PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 13-2370

ROMAN ZAK, Individually and On Behalf of All Others Similarly Situated,

Plaintiff - Appellant,

and

CAMERON MCINTYRE, Individually and On Behalf of All Others Similarly Situated

Plaintiff,

v.

CHELSEA THERAPEUTICS INTERNATIONAL, LTD.; SIMON PEDDER; WILLIAM D. SCHWIETERMAN,

Defendants – Appellees,

and

L. ARTHUR HEWITT; J. NICK RIEHLE,

Defendants.

Appeal from the United States District Court for the Western District of North Carolina, at Charlotte. Max O. Cogburn, Jr., District Judge. (3:12-cv-00213-MOC-DCK)

Argued: December 10, 2014 Decided: March 16, 2015

Before TRAXLER, Chief Judge, and, KEENAN and THACKER, Circuit Judges.

Vacated and remanded by published opinion. Judge Keenan wrote the opinion, in which Chief Judge Traxler joined. Judge Thacker wrote a separate dissenting opinion.

ARGUED: Richard William Gonnello, FARUQI & FARUQI, LLP, New York, New York, for Appellant. Barry M. Kaplan, WILSON SONSINI GOODRICH & ROSATI, Seattle, Washington, for Appellees. **ON BRIEF:** Lee M. Whitman, Tobias S. Hampson, WYRICK ROBBINS YATES & PONTON LLP, Raleigh, North Carolina; Gregory L. Watts, Seattle, Washington, Ignacio E. Salceda, Cheryl W. Foung, WILSON SONSINI GOODRICH & ROASATI, Palo Alto, California, for Appellees Chelsea Therapeutics International, Ltd., Simon Pedder, and William D. Schwieterman.

BARBARA MILANO KEENAN, Circuit Judge:

The plaintiffs in this case claim that Chelsea Therapeutics International, LTD. (Chelsea) and several of its corporate officers[1] (collectively, the defendants) violated Section 10(b) of the Securities Exchange Act of 1934 (the Exchange Act), 15 U.S.C. § 78j(b).[2] Chelsea stockholder Roman Zak, both individually and as a class representative for other investors (the plaintiffs), alleged that the defendants made materially misleading statements and omissions about the development and likelihood of regulatory approval for a new drug, Northera. After considering the defendants' motion to dismiss filed under Federal Rule of Civil Procedure 12(b)(6), the district court dismissed the complaint, holding that the plaintiffs' allegations were insufficient as a matter of law to establish that the defendants acted with the required scienter.

On appeal, the plaintiffs contend that the district court committed two errors. The asserted errors are: (1) the court's

[1] The complaint named as individual defendants Dr. Simon Pedder, President and Chief Executive Officer; Dr. William Schwieterman, Vice President and Chief Medical Officer; Dr. Arthur Hewitt, Vice President and Chief Scientific Officer; and Mr. Nick Riehle, Vice President and Chief Financial Officer. However, Dr. Hewitt and Mr. Riehle are not parties to this appeal.

[2] In a derivative claim, the plaintiffs also alleged that the individual defendants violated Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

consideration of certain documents filed with the Securities and Exchange Commission (SEC) that were submitted as exhibits with the defendants' motion to dismiss; and (2) the court's determination that the plaintiffs' allegations of scienter were legally insufficient.

Upon our review, we hold that the district court erred in taking judicial notice of the challenged documents filed with the SEC, because those documents did not relate to the contents of the complaint. We further hold that this error was not harmless, because the court incorrectly construed these documents as supporting its holding that the plaintiffs' allegations of scienter were legally insufficient. Finally, we hold that based on the defendants' failure to disclose critical information about the weaknesses of the new drug application, the plaintiffs' allegations were sufficient to support a strong inference of scienter. We therefore vacate the district court's judgment dismissing the plaintiffs' complaint and remand the case for further proceedings.

I.

The plaintiffs alleged in their pleadings the following facts, which we accept as true in our review of the district court's dismissal of the complaint under Federal Rule of Civil Procedure 12(b)(6). Matrix Capital Mgmt. Fund, LP v.

BearingPoint, Inc., 576 F.3d 172, 176 (4th Cir. 2009) (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007)). In 2006, Chelsea began its effort to gain approval from the Food and Drug Administration (FDA) concerning the right to market the drug Northera[3] as a treatment for symptomatic neurogenic orthostatic hypotension (NOH). NOH is a condition in which a dramatic drop in blood pressure occurs when a person stands. This drop in blood pressure causes symptoms such as dizziness, impaired vision, fatigue, weakness, nausea, and an inability to think clearly. NOH is associated with the presence of various disorders including Parkinson's disease, multiple systems atrophy, and pure autonomic failure.

After considering the "significant unmet need" for a clinically beneficial treatment of symptomatic NOH, the FDA assigned Northera "orphan drug status." Such status provided Chelsea with seven years of marketing exclusivity, and reduced certain time and expense requirements related to clinical trials mandated for FDA approval of the drug.

Before submitting its "new drug application" to the FDA, Chelsea conducted numerous clinical trials with certain "endpoints," or goals, to demonstrate the drug's efficacy and

[3] The drug's trade name is droxidopa.

safety. As relevant to this appeal, Chelsea conducted four efficacy trials, namely, Studies 301, 302, 303, and 306.[4]

Studies 301 and 302 began in 2008. Both those studies had the same general efficacy endpoint of demonstrating a statistically significant effect on lightheadedness and dizziness for individuals suffering from NOH. The endpoint for Study 301 was set forth in a "special protocol assessment" (SPA), which was an agreement between Chelsea and the FDA that the study design, trial size, and clinical goals could support regulatory approval. The SPA involving Study 301 also stated that the FDA expected two successful efficacy studies before it would grant regulatory approval of the new drug.

