UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Todd Schueneman, Plaintiff, vs. Arena Pharmaceuticals, Inc. et al., Defendants.	CASE NO. 10cv01959-CAB (BLM) ORDER GRANTING MOTION TO DISMISS WITHOUT PREJUDICE and DENYING MOTION TO STRIKE [Doc. Nos. 60, 62]

Defendants' motion to dismiss the Second Amended Complaint ("SAC") challenges whether Plaintiff sufficiently pleads a material misrepresentation and scienter. The Court held oral argument on Friday, October 25, 2013, and Defendants focused their argument on the reasons they contend the SAC fails to meet the Ninth Circuit's pleading requirements for scienter. For the reasons stated on October 25, 2013 and below, the Court agrees. Under the unique facts of this case, the SAC fails raise a strong inference of scienter.

PARTIAL FACTUAL BACKGROUND

The facts set forth herein are taken from the SAC or documents incorporated therein, and are accepted as true for purposes of this procedural juncture only. The SAC supplements the allegations of the Consolidated Amended Class Action Complaint already outlined by this Court's prior order, [Doc. No. 56]. Accordingly, this order does not fully recite the facts before the Court.

Plaintiff alleges that Arena Pharmaceuticals, Inc. ("Arena" or the "Company") and its most senior executives violated Section 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder by making materially false statements and/or omitting to disclose material facts concerning the safety and the completeness of the data needed for FDA approval of Arena's weight loss drug, lorcaserin – Arena's most important developmental drug.[1]

The Rat Study of lorcaserin at issue in this case was a key, long-term carcinogenicity study on rats designed to approximate a lifetime of human use, and to assess risk to humans. [¶6; *see also* ¶69.][2] By February 2007, the interim results of the ongoing Rat Study indicated that lorcaserin caused mammary, brain, skin and nerve-sheath tumors, including lethal, malignant mammary and brain tumors. [¶12; Doc. No. 61-5 at 8, Ex. D.] Starting in September 2007, the FDA told Arena its concern that the Rat data reflected potential effects in humans and that Arena needed to dispel this concern with data on animals and humans exposed to lorcaserin. [Doc. No. 61-5 at 7, Ex. D.][3]

The FDA and Arena representatives, including defendants Shanahan, Anderson and Behan, met in April 2008 to discuss, *inter alia*, the causes of mammary tumors in rats and the FDA's concern about the tumors' significance to humans. During this meeting, the FDA approved Arena's written warning to humans in the clinical trials and told Arena that animal mechanistic studies and continued clinical study of humans exposed to lorcaserin could dispel its concern about the Rat data. At that time, Arena

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[1] The "Defendants" are Arena Pharmaceuticals, Inc. ("Arena" or the "Company"); Jack Lief ("Lief"), Arena's President, CEO and Chairman; Robert E. Hoffman ("Hoffman"), Arena's CFO; Dominic P. Behan ("Behan"), Arena's Senior Vice President and Chief Scientific Officer; William R. Shanahan, Jr. ("Shanahan"), Arena's Senior Vice President and Chief Medical Officer; and Christy Anderson ("Anderson"), Arena's Vice President of Clinical Development.

[2] "¶_" refers to paragraphs in the SAC, Doc. No. 59.

[3] Page references to documents filed on the docket of this case refer to the ECF-generated page numbers.

representatives hypothesized that the tumors were attributable to a rodent-specific mechanism. [Doc. No. 61-5 at 8.]

The FDA allowed Arena to continue the ongoing phase 3 clinical trials on humans despite the tumor data because 1) the Rat Study data was incomplete, and thus, "the interim tumor incidence data would change (e.g., might be less worrisome) as full histopathology assessments became available after completion of the study"; 2) the "drug exposure in rats was nearly twice as high as predicted, which increased the safety margin to clinical exposure"; 3) "prolactin was a reasonable explanation of mode of action" based on "preliminary data," which would mean that the mammary tumors were due to a "rodent-specific mechanism"; 4) "there were no mammary tumors in mice" studied; 5) "only with continued clinical study was it possible to assess whether long-term dosing with lorcaserin increased serum prolactin levels in humans"; 6) "only with continuation of clinical dosing would we [the FDA] obtain an accurate assessment of lorcaserin's weight-loss efficacy and safety in diabetics"; and 7) "given that lorcaserin is non-genotoxic, we [the FDA] believed that cancer risk was low under the conditions of use in the ongoing clinical trials (not the case with chronic or indefinite use)." [Doc. Nos. 61-4 at 7, 14, 20, Ex. C; 61-5 at 5, 7-8, Ex. D.]

