PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

DAVID COZZARELLI; STEPHANIE COZZARELLI; FRANKFURT-TRUST INVESTMENT GESELLSCHAFT MBH; CAROLE SWOBODA; ROBERT SWOBODA,

Plaintiffs-Appellants,

v.

INSPIRE PHARMACEUTICALS INCORPORATED; CHRISTY L. SHAFFER, PH.D.; GREGORY L. MOSSINGHOFF; GARY D. NOVACK, PH.D.,

Defendants-Appellees,

and

DEUTSCHE BANK SECURITIES INCORPORATED; MORGAN STANLEY & COMPANY, INCORPORATED; PIPER JAFFRAY & CO; SG COWEN & CO, LLC,

Defendants.

No. 07-1851

Appeal from the United States District Court
for the Middle District of North Carolina, at Durham.
William L. Osteen, Senior District Judge.
(1:06-cv-00201)

Argued: October 30, 2008

Decided: December 12, 2008

Before WILKINSON, Circuit Judge, Irene M. KEELEY, United States District Judge for the Northern District of West Virginia, sitting by designation, and Henry E. HUDSON, United States District Judge for the Eastern District of Virginia, sitting by designation.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Keeley and Judge Hudson joined.

COUNSEL

ARGUED: Maya Saxena, SAXENA WHITE, P.A., Boca Raton, Florida, for Appellants. Barry M. Kaplan, WILSON, SONSINI, GOODRICH & ROSATI, Seattle, Washington, for Appellees. **ON BRIEF:** Christopher L. Nelson, Jennifer Keeney, SCHIFFRIN, BARROWAY, TOPAZ & KESSLER, L.L.P., Radnor, Pennsylvania; Joseph E. White, III, Christopher S. Jones, SAXENA WHITE, P.A., Boca Raton, Florida, for Appellants. Nicholas I. Porritt, C. Paul Chalmers, Scott A. Lowry, WILSON, SONSINI, GOODRICH & ROSATI, Washington, D.C., for Appellees.

OPINION

WILKINSON, Circuit Judge:

This case involves claims that a pharmaceutical company and three of its directors violated federal securities laws. Plaintiffs' primary allegation is that Inspire Pharmaceuticals, Inc. committed securities fraud by overstating the prospects for an experimental drug that the company was developing to treat dry eye disease. When we apply the careful scrutiny required by Congress in the Private Securities Litigation

Reform Act of 1995 and by the Supreme Court in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007), we conclude that plaintiffs' allegations are lacking. In particular, plaintiffs fail to raise the "strong inference" of wrongful intent that is necessary to support their securities fraud claims. We thus affirm the district court's dismissal of the complaint.

I.

Inspire is in the business of developing prescription drugs to treat diseases of the eyes, lungs, and sinuses. One of the company's flagship products is diquafosol tetrasodium ("diquafosol"), a treatment for dry eye disease. Inspire designed diquafosol both to prevent and to heal the long-term damage that dry eye disease causes to the cornea of the eye. Over-the-counter eye drops, in contrast, provide only short-term relief of dry eye symptoms.

Before Inspire could market diquafosol, the company had to demonstrate the drug's safety and efficacy to the satisfaction of the Food and Drug Administration. The FDA generally requires drug companies to conduct clinical trials with predetermined goals, or "endpoints," that must be satisfied. Endpoints may be either subjective or objective. A subjective endpoint is a goal relating to a symptom experienced by the patient, such as itchiness of the eye. An objective endpoint is a goal relating to a verifiable test.

A common objective test for dry eye drugs is known as "corneal staining," a procedure in which a fluorescent dye is used to highlight damaged areas of the cornea. The result of the test (or its "score") varies from zero to five depending on the number of highlighted areas. A score of zero is known as "corneal clearing." Clearly, a showing that diquafosol causes an improvement in patients' corneal staining scores would help the drug's chances for FDA approval. Even better would be a demonstration that diquafosol causes patients' number of

stained corneal areas to fall to zero, thus achieving corneal clearing.

To that end, Inspire performed a series of clinical trials for diquafosol. Of significance here is Study 105, a Phase III trial designed to demonstrate efficacy in a large patient population. Diquafosol met its primary objective endpoint in Study 105: patients using diquafosol showed a statistically significant improvement in their corneal staining scores. Importantly, a statistically significant number of patients also exhibited corneal clearing. But diquafosol failed to meet its subjective endpoint. While patients using the drug showed improvement with respect to a subjective symptom—the sensation of a foreign body in the eye—the subjective results were not statistically significant.

