal communications where an individual at ChemoCentryx indicated concern about the validity of GTI, none of these documents—to the extent they were not already reflected in Defendants' public qualifications about GTI—directly conflicts with Schall's opinions or suggests that *Schall* did not in fact believe his opinions. *See Tongue*, 816 F.3d at 203, 213–214 (finding no conflict between the defendants' statements that "the [trial] data are nothing short of stunning," and the FDA's repeated communications that the trial design was "unlikely to provide substantial support for" approval). Any conflict is particularly minimized by the fact that most of the cited internal communications were from February 2019—prior to Defendants' publication of the above articles citing new academic support for GTI. *See* ECF No. 303-68 at 2 (email from February 19, 2019); ECF No. 303-69 at 2 (email from February 24, 2019); ECF No. 303-70 (email

and presentation from February 28, 2019).

Accordingly, Defendants are entitled to summary judgment on this category of misrepresentations because the omitted facts do not show that Defendants "lacked the basis for making those statements that a reasonable investor would expect." *Omnicare*, 575 U.S. at 196; *see also Pardi*, 2024 WL 1056013, at *7 (rejecting the suggestion that a "company's failure to disclose the FDA's positions in real time establishes falsity," even when the "FDA had repeatedly indicated its disagreement that [a designated] endpoint was substantial enough to demonstrate the trial's clinical effectiveness").

c. ADVOCATE's Primary Endpoints

Plaintiff argues that Defendants "misled investors by touting ADVOCATE's 'efficacy' results, claiming avacopan satisfied both primary endpoints: 'non-inferiority' at week-26 and 'superiority' at week-52, as compared to 'standard of care.'" ECF No. 303-3 at 16 (citing ECF No. 47 ¶¶ 291–35 and Exhibits 1–37).

Plaintiff does not meaningfully argue that Defendants did not actually meet the two pre-specified primary endpoints of ADVOCATE—non-inferiority at week 26 and superiority at week 52.[8] Nor could it. The FDA in the Briefing Book explicitly agreed with Defendants that ADVOCATE "met its primary endpoints by demonstrating non-inferiority of avacopan to prednisone in disease remission at Week 26 . . . and sustained remission at Week 52 . . . based on the Applicant's specified margin." ECF No. 282-3 at 77.

Instead, Plaintiff argues that Defendants misled investors by making these statements without disclosing that: (1) the FDA disagreed with ADVOCATE's design regarding the primary endpoints and indicated that the non-inferiority endpoint by itself would not be sufficient to prove a successful study; (2) the FDA had reiterated that Defendants' relapse analysis was "problematic from a statistical point of view;" (3) ADVOCATE did not demonstrate avacopan's superiority over standard of care because the standard of care administered by ChemoCentryx did not include "maintenance therapy;" and (4) Defendants violated ADVOCATE's protocol by using a modified

[8] The Court addresses Plaintiff's argument that Defendants did not actually use the pre-specified BVAS scoring below.

version of "BVAS version 3." ECF No. 303-3 at 16–17.

Plaintiff's first three arguments boil down to contending that Defendants "should have used different [] methodologies, not that Defendants misrepresented the results they obtained from the methodologies they employed." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d at 878. But "merely alleging that defendants should have used different statistical methodology in their drug trials is not sufficient to allege falsity." *Id.* And it "'is not the Court's job' to determine whether the flaws Plaintiff alleges with the [use of non-inferiority as a primary endpoint were] 'so anomalous' that stating the topline results of their trial was 'fraudulent if [criticisms of those methodologies were] not disclosed.'" *Bazzelle v. Novocure Ltd.*, No. 1:23-CV-5146-GHW, 2025 WL 843668, at *12 (S.D.N.Y. Mar. 18, 2025) (quoting *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 731 (S.D.N.Y. 2018)).