The first study to conclude, Study 302, failed to meet its primary endpoint. Later documents showed that the results of Study 302 "clearly . . . dr[e]w the efficacy of [the drug] into question," and demonstrated that symptoms worsened for those individuals taking the drug.

After Chelsea announced to investors the disappointing results from Study 302, Chelsea petitioned the FDA to modify the SPA's endpoint for Study 301, which was ongoing. In November 2009, Chelsea representatives met with FDA officials, and later

[4] Chelsea also conducted clinical trials to establish the drug's safety, but the results of those trials are not directly relevant to our analysis in this appeal.

informed investors that the FDA had agreed to permit Chelsea to use a different assessment scale for Study 301 than was used in Study 302. The FDA officials also had recommended at the November 2009 meeting that Chelsea submit "a confirmatory pivotal study to support" the new drug application, because of the failed results in Study 302. Based on this additional recommendation, Chelsea announced plans to initiate a new clinical trial, Study 306, which would involve an eight-week treatment period.

In September 2010, Chelsea announced that Study 301 had concluded, and successfully had met its revised endpoint by showing a statistically significant improvement in participants' symptoms. However, Study 301, which employed a treatment period of only one week, was the sole efficacy study conducted by Chelsea that met its primary endpoint. Study 303, which included significantly longer treatment periods than Studies 301 and 302, did not meet its endpoint, and failed to demonstrate that the drug provided any "duration effect" on symptoms. Study 306, which also included a significantly longer treatment period, was abandoned after an interim analysis indicated that the study would not meet its endpoint.[5]

[5] Study 306 was later continued with a revised endpoint, focusing on the prevention of falls in patients suffering from (Continued)

On December 10, 2010, Chelsea met with FDA officials to assess the viability of submitting a new drug application based on Study 301 (the December 2010 meeting). During the December 2010 meeting, FDA officials again warned Chelsea that a single successful study typically was not sufficient to support approval of a new drug. Nevertheless, Chelsea announced that the FDA had "agreed" that Chelsea's new drug application for Northera could be submitted based on data from Study 301, the only study to meet its primary endpoint, and data from Study 302, which had not met its primary endpoint, without the need for any further efficacy studies.

During a conference call held with Chelsea investors, Dr. Simon Pedder, Chelsea's President and Chief Executive Officer, described the December 2010 meeting as a "successful outcome" that "reflect[ed] the strength of the data" generated by Chelsea's drug development program, and "mark[ed] a significant step forward for Chelsea." Dr. Pedder also stated that the FDA officials had clarified "that additional efficacy studies were not required" for a new drug application filing. On the same conference call, Dr. William Schwieterman, Chelsea's Vice President and Chief Medical Officer, represented that after the

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Parkinson's disease, but the results of the study would not be available until 2012.

December 2010 meeting, Chelsea was "very pleased" with the FDA's responses to Chelsea's questions about its application and supporting data. After these statements concerning the December 2010 meeting, Chelsea's stock price rose about 28 percent.

In September 2011, Chelsea announced that it had submitted to the FDA its new drug application based on purportedly "robust" efficacy data from Studies 301 and 302. However, as later observed by the FDA, these studies involved treatment periods of only one week.

In accordance with the FDA's initial evaluation process for new drug applications, an FDA staff member prepared a briefing document in advance of the meeting of the FDA's Cardiovascular and Renal Drugs Advisory Committee (the advisory committee), which was held to review Chelsea's application. The briefing document included the staff member's recommendation against approval of Northera, which recommendation was based in part on Chelsea's failure to demonstrate that the drug had a "durable effect (i.e., more than 4 weeks)."

On February 13, 2012, eight days before the FDA briefing document was made available to the public, Chelsea issued a press release. In the release, Chelsea stated that it was in "receipt of [the] briefing document," and that "several lines of inquiry . . . have emerged as significant components of the benefit-risk analysis of Northera," including that Chelsea's

drug development program "may not adequately establish a durable treatment effect as a result of the short duration of" the clinical trials. Notably, however, Chelsea's press release did not disclose that the FDA briefing document concluded with the recommendation that Northera not be approved. Also in that release, Chelsea stated that the advisory committee would review the application on February 23, 2012. Finally, the release included a website address where the FDA briefing document later would be made available.

After the February 13, 2012 press release issued, Chelsea's stock price dropped about 37.5 percent. When the briefing document became public eight days later on February 21, 2012, Chelsea's stock price dropped an additional 21 percent.

On February 23, 2012, however, the FDA advisory committee announced its non-binding recommendation in favor of approving Northera as a new drug. Several members of the advisory committee raised the same concerns outlined in the staff briefing document. Although the advisory committee chairperson voted in favor of approving the drug, he nevertheless stated, "virtually all [members of the advisory committee] agree that" the failed studies "do not provide confirmatory evidence of benefit. And the primary study, [Study] 301[,] also did not provide evidence regarding the duration of effect in any direct way."

On March 28, 2012, the FDA denied the new drug application. The FDA provided its decision in a "complete response letter," stating, among other things, that the FDA required an additional successful study to support "durability of effect."

About a week after the FDA's decision, the initial complaint in this case was filed. The plaintiffs later filed a consolidated class action complaint (the complaint), asserting violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 (Rule 10b-5). In their complaint, the plaintiffs, who purchased Chelsea stock between November 3, 2008 and March 28, 2012 (the class period), asserted numerous claims including that the defendants misled investors to believe that the FDA would approve Northera based on the results of only one successful efficacy study, even though the FDA repeatedly had warned Chelsea that two successful studies and evidence of "duration of effect" would be necessary for approval of the new drug. In their complaint, the plaintiffs identified dozens of allegedly misleading statements or material omissions by the defendants.