With these results in hand, Inspire sought approval to market diquafosol by submitting a New Drug Application to the FDA in June 2003. The FDA had no written guidance for approving dry eye treatments at the time, and the agency's requirements for approval were not altogether clear. It had been thought historically that the FDA would only approve a dry eye treatment that met both an objective endpoint and a subjective endpoint in two trials. But the only prescription treatment for dry eye ever to be approved, Restasis, had gained the FDA's blessing in 2002 despite failing to meet that rigorous standard. Thus, Inspire surmised that diquafosol might be approved despite missing its subjective endpoint in Study 105.

The FDA responded by telling Inspire that it had to conduct at least one more study to obtain approval. In private communications, the FDA gave Inspire two options. Inspire could conduct two additional trials that met both an objective endpoint and a subjective endpoint. Or it could conduct one additional trial that replicated—this time as a primary endpoint—the corneal clearing that Inspire had achieved in Study 105.

Inspire chose the latter option and commenced Study 109 in June 2004 with a primary endpoint of corneal clearing.

Inspire announced publicly that it was performing Study 109. But Inspire was tight-lipped regarding the details of the trial, as investment analysts noted at the time. In particular, Inspire stated that it would not disclose the primary endpoint of Study 109 because the company did not want to divulge the FDA's requirements for approval to the company's competitors, who could have used that information to plan their own studies.

However, Inspire did make a handful of public comments regarding Study 109. In prospectuses for stock offerings in July and November 2004, the company stated that it had a "clear understanding of the FDA's additional requirement" for approval of diquafosol. Inspire also referred to Study 109 as a "confirmatory" Phase III trial in those prospectuses and other public statements. Inspire CEO and Director Christy Shaffer further expressed in a conference call with investors and analysts on May 10, 2004 that Study 109's design was "very similar" to that of Study 105. And Shaffer stated in another conference call on November 4, 2004 that the primary endpoint of Study 109 was "a corneal staining endpoint." Despite the fact that Inspire had declined to disclose the exact endpoint of Study 109, and despite the fact that Inspire also had announced that Study 105 had achieved corneal clearing, some stock analysts speculated that the primary endpoint of Study 109 was only a relative improvement in corneal staining scores and that Study 109 was likely to meet that endpoint.

While Study 109 was ongoing, Shaffer and two other Inspire directors sold some of their shares in Inspire. Shaffer sold 2,000 shares in July 2004, 2,000 shares in August, and 10,000 shares in November (together, about 3% of her total holdings of shares and vested options). Also in November 2004, Gregory Mossinghoff sold 35,000 shares (12% of his

total holdings), and Gary Novack sold 5,700 shares (13%). Despite the sales, all three of the directors actually increased their net holdings in Inspire while Study 109 was pending through the acquisition of vested stock options.

On February 9, 2005, Inspire announced the results of Study 109. Diquafosol had failed to meet its primary endpoint, a statistically significant amount of corneal clearing. Inspire's stock price fell 44.5% from $16.00 on February 8 to $8.88 on February 9. On February 15, this action ensued.

Plaintiffs—David and Stephanie Cozzarelli, Robert and Carole Swoboda, and Frankfurt-Trust Investment-Gesellschaft mbH—filed a Consolidated Class Action Complaint on behalf of purchasers of Inspire stock. Plaintiffs alleged numerous violations of federal securities laws by Inspire, Shaffer, Mossinghoff, and Novack. In particular, plaintiffs claimed that defendants had violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as well as Rule 10b-5, by fraudulently misleading investors as to Study 109's likelihood of success. *See* 15 U.S.C. §§ 78j(b), 78t(a); 17 C.F.R. § 240.10b-5. Plaintiffs also alleged that defendants had violated Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (15 U.S.C. §§ 77k, 77l(a)(2), 77o) by similarly misleading investors about Study 109 in the prospectuses relating to the company's July and November 2004 stock offerings. Plaintiffs further claimed that Shaffer had committed insider trading in violation of Section 20A of the Exchange Act, 15 U.S.C. § 78t-1.

