UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CITY OF BIRMINGHAM RELIEF AND RETIREMENT SYSTEM; and OHIO CARPENTERS' PENSION FUND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS, INC.; STEPHEN R. DAVIS; and SRDJAN (SERGE) R. STANKOVIC,

Defendants.

Case No. 3:21-cv-00762-WQH-NLS

ORDER

HAYES, Judge:

The matter before the Court is the Motion for Reconsideration filed by Defendants Acadia Pharmaceuticals, Inc., Stephen R. Davis, and Srdjan (Serge) R. Stankovic. (ECF No. 75.)

I. PROCEDURAL BACKGROUND

On April 19, 2021, Denise Marechal initiated this action by filing a Class Action Complaint. (ECF No. 1.) On September 29, 2021, the Court issued an Order appointing City of Birmingham Relief and Retirement System ("Birmingham") as Lead Plaintiff. (ECF No. 38.)

On December 10, 2021, Birmingham and additional Plaintiff Ohio Carpenters' Pension Fund (collectively "Plaintiffs") filed an Amended Class Action Complaint (the "FAC"). (ECF No. 45.) The FAC alleges that Defendants violated federal securities laws by deceiving investors regarding the likelihood of Food and Drug Administration ("FDA") approval of a drug called pimavanserin to treat dementia-related psychosis in order to artificially inflate the market price of Acadia securities. The FAC brings the following claims: (1) violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants; and (2) violation of Section 20(a) of the Exchange Act against Defendants Davis and Stankovic.

On February 15, 2022, Defendants filed a Motion to Dismiss the FAC, requesting dismissal on the basis that "Plaintiffs have not met their burden to plead three essential elements of their Section 10(b) claims: falsity, scienter, and loss causation." (ECF No. 53-1 at 10.) On September 27, 2022, the Court issued an Order denying the Motion to Dismiss (the "September Order"). (ECF No. 65.)

On October 25, 2022, Defendants filed the Motion for Reconsideration, requesting reconsideration of the September Order. (ECF No. 75.) On November 21, 2022, Plaintiffs filed a Response in opposition to the Motion for Reconsideration. (ECF No. 78.) On November 28, 2022, Defendants filed a Reply. (ECF No. 80.)

II. THE SEPTEMBER ORDER (ECF No. 65)

In the September Order, the Court analyzed Defendants' challenges to, among other things, the Section 10(b) elements of falsity and scienter. Falsity refers to "a material misrepresentation or omission by the defendant." *In re Rigel Pharma., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). Scienter refers to "a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016).

The Court identified two categories of false or misleading statements alleged in the FAC: (1) allegations that Defendants affirmatively misrepresented the

existence or terms of an agreement with the FDA concerning the approval of pimavanserin to treat dementia-related psychosis; and (2) allegations that Defendants failed to disclose issues with the design and sub-group level results of the studies (including the "Harmony Study") used to support the application for FDA approval. (*See* ECF No. 65 at 14.) With respect to the former category, the Court determined that Defendants' statements suggested that the agreement with the FDA contained terms—notably, that the design of the Harmony Study "would not represent a further barrier to approval" and that the FDA would not "base its decision … on the data for individual subgroups" in the Harmony Study—that were inconsistent with the FDA's basis for ultimately denying approval. *Id.* at 16-17. The Court concluded that under these circumstances, "a plausible inference may be drawn at the pleading stage that Defendants misrepresented the existence or terms of the agreement." *Id.* at 15.

The Court further determined that the allegations in the FAC supported an inference that Defendants "were aware of the shortcomings" of the studies used to support the application, and that their failure to disclose these shortcomings when touting the results of the studies "rendered Defendants' positive statements regarding the results of the studies materially misleading." *Id.* at 19. In conducting this analysis, the Court held that "[t]he allegation that the data set of the Harmony Study was released in connection with a presentation to medical professionals is not sufficient at the pleading stage to establish that this disclosure was sufficient to counterbalance any misleading impression generated by Defendants' omissions," and did not, in any case, "occur until December 4, 2019, almost three months after the first allegedly misleading statement." *Id.* at 20-21.