In response, the defendants filed a motion to dismiss the complaint under Rule 12(b)(6), contending that the complaint failed to show that the defendants made any materially false statements or omissions, and that any such statements or omissions were not made with the required scienter. The

defendants attached to their motion several exhibits and asked the court to take judicial notice of them.

The exhibits relevant to this appeal include three documents that were filed with the SEC (collectively, the SEC documents). Two of these documents are SEC "Form 4" reports, filed by Dr. Schwieterman as the "Reporting Person," showing that while employed as a corporate officer he made two purchases of Chelsea stock during the class period.

The third document submitted by the defendants, a "Definitive Proxy Statement" that Chelsea filed with the SEC, listed the amount of Chelsea stock shares held by the company's officers at the end of February 2012, near the end of the class period. The Proxy Statement showed that Dr. Pedder owned 2.8 percent of all shares of Chelsea stock, while other officers owned lesser amounts of Chelsea stock. However, the Proxy Statement did not reflect whether any of these stock holdings had been acquired or sold during the class period.

At a hearing on the motion to dismiss, the defendants represented that none of the Chelsea officers had sold any shares of Chelsea stock during the class period. The defendants argued that the absence of such sales undermined any inference of scienter on the part of the defendants. The plaintiffs objected to the court's consideration of the SEC documents, asserting that the record did not show definitively "whether any

individual purchased stock or sold stock during the class period" because there had not been any discovery in the case.

At the conclusion of the hearing, the district court took judicial notice of the SEC documents, and granted the defendants' motion to dismiss. Applying the heightened pleading standards of the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u-4(b)(2), the court held that the plaintiffs' securities fraud claims failed because the plaintiffs did not plead allegations sufficient to support a strong inference of scienter.

The district court concluded that although the defendants' statements to investors during the class period "may have been overly optimistic about the [likelihood of the] FDA approving Northera," those statements did not demonstrate a strong inference of scienter for two reasons. First, the court observed that the defendants provided many warnings to investors regarding the sufficiency of the new drug application. Second, the court found that when weighing the competing inferences regarding scienter, "the most glaring" inference was "the fact that none of the individual defendants sold stock during the class period." (Emphasis in original). The court concluded that the lack of stock sales "tip[ped] the scales in favor of defendant[s'] motion" to dismiss, rendering the plaintiffs' allegations insufficient as a matter of law to

establish the required inference of scienter. After the district court entered its order dismissing the case with prejudice, the plaintiffs filed this timely appeal.

II.

In addressing the plaintiffs' arguments, we first state the applicable standard of review. We consider de novo the district court's dismissal of the plaintiffs' complaint under Federal Rule of Civil Procedure 12(b)(6). Wag More Dogs, LLC v. Cozart, 680 F.3d 359, 364 (4th Cir. 2012).

A.

The plaintiffs first argue that the district court erred by considering the SEC documents submitted by the defendants that were not integral to the complaint, and by concluding based on those documents that none of the individual defendants sold Chelsea stock during the class period. According to the plaintiffs, the district court's improper consideration and incorrect interpretation of these documents contributed to the court's erroneous conclusion that the defendants failed to plead sufficient facts supporting a strong inference of scienter.

In response, the defendants contend that the district court properly considered the SEC documents submitted with their motion to dismiss. Arguing that courts "routinely examine" SEC filings at the pleading stage of securities fraud litigation,

the defendants assert that the district court did not err in taking judicial notice of the contents of the two Form 4 exhibits and the Proxy Statement exhibit. The defendants submit that these documents supported the district court's findings that the individual defendants failed to sell shares of Chelsea stock, and did not knowingly or recklessly make misleading statements. We disagree with the defendants' arguments.

1.

As an initial matter, we set forth general legal principles involving securities fraud claims that are pertinent to this appeal. We also review principles addressing the scienter required for such claims.

The Exchange Act and related regulations ensure that public companies release information that will permit "investors to make informed investment decisions." Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 884 (4th Cir. 2014) (citing Taylor v. First Union Corp. of S.C., 857 F.2d 240, 246 (4th Cir. 1988)). Under Section 10(b) of the Act, companies are prohibited from using "any manipulative or deceptive device or contrivance" in connection with the sale of a security in violation of SEC rules. See 15 U.S.C. § 78j(b). Pursuant to regulatory proscription in Rule 10b-5, the following conduct is unlawful in connection with the sale of a security:

> To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . .

17 C.F.R. § 240.10b-5(b).

Generally, a plaintiff asserting a claim under Section 10(b) must establish: "(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." Yates, 744 F.3d at 884 (citation omitted); see Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1322 (2011). Because the district court dismissed the plaintiffs' complaint solely based on the sufficiency of the allegations of scienter, our review is limited to that one element of the plaintiffs' claims.

To demonstrate scienter, a plaintiff must show that the defendant acted with "a mental state embracing intent to deceive, manipulate, or defraud." Tellabs, 551 U.S. at 319 (citation omitted). Allegations of reckless conduct can satisfy the level of scienter necessary to survive a motion to dismiss. See Matrix Capital, 576 F.3d at 181. Reckless conduct sufficient to establish a strong inference of scienter is described as "severe," Ottman v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 344 (4th Cir. 2003), or conduct that is "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." Matrix Capital, 576 F.3d at 181 (citation and internal quotation marks omitted).

