UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GEORGE LEHMANN and INSURED BENEFIT PLANS, INC., Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

-against-

OHR PHARMACEUTICAL INC., JASON SLAKTER, SAM BACKENROTH, and IRACH TARAPOREWALA,

Defendant.

18 Civ. 1284 (LAP)

OPINION & ORDER

LORETTA A. PRESKA, Senior United States District Judge:

Plaintiffs George Lehmann and Insured Benefits Plans, Inc. ("Plaintiffs") bring the instant securities class action complaint against Ohr Pharmaceutical, Inc. ("Company"), Jason Slakter, Sam Backenroth, and Irach Taraporewala (collectively, "Defendants"). Plaintiffs assert claims of securities fraud under Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Securities and Exchange Commission Rule 10b-5 promulgated thereunder. Plaintiffs also allege violations of Section 20(a) of the Exchange Act. Plaintiffs' claims stem from their purchase of Ohr common stock. (Amended Complaint ("Am. Compl."), dated Aug. 7, 2018 [dkt. no. 44], at ¶ 22).

Defendants now move to dismiss the amended complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6)

for failure to plead with the specified particularity and failure to state a claim upon which relief may be granted.

For the reasons stated below, Defendants' motion is granted.

I. Background

In 2009, the Company purchased the rights to Squalamine, a drug developed by a company called Genaera and derived from the liver of the dogfish shark. (Am. Compl. at ¶ 2). Squalamine was thought to treat Wet Age-Related Macular Degeneration ("Wet AMD"), a degenerative eye disease. (Id. at ¶ 3). Genaera stopped testing Squalamine in 2007. (Id.) Lucentis was a drug developed by another company and approved by the Food and Drug Administration ("FDA") to treat Wet AMD. (Id.)

After purchasing Squalamine, the Company began developing the drug to be delivered through an eye drop, as opposed to Genaera's intravenous delivery method. (Id. at ¶ 4). The Company's first testing in humans was its phase II clinical trial in 2012 called the "IMPACT Trial." (Id. at ¶ 5). Prior to the results of the IMPACT Trial, Defendants allegedly misrepresented Squalamine by saying it "produced beneficial effects and significant improvement in best corrected visual acuity." (Id. at ¶ 6).

The IMPACT Trial consisted of a control arm in which patients received placebo eye drops twice a day in combination with injections of Lucentis. It also consisted of a treatment arm in which patients received Squalamine eye drops twice a day in combination with injections of Lucentis. (Id. at ¶ 5). The primary endpoint of the study was the reduction in Lucentis injections after nine months to maintain vision, and the secondary endpoint was improvement in vision. (Id.) Improvement in vision, also known as best corrected visual acuity, was measured by the Early Treatment Diabetic Retinopathy Study, the Standard Eye Chart. (Id.)

Plaintiffs point to three categories of misleading information relating to the IMPACT Trial.

First, Plaintiffs point to the "Interim Results" that were announced by the Company in June 2014 and contained the first half of the patients enrolled in the IMPACT Trial. (Id. at ¶ 8). The Company reported that patients in the treatment arm, testing Squalamine, saw a mean vision improvement of 10.4 letters on the Standard Eye Chart, while patients in the control arm had a mean improvement of 6.3 letters. (Id.) The results were allegedly misleading because "in the prior trials of Lucentis, patients gained a mean of 7.94 letters - 1.64 higher than" the control arm announced in the Interim Results. (Id. at

10). Plaintiffs say "if patients in the [control group] had performed consistently with prior trials, the relative difference in visual acuity between the two arms" would not be "clinically meaningful." (Id.) The Amended Complaint does not allege that the Company in any way doctored the results; it alleges the control arm was inconsistent with prior trials. The Company hired Vista Partners LLC ("Vista") to tout the results of the Interim Report, and the Company's stock price increased 60 percent in two days. (Id. at ¶ 9).

Second, Plaintiffs point to the final Classic Lesions Results of the IMPACT Trial announced in March 2015. (Id. at ¶ 11). The Company allegedly misled investors here because it "failed to disclose the [control arm] once again materially underperformed in the IMPACT Trial compared to the results from past Lucentis trials." (Id. at ¶ 12). Again, Plaintiffs do not allege any chicanery in the study itself, but rather the gravamen of the Amended Complaint points to a "failure to disclose" prior results. (Id.)

