IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:12-cv-213-MOC-DCK

CAMERON MCINTYRE,	)	
	)	
Plaintiff,	)	
	)	**ORDER**
Vs.	)	
	)	
CHELSEA THERAPEUTICS INTERNATIONAL, LTD., et al.,	)	
	)	
Defendants.	)	
	)	

THIS MATTER is before the court on Defendants' Motion to Dismiss Consolidated Securities Class Action Complaint (#70). Having considered the motion, the pleadings, and the oral arguments made in open court on June 19, 2013, the court enters the following findings, conclusions, and order.

FINDINGS AND CONCLUSIONS

I. BACKGROUND

The complaint in this matter alleges that Chelsea Thereapeutics International and four individual defendants ("defendants") violated federal securities laws by making materially false and misleading statements and omitting critical information regarding the development and approval of the drug Northera. Northera, also known by its generic name droxidopa, was designed to treat a disorder known as symptomatic neurogenic orthostatic hypotension ("NOH"), a sudden fall in blood pressure that occurs when a person assumes a standing position. The disorder is commonly associated with diabetes, Parkinson's disease, and other neurological disorders.

Before Chelsea could market Northera, it had to demonstrate the drug's safety and effectiveness to the FDA. To do this, Chelsea conducted a series of tests with certain predetermined goals, or endpoints, the results of which would be submitted to the FDA in a New Drug Application. At that point, the FDA could approve the drug, request additional information on the drug, or deny the application altogether.

Four clinical trials were conducted to determine Northera's health and safety in large number of patients, the first of which, Studies 301 and 302, began in early 2008. The primary endpoint for these two studies was the same: Item 1 of the Orthostatic Hypotension Symptom Assessment scale ("OHSA") which measures a patient's dizziness or light-headedness. Together, the OHSA scale and another scale, the Orthostatic Hypotension Daily Activity Scale ("OHDAS"), form the Orthostatic Hypotension Questionnaire ("OHQ"). Study 302, the first to conclude, was a disappointment as it failed to demonstrate a statistically significant effect on Item 1 of the OHSA scale. It may, however, have shown a nominal improvement on the OHQ based on some statistical analyses.

When Study 302 failed to meet its endpoint, Chelsea petitioned the FDA to modify Study 301, which was ongoing at that time. The FDA agreed, allowing Chelsea to change Study 301's endpoint from Item 1 of the OHSA to the relative mean change in the patient's OHQ. The FDA confirmed that the Special Assessment Protocol ("SPA") it had originally granted to Study 301 was still in effect. An SPA is an agreement that the study design, including trial size, clinical endpoints and/or data analyses could help support regulatory approval. In September 2010,

Chelsea announced that Study 301 met its primary endpoint—the study indicated a statistical improvement over the placebo on the composite OHQ.[1]

The FDA agreed to accept the Chelsea's New Drug Application ("NDA") for Northera based on the data from Studies 301 and 302 but warned that one successful study is not usually sufficient for NDA approval. It also requested "validation data" for certain instruments used in the studies and justification for why the results of Study 301 were clinically meaningful. Chelsea submitted its NDA the following year in September of 2011.

The application was first reviewed by FDA Staff ("the briefing committee"), who prepared a report in advance of the meeting of the Cardiovascular and Renal Drugs Advisory Committee ("the Advisory Committee") that, in turn, would provide a nonbinding recommendation to the FDA. The briefing committee recommended that Northera not be approved. One reason cited was that "the safety data base of [the] development program was not robust." ECF No. 82-2 at 4. The Advisory Committee, however, went against the briefing committee's recommendation and on February 23, 2012, recommended that Northera be approved. While hopeful that Northera would be approved, Chelsea warned investors that the FDA was not bound by the Advisory Committee's recommendation. See ECF No. 71-15 ("the FDA is not bound by the recommendations of its advisory committees."). On March 28, the FDA issued its response letter denying Chelsea's Northera NDA.