The Court held that an inference of scienter was supported by the allegations that the FDA denied the application on grounds plausibly inconsistent with Defendants' descriptions of an agreement with the FDA, coupled with factual allegations of Defendants' awareness of the actual terms of any such agreement and Defendants' intent that their statements be understood in the manner alleged. The

Court held that the scienter inference was further supported by the individual Defendants' pattern of stock sales. The Court weighed the inference of scienter against the competing inference—"that Defendants did not intentionally or recklessly mislead investors"—and determined that "a reasonable person would deem the inference of scienter cogent and at least as compelling" as the opposing inference at the pleading stage. *Id.* at 24-25.

III. CONTENTIONS

Defendants contend that the September Order's "scienter analysis departs from the requisite application of [the applicable pleading standards] in three ways, each of which warrants reconsideration for clear error." (ECF No. 75-1 at 7.) First, the September Order "improperly credits Plaintiffs' conclusory allegations of Defendants' 'access' to unspecified information" in the absence of allegations describing the content of this information or linking it to Defendants. *Id.* Second, allegations of the individual Defendants' stock sales cannot support the requisite inference of scienter. Third, the September Order "does not appropriately weigh all nonculpable inferences against those favoring Plaintiffs." *Id.* at 9. Defendants further contend that the September Order's "falsity analysis also departs from controlling law" by "improperly rel[ying] on disputes about trial design to support falsity" and "disregard[ing] Defendants' disclosures of the very facts Plaintiffs allege were misleadingly omitted." *Id.* at 11, 13.

Plaintiffs contend that there is no basis for reconsideration because "what Defendants label as 'clear errors' are mere disagreements with how the Court weighed the facts and applied the law." (ECF No. 78 at 6.) With respect to scienter, Plaintiffs contend that Defendants' position "that Acadia's 'agreement' with the FDA was 'unspecified' ignores" the allegations of Defendants' own statements purporting to describe an agreement that was "inconsistent with the FDA's subsequent reasons for denying approval." *Id.* at 8-9. Plaintiffs contend that Defendants "falsely assume[] that the Court based its entire scienter analysis on only the stock-sale allegations,

when it is obvious that such sales were just one piece of the Court's holistic review. *Id.* at 10. Plaintiffs contend that the Court "considered ***all*** plausible scienter inferences … [and] weighed them against any competing inferences." *Id.* at 9-10. With respect to falsity, Plaintiffs contend that Defendants' critique of the Court's reasoning is unfounded because the FAC does more than raise "a bare disagreement on the statistical methodology to be used in a clinical trial." *Id.* at 13. Plaintiffs further contend that the Court considered Defendants' purported disclosures and correctly applied the law in analyzing the effect of such disclosures on Plaintiffs' claims at this stage of the litigation.

IV. LEGAL STANDARD

Rule 54(b) of the Federal Rules of Civil Procedure "explicitly grant courts the authority to modify their interlocutory orders." *Balla v. Idaho State Bd. Of Corr.*, 869 F.2d 461, 465 (9th Cir. 1989). To determine the merits of a request to reconsider an interlocutory order, district courts in this circuit apply the standard for Rule 59(e) reconsideration motions. *See, e.g., Cooney v. California*, No. 13-cv-01373-BAS (KSC), 2015 WL 3952184, at *1 (S.D. Cal. June 29, 2015) (same).

Reconsideration under Rule 59 is "an extraordinary remedy, to be used sparingly in the interest of finality and conservation of judicial resources." *Kona Enters., Inc. v. Estate of Bishop*, 229 F.3d 877, 890 (9th Cir. 2000) (quotation omitted). "Whether or not to grant reconsideration is committed to the sound discretion of the court." *Navajo Nation v. Confederated Tribes & Bands of the Yakama Indian Nation*, 331 F.3d 1041, 1046 (9th Cir. 2003). "Reconsideration is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." *Sch. Dist. No. 1J v. ACandS, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993). A motion for reconsideration "may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation." *Kona Enters.*, 229 F.3d at 890. A motion for

reconsideration is likewise not a vehicle for relitigating issues that have been previously adjudicated. See *Weeks v. Bayer*, 246 F.3d 1231, 1236 (9th Cir. 2001) (stating that granting a party a "second bite at the apple" is "not the purpose of Rule 59").