Claims of securities fraud are subject to a heightened pleading standard under the PSLRA. Yates, 744 F.3d at 885. Under this heightened pleading standard, the allegations of a securities fraud claim must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" regarding the acts allegedly violating the Exchange Act. 15 U.S.C. § 78u-4(b)(2). To evaluate the strength of scienter inferences, courts engage in a comparative analysis. Yates, 744 F.3d at 885; see Tellabs, 551 U.S. at 326-27. "[A]n inference of scienter can only be strong . . . when it is weighed against the opposing inferences that may be drawn from the facts in their entirety." Yates, 744 F.3d at 885 (quoting Cozzarelli v. Inspire Pharms. Inc., 549 F.3d 618, 624 (4th Cir. 2008)).

After comparing the "malicious and innocent inferences cognizable from the facts pled," a complaint will not be dismissed so long as "the malicious inference is at least as compelling as any opposing innocent inference." Id. (quoting

Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009)). In evaluating these inferences, we consider the scienter allegations holistically and accord those allegations "the inferential weight warranted by context and common sense." Matrix Capital, 576 F.3d at 183 (citing Cozzarelli, 549 F.3d at 625-26).

2.

In view of these principles, we turn to address the plaintiffs' claims that the district court erred in its scienter analysis by considering the SEC documents submitted by the defendants that were not integral to the complaint. Generally, when a defendant moves to dismiss a complaint under Rule 12(b)(6), courts are limited to considering the sufficiency of allegations set forth in the complaint and the "documents attached or incorporated into the complaint." E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013). Consideration of extrinsic documents by a court during the pleading stage of litigation improperly converts the motion to dismiss into a motion for summary judgment. E.I. du Pont de Nemours & Co., 637 F.3d at 448. This conversion is not appropriate when the parties have not had an opportunity to conduct reasonable discovery. Id.; see Fed. R. Civ. P. 12(b), 12(d), and 56.

Courts therefore should focus their inquiry on the sufficiency of the facts relied upon by the plaintiffs in the complaint. Am. Chiropractic Ass'n v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir. 2004). Consideration of a document attached to a motion to dismiss ordinarily is permitted only when the document is "integral to and explicitly relied on in the complaint," and when "the plaintiffs do not challenge [the document's] authenticity." Id. (quoting Phillips v. LCI Int'l Inc., 190 F.3d 609, 618 (4th Cir. 1999)); see Cozzarelli, 549 F.3d at 625 (considering investment analyst reports attached to the defendants' motion to dismiss because the complaint quoted from those reports and the plaintiffs did not challenge the reports' authenticity).

We have recognized a narrow exception to this standard, under which courts are permitted to consider facts and documents subject to judicial notice without converting the motion to dismiss into one for summary judgment. Clatterbuck, 708 F.3d at 557. Under Federal Rule of Evidence 201, courts at any stage of a proceeding may "judicially notice a fact that is not subject to reasonable dispute," provided that the fact is "generally known within the court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Nevertheless, when a court considers relevant facts from the public record at the pleading

stage, the court must construe such facts in the light most favorable to the plaintiffs. Id. Moreover, the determination whether a fact properly is considered under this exception depends on the manner in which a court uses this information. Id. (holding that the district court improperly considered contents of a public record as an established fact and as evidence contradicting the complaint). With these principles in mind, we turn to consider the district court's use of the challenged SEC documents.

The plaintiffs' complaint stated in general terms that, in investigating the case, plaintiffs' counsel had reviewed the public filings submitted to the SEC. However, the complaint did not otherwise refer to any SEC filings, or the contents of such filings, to support the plaintiffs' allegations. In fact, the complaint did not contain any allegation suggesting that the individual defendants made any sales or purchases of Chelsea stock during the class period.

Although plaintiffs asserting securities fraud claims frequently bolster allegations regarding scienter by asserting unusual sales of stock by individuals accused of committing securities fraud, the plaintiffs in the present case did not include this type of allegation in their complaint. And such allegations of unusual stock sales are not required to demonstrate a strong inference of scienter in a securities fraud

case. See Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1253 n.3 (11th Cir. 2008) ("[S]uspicious stock sales are not necessary to create a strong inference of scienter.") (citing Tellabs, 551 U.S. at 325). Therefore, because the SEC documents were not explicitly referenced in, or an integral part of, the plaintiffs' complaint, the district court should not have considered those documents in reviewing the sufficiency of the plaintiffs' allegations.

Our conclusion is not altered by the defendants' contention that the district court was entitled to take judicial notice of the contents of the SEC documents because the accuracy of those documents cannot reasonably be questioned. Even if the SEC documents and their contents could have been reviewed in accordance with Rule 201, the district court in the present case incorrectly construed the information contained in the SEC documents.

Instead of considering the information in the light most favorable to the plaintiffs, the court found that the documents established the "fact that none of the individual defendants" sold Chelsea stock during the class period. Notably, however, the referenced SEC documents fail to establish any such fact.

The Form 4 documents merely indicate that a single Chelsea corporate officer, Dr. Schwieterman, made two purchases of Chelsea stock during the class period, while the Proxy Statement

shows that each corporate officer held some shares of Chelsea stock at a certain point near the end of the class period. The record does not reflect for comparative purposes how many shares of stock the individual defendants held at the beginning of the class period, or provide any other basis for determining whether corporate officers other than Dr. Schwieterman purchased or sold any of their Chelsea stock during that period.

Instead, the Form 4 documents list only Dr. Schwieterman as the "Reporting Person," and do not contain any reference to any other corporate officer. And the Proxy statement provides only a "snapshot in time" of stock shares owned by the various Chelsea officers as of February 29, 2012. Therefore, regardless whether the information contained in the SEC documents could be considered under the judicial notice provisions of Rule 201, such information did not provide a factual basis for the court's conclusion that no individual defendant sold Chelsea stock during the class period. See Clatterbuck, 708 F.3d at 557-58.