[1] The third study, Study 303, measured the effect of Northera on patients who had previously demonstrated a benefit from the drug in Studies 301 or 302. Study 303 was completed in May 2010 and did not demonstrate efficacy. Study 306 was originally designed to have the same endpoint as revised Study 301 but after an interim analysis indicated that Study 306 would not meet its primary endpoint, Chelsea modified the Study to focus on the prevention of falls in Parkinson's disease patients. As modified, the study would not be available until 2012 and so was not included in Chelsea's New Drug Application.

Approximately one week later on April 4, 2012, an initial complaint was filed; and by October 5, 2012, a consolidated Amended Complaint was filed alleging that Chelsea and the four individual defendants had violated § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. It further alleges that the four individual defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

II. Judicial Notice

Defendants request that the court take judicial notice of a number of documents, some of which are explicitly referenced in the complaint and others which are not but, defendant argues, are nevertheless subject to judicial notice. Under well-established precedent from the Supreme Court as well as this and other circuits, in ruling on a motion to dismiss a court "must examine the facts as a whole, including facts found in 'documents incorporated into the complaint by reference.'" Cozzarelli v. Inspire Pharmaceuticals Inc., 549 F.3d 618, 625 (4th Cir. 2008) (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007). To that end, "a court ruling on a 12(b)(6) motion may look to documents or articles cited in the complaint, SEC filings, press releases, stock price tables, and other material on which the plaintiff's allegations necessarily rely." Greenhouse v. MCG Capital Corp., 392 F.3d 650 (4th Cir. 2004) (internal quotation marks omitted). Specifically with respect to judicial notice of SEC filings:

> When a district court decides a motion to dismiss a complaint alleging securities fraud, it may review and consider public documents required by law to be and which actually have been filed with the SEC, particularly where Plaintiff has been put on notice by defendant's proffer of these documents.

Bryant v. Avado Brands, Inc., 187 F.3d 1271, 1276 (11th Cir. 1999) (quoting Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 47 (2d Cir. 1991).

Accordingly, the court will consider documents which were specifically referenced or relied upon in the complaint and will also grant Chelsea's request and take judicial notice of its SEC filings.

III. Analysis

To successfully allege a securities fraud claim in violation of section 10(b) of the Exchange Act, a plaintiff must satisfy the following elements: "(1) the defendant made a false statement or omission of material fact (2) with scienter (3) upon which the plaintiff justifiably relied (4) that proximately caused the plaintiff's damages." Cozzarelli, 549 F.3d 618, 623 (quoting Teachers' Ret. Sys. Of LA v. Hunter, 477 F.3d 162, 172 (4th Cir. 2007)). Defendants move to dismiss the case on the basis that plaintiff has failed to allege (1) a false or misleading statement or omission of material fact; or (2) that any such statement was made with scienter.

While the court agrees there is a substantial question as to whether the first element is satisfied, the court need not reach that issue as plaintiff has failed to allege facts giving rise to an inference of scienter. The Private Securities Litigation Reform Act (the "PSLRA") requires a plaintiff to, among other things, "state with particularity facts giving rise to a strong inference that the defendant acted" with scienter. 15 U.S.C. § 78u-4(b)(2); Cozzarelli, 549 F.3d 618. "In a securities fraud action, the term 'scienter' refers to a mental state embracing intent to deceive, manipulate, or defraud." Ottmann v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 343 (4th Cir. 2003) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 194 n. 12, 96 S.Ct. 1375, 47 L.Ed.2d 668 (1976) (internal quotation marks omitted). Additionally, a showing of recklessness may suffice which, the Fourth Circuit has explained, requires "an act so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the

defendant must have been aware of it." Ottmann, 353 F.3d at 343 (quoting Phillips v. LCI Int'l, Inc., 190 F.3d 609, 621 (4th Cir. 1999).