To support the hypothesis that the mammary tumors were due to a "rodent-specific mechanism", the FDA 1) "asked for mechanistic studies exploring the role of prolactin"; 2) "requested a draft report of the rat and mouse carcinogenicity studies as soon as possible"; and 3) "requested changes to the clinical protocol to include analysis of human serum prolactin." [*Id.*; ¶88.] Further, the FDA requested from the Company that the "updated informed consent forms [for the clinical trial] included the nonclinical breast and brain cancer findings." [Doc. No. 61-5 at 8, Ex. D.] In addition, "the FDA directed Defendants to prepare bi-monthly updates on the Rat Study's results as data became available for both mammary and brain tumors." [¶¶15-16, 19, 23, 25, 77-78, 83, 88.]

The bimonthly updates continued until the Rat Study was completed and draft

report of the Rat Study was submitted to the FDA on February 3, 2009. [Doc. No. 61-4 at 14, Ex. C.] "The Rat Study found that breast tumors developed at all doses, and that lorcaserin caused brain tumors as well as many other malignant tumors." [¶¶28, 101.] "[T]he final Rat Study data . . . was further revised from the data that Defendants reported to the FDA in April 2008 to show an increase in benign tumors and a decrease in malignant tumors." [¶100.] The data Defendants submitted to the FDA failed to sufficiently demonstrate that the results of the Rat Study were irrelevant to humans. [¶101.]

STANDARD OF REVIEW

The pleading requirements for scienter under Section 10(b) of the Exchange Act are set forth in 15 U.S.C. § 78u-4(b)(2) is as follows:

(2) Required state of mind

(A) In general

> . . . in any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, 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) (emphasis added). In the Ninth Circuit, the required state of mind is that "the plaintiffs must show that defendants engaged in 'knowing' or 'intentional' conduct." *South Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 782 (9th Cir. 2008) (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 975 (9th Cir. 1999). "We have held that reckless conduct can also meet this standard 'to the extent that it reflects some degree of intentional or conscious misconduct,' or what we have called 'deliberate recklessness.'" *Id.* "The absence of a motive allegation, though relevant, is not dispositive." *Matrixx Initiatives, Inc. v. Siracusano,* 131 S. Ct. 1309, 1324 (2011).

In determining whether Plaintiffs have adequately pled scienter on a motion to dismiss, the Court must 1) accept all factual allegations as true, 2) consider the

complaint and "other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions" to determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard," and 3) take into account plausible opposing inferences. *Tellabs*, 551 U.S. at 322-23.

ANALYSIS

Plaintiff argues that Defendants, as members of the Lorcaserin Team,[4] made statements that the results of animal testing were positive despite the fact that they "did not reasonably believe that the results of the Rat Study posed no threat to human use." [*See* Doc. No. 61 at 1.] At oral argument, Plaintiff focused on Defendants' failure to disclose that they had failed to dispel a material risk that had come to fruition – the FDA's concern that the rats in the Rat Study experienced a drug-related increase in tumors that could be relevant to humans using lorcaserin.

The allegations of the SAC give rise to a core operations inference of knowledge about the lorcaserin Rat Study for defendants Arena, Lief, Behan, Shanahan, and Anderson.[5] Specifically, the SAC provides "additional detailed allegations about the defendants' actual exposure to information" that gives rise to the inference that these defendants knew about the Rat Study data and Arena's communications with the FDA about it. *See South Ferry LP, #2*, 542 F.3d at 784-85.

A. March 12, 2009 Statement

Having reviewed the alleged false and materially misleading statements, the Court begins its analysis of Defendants' alleged scienter on March 12, 2009. Prior thereto, the allegations of this case fail to show that Defendants had a duty to disclose interim information about the Rat Study or their dialogue with the FDA about it or that

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[4] Defendant Hoffman is not alleged to be part of the Lorcaserin Team.

[5] The SAC does not sufficiently plead a core operations inference for defendant Hoffman. Defendant Hoffman is **dismissed** from this action as a result of Plaintiff's failure to sufficiently plead his knowledge of the Rat Study data.

they made deliberately reckless misleading statements about the Rat Study .[6] *Matrixx*, 131 S. Ct. at 1321-22 ("companies can control what they have to disclose under these [securities law] provisions by controlling what they say to the market").

