UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	SACV 15-00865 AG (JCGx)	Date	July 25, 2017
Title	HSINGCHING HSU v. PUMA BIOTECHNOLOGY, INC. ET AL.		

Present: The Honorable	ANDREW J. GUILFORD	
Lisa Bredahl	Not Present	
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:	

Proceedings: [IN CHAMBERS] ORDER DENYING MOTION TO DISMISS FIRST AMENDED COMPLAINT

Lead Plaintiff Norfolk County Council, as administering authority of the Norfolk Pension Fund, and various others filed this lawsuit under the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4. Back in September 2016, this Court denied a motion to dismiss the consolidated complaint for failure to adequately plead certain violations of the federal securities laws. (Order, Dkt. No. 76 at 15–20.) Several months later, Lead Plaintiff filed a motion to amend the consolidated complaint. (Mot. to Amend, Dkt. No. 120 at 1.) According to Lead Plaintiff, the proposed amendment was designed to "[c]onform the operative pleading to the evidence obtained in discovery," but not to "add any new parties or new claims." (*Id.* at 1–2.) Defendants Puma Biotechnology, Inc., Alan H. Auerbach, and Charles R. Eyler apparently agreed "not to oppose" the motion, subject to the "right to challenge the legal sufficiency of that complaint by means of a motions to dismiss." (*Id.* at 1 n.1.) A few days after the Court approved Lead Plaintiff's proposed amendment, Defendants moved to stay nearly all discovery under 15 U.S.C. § 78u-4(b)(3)(B). And a few weeks after that, Defendants moved to dismiss the newly amended portions of the complaint under Federal Rule of Civil Procedure 9(b), Federal Rule of Civil Procedure 12(b)(6), and the pleading requirements set forth in the PSLRA, *see* 15 U.S.C. § 78u-4(b)(3)(A).

For the following reasons, the Court DENIES the motion to dismiss. (Dkt. No. 146.) The motion to stay discovery is MOOT. (Dkt. No. 132.)

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1. BRIEF BACKGROUND

The Court has already stated the salient facts in this putative securities class action. But a brief recitation is necessary for present purposes. *See Skilstaf, Inc. v. CVS Caremark Corp.*, 669 F.3d 1005, 1014 (9th Cir. 2012) (facts alleged in the complaint must be accepted as true and construed in the light most favorable to the non-moving party).

Puma is a pharmaceutical company that acquires and develops new cancer treatment drugs. One of those drugs, called "neratinib," is used as an "extended adjuvant treatment" for HER2-positive breast cancers. After a clinical trial of neratinib, called the "ExteNET trial," Puma allegedly mislead investors concerning the purported success of the drug versus a placebo (the "disease-free survival" rate), as well as the drug's continued effectiveness over time (the "Kaplan-Meier" curves). Lead Plaintiff says that when the actual results of the clinical trial were finally revealed, Puma's stock price plummeted due to the drug's supposed ineffectiveness. (Order, Dkt. No. 76, at 2–4.)

Defendants moved to dismiss the consolidated complaint for failure to state a claim upon which relief can be granted, failure to plead fraud with particularity, and failure to satisfy the heightened pleading standards of the PSLRA. (Mot. to Dismiss, Dkt. No. 60 at 11–12.) This Court considered all of those arguments, but ultimately concluded that Lead Plaintiff had alleged "enough to allow this case to get out of the starting gate" and that Puma's arguments were "really a better measure of whether Norfolk County Council's case will be victorious past the eighth pole and down to the finish line." (Order, Dkt. No. 76 at 17.) Further, the Court anticipated that "[l]ooming ahead, just around the turn, may be a summary judgment motion." (*Id.* at 20.)

Several months later, after conducting discovery, Lead Plaintiff filed an "unopposed" motion to amend the consolidated complaint. (Mot. to Amend, Dkt. No. 120 at 1.) The amended complaint didn't change that much, all things considered. Beyond statements about the success rate of neratinib and the drug's performance over time, Lead Plaintiff has now included some other alleged misstatements that Puma made concerning the ExteNET trial. (Mot. to Amend, Dkt. No. 120 at 3; *see generally* Redline of Am. Compl., Dkt. No. 120-2.) For example, Lead Plaintiff alleges that during a July 22, 2014 conference call with investors,

Defendant Auerbach made the statements that follow. First, in his opening remarks, Auerbach stated that "[f]rom a safety perspective, [Puma] has not yet seen the safety results from the ExteNET trial for neratinib, as the data is still being validated." (Am. Compl., Dkt. No. 138 at 20.) Second, after being questioned about certain side effects, Auerbach said that the company "anticipate[s] that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib." (*Id.* at 21.) Third, after being questioned about the dropout rates from the trial, Auerbach said "I don't have that. . . . That's part of the stuff being validated, but we anticipate . . . that [the dropout rate] should be somewhere in the 5% to 10% range." (*Id.*) But all of those statements were false, Lead Plaintiff says, because various Puma executives (including Auerbach) already had the "top-line" safety results. (*Id.* at 17.) Those results apparently revealed that 39.9% of patients receiving neratinib experienced grade 3 to 4 diarrhea and, further, that the overall dropout rate for neratinib patients was 27.6%. (*Id.*) What's more, the top-line results were ultimately consistent with the final results of the trial. (*Id.* at 25–29.) The amended complaint also includes some additional allegations concerning Defendants' fraudulent intent. For example, Lead Plaintiff now alleges that Auerbach and Eyler "actively sought to have Puma acquired by a larger pharmaceutical company" before the actual ExteNET results were released so that they could reap "payments . . . in excess of $27 million, largely due to accelerated equity awards." (*Id.* at 32.)