Third, Plaintiffs point to the final Occult Lesions Results announced by the company in May 2015. (Id. at ¶ 13). These suffer from the same problem as the above two data points, i.e., a "fail[ure] to disclose that, had the [control group] not materially underperformed in comparison to historical trials,

the results would not have been clinically meaningful." (Id. at ¶ 13).

In January 2018, the Company announced the results of its phase III MAKO Trial. (Id. at ¶ 16). As Plaintiffs characterize it, the results were an "utter disaster as patients in the [treatment arm] performed worse than the [control arm]." (Id.) The Company's stock price subsequently dropped 81.2 percent. (Id.) Defendants are alleged to have had access to the prior clinical trials that are relied on by Plaintiffs to show that the results touted by the Company were misleading. (Id. at ¶ 17).

II. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 554, 570 (2007)). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Twombly, 550 U.S. at 555). Moreover, "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (internal quotation marks and citations

omitted). In assessing whether a plaintiff has met this standard, the Court must accept all non-conclusory factual allegations as true and draw all reasonable inferences in the plaintiff's favor. Goldstein v. Pataki, 516 F.3d 50, 56 (2d Cir. 2008) (internal quotation omitted).

In considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "the district court is normally required to look only to the allegations on the face of the complaint." Roth v. Jennings, 489 F.3d 499, 509 (2d Cir. 2007). However, "[i]n certain circumstances, the court may permissibly consider documents other than the complaint in ruling on a motion under Rule 12(b)(6)." Id. Accordingly, the Court "may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007).[1]

[1] Plaintiffs move to strike [dkt. no. 59] a number of documents submitted by Defendants in their motion to dismiss. The Court did not rely on material objected to. Therefore, Plaintiffs' motion to strike is denied as moot.

Securities fraud claims must also meet the heightened pleading requirements under Federal Rule of Civil Procedure 9(b) ("Rule 9(b)") and the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b). ATSI Commc'ns, 493 F.3d at 99. A complaint alleging securities fraud must abide by Rule 9(b)'s requirement that "the circumstances constituting fraud . . . shall be stated with particularity." Fed. R. Civ. P. 9(b). "A securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." ATSI Commc'ns, 493 F.3d at 99. "[I]f an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

The PSLRA applies to the element of scienter. ATSI Commc'ns, 493 F.3d at 99. Scienter is "'a mental state embracing intent to deceive, manipulate, or defraud.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)). In order to plead scienter adequately, "'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.'" Id. (quoting 15 U.S.C. § 78u-4(b)(2)).

III. Discussion

To recover damages in a private securities-fraud action under § 10(b) of the Exchange Act, a plaintiff must prove "(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." Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds, 568 U.S. 455, 460-61 (2013). To make out a prima facie case under § 20(a) of the Exchange Act, a plaintiff must show a primary violation, such as of § 10(b). Ganino v. Citizens Utilities Co., 228 F.3d 154, 170 (2d Cir. 2000). In other words, if there is no § 10(b) violation, there is no § 20(a) violation.

For the following reasons, Plaintiffs fail to plead either a material misrepresentation or omission or scienter. They therefore have not plead either a § 10(b) or a § 20(a) violation.

a. Misrepresentation or Omission

On misrepresentation, both Plaintiffs and Defendants agree that what is at issue are opinions expressed by Defendants. The Supreme Court has ruled that false statements of opinion can be actionable if either "the speaker did not hold the belief she professed" or "the supporting fact[s] she supplied were untrue." Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 135 S. Ct. 1318, 1327 (2015). Proving this is "no small task for an investor." Id. at 1332. A statement of opinion is "not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." Id. at 1329. Furthermore, "a statement of opinion is not misleading just because external facts show the opinion to be incorrect." Id.