In this context, "an inference of scienter can only be strong—and compelling, and powerful—when it is weighed against the opposing inferences that may be drawn from the facts in their entirety." Id., 549 F.3d at 624 (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 323-24 (2007). That is, "when the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed." Cozzarelli, 549 F.3d at 624.

Plaintiff's theory is that defendants intentionally misled investors to believe that the FDA would approve Northera based on the results of only one successful study, thereby artificially inflating Chelsea's stock price. According to plaintiffs, defendants were motivated to mislead investors and inflate stock values in this way to stave off bankruptcy and fund clinical trials. Pl.'s Br. 28. To that end, Chelsea pushed forward with the Northera NDA in spite of the FDA's warnings that Study 301, by itself, would be insufficient for approval, a fact which Chelsea failed to disclose to investors. These allegations, however, when weighed against the opposing inferences that may be drawn from the facts in their entirety, fail to satisfy the PSLRA's requirement of a strong inference of scienter.

With regards to defendants' alleged motivations, the Fourth Circuit has already addressed and dismissed plaintiff's argument in Cozzarelli, 549 F.3d 618. There, as here, the plaintiffs alleged that defendants were motivated to mislead investors because the "company needed to raise money to fund its operations." Id. at 627. The court rejected this argument, explaining its decision as follow:

> Plaintiffs' conclusory allegations regarding defendants' motives to defraud also lack merit. Plaintiffs claim that Inspire was motivated to make public

> statements about diquafosol that were overly optimistic because the company needed to raise money to fund its operations. They also claim that Shaffer had an incentive to puf up the outlook of Study 109 falsely because her compensation was tied to the company's performance. But a strong inference of fraud does not arise merely from seeking capital to support a risky venture. Indeed, the motivations to raise capital or increase one's own compensation are common to every company and thus add little to an inference of fraud. *See Ottmann v. Hanger Orthopedic Group, Inc.*, 353 F.3d 338, 352 (4th Cir.2003). All investments carry risk, particularly in a field like biopharmaceuticals. If we inferred scienter from every bullish statement by a pharmaceutical company that was trying to raise funds, we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation—exactly what Congress sought to avoid by enacting the PSLRA.

Id. at 627. The Fourth Circuit is quite clear that plaintiff's principal theory of scienter simply does not satisfy the PSLRA's heightened pleading requirements.

Plaintiff also argues that the defendants' communications with the FDA regarding the Northera NDA establish a showing of recklessness. The court disagrees. Plaintiff makes much of the fact that Chelsea only had one successful study on Northera and, according to plaintiff, the FDA requires two successful studies before approving an NDA.

While the briefing committee transcript is certainly not a model of clarity of the FDA's NDA requirements, it casts significant doubt on plaintiff's contention that one successful study would not be sufficient. Compl., ECF 65 ¶ 97; Transcript, ECF 82-1 7. Dr. Steve Graham, FDA Deputy Director of the Division of Cardiovascular and Renal Products, explained that: "[T]he question was . . . was this study in and of itself going to be sufficient, if successful, to support an application? And we never know what the answer is. As Norman says, an overwhelming effect in one study, you'd be a fool not to approve it." Id. Furthermore, as noted by defendants, there is clear statutory authority that "data from one adequate and well-controlled clinical investigation and confirmatory evidence" may be sufficient for approval. See 21 U.S.C. § 355(d)(7). While defendants may have been overly optimistic about the FDA approving

Northera, such optimism does not rise to the level of recklessness articulated in Phillips, 190 F.3d at 621, especially in light of the numerous warnings that Chelsea gave investors regarding the sufficiency of Northera's NDA. Chelsea warned investors that the FDA might reject the NDA on the grounds that the OHQ as "the appropriate primary endpoint of Study 301"; that the safety database information in the NDA is inadequate to establish clinical safety of Northera"; or that the clinical data regarding the clinical efficacy was "insufficient." Chelsea Thereapeutics International, Ltd. 10-Q, ECF No. 71-3 3.