V. SCIENTER

Defendants first contend that the September Order "improperly credits Plaintiffs' conclusory allegations of Defendants' 'access' to unspecified information" in the absence of allegations describing the content of this information or linking it to Defendants. (ECF No. 75-1 at 7-8.)

In its discussion of scienter, the Court stated: "Defendants plausibly would have been aware of the terms of any agreement with the FDA and the alleged shortcomings with the design and results of the [supporting studies]." (ECF No. 65 at 22.) In support of this determination, the Court cited the allegation that "Defendants Davis and Stankovic 'possessed the power and authority to control the contents of Acadia's SEC filings, press releases, and other market communications' and had 'access to material information available to them but not to the public.'" *Id.* (quoting FAC, ECF No. 45 ¶ 26).

As the Court noted in the September Order, a "court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007). The allegation that Defendants had "access to material information" regarding an agreement with the FDA is supported by other factual allegations contained in the FAC, including Defendants' own statements describing an agreement with the FDA and representations that the agreement was "documented in our minutes." (ECF No. 45 ¶ 132.) Accordingly, the Court did not err in determining that Defendants plausibly would have been aware of the terms of an agreement with the FDA.[1]

[1] While the September Order describes the FAC's allegations as plausible, the Court did not ultimately base its determination that the scienter requirement was adequately pleaded based on the

Defendants assert that a complaint that relies on a contradiction between internal reports and challenged statements must allege the contents of such reports to demonstrate scienter. The cases cited by Defendants in support of this position address situations in which plaintiffs allege the existence of negative internal reports that contradict defendants' public statements without alleging the actual content of such reports. *See, e.g., Nguyen v. Endologix, Inc.*, 962 F.3d 405, 417 (9th Cir. 2020); *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999). Under such circumstances, specific allegations regarding the content of the internal reports are necessary to support plaintiffs' claims. *See id.* However, Plaintiffs in this case allege that Defendants' statements contradict an agreement with the FDA, not internal reports. Accordingly, the FDA's denial of Defendants' application in a manner plausibly inconsistent with Defendants' prior description of their agreement with the FDA adequately supports Plaintiffs' allegations that Defendants' statements were not consistent with the terms of any actual agreement.

Likewise, Defendants' awareness of the design and sub-group level results of the supporting studies based on their access to material information is supported by their public statements, which repeatedly reference these aspects of the studies. In addition, the plausible allegations that Defendants intentionally or recklessly misrepresented the terms of an agreement with the FDA buttress the allegation that Defendants acted with scienter in shielding negative information about the studies from the public.

Defendants next contend that allegations of the individual Defendants' stock sales cannot support the requisite inference of scienter. While Defendants are correct that the stock sales alone would be insufficient, the Court considered the stock sales as one of several factors supporting such an inference. *See id.* at 22-24.

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mere plausibility of the allegations. It instead expressly weighed the allegations against nonculpable inferences and determined that the inference of scienter was "cogent and at least as compelling as any opposing inference." (ECF No. 65 at 25.)

Finally, Defendants contend that the September Order "does not appropriately weigh all nonculpable inferences against those favoring Plaintiffs." (ECF No. 75-1 at 9.) In particular, Defendants contend that the Court improperly discounted the allegations concerning the release of the Harmony Study data set during the class period, as well as the possibility that the FDA broke its agreement with Acadia in denying approval of the application.