This language was applied in the FDA context by the Court of Appeals in Tongue v. Sanofi, 816 F.3d 199, 212 (2d Cir. 2016). In Tongue, plaintiffs' case "essentially boil[ed] down to an allegation that the statements were misleading for failure to include a fact that would have potentially undermined Defendants' optimistic projections." Id. But the Court of Appeals explained, "Omnicare imposes no such disclosure requirements on issuers." Id.

Specifically commenting on the actionability of opinions regarding trial results, the Court of Appeals noted that it had

previously rejected "a dispute about the proper interpretation of data" as a basis for liability. Id. at 214; Kleinman v. Elan Corp., plc, 706 F.3d 145, 154 (2d Cir. 2013)("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement.")

With respect to the interpretation of the interim and final IMPACT Trial results, there was no misrepresentation. Plaintiffs' argument boils down to the assertion that the IMPACT Trial's failure to perform consistently with prior comparable studies necessitated the Company's providing more context. (Lead Plaintiffs' Memorandum Of Law In Opposition To Defendants' Motion To Dismiss ("Pl. Opp."), dated May 31, 2019 [dkt. no. 68], at 13). Said differently, Plaintiffs say that in order to remedy the IMPACT Trial's turning out "worse" for shareholders because it later failed in phase III, Defendants were required to make more disclosures. In omitting the prior results, Plaintiffs allege that there was a misrepresentation.

This is not the law. Defendant's omission is a "failure to include a fact that would have potentially undermined Defendants' optimistic projections." Tongue, 816 F.3d at 212. As seen above, the Supreme Court and Court of Appeals have said that such a failure is not actionable in this context. Plaintiffs' attempt to analogize to failures to disclose an

illegal bribery scheme, a three-month long Stop Work Order, and subpoenas from the Securities and Exchange Commission, and information requests from the Department of Justice, are unavailing. DoubleLine Capital LP v. Odebrecht Fin., Ltd., 323 F. Supp. 3d at 444 (S.D.N.Y. 2018) (company failed to disclosure its participation in an illegal bribery and kickback scheme); In re Chicago Bridge & Iron Co. N.V. Sec. Litig., 2018 WL 2382600, at *8 (S.D.N.Y. May 24, 2018) (company failed to disclose a three-month Stop Work Order); Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC, 164 F. Supp. 3d 568, 584 (S.D.N.Y. 2016) (company failed to disclose an SEC-DOJ investigation).

The Court is more persuaded by cases cited by Defendants finding no liability in the medical context. See, e.g., In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 528, 543-44 (S.D.N.Y. 2015), In re MELA Scis., Inc. Sec. Litig., 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012), City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 170 (3d Cir. 2014), Fait v. Regions Fin. Corp., 655 F.3d 105, 113 (2d Cir. 2011), In re Express Scripts Holding. Co. Sec. Litig., 2018 WL 2324065, at *9 (S.D.N.Y. May 22, 2018), and City of Omaha, Neb. Civilian Emps.' Ret. Sys. v. CBS Corp., 679 F.3d 64, 69 (2d Cir. 2012). The only retort Plaintiffs have is to say that they are "inapposite as all were either decided before Omnicare or otherwise did not apply Omnicare's opinion standard." (Pl. Opp. at n.8). As

Defendants correctly point out, however, "Omnicare did not reject the Fait v. Regions Fin. Corp., 655 F.3d 105 (2d Cir. 2011) standard in the Second Circuit but expanded it. Fait requires alleging both falsity and disbelief, whereas Omnicare requires allegations of either. Thus, any cases pre-Omnicare are not inapposite and still may address objective falsity or subjective disbelief." (Def. Rep. at n.3).

Additionally, Defendants argue that providing the historical studies to put the control arm in context would not have been relevant because the historical studies relied on by Plaintiffs to establish an appropriate control benchmark are not comparable. (Def. Mot. at 6-10). For instance, "[a]ll studies without [pro re nata][2] Lucentis dosing are inappropriate comparators. Monthly Lucentis produces very different visual and anatomical differences versus [pro re nata dosing]." (Id. at 9). While the Court does not rely on this argument, it notes Plaintiffs' failure to defend evidently different aspects of the various Lucentis experiments that they argue are comparable.