On defendants' motion, the magistrate judge issued a recommendation that the complaint be dismissed. *See In re Inspire Pharm., Inc. Sec. Litig.*, 515 F. Supp. 2d 631, 634 (M.D.N.C. 2007). Applying the heightened pleading standards of the Private Securities Litigation Reform Act, the judge held that plaintiffs' claims under the Exchange Act failed because plaintiffs had not established a strong inference of scienter. *See id.* at 639-40. Further, plaintiffs' entire action

warranted dismissal because plaintiffs had insufficiently pled the requisite element that was common to all of plaintiffs' claims: a false or misleading statement by defendants. *See id.* at 640-41. The district court accepted the magistrate's recommendation and dismissed the complaint with prejudice. *See id.* at 633. This appeal followed.

II.

A.

We begin with plaintiffs' claims under Section 10(b) of the Exchange Act and Rule 10b-5. Those provisions act to protect the integrity of the market in securities and prohibit fraud in connection with the purchase or sale of a security. *See* 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. A successful securities fraud plaintiff must show that: "(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." *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 172 (4th Cir. 2007) (internal quotations omitted). To prove the necessary mental state of scienter, negligence is not enough. A plaintiff must show either "intentional misconduct" or 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." *Ottmann v. Hanger Orthopedic Group, Inc.*, 353 F.3d 338, 343-44 (4th Cir. 2003) (internal quotations omitted).

These substantive elements of a securities fraud claim are demanding. But the potential liability for defendants also can be significant. As a result, there is a danger that some Exchange Act suits seek only valuable settlements and fees rather than success on the merits. Indeed, securities fraud actions, "if not adequately contained, can be employed abusively to impose substantial costs on companies and individu-

als whose conduct conforms to the law." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2504 (2007).

To eliminate such abuse, Congress enacted the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737. *See Tellabs*, 127 S. Ct. at 2504. Through the "[e]xacting pleading requirements" of the PSLRA, Congress charged courts to be vigilant in preventing meritless securities fraud claims from reaching the discovery phase of litigation. *Id.* at 2504, 2508. In particular, Congress required that plaintiffs make specific allegations of false statements or else face dismissal. *See* 15 U.S.C. § 78u-4(b). And Congress instructed courts to dismiss any securities fraud complaint that does not "state with particularity facts giving rise to a strong inference that the defendant acted" with scienter. *Id.* § 78u-4(b)(2).[1]

[1]15 U.S.C. § 78u-4(b) provides in relevant part:

> (1) In any private action arising under this chapter in which the plaintiff alleges that the defendant —
>
> (A) made an untrue statement of a material fact; or
>
> (B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading;
>
> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if 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.
>
> (2) In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.
>
> (3) (A) In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of paragraphs (1) and (2) are not met.

The Supreme Court in *Tellabs* underscored that "meritorious private actions to enforce federal antifraud securities laws are an essential supplement to criminal prosecutions and civil enforcement actions." 127 S. Ct. at 2504. But it also made clear that raising a "strong inference" of scienter is no small burden. The Court recognized that the PSLRA "unequivocally raised the bar for pleading scienter." *Id.* at 2509 (internal quotations omitted). And in defining just how "strong" an inference of scienter must be, the Court gave that standard teeth, using adjectives like "cogent," "compelling," "persuasive," "effective," and "powerful." *Id.* at 2510. The Court held that the test applied by the Seventh Circuit below—requiring only that a reasonable person could infer that scienter existed—did not demand a strong enough inference of scienter to satisfy the statutory language. *See id.* at 2509-10. Instead, the Court held that 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. *See id.*

Tellabs therefore prescribed the following test: "A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 2510. Thus, 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. Only then, the Court held, will the PSLRA serve its purpose of derailing "frivolous, lawyer-driven litigation." *Id.* at 2509.

To sum up, *Tellabs* recognized that securities fraud actions serve an important purpose—but only when those actions are meritorious. *See id.* at 2504, 2509. The PSLRA balances these concerns by requiring courts to sort out the meritorious claims from the abusive ones early in litigation, and *Tellabs* obligates courts do so with care. Keeping in mind the duty that Congress and the Supreme Court have thus placed upon us, we

turn to the specific allegations of securities fraud in plaintiffs' complaint.

B.

The theory underlying plaintiffs' securities fraud claims amounts to this: Inspire and its directors intentionally misled the public to believe that Study 109 was likely to succeed, thereby artificially inflating Inspire's stock price to the financial benefit of the company and the individual directors. To support that theory, plaintiffs allege that certain statements by defendants misled investors regarding the endpoint of Study 109. Plaintiffs rely primarily on Shaffer's statement on a conference call in November 2004 that Study 109 had "a corneal staining endpoint." They also point to statements that Study 109 was a "confirmatory" trial and that Study 109 was "very similar" to Study 105.