We also disagree with the defendants' argument that even if the district court erred in this regard, the court's consideration of the SEC documents did not affect the outcome of the court's decision concerning the adequacy of the plaintiffs' allegations. In weighing the competing inferences, the district court concluded that the defendants' purported failure to sell Chelsea stock during the class period "tip[ped] the scales" of

the competing inferences of scienter. In fact, the district court cited only one other competing inference when considering the element of scienter, namely, that the defendants informed investors regarding certain weaknesses of Chelsea's drug development program. Therefore, the district court's comparison of inferences undoubtedly was affected by its error relating to the content of the SEC documents. Accordingly, we conclude that the court's consideration of the challenged SEC documents was not harmless.

B.

The plaintiffs argue that in addition to the district court's error in relying on the challenged SEC documents, the court further erred in concluding that their allegations of scienter were insufficient as a matter of law. In asserting that they pleaded facts permitting a strong inference of scienter, the plaintiffs rely on their allegations that the defendants intentionally or recklessly failed to disclose that the FDA expected Chelsea to produce two successful studies showing evidence of durability of effect. The plaintiffs place particular emphasis on their allegation that the defendants intentionally misled investors in the February 13, 2012 press release, by failing to disclose that the FDA briefing document included a recommendation against approval of Northera. The plaintiffs assert that because the defendants were aware of this

adverse recommendation but withheld it, such conduct supports a strong inference of wrongful intent.

In response, the defendants maintain that the plaintiffs failed to allege sufficient facts to support a strong inference of scienter. The defendants submit that because they disclosed to investors various weaknesses of their new drug application, the defendants' omission of other information does not support a strong inference of scienter. With respect to the February 13, 2012 press release, the defendants argue that their omission of the adverse FDA staff recommendation does not demonstrate wrongful intent, because the press release included a website address where investors eight days later could locate the full FDA briefing document. We disagree with the defendants' position.

As the Supreme Court emphasized in Matrixx Initiatives, "companies can control what they have to disclose under [Section 10(b) and Rule 10b-5(b)] by controlling what they say to the market." 131 S. Ct. at 1322. Thus, while Chelsea and its corporate officers may have lacked an independent, affirmative duty to disclose the adverse FDA staff recommendation and the shortcomings of Chelsea's evidence of efficacy, the defendants' failure to do so must be viewed under Section 10(b) and Rule 10b-5(b) in the context of the statements that they affirmatively elected to make. See id.

Based on our de novo review, we conclude that the plaintiffs' complaint, when viewed in its entirety, contains sufficient allegations giving rise to a strong inference of scienter. This strong inference of intentional or reckless conduct is supported by the plaintiffs' allegations that material, non-public information known to the defendants about the status of the new drug application and required efficacy studies conflicted with the defendants' public statements on those subjects.

According to the plaintiffs' allegations, although the defendants knew that the FDA expected two successful efficacy studies demonstrating durability of effect to support regulatory approval of Northera, none of the defendants' statements to investors addressed this critical expectation. After the defendants met with FDA officials in December 2010 to discuss submission of the new drug application based only on Study 301, the defendants instead informed investors that the FDA had "agreed" that Chelsea could submit its new drug application for Northera "without the need for any further efficacy studies." However, even assuming that this statement truthfully represented an FDA communication that Chelsea's new drug application could be submitted, the statement was misleading given the FDA's continuing expectation that two successful efficacy studies would be required for approval of Northera.

The defendants also were aware by December 2010 that the lone successful efficacy trial, Study 301, involved a treatment period of only one week, in contrast to the failed Study 303 and the abandoned Study 306, which both involved much longer treatment periods. Nonetheless, the defendants described their December 2010 meeting with the FDA as a "successful outcome" reflecting the "strength of the data" gathered during the clinical trials.

The issue of durability of effect is a core component of the plaintiffs' allegations, along with the FDA's expectation of two successful studies. Critically, the plaintiffs alleged that Chelsea knew that the FDA expected evidence of durability of effect, not just evidence of efficacy, and that "Chelsea was aware of Study 301 and Study 302's durational-benefit shortcomings." JA 65 ¶ 106.

Although the FDA can approve a new drug based on results of only one successful study, the study must be "adequate" and the data must present "substantial evidence that the drug will have the effect it purports." See 21 U.S.C. § 355(d). Additionally, the plaintiffs did not allege that Chelsea unreasonably sought review by the FDA on the basis of one successful study. The plaintiffs instead alleged that the defendants misled investors regarding the risk of submitting the new drug application

supported only by a single, one-week study providing scant evidence of durability of effect.

The plaintiffs also made a significant allegation concerning the defendants' failure to disclose in the February 13, 2012 press release that the FDA briefing document contained a recommendation against approval of Northera. In its press release, Chelsea instead stated that Chelsea had received the briefing document and disclosed that "several lines of inquiry" had emerged, including that the efficacy trials "may not adequately establish a durable treatment effect."[6] Chelsea's omission of the information regarding the adverse FDA staff recommendation, when viewed in the context of the known problems of the efficacy studies and Chelsea's earlier remarks regarding those studies, supports the inference that Chelsea intentionally or recklessly misled investors.

These allegations are significantly stronger than the allegations we considered in Cozzarelli, a case on which the defendants rely. In Cozzarelli, which also involved a pharmaceutical company's attempt to gain FDA approval for a drug, the plaintiffs' primary allegation of scienter focused on a corporate officer's use of an imprecise medical term when

[6] Contrary to the dissent's assertion, the change in Chelsea stock prices after Chelsea's statements is relevant to the element of materiality, and does not impact our consideration of the allegations of scienter.

describing the endpoint of a clinical study, allegedly with the intent to mislead investors to think that the study was likely to succeed. 549 F.3d at 624-26. We concluded that not only was the general term used by the corporate officer "more or less interchangeable" with the precise term not referenced, but that the pharmaceutical company also informed investors that it would not disclose the details of the study for "competitive reasons." Id. at 626. Therefore, we concluded in Cozzarelli that the corporate officer's chosen language did not support a strong inference of scienter.[7] Id. at 627-28.