In its analysis, the Court explicitly considered Defendants' position on disclosure and explained why that position was ultimately not persuasive. (*See* ECF No. 65 at 24 ("The competing inference—that Defendants did not intentionally or recklessly mislead investors—is supported in part by Defendants' release of the Harmony Study's dataset in connection with a presentation to medical professionals. However, this disclosure occurred almost three months after the initial actionable omission and was followed by Defendants' assurances that Acadia had an agreement with the FDA").) Defendants' disagreement regarding the weight of the competing inferences is not adequate grounds for reconsideration. Further, the Court does not find at this stage that the possibility that the FDA broke its agreement with Acadia outweighs the competing inference that Defendants misrepresented the terms of the agreement. Defendants' request for reconsideration of the Court's determination that Plaintiffs adequately pleaded the element of scienter is denied.

VI. FALSITY

Defendants contend that the September Order "improperly relies on disputes about trial design to support falsity." (ECF No. 75-1 at 11.) In support of this contention, Defendants cite authority that "disagreements over statistical methodology and study design are insufficient to allege a materially false statement." *In re Rigel*, 697 F.3d at 877.

While the FAC contains allegations suggesting disagreement over statistical methodology and study design, the Court did not determine that falsity was adequately alleged based on the existence of such disagreements. (*See* ECF No. 65

at 18-19 ("There are no adequately alleged facts from which the Court can infer that Defendants' objective descriptions of the Acadia studies were false. Further, Defendant's interpretation of the data and results of the studies were plainly expressions of opinion.").) Instead, the Court held that several of Defendants' statements were plausibly misleading because they omitted existing adverse information. *Cf. In re Rigel*, 697 F.3d at 878 ("Plaintiff is alleging that Defendants should have used different statistical methodologies, not that Defendants misrepresented the results they obtained from the methodologies they employed."). Accordingly, the Court determined that its analysis was governed by binding authority that "'once defendants cho[o]se to tout' positive information to the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." *Schueneman*, 840 F.3d at 705-06 (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) (alteration in original)). Further, in this case, the allegations concerning the omission of adverse information must be considered in conjunction with the allegations that Defendants misrepresented an agreement with the FDA concerning the exact same information. Defendants have failed to identify any clear error with this aspect of the Court's analysis.

Defendants alternatively contend that the September Order "disregards Defendants' disclosures of the very facts Plaintiffs allege were misleadingly omitted." (ECF No. 75-1 at 13.)

A defendant can rebut allegations that an omission was misleading by either showing that no omission occurred or that the omission was not material. *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1008 (9th Cir. 2018) ("Even if a statement is not false, it may be misleading if it omits material information."). In the September Order, the Court characterized Defendants as disputing the materiality of their alleged omissions under a truth-on-the-market defense, based on the allegations that "[o]n December 4, 2019, Acadia presented the Harmony Study's top-line results"

and "released the full data set of the Harmony Study" in connection with the presentation. (ECF No. 45 ¶ 62.) As the Court noted, to support a truth-on-the-market defense, Defendants have the burden of "prov[ing] that the information that was withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations.'" *Provenz*, 102 F.3d at 1492-93 (quoting *Kaplan v. Rose*, 49 F.3d 1363, 1376 (9th Cir. 1994)). The Court determined that "[t]he allegation that the data set of the Harmony Study was released in connection with a presentation to medical professionals is not sufficient to counterbalance any misleading impression generated by Defendants' omissions."[2] (ECF No. 65 at 20.)

Defendants contend that the Court erred by applying the truth-on-the-market doctrine, a defense to materiality, because their disclosure instead demonstrates that they did not engage in any actionable omission in the first place. In support of their position, Defendants cite *In re Obalon Therapeutics, Inc.*, No. 3:18-cv-0352-AJB-WVG, 2019 WL 4729461 (S.D. Cal. Sept. 25, 2019). In *Obalon*, the defendants presented evidence that information allegedly omitted from securities filings related to an initial public offering was in fact disclosed by the defendants in various other public securities filings. The plaintiff asserted that this raised a truth-on-the-market defense that could not be resolved at the motion-to-dismiss stage. However, the court rejected the application of the truth-on-the-market doctrine, instead holding that the disclosure demonstrated the absence of any omission, on the basis that a truth-on-the-market defense is implicated when the information at issue "was made credibly available to the market by ***other sources***." *Id.* at *6 (emphasis in original) (quoting

[2] The Court's description of this presentation as being made "to medical professionals," (ECF No. 65 at 20), is supported by the immediately preceding allegation that "Acadia announced that it would present the Harmony Study results at the 12th Clinical Trials on Alzheimer's Disease ('CTAD') Meeting in December 2019." (ECF No. 45 ¶ 61.)