The district court held that plaintiffs had not satisfied the PSLRA because they had not alleged with sufficient particularity that defendants' statements were misleading. We agree with the district court that the PSLRA establishes strict requirements for pleading falsity with specificity and that there is a substantial question as to whether plaintiffs' allegations of falsity were adequate. *See Hunter*, 477 F.3d at 171-75. But we also find it quite clear—and the district court did as well—that plaintiffs failed to allege facts giving rise to a strong inference of scienter. We therefore assume for the sake of argument that defendants' statements were misleading and turn to plaintiffs' theory of scienter.

C.

Plaintiffs attempt to establish a strong inference of scienter through the following allegations. Plaintiffs' primary claim is that defendants knew both that the primary endpoint of Study 109 was "corneal clearing" and that "corneal clearing" was different than "corneal staining," so Shaffer's statement that

Study 109 had "a corneal staining endpoint" must have been intentionally false. Plaintiffs also claim that corneal clearing is "almost impossible" to achieve—based on quotations from anonymous doctors who worked on Studies 105 and 109—and that defendants therefore knew that Study 109 would likely fail. Plaintiffs also argue that defendants had multiple financial motivations to commit fraud. Plaintiffs allege that Inspire was losing money in 2004 and needed to raise capital, and they allege that Shaffer's compensation was tied to the performance of the company and diquafosol. Plaintiffs also claim that the individual defendants sold large numbers of their own Inspire shares while Study 109 was pending. When all of these allegations are combined, plaintiffs contend that a strong inference of scienter emerges.

We disagree. Plaintiffs' proposed inference of scienter depends on stringing together a series of isolated allegations without considering the necessary context. Plaintiffs insist that we should rely solely on their discrete allegations, and they urge us not to look beyond the complaint for additional facts. In particular, the complaint quotes selectively from various reports by investment analysts, and plaintiffs argue that we should not consider the reports in full. That argument is erroneous. While we must accept plaintiffs' factual allegations as true, the Supreme Court in *Tellabs* held that we should not decide the issue of scienter by viewing individual allegations in isolation. *See* 127 S. Ct. at 2509. Rather, we must examine the facts as a whole, including facts found in "documents incorporated into the complaint by reference." *Id.* Furthermore, plaintiffs nowhere challenge the authenticity of the analyst reports attached to defendants' motion to dismiss and cited in plaintiffs' complaint. Our consideration of such documents is undoubtedly proper. *See Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004).

The content of these analyst reports makes clear why plaintiffs urge us not to look beyond the complaint itself: the reports demonstrate the fundamental weakness of plaintiffs'

case. The reports reveal that Inspire "never confirmed the primary endpoint" of Study 109 publicly and that the company even expressly stated that it would not announce the specifics of Study 109 for "competitive reasons." As Morgan Stanley explained in August 2004: "Inspire does not want to disclose details, such as endpoints, that its competitors could use in their development programs." In addition, that same report by Morgan Stanley makes clear that Inspire had achieved "clearing of corneal staining" in Study 105 and had announced that result to the public. Finally, the analysts did opine that the endpoint for Study 109 was a reduction in corneal staining scores. But the analysts also admitted that—due to Inspire's refusal to disclose the endpoint—their opinions were just that: opinion, "assum[ption]," and "belief."

These facts suggest an inference that defendants withheld information from the market with the intent to protect Inspire's competitive interests. As the analyst reports suggest, Inspire had expended substantial time and resources to learn the FDA's requirements for approval of a dry eye treatment, and the company did not want to divulge that information to its rivals. It is beyond our purview to determine whether that decision was correct as a matter of business judgment. But a decision to seek a competitive advantage, whether wise or not, is quite different from an intent to deceive. Indeed, plaintiffs do not suggest that withholding information to protect one's competitive interests is anything other than a legitimate business call. Rather, plaintiffs suggest only that it is the wrong inference to draw from the facts alleged.

We thus have two competing inferences based on the facts as a whole. Plaintiffs argue that the facts support a nefarious intent, and defendants argue that the facts support an innocent one. Under the PSLRA and *Tellabs*, we must weigh those competing inferences and determine whether plaintiffs' inference of scienter is "cogent and at least as compelling" as defendants' inference of a legitimate business judgment. 127 S. Ct. at 2510. As explained below, we conclude that no

strong inference of scienter exists because the inference that defendants acted with the nonfraudulent intent to protect their competitive advantage is more powerful and compelling than the inference that defendants acted with an intent to deceive.