In 2009, Defendants knew in order to obtain FDA approval to market lorcaserin, Arena needed to demonstrate the Rat Study supported lorcaserin's safety profile with respect to potential carcinogenicity. Specifically, in light of interim Rat Study data showing "a high incidence of mammary tumors in female" rats and "an apparent dose-dependent increase in incidence of malignant mammary tumors" in female rats, the FDA had told Defendants in 2008 that Arena needed to show that the drug's mechanism or tumorigenic mode of action for mammary tumors is not relevant to humans. [Doc. No. 61-4 at 14, Ex. C; ¶¶70, 101.] To do so, the FDA requested that the Company complete animal mechanistic studies, among other things, exploring whether mammary tumors found in the Rat Study were attributable to a rat-specific mechanism. The FDA considered Defendants' hypothesis that the tumors were the result of a rat-specific mechanism to be plausible, but required more data to support this hypothesis.

Plaintiff pleads that, by February 2009, "[t]he final Rat Study data that Defendants submitted to the FDA showed that tumors in female rats occurred at ***all*** doses and increased multiple tumor types in male rats, and that tumors occurred early and were very aggressive, leading to premature deaths." [*See*, *e.g.*, ¶101 (emphasis in SAC).] Plaintiff pleads that Defendants knew the purportedly adverse results undermined the long-term safety and sufficiency of the data needed for Arena's New

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[6] For example, Defendants' March 17, 2008 press release is about cardiovascular safety. The press release announces a specific cardiovascular safety milestone and limits its content to the implications of achieving that milestone. While Defendants may have possessed unfavorable carcinogenicity information at the time, the press release did not address or even allude to lorcaserin's carcinogenicity or overall safety profile. Nor are there any facts to infer that like the human trials there were safety milestones for the Rat Study that should have been disclosed. As such, Defendants' statements did not mislead investors about safety or the Company's carcinogenicity studies.

Drug Application ("NDA"). Plaintiff also pleads that Defendants knew or deliberately disregarded the fact that Arena had not satisfied the FDA's request for scientific evidence showing the mammary tumors were caused by rat-specific mechanism, which was required to address the FDA's concern that the Rat Study was relevant to humans. Plaintiff pleads that satisfying this request was especially important because, with respect to the Rat Study, "[n]o safety margin was identified for the mammary tumors and the safety margin for brain tumors was uncertain." [¶101.]

According to the SAC, Defendants would have known that "[w]hen safety margins are absent or uncertain in a carcinogenicity study, it is critical that a drug sponsor demonstrate that the drug's mechanism or tumorigenic mode of action is not relevant to humans." [¶70.] Again, Plaintiff contends that Defendants failed to make this demonstration. Plaintiff therefore argues "considering the facts alleged in the Complaint, it is at least as likely than not that the Defendants knew of the Rat Study's adverse results, knew that the FDA had concerns about the Rat Study's adverse results and that the FDA believed that there was risk to humans, and that Defendants deliberately chose to hide this material information from investors." [Doc. No. 61 at 10.]

Plaintiff argues that with this factual backdrop, on March 12, 2009, defendant Lief made the following statement: "Well, the confidence [on lorcaserin's potential] is not just based on the blinded data, of course, the confidence is based on the Phase II data, the Phase I data, ***the preclinical studies that was done, all the animal studies that have been completed***." [¶144 (emphasis added).] According to Plaintiff, when Defendants made statements about lorcaserin's safety Defendants should have disclosed the adverse results observed in the Rat Study and the FDA's concerns that they were relevant to humans and could not have reasonably believed that the results of the Rat Study were positive, favorable, or encouraging.

Based on a holistic view, the Court concludes Plaintiff has not established that Defendants' statement to the market about their increasing confidence in lorcaserin's

overall safety profile in March 2009 (and thereafter), demonstrates as strong inference of deliberate recklessness. Despite the SAC's negative characterization of the Rat data, the documents relied upon by the SAC tell a more complete story that the Court considers for purposes of its scienter analysis.

By the time Defendants finalized the Rat Study data, the number of malignant tumors identified by the interim data were revised downward through the peer-review process.[7] The final Rat Study data showed there was no significant cancer in any of the groups that would be clinically relevant to an assessment of human risk or use. The facts alleged do not persuasively show that Defendants were or should have been suspicious of this cancer data. Thus, the Court concludes the record supports the more plausible inference that Defendants, when speaking about lorcaserin's overall safety profile and potential, reasonably believed it to be positive, favorable, or encouraging. In addition, the FDA ultimately accepted and agreed with Arena's final data on the amount of cancer, which further supports an absence of scienter regarding the accuracy of the favorable cancer data. [*See* Doc. Nos. 44-6 at 10; 44-6 at 59; 60-4 at 17.][8]

B. September 18, 2009 Statement

Whether defendant Anderson's September 18, 2009 gives rise to a strong inference of scienter is a closer question. Defendant Anderson made the following alleged materially false and misleading statement on September 18, 2009: "We've I think put together pretty much all of the data that we now need for this NDA. We have ***favorable results on everything*** that we've compiled so far. . . ." [¶190 (emphasis added); Doc. No. 44-5 at 23, Ex. J.] This statement, having been made by the Company's Vice President for Lorcaserin Development and the person in charge of

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[7] The FDA contemplated such a downward revision might occur in allowing human trials to go forward. [¶¶100, 123; Doc. No. 61-5 at 9, Ex. D.]