In contrast, the present case involves numerous allegedly misleading statements and omissions by the defendants that were not caused by the use of imprecise language or the execution of a legitimate business decision. Instead, the plaintiffs' allegations, when considered in the context of the entire complaint, permit a strong inference that the defendants either

[7] After concluding that the plaintiffs' allegations in Cozzarelli failed to show scienter based on the allegedly intentional false statement by a corporate officer, we proceeded to consider the plaintiffs' other allegations of scienter, which involved the company's financial motivations and the sales of stock by corporate officers. 549 F.3d at 628. We concluded that even considering these additional allegations, the plaintiffs' complaint failed to demonstrate a strong inference of scienter. Id. Here, however, because the nature of the alleged misstatements and omissions themselves give rise to a strong inference of scienter, we need not consider the plaintiffs' additional allegations regarding the defendants' financial motivations.

knowingly or recklessly misled investors by failing to disclose critical information received from the FDA during the new drug application process, while releasing less damaging information that they knew was incomplete.[8]

We emphasize that our conclusion does not stand for the proposition that a strong inference of scienter can arise merely based on a defendant's failure to disclose information. Rather, the scienter inquiry necessarily involves consideration of the facts and of the nature of the alleged omissions or misleading statements within the context of the statements that a defendant affirmatively made.[9] See Matrixx Initiatives, 131 S. Ct. at 1322 (stating that "companies can control what they have

[8] The dissenting opinion states that Dr. Pedder acknowledged one of the obstacles to drug approval by stating, after the December 2010 meeting, that the FDA was interested "in seeing 'two additional studies.'" However, Dr. Pedder's statement did not acknowledge that the FDA expected to see two successful studies showing durability of effect. Rather, Dr. Pedder stated that the FDA "was clear that additional efficacy studies were not required for an NDA filing," but that the FDA was interested in two specific types of studies unrelated to durability of effect. Additionally, the dissent appears to rely on the defendants' statements made on March 28, 2012, after the FDA denied the new drug application. The defendants' statements at that point, however, are not relevant to the plaintiffs' allegations of scienter.

[9] As observed in the dissenting opinion, this Court many times has concluded that a plaintiff asserting securities fraud claims failed to plead allegations demonstrating a strong inference of scienter. Such conclusions, however, are necessarily fact-dependent and do not compel a result in the present case.

to disclose under [Section 10(b) and Rule 10b-5(b)] by controlling what they say to the market").

The inference of scienter here is at least as compelling as the opposing inference that Chelsea officials had signaled to investors that there were some weaknesses in their new drug application regarding efficacy studies for Northera, and simply failed to provide further details regarding information received from the FDA. See Yates, 552 F.3d at 891. We therefore conclude that the plaintiffs' allegations are sufficient to support the required inference of scienter. Our conclusion, however, is limited to the sufficiency of the complaint regarding the element of scienter, and does not address the sufficiency of the allegations with respect to the remaining elements of the plaintiffs' securities fraud claims, which will be considered by the district court in the first instance on remand.[10]

III.

For these reasons, we hold that the district court erred in dismissing the plaintiffs' complaint on the basis that the allegations supporting an inference of scienter were legally

[10] We do not address the plaintiffs' derivative Section 20(a) claims, which also should be considered on remand.

insufficient. Accordingly, we vacate the district court's judgment and remand the case for further proceedings.

VACATED AND REMANDED

THACKER, Circuit Judge, dissenting:

Since the enactment of the PSLRA, we have published eight decisions reviewing the dismissal of a securities fraud suit for failure to plead facts supporting a strong inference of scienter; in all of them, we concluded that the inference was lacking. See Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 894 (4th Cir. 2014); Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc., 576 F.3d 172, 176 (4th Cir. 2009); Pub. Emps.' Ret. Ass'n of Colo. v. Deloitte & Touche LLP, 551 F.3d 305, 306 (4th Cir. 2009); Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 628 (4th Cir. 2008); Teachers' Ret. Sys. of La. v. Hunter, 477 F.3d 162, 184 (4th Cir. 2007); In re PEC Solutions, Inc. Sec. Litig., 418 F.3d 379, 388-90 (4th Cir. 2005); Ottmann v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 352-53 (4th Cir. 2003); Phillips v. LCI Int'l, Inc., 190 F.3d 609, 620 (4th Cir. 1999). In my view, the inference is lacking in this case, too.

The PSLRA requires a plaintiff in a securities fraud suit to "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). To establish this strong inference, a plaintiff must persuade the court that it is as likely as not that the defendant acted with fraudulent intent or, at the very least, with "such severe recklessness that the danger of misleading investors was either known to the defendant

or so obvious that the defendant must have been aware of it." Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 623 (4th Cir. 2008) (internal quotation marks omitted). Here, the allegations do not strongly imply either fraudulent intent or severe recklessness. Instead, the allegations suggest that Chelsea -- while acknowledging the various challenges and setbacks encumbering its bid for FDA approval -- submitted the Northera application with justifiable confidence in its chances for success. I therefore respectfully dissent.[1]

I.

A.

Scienter, as defined by the Supreme Court, is "a mental state embracing intent to deceive, manipulate, or defraud." Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976). The federal circuit courts agree that reckless behavior may be enough to satisfy the scienter requirement in a securities fraud suit,[2] but they "differ on the degree of

[1] I do not object to the majority's determination that the district court misused the challenged SEC documents. However, in my view, the court's reliance on those documents is of no consequence. The plaintiffs' complaint ought to fail regardless.