D.

Upon examination, Inspire's legitimate business motivations explain each of the facts alleged in the complaint more convincingly than plaintiffs' tenuous theory of wrongful intent. We shall address each of those allegations in turn, but we first note that plaintiffs have not alleged the existence of any internal documents from Inspire or other direct statements contradicting the inference that defendants acted with a lawful intent based on their competitive interests. While that sort of "smoking-gun" allegation is not necessary to support an inference of scienter, *see Tellabs*, 127 S. Ct. at 2510, plaintiffs do have the difficult task of establishing a countervailing, cogent inference of scienter through indirect and circumstantial allegations.

Plaintiffs' scienter theory depends principally on Shaffer's statement that Study 109 had "a corneal staining endpoint." Plaintiffs insist that Shaffer was intentionally lying because she knew both that the endpoint of Study 109 was "corneal clearing" and that there was an irreconcilable distinction between the terms "corneal clearing" and "corneal staining." But that argument ignores reality. In fact, the two terms are more or less interchangeable—or at least interchangeable enough to dispel a strong inference of fraud. "Corneal staining" is a procedure, and "corneal clearing" is one possible result of that procedure. "[A] corneal staining endpoint" is thus a general, descriptive phrase that encompasses a spectrum of possible endpoints, including corneal clearing. It is difficult to infer intent to deceive from Shaffer's reference to the general phrase rather than the specific result at the end of the spectrum. Furthermore, Shaffer had a perfectly legitimate reason to refer to "corneal staining" generally rather than to

"corneal clearing" in particular—protection of Inspire's competitive interests. Shaffer's reference to "a corneal staining endpoint" therefore supports at most an inference of imprecise or even negligent use of language, not an inference of scienter.

We also find unpersuasive plaintiffs' other primary allegation supporting its theory of scienter. Plaintiffs argue that defendants knew that the corneal clearing endpoint of Study 109 was "almost impossible" to achieve and thus acted with wrongful intent by leading investors to believe that Study 109 would succeed. Again, the facts in their entirety belie plaintiffs' theory. Morgan Stanley's report in August 2004 makes clear that Study 105 had achieved corneal clearing. That fact bears more significantly on defendants' outlook regarding Study 109 than statements from anonymous doctors who said that corneal clearing was nearly impossible to achieve. Based on the fact that defendants achieved corneal clearing in Study 105 and then set out to achieve it again in Study 109, it is much more likely that defendants thought that Study 109 would succeed than that they thought it would fail. Further proving the point, much of the complaint portrays diquafosol as the "lead development product" on which Inspire's future as a company depended. *Consolidated Class Action Complaint* ¶ 101. It is improbable that Inspire would stake its existence on a drug and a clinical trial that the company thought was doomed to failure. Plaintiffs' inference of fraud based on the supposed impossibility of corneal clearing is thus not even plausible, much less convincing.

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 puff 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. Furthermore, the fact that some analysts relied on defendants' hopeful statements to speculate—as the analysts admitted they were doing—that Study 109 would succeed adds little to an inference of scienter. Speculation by investors and subsequent buyers' remorse cannot support an Exchange Act suit alone.

Finally, the individual defendants' sales of Inspire stock were not "unusual or suspicious" and thus do not add support to an inference of scienter. *In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 390 (4th Cir. 2005). When we consider the directors' total number of shares and vested stock options as stated in SEC filings, the stock sales highlighted by plaintiffs were modest to de minimis: Novack, Mossinghoff, and Shaffer sold 13%, 12%, and 3% of their holdings, respectively. *See id.* at 390 n.10; *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 185 (4th Cir. 2007). Moreover, the total holdings of each defendant increased while Study 109 was ongoing, hardly suggesting that the defendants sought to dump their shares at an inflated price. And as the district court observed, both Mossinghoff and Novack "resigned from Inspire around the time of their sales, indicating that their departures, rather than an intent to defraud, may have prompted them to sell their stock." *In re Inspire Pharm., Inc. Sec. Litig.*, 515 F. Supp. 2d 631, 640 (M.D.N.C. 2007) (internal citation omitted).[2]

[2]Plaintiffs make two additional allegations in support of their scienter claims, but those allegations also lack persuasive force. Plaintiffs allege