Nguyen v. Radient Pharm. Corp., No. SACV11-0406, 2011 WL 5041959, at *6 (C.D. Cal. Oct. 20, 2011)).

Obalon does not stand for the broad proposition that the truth-on-the-market defense never applies when, as is alleged in this case, a defendant itself disseminates information allegedly omitted from a particular statement. As an initial matter, the authority cited by the Court in the September Order does not suggest the existence of any such bright-line rule. *See Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996) ("In a 'fraud on the market' case 'an omission is materially misleading only if the information has not already entered the market.'" (quoting *In re Convergent Tech. Sec. Litig.*, 948 F.2d 507, 513 (9th Cir. 1991))). Further, while *Obalon* states that a truth-on-the-market defense involves a disclosure "by other sources," Defendants offer no support for the position that this qualifier is intended to refer to the identity of the party disclosing the information. To the contrary, the very case cited by *Obalon* for the "other sources" phrase characterized a defendant's assertion of their own disclosure as a truth-on-the-market defense and rejected the defense as premature at the pleadings stage. *See Nguyen*, 2011 WL 5041959, at *6 (analyzing a defendant's assertion that it publicly disclosed information omitted from a press release in other securities filings). To the extent that application of the truth-on-the-market defense requires that information come from "other sources," this phrase is better understood as requiring the information to come from other types of statements, documents, or evidence than the allegedly actionable statement. Otherwise, any disclosure of information by a defendant, no matter how obscure or remote in time or context from the allegedly misleading statement omitting that information, would categorically negate the element of falsity. In this case, Defendants' release of the data set at issue implicates a truth-on-the-market theory because the release of the data set occurred at a distinct time and in a distinct manner from the allegedly actionable statements.

Defendants contend that "[i]f Plaintiffs can rely on the efficient market hypothesis to plead that [ ] ***allegedly misleading statements*** made at [other]

healthcare conferences were rapidly digested by the market," then Defendants are entitled to the same presumption with respect to the Harmony Study data released at the conference on December 4, 2019. (ECF No. 75-1 at 14.) Defendants further contend that the allegations do not establish that the information disclosed was not adequately transmitted to the market. However, the burden is on Defendants to support their defense, and the Court declines to draw an inference in favor of Defendants at the pleadings stage that all information disseminated at various conferences and in different forms was necessarily transmitted to the market with the same intensity as Defendants' allegedly misleading statements.[3] *See In re Amgen Inc. Sec. Litig.*, 544 F.Supp.2d 1009, 1025 (C.D. Cal. 2008) (stating that courts "rarely" dismiss a complaint based on a truth-on-the-market defense because such a defense is "intensely fact-specific"). Further, as the Court has noted, the release of the Harmony Study data did not occur until mid-way through the class period and was followed by Defendants' public assurances regarding an agreement with the FDA. Defendants' request for reconsideration of the Court's determination that Plaintiffs adequately pleaded the element of falsity is denied.

VII. CONCLUSION

IT IS HEREBY ORDERED that the Motion for Reconsideration (ECF No. 75) is denied.

Dated: February 2, 2023

William Q. Hayes

Hon. William Q. Hayes
United States District Court

[3] The Court rejects Defendants' contention that the Court should have granted judicial notice of evidence presented for the first time in Defendants' Reply brief, particularly given that Defendants raised the disclosure defense in their initial brief. *See Provenz*, 102 F.3d at 1483 (stating that a court should not consider new evidence presented in a reply unless the opposing party has had an opportunity to respond).