Furthermore, "fatal to Plaintiff['s] case is the absence of any serious conflict between the FDA's interim, albeit repeated, concerns about" non-inferiority as a primary endpoint and Defendants' statements that ADVOCATE had in fact achieved its pre-specified endpoints as described—including both non-inferiority at week 26 and superiority at week 52. *Tongue*, 816 F.3d at 212; *see also id.* at 203, 213–214 (finding no conflict between the defendants' statements that a drug demonstrated a "strong and robust treatment effect," and that "the data are nothing short of stunning," and the FDA's repeated communications that the trial design was "unlikely to provide substantial support for" approval). That is particularly true when FDA's criticisms related to the use of non-inferiority as a primary endpoint *alone* and agreed with Defendants' revised approach to add a superiority analysis at week 52. *See* ECF No. 303-34 at 7.

Defendants also provided the basis for their topline results—explaining that "[r]emission was defined as a BVAS score of zero and being off glucocorticoid treatment for ANCA vasculitis for at least the preceding four weeks" and that the "pre-specified primary endpoints were remission of acute vasculitis activity at week 26 and sustained remission at week 52, where avacopan therapy was at least statistically non-inferior to the currently used glucocorticoid-containing standard of care (glucocorticoid SOC)." ECF No. 282-1 at 2. Defendants thus accurately described how ADVOCATE achieved its primary endpoints, and Plaintiff's (or even

the FDA's) disagreement with the legitimacy of one of those endpoints does not by itself create an actionable omission. *See Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154–55 (2d Cir. 2013) (finding no misleading omission where the plaintiff argued that the defendants "were able to tout positive results only because they deviated from the established protocol . . . and changed the metrics by which data was analyzed," since the defendants had accurately disclosed their method of analysis); *Bazzelle*, 2025 WL 843668, at *12 (no securities-fraud claim where the defendants "accurately disclosed [trial] topline results" and instead criticize defendants for describing the results "in positive terms . . . based on a trial whose design and methodology [the plaintiff] disputes").

The same is true for Plaintiff's argument that Defendants did not show superiority because they failed to provide maintenance therapy as part of their standard of care—Defendants' trial design does not become a basis for a securities fraud claim just because Plaintiff disagrees with it.[9] *See In re Amarin Corp. PLC Sec. Litig.*, 2022 WL 2128560, at *3 (finding that "different interpretations" as to how to interpret whether the defendant's chosen methodology "affected the trial's results" are "not sufficient to establish that the defendants' interpretations of the data in the topline results lacked a reasonable basis") (internal quotation omitted). And the same problems plague Plaintiff's final argument that Defendants misrepresented the achievement of ADVOCATE's primary endpoints by using a modified version of "BVAS version 3" to evaluate results rather than the official BVAS version 3 used by FDA adjudicators. Contrary to Plaintiff's allegations, the record does not show any genuine dispute that, as recognized by the FDA, Defendants explicitly specified that ADVOCATE would employ a modified version of BVAS 3 that would capture only "active" AAV and not "persistent" AAV. *See* ECF No. 282-18 at 99 (ADVOCATE trial protocol establishing that the BVAS scoring would only record "the presence

[9] The Court also notes that Plaintiff primarily relies on the FDA's feedback that "treatment comparison in the complementary rituximab induction subgroup may not be considered meaningful because these patients did not receive maintenance therapy," but that in that same document, the FDA added the caveat that "at the time the study was designed, repeat dosing with rituximab was not established as maintenance therapy." ECF No. 282-2 at 9–10. The shifting scientific views around the standard of care here illustrate why securities law is generally not the appropriate forum to litigate disagreements over proper trial design and methodologies.

of active AAV"); *see also* ECF No. 282-ECF No. 282-2 at 10 (FDA Briefing Book recognizing that the "pre-specified analysis" in ADVOCATE was a "modified BVAS" that did not capture "persistent vasculitis"). Defendants thus did not misrepresent their trial results, even if Plaintiff contends that the unmodified BVAS 3 scoring would have been more reliable.