Additionally, Plaintiffs make much hay about the use of the term "clinically meaningful." They point to a single doctor's view that "for a Wet AMD treatment to be considered clinically

[2] I.e., dosed as needed, not on a regimented routine. (Def. Mot. at 8).

meaningful, it must improve vision by at least 4 letters." (Pl. Opp. at 5). "[S]tatements containing simple economic projections, expressions of optimism, and other puffery are insufficient" to establish a 10(b) violation. Novak v. Kasaks, 216 F.3d 300, 315 (2d Cir. 2000). For this reason, "clinically meaningful" is legally meaningless.

Even if the term did have content, Plaintiffs have certainly not established that their definition is the definition of the term. Such an establishment could come through other usage in the industry or FDA regulations and requirements. Additionally, the term, as a matter of law, is not a statement of fact, but is instead puffery, much like the term "success." Okla. Firefighters Pension & Ret. Sys. v. Xerox Corp., 300 F. Supp. 3d 551, 570 (S.D.N.Y. 2018). Meaningfulness, especially in the medical context, is a more subjective concept than is the presentation of raw data. While there may be night and day, e.g., describing cyanide as a cure for the common cold as "clinically meaningful" would likely be fraud, this is a case of dawn and dusk where the statements are clear puffery.

The Court also holds that Defendants' opinions regarding Genaera's earlier studies are not actionable. Plaintiffs call these opinions misleading because the Genaera trials did not

demonstrate Squalamine had a favorable biological effect, Genaera terminated its development of the drug, and Genaera's trials for Squalamine were inferior to those produced by Lucentis. (Pl. Opp. at 11).

In support, Plaintiffs cite to a statement from Genaera that says, "[T]here is no attractive or pragmatic option for the registration and commercialization of [Squalamine] for the treatment of wet AMD" based on "preliminary information from investigators on patients" as well as "evolving FDA guidance on clinical endpoints." (Am. Compl. at ¶ 40). This does not speak solely to the actual biological effects of the drug, and considering the fact that Ohr would change the administration of the drug from intravenous to eye drop, this statement is not actionable. This is exactly what the Supreme Court was referring to in Omnicare when it said, "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts." 135 S.Ct. at 1329.

In Omnicare, the Supreme Court dealt with a provision parallel to Section 10(b), Section 11, saying that the section was not "an invitation to Monday morning quarterback an issuer's opinions." Omnicare, 135 S.Ct. at 1327. In that case, the company's statement, "We believe we are obeying the law" turned out to be false in that the company was not obeying the law.

Id. The Supreme Court declined to find the company liable because Section 11 "does not allow investors to second-guess inherently subjective and uncertain assessments." Id. In the face of uncertainty, an opinion can still be reasonable even if new facts later undermine it.

In the medical research context, this is all the more important. On Plaintiffs' account, it is unclear whether the Company should have embarked on the phase III study after the success of the phase II study - should the Company have ignored what Plaintiffs say were aberrant results, or should it have investigated further? As an ex post matter, it is clear that Plaintiffs are unhappy with the results of the MAKO Trial. The shareholders, however, are not the only ones implicated here - those suffering from wet AMD are also undoubtedly disappointed with the results. Does this necessarily mean that pursuing the MAKO Trial was unwise?

This Court will not adopt a rule that discourages free scientific inquiry in the name of shielding investors from risks of failure. Science is risky. Science advances through those willing to take those risks and break with consensus. See generally Thomas S. Kuhn, The Structure of Scientific Revolutions, UNIV. CHI. PRESS, 1970. With science suffering from a replication crisis, see generally Kristin Firth, David A.

Hoffman & Tess Wilkinson-Ryan, Law and Psychology Grows Up, Goes Online, and Replicates, 15 J. EMPIRICAL LEGAL STUDIES 320, 323-24 (2018), this Court is happy to report that the law does not abide attempts at using the judiciary to stifle the risk-taking that undergirds scientific advancement and human progress. The answer to bad science is more science, not this Court's acting as the Southern District for the Inquisition. Cf. Whitney v. California, 274 U.S. 357 (1927) ("If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the process of education, the remedy to be applied is more speech, not enforced silence.") (Brandeis, J., concurring).

b. Scienter

A plaintiff may plead scienter by alleging facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, 493 F.3d at 99. Conscious recklessness implies "a state of mind approximating actual intent, and not merely a heightened form of negligence." South Cherry St., LLC v. Hennessee Group LLC, 573 F.3d 98, 109 (2d Cir. 2009).