Thus, even when we accept all of plaintiffs' factual allegations as true, the record as a whole does not support a strong inference of scienter. The most persuasive inference is that defendants acted with a lawful intent to protect their competitive interests—an intent that plaintiffs do not suggest is illegitimate. And that inference is more compelling than the inference that defendants acted with an intent to mislead or deceive. The district court therefore properly dismissed plaintiffs' claims under Section 10(b) and Rule 10b-5. Plaintiffs' claims under Sections 20(a) and 20A of the Exchange Act are derivative of their Section 10(b) and Rule 10b-5 claims, so the 20(a) and 20A claims were properly dismissed as well. *See* 15 U.S.C. §§ 78t(a), 78t-1; *Hunter*, 477 F.3d at 188; *N.J. Carpenters Pension & Annuity Funds v. Biogen Idec, Inc.*, 537 F.3d 35, 58 (1st Cir. 2008).

III.

We turn next to plaintiffs' claims under the Securities Act. Sections 11 and 12(a)(2) of the Securities Act apply to registration statements and prospectuses for securities, respectively. Both provisions prohibit materially false statements or omissions, although proof of scienter is not required. *See* 15 U.S.C. §§ 77k, 77l; *Herman & MacLean v. Huddleston*, 459 U.S. 375, 381-82 (1983); *Newcome v. Esrey*, 862 F.2d 1099, 1106 (4th Cir. 1988) (en banc).

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that the SEC is investigating Inspire and Shaffer for fraud, but that assertion is too speculative to add much, if anything, to an inference of scienter. In fact, defendants represented at oral argument—and plaintiffs did not dispute—that the SEC's investigation has already settled without a finding of culpability for securities fraud. Plaintiffs further allege that Shaffer lied when she certified Inspire's financial statements in accordance with the Sarbanes-Oxley Act of 2002, but that bare allegation does not provide independent support for an inference of scienter. *See Cent. Laborers' Pension Fund v. Integrated Elec. Servs., Inc.*, 497 F.3d 546, 555 (5th Cir. 2007); *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1265-67 (11th Cir. 2006).

Plaintiffs claim that Inspire and Shaffer violated Sections 11 and 12(a)(2) because the company's registration statement and prospectuses for its July and November 2004 stock offerings were false and misleading.[3] The prospectuses stated that Inspire had a "clear understanding of the FDA's additional requirement for the regulatory approval of diquafosol." And the prospectuses referred to Study 109 as a "confirmatory" Phase III trial. Plaintiffs allege that these statements were misleading because Inspire failed to disclose that the primary endpoint of Study 109, corneal clearing, was different than the primary endpoint of Study 105, an improvement in corneal staining scores.[4] We hold that plaintiffs' claims fail because plaintiffs have not alleged that the prospectuses were false with the particularity required by Federal Rule of Civil Procedure 9(b).

Rule 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." As almost every circuit court to examine the issue has held, Rule 9(b) applies to allegations under the Securities Act where those allegations sound in fraud. *See ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 68 (1st Cir. 2008) (collecting cases); *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1277-78 (11th Cir. 2006) (collecting additional cases). *But see In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 314-15, 318-19 (8th Cir. 1997). Although claims under Sections 11 and 12(a)(2) may not have fraud as an element, Rule 9(b) refers to "alleging fraud," not to causes of action or elements of fraud. When a plaintiff makes an allegation that has the substance of fraud, therefore, he cannot

[3]Plaintiffs do not appeal the dismissal of their Securities Act claims against Mossinghoff and Novack.

[4]We note that plaintiffs claim only that the statements in the prospectuses were false without specifying any additional false statements in a registration statement. Because defendants have not raised the issue, we assume that the prospectuses were incorporated into the registration statement for the July and November offerings, thus allowing for a claim under Section 11.

escape the requirements of Rule 9(b) by adding a superficial label of negligence or strict liability. Allowing a plaintiff to do so would undermine one of the primary purposes of Rule 9(b): protecting defendants from the reputational harm that results from frivolous allegations of fraudulent conduct. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999); *Wagner*, 464 F.3d at 1277-78.