[8] Considered holistically in the context of the current allegations before the Court, Plaintiff's other allegations related to scienter, *e.g.* the FDA inspection, confidential witnesses, insider sales and budget cuts, do not meaningfully contribute to a strong inference of scienter with respect to the overall safety statements.

putting together the NDA, communicated to investors that Arena had checked all the boxes that it needed to for its NDA submission. Plaintiff alleges that Defendants had not checked all the boxes and they knew it.

According to Plaintiff, this statement was materially false and misleading because Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism with data on prolactin levels in animals exposed to lorcaserin. The Court concludes that the record before the Court may contain enough facts to show a strong inference of scienter for defendant Anderson based on her September 2009 statement. Specifically, Plaintiff may be able to show facts from the current record supporting a conclusion that it was more than just a difference of scientific opinion that led to the FDA's conclusion that Defendants failed to demonstrate that the Rat Study was irrelevant to humans. The factual record may give rise to the more plausible inference that defendant Anderson knew or deliberately disregarded facts that seriously undermined any belief Defendants may have had regarding the sufficiency of the data.

However, in coming to this conclusion, the Court finds itself combing through portions of the record that the SAC does not specifically identify, or that the parties have not sufficiently briefed for purposes of this motion to dismiss. To fairly conduct a holistic analysis of scienter, Plaintiff should amend to set forth the portions of the record that show this case to be about more than a difference of scientific opinion between the Company and the FDA on the sufficiency of the mechanistic studies regarding lorcaserin's mechanism or tumorigenic mode of action. By allowing for such an amendment, Defendants can properly respond to whether they made an affirmative misrepresentation regarding the completeness, sufficiency or favorableness of Arena's results.[9]

[9] Should Plaintiff choose to amend, Plaintiff is directed to dramatically limit his amended complaint to the alleged materially false and misleading statements that support Plaintiff's theory that Defendants knew they had to and failed to substantiate

The Company presented the FDA with an analysis of the Rat Study's mammary tumors that combined cancer data with non-cancer data.[10] "[C]ombining mammary tumors in rats is an accepted practice used by other sponsors and [Arena]." [Doc. No. 61-4 at 6.] Like the Company's interim Rat Study data, the final, combined data showed an unusually high and dose dependent incidence of mammary tumors in female rats. Plaintiff pleads with respect to this data that, "[n]o safety margin was identified for the mammary tumors and the safety margin for brain tumors was uncertain." [¶101.] As a result, defendant Anderson would have known that "[w]hen safety margins are absent or uncertain in a carcinogenicity study, it is critical that a drug sponsor demonstrate that the drug's mechanism or tumorigenic mode of action is not relevant to humans." [¶70.]

Further, as pled, defendant Anderson knew that the FDA had directed the Company in 2008 to substantiate their hypothesis that the mammary tumors were due to a rat-specific mechanism. The Company had been directed to complete animal mechanistic studies, among other things, to substantiate their hypothesis.[11] In the end, the FDA concluded "the mechanistic studies provided by the sponsor thus far have failed to persuasively demonstrate a link between lorcaserin emergent mammary tumors and prolactin, as it has been demonstrated for haloperidol." [Doc. No. 61-4 at 7, Ex. C; *see also* Doc. No. 61-5 at 5, Ex. D ("Drs. Alavi and Bourcier do not believe that the totality of data provided by the sponsor support the hypothesis that lorcaserin

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their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism with data on prolactin levels in animals exposed to lorcaserin.

[10] Defendants incorrectly suggested at oral argument that the FDA unexpectedly chose to perform this combined analysis.

[11] Despite Defendants' argument otherwise, it does not appear that this direction was contingent on the clinical significance of the study's cancer findings. [*See*, *e.g.*, Doc. Nos. 61-4 at 7 ("mammary tumor development in rodents is generally recognized to progress from hyperplasia to benign to malignant"), Ex. C; 61-5 at 5, Ex. D ("while fibroadenomas may not represent a life-threatening risk to humans, a drug that increased the incidence of these breast tumors would add at least a temporary emotional burden to women following detection of a breast mass of unknown histology").]

increases prolactin levels in rats to an extent commensurate with the increase in the incidence of mammary tumors observed in the 2-year carcinogenicity study").]