Accordingly, the Court finds that there is no triable issue of fact as to whether Plaintiff can demonstrate falsity for the statements relating to ADVOCATE's achievement of its primary endpoints. *See In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d at 879 ("Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results.").

d. Steroid Statements

Plaintiff challenges the "steroid statements" in which it alleges that Defendants represented that ADVOCATE eliminated steroid usage as a variable and showed that avacopan could replace steroids. *See* ECF No. 303-3 at 17–18 (pointing to statements where Schall explained that ChemoCentryx "simply took the steroids out of the mix" and that ADVOCATE "resoundingly" showed "that steroids need not be used when avacopan is available") (quoting ECF No. 47 ¶¶ 351–404 and Exhibits 1–37). Plaintiff argues that the "steroid statements" were misleading because Defendants omitted the fact that 64% of avacopan patients in ADVOCATE used steroids to treat their AAV and that steroid usage for the purpose of treating AAV was no different between the avacopan and "standard of care" arms of the trial. *Id.* And Plaintiff contends that Defendants were aware of this issue because the DMC and FDA had both expressed that the avacopan patients' receipt of steroid treatment would confound comparisons between the treatment arms and undermine any efficacy results.

The Court finds that the full context of Defendants' various "steroid statements" demonstrates that a reasonable investor would have understood Defendants' "steroid statements" as far more limited opinion statements than as depicted by Plaintiff. For example, Defendants consistently framed the goal of avacopan as eliminating the need for "chronic" or "daily" steroid usage—rather than any steroid usage at all—in the existing standard of care. *See, e.g.*, ECF No.

47 ¶¶ 275, 284 ("And by eliminating the need for daily prednisone, we reduce in a statistically significant way the steroid related toxicities . . . ."); *id.* ¶ 378 ("Second, eliminating the need for chronic steroid therapy and the many illnesses associated with that current chronic steroid containing standard of care."); *id.* ¶¶ 319, 381 ("[T]he chronic high-dose steroids which are quite toxic, is really something everyone would love to get rid of. So, what we did is, we took a two-arm study and we said, let's do avacopan instead of the glucocorticoids. Certainly, let's try to eliminate the need for daily steroids in this trial."). And on the November 25, 2019 investor call, where Schall made one of the challenged steroid statements, Schall responded to investors that he "[did not] know" but that "what we showed is that you do not need the chronic steroid regimen." ECF No. 282-26 at 19–20. Similarly, where Plaintiff quotes Schall as saying that the ADVOCATE trial "resoundingly" provided evidence that avacopan could replace steroids, Schall also explained that he thought "that *this may be the beginning* given the breadth of these results across all of these spectrum of total burden of disease." *See* ECF No. 47 ¶ 355.

Moreover, there is no genuine dispute that Defendants had disclosed prior to the beginning of the Class Period that the ADVOCATE trial design permitted steroid usage in the avacopan treatment group as it was needed to treat worsening disease. *See* ECF No. 282-4 at 13 ("[T]he protocol allows for the use of low-dose glucocorticoids (up to 10 mg/day prednisone or equivalent) to treat adrenal insufficiency, and/or to treat worsening or relapsing disease."); *id.* at 18 ("The use, if warranted, in both treatment groups, of a limited amount of non-protocol specified glucocorticoids is allowed at baseline, as is the use of "rescue" glucocorticoids during the study. However, the protocol specifies the indication, dose, duration and tapering schedule for nonprotocol supplied glucocorticoids to limit the impact of their use on the study results."). And Defendants had specifically defined patients as being in "remission" if they did not use steroids *in the four weeks prior to the primary endpoint assessments* at Week 26 and Week 52. *See* ECF No. 282-4 at 8.

Nor is there any genuine dispute that Defendants published the data showing the actual rates of steroid usage in the ADVOCATE treatment arms and reflecting that steroid usage was comparable in the two treatment arms. In the *NEJM article*, Defendants published several tables

of data indicating that 87.3% of patients in the avacopan treatment arm received steroids in the ADVOCATE trial and providing the week-by-week steroid usage of patients across the two treatment arms. ECF No. 282-19, Tables S5 and S6; *see also* ECF No. 282-17 at 11 (citing the fact that "[g]lucocorticoids were used by patients in the avacopan group" as one of ADVOCATE's "limitations"). And in other presentations, Defendants similarly published charts containing the actual week-by-week steroid usage by patients in the two treatment groups. *See* ECF No. 282-30 at 11–12; ECF No. 282-31 at 11. A reasonable investor would thus have known that in making the challenged "steroid statements," Defendants were counting patients in the avacopan group as responding to avacopan even if many of them were taking steroids as needed.