This alleged deficiency, if it can indeed even be called that, certainly does not rise to the level of scienter or an "extreme departure from ordinary care," especially when it is weighed against the strong competing inferences that weigh in favor of defendants, the most glaring of which is the fact that none of the individual defendants sold stock during the class period. Indeed, one defendant actually bought over $359,000 worth of stock in the open market during the class period. Form 4, ECF No. 71-23. While plaintiff is correct that this fact that by itself is not necessarily dispositive of whether scienter is successfully alleged, Pl.'s Mem. 30 n.17, it certainly tips the scales in favor of defendant's motion.

The cases cited by plaintiff for the proposition that scienter is established by virtue of the individual defendants' positions are of little relevance here as the Amended Complaint fails to satisfy the PSLRA's heightened pleading requirement for scienter. These cases stand for the proposition that scienter can be established as to an individual defendant through statements that the defendant should have known were false or misleading by virtue of their position. That is simply not the issue in the present case. As discussed above, plaintiff attempts to establish a showing of scienter or recklessness by alleging that Chelsea 1) was on the verge of bankruptcy and 2) knew the NDA would fail as the FDA was going to require two successful studies.

Additionally, Chelsea gave investors several clear and explicit warnings regarding the prospects for the Northera NDA.

As discussed above, the court is guided by the binding principles set forth by the Fourth Circuit Court of Appeals in Cozzarelli, as well as others. Consistent with those principles and the PSLRA's requirement that plaintiff allege a strong inference of scienter, the court has weighed the competing inferences and finds that the Amended Complaint falls fall short of that mandate. Accordingly, the court will grant defendant's motion and dismiss Count I.

IV. Section 20(a) Claims

The parties agree that the claims in Count II, which arise under Section 20(a) of the Exchange Act, cannot be sustained in the absence of an underlying primary violation, to wit, the section 10(b) claims. As Count I has been dismissed, the court must also dismiss Count II.

V. Leave to Amend

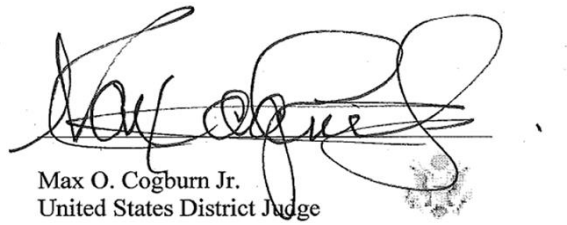
Plaintiff requests that in the event the court finds the Amended Complaint deficient, he be granted leave to amend under Rule 15(a). Pl.'s Mem. 30 n. 18. The court, however, having carefully considered the briefs, the exhibits, and the extensive Amended Complaint, finds that doing so would be futile and will deny this request. See In re PEC Solutions, Inc. Sec. Litig., 418 F.3d 379, 391 (4th Cir. 2005) ("Leave to amend need not be given when amendment would be futile."). The pleadings illustrate the factual allegations clearly and the court has considered this case extensively. Granting plaintiff leave to amend would not change the fact that 1) none of the individual defendants sold stock during the class period; 2) Chelsea gave investors numerous warnings regarding the sufficiency of the Northera NDA; and 3) that the Fourth Circuit Court of Appeals has already flatly rejected plaintiff's principal theory of scienter.

Furthermore, plaintiff has given no indication how a second Amended Complaint might cure any of the above deficiencies, and a proposed Second Amended Complaint was not proffered. The only mention of leave to amend comes in a footnote at the very end of Plaintiff's brief. See Cozzarelli., 549 F.3d at 630-31 (denying leave to amend where plaintiff requested leave to amend in a footnote and never in a formal motion). Accordingly, the court enters the following order granting defendants' motion and dismissing this case with prejudice.

CONCLUSION AND ORDER

IT IS, THEREFORE ORDERED that defendants' Motion to Dismiss (# 70) is **GRANTED** and this case is **DISMISSED WITH PREJUDICE**.

Signed: October 9, 2013



Max O. Cogburn Jr.
United States District Judge