The SAC does not plead what Defendants should have understood to be the threshold showing in order to satisfy the FDA's request that Arena substantiate its hypothesis that the mammary tumors found in the Rat Study were due to a rat-specific mechanism. The FDA concludes in detail why the mechanistic study results failed to connect the mammary tumors to a rat-specific mechanism. The details provided may show that the mechanistic studies failed to substantiate Arena's hypothesis, regardless of what threshold standard applied. There also may be a generally accepted standard to which this Court is unaware.

The FDA outlined the following observations, among others, about the mechanistic studies' results:

- Lorcaserin had no effect on serum prolactin in female rats and reduced prolactin in males by 50% in the rat carcinogenicity study; and
- The single and multiple doses of lorcaserin (10 to 100 mg/kg) consistently failed to show a significant rise in serum prolactin levels in female rats at any time period;

[*See* Doc. No. 61-4 at 7, 21, Ex. C.] The FDA expressed concern that lorcaserin did not robustly increase serum prolactin under all circumstances, which would demonstrate a link between lorcaserin emergent mammary tumors and prolactin. [*Id.* at 8.] While Defendants argue this is a matter or scientific opinion, facts such as the ones set forth above may tip the scales of the Court's scienter analysis in favor of sustaining Plaintiff's complaint on this issue.

In conclusion, the Court has determined that amendment of Plaintiff's complaint may not be futile. Plaintiff may be able to persuade the Court that defendant Anderson (and/or other defendants) knew the NDA would not include the scientific evidence that was specifically requested by the FDA and was deliberately reckless in conveying to the market that the Company had completed the tasks necessary for the NDA. Further,

Anderson (and/or other defendants) may have hoped the final Rat Study data was sufficient to address the FDA's safety concerns regarding the statistically significant development of mammary tumors. Plaintiff may, however, persuade the Court that it is equally plausible that Anderson, as Arena's Vice President of Clinical Development, knew the scientific evidence related to the Rat Study did not sufficiently establish a correlation between lorcaserin emergent mammary tumors and prolactin, such that the Rat Study could be characterized as having favorable results in light of this unresolved safety concern.[12]

C. Section 20(a)

Plaintiff's claim under Section 20(a) of the Exchange Act requires a primary violation of Section 10(b), and must show that each defendant "directly or indirectly" controlled the violator. *Paracor Fin., Inc. v. Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996). As currently pled, the SAC fails to plead a strong inference of scienter for purposes of establishing a primary violation of Section 10(b). Accordingly, the Section 20(a) claim also fails. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002).

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss [Doc. No. 60] is **GRANTED WITHOUT PREJUDICE** to Plaintiff filing a motion to amend the complaint for a putative class period not to exceed May 11, 2009[13] through January 27, 2011. Any motion to amend shall be filed on or before **November 27, 2013** and

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[12] The Court declines to address whether other defendants can be held liable for defendant Anderson's September 2009 statement.

[13] The alleged materially false and misleading statement set forth in ¶162 that long-term safety has been demonstrated for lorcaserin is the first statement that may be actionable depending on the strength of any amended complaint. Again, statements should be reduced to those that tie into Plaintiff's theory that Defendants knew they had to and failed to substantiate their hypothesis that the tumors found in the Rat Study were due to a rat-specific mechanism with data on prolactin levels in animals exposed to lorcaserin. For example, statements limited to the BLOOM and BLOSSOM clinical trials should be removed from any amended complaint.

limited to addressing whether the amended complaint sufficiently pleads a strong inference of scienter. Any such motion may bring to the Court's attention any new facts supporting scienter and any facts in the current record that Plaintiff believes bolsters the SAC with respect to scienter. Any motion to amend shall not include defendant Hoffman as a defendant in the proposed amended complaint. **Defendant Hoffman is dismissed from this action with prejudice** as a result of Plaintiff's failure to sufficiently plead his knowledge of the Rat Study data. Finally, **no extensions of the motion to amend deadline will be granted**. Any opposition to Plaintiff's motion to amend shall be limited to scienter, and Defendants do not waive any arguments by limiting their opposition papers to the issue of scienter. Plaintiff shall not file a separate motion to strike in response to any opposition to Plaintiff's motion to amend.

To the extent the Court, for purposes of conducting its scienter analysis, pointed to materials complained of in Plaintiff's Motion to Strike, the Motion [Doc. No. 62] is **DENIED**. The Court otherwise did not rely on the materials complained of and, therefore, the Motion is otherwise denied as moot.

IT IS SO ORDERED.

DATED: November 4, 2013

CATHY ANN BENCIVENGO
United States District Judge