Plaintiff responds to Defendants' disclosure arguments by citing the Court's prior class certification order, in which the Court rejected Defendants' contention that the JIMR article disclosed that after being tapered off steroids at the beginning of the trial, patients in the ADVOCATE trial were permitted to receive non-study supplied steroids for reasons such as adrenal insufficiency or worsening of the disease. ECF No. 303-3 at 37–38 (citing ECF No. 131 at 10). The Court previously found that the JMIR article failed to disclose that steroid use "was similar between the prednisone and avacopan group" or that 64% of avacopan patients were prescribed prednisone to treat their AAV. ECF No. 131 at 10.

But the Court's analysis is now informed by a fuller summary-judgment record and different legal and factual arguments. First, the Court conducted its prior analysis to resolve whether Defendants' disclosures demonstrated a lack of price impact from the alleged misrepresentations—not whether a reasonable investor would have been misled by the "steroid statements" given the context of the above disclosures. Second, the Court looked only at the JMIR article, which—unlike the NEJM article and the other presentations cited above—did not publish the data reflecting actual steroid usage across the two treatment arms and indicating that 87.3% of patients in the avacopan group received steroids. So "even if Defendants had a duty to disclose the FDA's statements, Defendants specifically disclosed the thrust of the concerns Plaintiff asks the Court to infer from the FDA statements at issue." *Strezsak*, 2024 WL 1160900, at *6. Plaintiff in its opposition does not respond to this 87.3% disclosure and does not explain

why Defendants were obligated specifically to express that 64% of patients in the avacopan group received steroids to treat AAV—which is merely a more granular presentation of the 87.3% figure. And Defendants are not required to disclose the most negative framing of their trial data as a matter of securities law. *See Philip Morris*, 89 F.4th at 420 (reiterating the "fundamental principle that the securities laws do not 'require[]' the '[p]eople in charge of an enterprise . . . to take a gloomy, fearful[,] or defeatist view" of the enterprise's standing (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004))).

Plaintiff has not otherwise explained why Defendants' interpretation of the trial data—that ADVOCATE demonstrated that avacopan could begin to replace chronic steroid usage—is "irrational or unreasonable" such that their opinions are actionable. *See Tongue*, 816 F.3d at 214. Indeed, the record contains evidence supporting Defendants' basis for their statements. *See, e.g.*, ECF No. 282-17 at 11 (NEJM article summarizing that although patients in the avacopan group also used glucocorticoids, "the mean daily glucocorticoid dose in the avacopan group was one third of that in the prednisone group"); ECF No. 303-62 at 5 ("There was a similar number of patients in each treatment group who used glucocorticoids for persistent vasculitis, worsening of vasculitis, and maintenance of remission. However, more than twice as many patients in the prednisone grom compared to the avacopan group had glucocorticoid use for relapses (38 vs. 17)."). Accordingly, because Plaintiff's challenge to the "steroid statements" "are little more than a dispute about the proper interpretation [or presentation] of data," the Court grants Defendants' motion for summary judgment as to this category of misrepresentations. *Tongue*, 816 F.3d at 214.

e. Interactions with FDA

Lastly, Plaintiff argues that Defendants' optimistic statements about the regulatory path with the FDA being clear and the FDA not having highlighted any particular issues that would have to be discussed at AdCom were misleading because Defendants failed to disclose the FDA's communications of concerns discussed above.

To begin, the fact that the FDA *did* ultimately approve avacopan for use in the U.S. market may by itself be enough to demonstrate that Defendants had a reasonable basis for interpreting the regulatory path to be clear. *See Philip Morris*, 89 F.4th at 420–21 (holding that where "the FDA

eventually accepts a defendant's interpretation of the data, that interpretation is per se reasonable as a matter of law" (quoting *Tongue*, 816 F.3d at 214) (internal quotation marks and modifications omitted)).

Furthermore, courts have repeatedly held that statements of optimism regarding the FDA regulatory process or even likelihood of approval are not misleading merely because a defendant has not publicly disclosed FDA feedback or criticism communicated to the defendant. Indeed, defendants have "no legal obligation to loop the public into each detail of every communication with the FDA." *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)); *see also Tongue*, 816 F.3d at 214 ("[N]o sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA.").