Here, plaintiffs' allegations sound in fraud and thus are subject to Rule 9(b). The complaint treats the allegedly false statements in Inspire's prospectuses as part of a single, coordinated scheme to defraud investors. Indeed, plaintiffs' allegations regarding the prospectuses—that they were misleading because they failed to disclose the primary endpoint of Study 109—are exactly the same as plaintiffs' allegations of fraud under the Exchange Act. The complaint also claims that the false statements in the prospectuses support plaintiffs' Exchange Act counts. But plaintiffs cannot make that claim with a straight face without also admitting that the complaint alleges the prospectuses to be fraudulent. Plaintiffs argue that Rule 9(b) should not apply because the complaint "expressly exclude[s] and disclaim[s] any allegation that could be construed as alleging fraud" with respect to the Securities Act claims. *Consolidated Class Action Complaint* ¶¶ 73, 77. However, a conclusory disclaimer cannot alter the substance of plaintiffs' allegations, which sound in fraud. *See Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 160 & n.24 (3d Cir. 2004); *Wagner*, 464 F.3d at 1278.

Applying Rule 9(b), plaintiffs have not explained with the necessary particularity why the statements that they cite in the prospectuses were false or misleading. *See Hillson Partners Ltd. P'ship v. Adage, Inc.*, 42 F.3d 204, 209 (4th Cir. 1994); *Rombach v. Chang*, 355 F.3d 164, 170, 172 (2d Cir. 2004). Plaintiffs argue only that the prospectuses should have disclosed that Study 109's endpoint was different than Study 105's endpoint. But plaintiffs have not alleged that the prospectuses even mentioned the endpoints of either study. Plain-

tiffs have thus failed to provide any reason to think that describing Study 109 as "confirmatory" suggested that the endpoints of the studies were the same. Rather, that phrase implies only that Study 109 was meant to "confirm" the efficacy of diquafosol—which was true. And regardless of what the "FDA's additional requirement" for approval of diquafosol was, we are at a loss to understand how Inspire's statement that it had a "clear understanding" of that requirement could be false or misleading. Because plaintiffs have not provided credible explanations of the falsity of these statements, we have serious doubts that plaintiffs have even "nudged the[se] claims across the line from conceivable to plausible," as required by the minimal pleading standards of Rule 8. *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). Regardless, plaintiffs have failed to plead the falsity of the prospectuses with the particularity required by Rule 9(b), so their allegations under Sections 11 and 12(a)(2) must fail.

Rather than explaining the merits of their allegations, plaintiffs take issue with the precise language used by the district court when it dismissed plaintiffs' Securities Act claims. Plaintiffs argue that the district court improperly held that their claims under the Securities Act required a predicate violation of the Exchange Act. Plaintiffs are incorrect. The district court explained that plaintiffs' Securities Act claims "cannot succeed in the absence of misleading statements." *In re Inspire Pharm., Inc. Sec. Litig.*, 515 F. Supp. 2d 631, 641 (M.D.N.C. 2007). And the district court held that plaintiffs' claims were lacking these "predicate statements," not a predicate Exchange Act violation. *Id.* Thus, the district court committed no error in dismissing plaintiffs' claims under Sections 11 and 12(a)(2). The district court also correctly dismissed plaintiffs' Section 15 claim against Shaffer because that section creates control-person liability only where Sections 11 or 12 have been violated. *See* 15 U.S.C. § 77o; *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656 n.7 (4th Cir. 2004).[5]

[5]We need not address defendants' arguments that plaintiffs' Securities Act claims were deficient for other reasons, namely that plaintiffs lacked standing under Sections 11 and 12(a)(2) and that defendants did not "offer or sell" stock to plaintiffs within the meaning of Section 12(a)(2).

IV.

Finally, plaintiffs claim that that the district court erred by dismissing their complaint with prejudice rather than granting plaintiffs leave to amend. We hold that the district court did not abuse its discretion in denying leave to amend. *See In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 391 (4th Cir. 2005). Although the district court did not state its reasons for dismissing the complaint with prejudice, it is clear that amendment would be futile in light of the fundamental deficiencies in plaintiffs' theory of liability. *See id.* Furthermore, plaintiffs never filed a motion for leave to amend before the district court, nor did they present the district court with a proposed amended complaint. Plaintiffs instead requested leave to amend only in a footnote of their response to defendants' motion to dismiss, and again in the final sentence of their objections to the recommendation of the magistrate judge. Those requests did not qualify as motions for leave to amend, *see* Fed. R. Civ. P. 7(b), 15(a), and we cannot say that the district court abused its discretion by declining to grant a motion that was never properly made. *See, e.g.*, *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1259 (D.C. Cir. 2004).

The district court's judgment of dismissal with prejudice is therefore

AFFIRMED.