In the instant case where a false opinion is alleged, the scienter and misrepresentation requirements of § 10(b) collapse together because "a material misstatement of opinion is by its

nature a false statement, not about the objective world, but about the defendant's own belief." Podany v. Robertson Stephens, Inc., 318 F. Supp. 2d 146, 154 (S.D.N.Y. 2004); see also In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016). As this court has previously said, "[P]roving the falsity of the statement 'I believe this investment is sound' is the same as proving scienter, since the statement (unlike a statement of fact) cannot be false at all unless the speaker is knowingly misstating his truly held opinion." 318 F. Supp. 2d at 154 (S.D.N.Y. 2004).

"If the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter. There is also scienter if the management is reckless in dealing with such adverse facts." In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), aff'd sub nom. State U. Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404 (2d Cir. 2009). On the flip side, "if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents

the marketing of the drug or makes it necessary to take the drug off the market." Id.

Plaintiffs allege that Defendants had access to omitted facts and information, namely other trial data, that would have put their positive claims in the proper context (Pl. Opp. at 24-29). For the reasons stated above, the Court rejects this argument as establishing a misrepresentation. The Court also rejects knowledge of this information as establishing scienter. Had the MAKO Trial succeeded, which Plaintiffs do not allege was out of the realm of possibility as envisioned by Defendants, then there clearly would have been no scienter. It cannot be the case that ex ante intent is based on ex post results.

Additionally, Plaintiffs do not allege any direct financial benefit to individual defendants but instead point to the Company's desire to "avoid bankruptcy" as Defendants' motive. (Pl. Opp. at 29). Avoiding bankruptcy, raising capital, or a "general motivation to act in one's own economic self interest" cannot form the basis for finding the requisite scienter. Tabak v. Canadian Solar Inc., 549 F. App'x 24, 29 (2d Cir. 2013); see also Ganino v. Citizens Utilities Co., 228 F.3d 154, 170 (2d Cir. 2000), Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001).

Plaintiffs attempt to distinguish cases cited by Defendants for this proposition by saying, "The cases . . . are

distinguishable because none involved companies conducting multiple offerings to avoid bankruptcy, after having received multiple auditor going concern letters." (Pl. Opp. at 30 n.26). It is unclear why this distinction should have any legal import. The same rationale undergirding the rule as applied to a single bankruptcy, i.e., motives common to all corporations cannot be used to establish specific motive, also applies here, as most companies would try to avoid bankruptcy multiple times if they were able to do so.

The cases cited by Plaintiffs are unavailing. See In re IMAX Sec. Litig., 587 F. Supp. 2d 471, 483 (S.D.N.Y. 2008) (finding that continuing as a going concern was but one factor, and scienter was only adequately pled based on this plus recklessness allegations, company's increasing aggressive accounting of the subject revenue, and violations of GAAP); In re Complete Mgmt. Inc. Sec. Litig., 153 F. Supp. 2d 314, 327-28 (S.D.N.Y. 2001) (admitting that "a generalized desire to maintain a higher stock price will not rise to the level of motive" but finding that the "artificial inflation of a stock price in order to achieve some more specific goal may satisfy the pleading requirement," which in that case came in the form of alleging "unusual insider trading activity" on the part of defendants). These additional elements do not exist here.

Accordingly, because neither scienter nor material misrepresentation has been plead here, there is no § 10(b) violation, and because there is no primary violation, there is no § 20(a) violation.

The Court does not reach Defendants' additional arguments.

IV. Conclusion

For the reasons stated above, Defendants' motion to dismiss [dkt. no. 44] is granted, and Plaintiff's motion to strike [dkt. no. 59] various documents is denied as moot. The Clerk of the Court shall mark the action closed and deny all pending motions as moot.

SO ORDERED.

Dated: New York, New York
September 20, 2019

Loretta A. Preska

LORETTA A. PRESKA
Senior United States District Judge