Defendants suggest that their current motion to dismiss isn't an attempt to re-hash the last clash over the pleadings, or a roundabout request to reconsider the Court's previous order. Rather, the instant motion concerns only the new allegations in the amended complaint. (*Compare* Mot. to Dismiss, Dkt. No. 146 at 4, *with* Opp'n, Dkt. No. 149 at 1.)

2. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." With that liberal pleading standard, the purpose of a motion under Rule 12(b)(6) is "to test the formal sufficiency of the statement of the claim for relief." 5B C. Wright & A. Miller, Federal Practice and Procedure § 1356, p. 354 (3d ed. 2004). To survive a motion to dismiss, a complaint must contain sufficient factual material to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550

U.S. 544, 570 (2007). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Securities fraud claims, like the ones in this case, require more still. Such claims also "must satisfy the heightened pleading requirements of both Federal Rule of Civil Procedure 9(b) and the [PSLRA]." *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 876 (9th Cir. 2012). In this context, Rule 9(b) "requires particularized allegations of the circumstances constituting fraud, including identifying the statements at issue and setting forth what is false or misleading . . . about the statement and why the statements were false or misleading at the time they were made." *Id.* And on top of that, the PSLRA requires "plaintiffs to state with particularity both the facts constituting the alleged violation and the facts evidencing" that the defendants had the required state of mind. *Id.*

3. ANALYSIS

Although Defendants didn't oppose Lead Plaintiff's proposed amendment, they now argue that the complaint contains "new claims and theories" that ultimately "fall far short" of the heightened pleading standards at play. (Mot. to Dismiss, Dkt. No. 146 at 11.) First, Puma says that Auerbach's statements regarding the safety profile and dropout rate of the ExteNET trial are merely "forward-looking" predications that are subject to the PSLRA's safe harbor provisions. (*Id.*) Second, Puma says that the new allegations concerning scienter lack particularity as required under Rule 9(b) and the PSLRA. (*Id.* at 4.) The Court disagrees.

3.1 Forward-Looking Statements

At the pleading stage, the PSLRA provides a safe harbor for "forward-looking statements." *See In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010). A forward-looking statement is, for example, one that concerns financial items like "a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, [or] capital structure." 15 U.S.C. § 78u-5(i)(1)(A). As another example, forward-looking statements may also concern "the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer."

15 U.S.C. § 78u-5(i)(1)(B). The safe harbor provision insulates a person from liability for a violation of the securities laws if the statement is (1) "identified as a forward-looking statement" and (2) "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u–5(c)(1)(A).

As just described, Lead Plaintiff alleges that Defendant Auerbach allegedly made the following misstatements or omissions regarding the ExteNET trial: (1) "From a safety perspective, [Puma] has not yet seen the safety results from the ExteNET trial for neratinib, as the data is still being validated"; (2) "[W]e would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib"; and (3) "I don't have [the dropout rate from the trial]. . . . That's part of the stuff being validated, but we anticipate . . . that [the dropout rate] should be somewhere in the 5% to 10% range." (Am. Compl., Dkt. No. 138 at 20–21.)

As a brief aside, the parties seem to agree that these statements weren't made by, and aren't directly attributable to, Defendant Eyler. (*Compare* Opp'n, Dkt. No. 149 at 20, *with* Reply, Dkt. No. 153 at 16–17.) Lead Plaintiff thus concedes that Eyler probably isn't liable under Section 10(b) of the Securities and Exchange Act of 1934 for "any of the new safety statements." (Opp'n, Dkt. No. 149 at 20.) Although the Court appreciates that clarification, the parties failed to thoroughly meet and confer regarding this ancillary issue. (*Id.*) As such, the Court declines the parties' oblique invitation to comment further on Eyler's potential liability under any other provision of the Exchange Act. *See Lopez v. Wells Fargo Bank, N.A.*, No. SACV 16-01409 AG (KESx), 2016 WL 6088257, at *2 (C.D. Cal. Oct. 17, 2016). Going forward, the Court expects the parties to fully honor Local Rule 7-3.