For example, in *Tongue*, the plaintiffs alleged defendants to have presented misleadingly optimistic projections regarding the timing of FDA approval by failing to disclose the fact that the FDA had communicated repeated concerns about the trial methodology, including that the study design issued would mean that the clinical trial was "unlikely to provide substantial support for" approval. *Tongue*, 816 F.3d at 203–04, 211. There, the Second Circuit rejected plaintiffs' theory because there was no "serious conflict between the "FDA's interim, albeit repeated, concerns about methodology and Defendants' optimism about FDA approval." *Id.* at 212. The Second Circuit added that the "Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections . . . . Certainly, Plaintiffs would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed, but *Omnicare* does not impose liability merely because an issuer failed to disclose information that ran counter to an opinion expressed in the registration statement." *Id.*

And in *Strezsak v. Ardelyx Inc.*, the plaintiffs challenged the defendants' descriptions of their interactions with the FDA as having "gone exceedingly well" and that there was "nothing [untoward] [or] anything that causes us concern" because the FDA had "indicated that Defendants would need to demonstrate clinical relevance and provide a justification for approval given that [the new drug at issue] showed a smaller effect size than seen in already approved agents." 2024

WL 1160900, at *5. Applying *Omnicare*, the court found that defendants' opinions were not actionable because the FDA's statement did not support the inference that approval for defendants' drug was in jeopardy or that its review process was "not actually proceeding in an ordinary manner." *Id.* It further explained that in the context of a "years-long iterative dialogue with the FDA, . . . Defendants were free to express optimism in their application and the prospects for approval, and the feedback from the FDA did not render those expressions of optimism false. To the extent that feedback presented views contrary to those expressions of optimism, Defendants had no obligation to share every opinion raised by the FDA absent more compelling circumstances" not present in the record. *Id.* at *7; *see also Pardi*, 2024 WL 1056013, at *7 ("FDA's expression of its view that the results likely would not be applicable to the U.S. population does not show that [defendant's] confidence in the likelihood of approval was necessarily objectively false or not honestly held.").

Moreover, Defendants here actually *did* caution investors that FDA approval was not guaranteed—warning that "[e]ven if we believe the preclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA," that development may be delayed by "the need to conduct additional trials," that the FDA may "limit the approved indications for use of the product, [or] require that contraindications, warnings or precautions be included in the product labeling," and even that the "FDA may ultimately decide" not to approve avacopan at all. *See* ECF No. 282-28 at 26, 29, 37, 57.

In sum, there is no triable issue of fact as to falsity because there is an absence of "any serious conflict between the FDA's interim, albeit repeated, concerns about methodology and Defendants' optimism about FDA approval," especially as the FDA ultimately approved avacopan based on the ADVOCATE trial. *Tongue*, 816 F.3d at 212. Accordingly, the Court grants Defendants' motion for summary judgment as to this category of statements.

B. 20(a) and 20A Claims Against Schall

Plaintiff has alleged two derivative claims against Schall: a Section 20A claim for insider trading and a Section 20(a) control person claim. "Claims under Section 20A are derivative and therefore require an independent violation of the Exchange Act." *Johnson v. Aljian*, 490 F.3d 778,

781 (9th Cir. 2007); *see also* 15 U.S.C. § 78t-1(a). Similarly, a Section 20(a) claim requires that "a plaintiff must first prove a primary violation of underlying federal securities laws, such as Section 10(b) or Rule 10b–5." *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1052 (9th Cir. 2014); *see also* 15 U.S.C. §78t(a).

Because the Court grants summary judgment in favor of Defendants on the Section 10(b) claims as described above, the Court thus also grants summary judgment in favor of Schall as to the Section 20A insider trading and Section 20(a) control person claims. *See In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 394 (9th Cir. 2010); *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 419 (9th Cir. 2020).

CONCLUSION

For the foregoing reasons, the Court grants summary judgment in favor of Defendants. Lead Plaintiff's motion for partial summary judgment is denied as moot. All pending deadlines and hearings in this action are vacated. Judgment is entered in favor of Defendants and against Plaintiffs.

IT IS SO ORDERED.

Dated: August 15, 2025

JON S. TIGAR
United States District Judge

United States District Court
Northern District of California