[2] For its part, the Supreme Court has never stated whether recklessness is enough to satisfy the section 10(b) scienter requirement. See Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1323 (2011) (noting that the Court has "not decided whether recklessness suffices to fulfill the scienter (Continued)

recklessness required." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 n.3 (2007). The distinctions among the circuits include variations in terminology, with courts "referring to the recklessness standard variously as 'deliberate' or 'conscious recklessness,' 'severe recklessness,' and 'a high degree of recklessness.'" Ann Morales Olazábal, Defining Recklessness: A Doctrinal Approach to Deterrence of Secondary Market Securities Fraud, 2010 Wis. L. Rev. 1415, 1424 (footnotes omitted) (collecting cases).

In this circuit, we recognize that allegations of recklessness can satisfy the scienter requirement, see Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc., 576 F.3d 172, 181 (4th Cir. 2009); see also Ottmann v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 344 (4th Cir. 2003) (recognizing for the first time in this circuit that "a securities fraud plaintiff may allege scienter by pleading not only intentional misconduct, but also recklessness"), but we insist that the recklessness must be "severe" -- that is, "a slightly lesser species of intentional misconduct." Ottmann, 353 F.3d at 344 (internal quotation marks omitted); see also Cozzarelli, 549 F.3d at 623; Teachers' Ret. Sys. of La. v. Hunter, 477 F.3d 162, 184 (4th

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requirement" and finding it unnecessary to settle the issue under the circumstances of the case).

Cir. 2007). This definition of recklessness, we have stated, "comports with the observation of the Supreme Court that '[t]he words "manipulative or deceptive" used in conjunction with "device or contrivance" strongly suggest that § 10(b) was intended to proscribe knowing or intentional misconduct.'" Ottmann, 353 F.3d at 344 (alteration in original) (quoting Ernst & Ernst, 425 U.S. at 197).

Our decision in Cozzarelli v. Inspire Pharmaceuticals, Inc. makes clear that pleading scienter -- whether in the form of fraudulent intent or severe recklessness -- requires a showing of "wrongful intent." 549 F.3d at 621. There, a group of shareholders alleged that a drugmaker seeking FDA approval of an experimental eye-disease treatment misled investors into believing that an important clinical trial was likely to succeed. See id. at 624-25. The drugmaker allegedly nurtured this false impression by withholding details about the trial's endpoint while simultaneously representing that the trial was "very similar" to a previous successful trial. Id. at 625 (internal quotation marks omitted). We concluded that the allegations supported an inference that the drugmaker sought only to protect its competitive advantage in the marketplace; this inference, we stated, "is more powerful and compelling than the inference that [the drugmaker] acted with an intent to deceive." Id. at 626 (emphasis supplied).

In the years since Cozzarelli, our court has occasionally neglected to note that the recklessness necessary to support a finding of scienter must be "severe." Compare Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 884 (4th Cir. 2014) ("At the pleading stage, alleging either intentional or severely reckless conduct is sufficient." (emphasis supplied)), with Matrix Capital, 576 F.3d at 181 ("Pleading recklessness is sufficient to satisfy the scienter requirement."). The standard, though, remains unchanged. We have consistently stated that an allegedly reckless act must be "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." Matrix Capital, 576 F.3d at 181 (internal quotation marks omitted); see also Pub. Emps.' Ret. Ass'n of Colo. v. Deloitte & Touche LLP, 551 F.3d 305, 314 (4th Cir. 2009) ("In order to establish a strong inference of scienter, plaintiffs must do more than merely demonstrate that defendants should or could have done more. They must demonstrate that [defendants] were either knowingly complicit in the fraud, or so reckless in their duties as to be oblivious to malfeasance that was readily apparent."). This understanding of scienter -- that it necessarily entails a "culpable state of mind," Ottmann, 353

F.3d at 348 -- preserves section 10(b) as a prohibition on securities fraud. It ensures that corporations and their officers cannot escape liability through willful blindness -- that is, purposeful ignorance of the truth of their own representations -- while, at the same time, it prevents section 10(b) from devolving into a penalty for business decisions that, in hindsight, appear questionable.

B.

Here, under the PSLRA's heightened pleading standard, the plaintiffs were required to allege facts giving rise to a strong inference of fraudulent intent or severe recklessness. See 15 U.S.C. § 78u-4(b)(2)(A); Cozzarelli, 549 F.3d at 623. This is "no small burden." Cozzarelli, 549 F.3d at 624. Though the inference of scienter "need not be irrefutable," it "must be more than merely 'reasonable' or 'permissible.'" Tellabs, 551 U.S. at 324. Unless a "reasonable person would deem the inference of scienter . . . at least as compelling as any opposing inference" of nonfraudulent intent, the pleading fails. Id. The plaintiffs' complaint here does not satisfy this standard.

1.

Reviewing the complaint in its entirety, it is clear that Chelsea had plenty of reason to believe the FDA would be

receptive to its application. More importantly, the facts strongly suggest that Chelsea acted on just such a belief.

To merit FDA approval, an application must present "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d). Though here the plaintiffs' complaint states that the FDA generally "requires at least two adequate and well-controlled studies," J.A. 59,[3] federal law expressly authorizes the FDA to make the requisite finding of "substantial evidence" based solely on "data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation)," 21 U.S.C. § 355(d). Likewise, as the complaint recognizes, the FDA Guidelines note that the agency "may acknowledge the persuasiveness of a single, internally consistent, strong multicenter study." J.A. 60.