Turning back to the issue at hand, Defendants argue that Auerbach's statements are subject to the safe harbor provision of the PSLRA because they're clearly related to "the expected outlook for a drug under development" and were accompanied by an unequivocal disclaimer that "the fully validated data would not be available until the future." (Mot. to Dismiss, Dkt. No. 146 at 13–14.) In support, Defendants cite various cases where statements regarding future performance of a drug was found to be forward-looking for purposes of the safe harbor provision. *See, e.g.*, *In re Arrowhead Research Corp. Sec. Litig.*, No. CV 14-07890 CBM

(ASx), 2016 WL 6562066, at *6–7 (C.D. Cal. Mar. 29, 2016). But Lead Plaintiff's allegations aren't so easily dismissed. As district courts in the Ninth Circuit have consistently recognized, statements concerning "past or present facts are not covered by the safe harbor provision" merely because they're tied to forward-looking statements. *See Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 965 (N.D. Cal. 2014).

Here, Defendant Auerbach's alleged misstatements or omissions aren't forward-looking because, at the time of the conference call, "he had the very ExteNET diarrhea . . . and dropout rate[s] . . . that were ultimately disclosed 11 months later." (Opp'n, Dkt. No. 149 at 11; *see also* Am. Compl., Dkt. No. 138 at 17, 25, 28.) In other words, Auerbach told investors that Puma didn't have the "safety results" or "dropout rates" because the numbers were still being crunched and, instead, directed their attention to historically positive results for neratinib trials. (Am. Compl., Dkt. No. 138 at 20–21.) But just days before making those alleged statements, Auerbach received an email from Puma's Senior Director of Clinical Science regarding "ExteNET top-line safety tables" that identified the precise information investors sought—the safety results and the dropout rates. (*Id.* at 16–17.) Whether that data was still in preliminary form, or required further validation, isn't really the point. Rather, Lead Plaintiff alleges that some form of reliable data was actually available, that Defendants Puma and Auerbach knew that the current results weren't in line with historical information they provided, and that they instead chose to mislead investors so that they could benefit from an increase in stock price. (*Id.*) Defendants shouldn't benefit from safe harbor by simply saying they "anticipated" success when, in fact, they had a reasonable belief that defeat was just around the corner.

Because the Court concludes that the misstatements or omissions identified in the amended complaint aren't covered by the safe harbor provision, it need not address whether the purported cautionary language was "meaningful." *See Mulligan*, 36 F. Supp. 3d at 965. At any rate, it would be strange to call cautionary statements "meaningful" where such language would itself be "misleading in light of historical fact[s] . . . that were established at the time the statement was made." *See In re Harman Int'l Indus., Inc. Sec. Litig.*, 791 F.3d 90, 102 (D.C. Cir. 2015).

3.2 Scienter or Intent to Defraud

To plead a violation of Section 10(b) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5, a plaintiff must adequately allege (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 on the misrepresentation or omission, (5) economic loss, and (6) loss causation. *See In re Rigel Pharm.*, 697 F.3d at 876.

When it comes to "scienter," the PSLRA requires that a complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). And the required state of mind, as courts have described it, is that the defendant had an intention "to deceive, manipulate, or defraud." *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1065–66 (9th Cir. 2008) (internal quotation marks omitted). Courts have also said a complaint "must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1180 (9th Cir. 2009) (internal quotation marks omitted). But in any case, "[t]he inference that the defendant acted with scienter need not be . . . of the 'smoking-gun' genre." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).

After conducting some discovery, Lead Plaintiff amended the consolidated complaint to add further allegations concerning Defendants' motive and opportunity to defraud investors. (Am. Compl., Dkt. No. 138 at 29.) Beyond all the previous allegations about Defendants' stock sales and performance-based compensation, Lead Plaintiff now says that Auerbach and Eyler "actively sought to have Puma acquired by a larger pharmaceutical company." (*Id.* at 32.) According to the amended complaint, a sale would have triggered a "change of control provision" that would have allowed Auerbach and Eyler to immediately sell over 6 million shares of their stock and collected accelerated equity awards "in excess of $27 million." (*Id.*) Now, Defendants move to dismiss this additional allegation. They argue that, standing alone, Lead Plaintiff's new allegations don't withstand scrutiny or support a strong inference of scienter. (Mot. to Dismiss, Dkt. No. 146 at 18.)

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But this Court has already engaged with the pleadings in this case and, after thoroughly considering the adequacy of the allegations under Rule 9(b) and the PSLRA, concluded that Lead Plaintiff has "has pled . . . scienter well enough to allow this case to get out of the starting gate." (Order, Dkt. No. 76 at 17–20.) Specifically, the Court stated that "taken together and examined alongside the other allegations in this case, Norfolk County Council's allegations . . . are enough, even if barely so." (*Id.* at 19.) And here, Lead Plaintiff's additional allegations concerning Defendants fraudulent intent serve to buttress—rather than detract—from the already adequate allegations of scienter. *See Tellabs*, 551 U.S. at 323–33 ("The inquiry, as several Courts of Appeals have recognized, is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individualized allegation, scrutinized in insolation, meets that standard."). Defendants haven't presented a compelling reason for the Court to reverse course at this stage.

4. DISPOSITION

For these reasons, the Court DENIES the motion to dismiss. (Dkt. No. 146.) Because the motion to dismiss is no longer pending, Defendants' motion to stay all discovery under 15 U.S.C. § 78u-4(b)(3)(B) is MOOT. (Dkt. No. 132.)

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