Chelsea based its FDA application on two sets of data. First and foremost, there was the data from Study 301, which successfully demonstrated the drug's efficacy. In addition, Chelsea offered supplemental data from Study 302, which, though failing to meet its primary endpoint, showed what Chelsea later

[3] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal.

determined to be a "nominally statistically significant improvement" in the score used to measure the drug's clinical efficacy. J.A. 42. These were the data that the advisory committee reviewed in February 2012, and the committee voted, seven to four, to recommend approving the drug. The chairperson, who was among those voting in favor of approval, explained that there was "no question in [his] mind that this drug is efficacious, particularly in a subset of patients." J.A. 203.[4] Other members echoed those remarks. One said he saw "substantial evidence of substantial benefit for some patients." Id. at 205. Another said he "could not in a clear conscience vote no and deprive those patients from the benefits they can derive at this point from this medication." Id. at 67.

Nonetheless, the plaintiffs assert that Chelsea knew the FDA expected two successful studies. This claim rests, in large part, on a discussion that took place at the advisory committee meeting. There, one FDA administrator, Dr. Steve Graham ("Graham"), recalled that the "very first thing we said" in the special protocol assessment for Study 301 was "that the study in and of itself wouldn't be sufficient, that we wanted

[4] The complaint quotes selectively from the advisory committee meeting transcript. Accordingly, although this comment does not appear in the complaint, we may consider it here because it is incorporated into the complaint by reference. See Cozzarelli, 549 F.3d at 625.

two studies." J.A. 61. According to Graham, the FDA also "said that we wanted durability," a statement the agency "repeated on at least two subsequent occasions on information letters to the company." Id. However, at that very same meeting, Graham himself conceded that Study 301 alone, if successful, may be sufficient to support the application. If, he said, that single study presented "an overwhelming effect[,] . . . you'd be a fool not to approve it." Id. at 62.

In its December 20, 2010 press release, Chelsea announced that the FDA had "agreed" that the proposed application "could be submitted" based on Studies 301 and 302 "without the need for any further efficacy studies." J.A. 233. The plaintiffs' complaint does not dispute the literal truth of this announcement. Nor is there any reason to doubt that Chelsea interpreted the FDA's feedback as highly encouraging. The company's actions are proof positive that it did. Rather than wait to complete Study 306, Chelsea pressed ahead and submitted its application exactly as it said it would, with only Study 301 and supplemental support from Study 302 to its credit. Against this backdrop, the most compelling inference is not that Chelsea acted with wrongful intent, but that it believed its prospects were good. See Kuyat v. BioMimetic Therapeutics, Inc., 747 F.3d 435, 441 (6th Cir. 2014) (concluding that a medical-device manufacturer "could legitimately believe that the

statistically significant results" of its study "would be sufficient to obtain approval by the FDA," despite private communications in which the FDA indicated that it expected a more expansive study than the one provided).

2.

The plaintiffs' claim that Chelsea's public statements were intentionally fraudulent or severely reckless runs into another problem, which is that those statements were not unreservedly optimistic. On the contrary, the company consistently acknowledged the obstacles in its path.

In a December 2010 conference call, Chelsea's CEO acknowledged that the FDA had expressed an interest in seeing "two additional studies." J.A. 81. Later, in its September 30, 2011 quarterly report to the SEC -- from which the plaintiffs' complaint quotes -- the company listed numerous reasons why the FDA "may not accept or approve" the Northera application. Id. at 141. When the FDA staff issued its briefing document opposing Chelsea's application, the company issued a press release noting its receipt of the document and explaining that "several lines of inquiry . . . have emerged as significant components of the benefit-risk analysis of Northera." Id. at 248 (internal quotation marks omitted). These issues, according to the February 2012 press release, included "the short duration of our clinical studies, the limited size of our study

population given the orphan indication and the challenges in quantifying symptomatic and clinical benefit." Id. (internal quotation marks omitted). Similarly, when the FDA rejected Chelsea's application in March 2012, the company explained in a press release that it had received the FDA's complete response letter, and that this letter requested data from an "additional positive study to support efficacy."[5] Id. at 68. The company continued to say that it planned to "request a meeting with the FDA to review the Agency's comments, clinical trial recommendations and to help determine appropriate next steps toward securing approval of Northera." Id. at 69.

The market responded to these statements accordingly. As the majority notes, Chelsea's stock dropped 37.5 percent following the February 2012 press release discussing the FDA briefing document. Likewise, the stock fell 28 percent in response to the March 2012 press release discussing the FDA's rejection of droxidopa. These reactions call into question whether Chelsea's press releases were misleading at all -- let

[5] The company issued this press release on March 28, 2012. This date is significant both because it is the same day that Chelsea received the FDA's complete response letter and because it marks the final day of the class period. Despite the majority's claim to the contrary, see ante at 29 n.8, the company's statements on this date are indeed relevant to the scienter inquiry because they undermine the plaintiffs' assertion that Chelsea intentionally or recklessly failed to disclose critical information during the class period.

alone whether the danger of misleading people was "so obvious" that making those statements must have been severely reckless. Cozzarelli, 549 F.3d at 623 (internal quotation marks omitted).

II.

As we stated in Cozzarelli, we do not infer scienter "from every bullish statement by a pharmaceutical company that was trying to raise funds." 549 F.3d 618, 627 (4th Cir. 2008). If we did, "we would choke off the lifeblood of innovation in medicine by fueling frivolous litigation." Id. Today's decision clears the way for more litigation, heightening the risk that shareholders will exploit the judicial process to extract settlements from corporations they chose to fund. This is exactly what Congress sought to prevent when it enacted the PSLRA. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 320 (2007). Accordingly, I would affirm the judgment of the district court.