6-6-2014

City of Edinburgh Council as A v. Pfizer Inc

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 13-2314

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CITY OF EDINBURGH COUNCIL AS ADMINISTERING AUTHORITY FOR THE LOTHIAN PENSION FUND; ARCA S.G.R.S.P.A,
Appellant

v.

PFIZER, INC., as successor in interest to WYETH, a Delaware Corporation; ROBERT ESSNER; BERNARD POUSSOT; KENNETH J. MARTIN; ROBERT R. RUFFOLO; WYETH

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On Appeal from the United States District Court
for the District of New Jersey
D.C. Civil Action No. 2-10-cv-03105
(Honorable Susan D. Wigenton)

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Argued: January 8, 2014

Before: SMITH, SHWARTZ, and SCIRICA, Circuit Judges.

(Filed: June 6, 2014)

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OPINION OF THE COURT

SCIRICA, *Circuit Judge*

In this private securities fraud class action under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), two institutional investors allege a pharmaceutical company and its executives made materially false and misleading statements in violation of the Securities Exchange Act of 1934 (the "Exchange Act") regarding interim clinical trial data related to the development of an experimental Alzheimer's drug. The District Court granted defendants' motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. We will affirm.[1]

I.

Plaintiffs-appellants City of Edinburgh Council as Administering Authority for the Lothian Pension Fund and Arca S.G.R. S.p.A. (the "Funds")[2] bring suit on behalf of a class of investors who purchased Wyeth, Inc. common stock

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[1] The District Court had jurisdiction under 28 U.S.C. § 1331 and 15 U.S.C. § 78aa. We have jurisdiction under 28 U.S.C. § 1291.

[2] Security Police and Fire Professionals of America Retirement Fund, a lead plaintiff below, is not a party to this appeal.

between May 21, 2007, and July 29, 2008 (the "Class Period"). The Funds allege Wyeth and four former Wyeth executives—defendants Robert Essner, Bernard Poussot, Jr., Kenneth J. Martin, and Robert R. Ruffolo, Jr.—made materially false and misleading statements regarding the development of the experimental Alzheimer's drug bapineuzumab. Defendant Pfizer Inc. is the successor-in-interest to Wyeth, which it acquired in 2009.

The Funds bring three claims: (1) securities fraud under section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Securities and Exchange Commission ("SEC") Rule 10b-5; (2) control person liability under section 20a of the Exchange Act, 15 U.S.C. § 78t; and (3) insider trading under section 20A of the Exchange Act, 15 U.S.C. § 78t-1(a).[3]

A.

Approximately 5 million Americans and 26 million people worldwide suffer from Alzheimer's disease. Wyeth and Elan Corporation, plc ("Elan"),[4] an Ireland-based pharmaceutical company, embarked on a joint venture to

[3] Because the District Court granted defendants' Rule 12(b)(6) motion to dismiss, we assume the Funds' well-pleaded, nonconclusory factual allegations to be true. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). We may consider documents incorporated into the complaint, *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009), and take judicial notice of SEC filings, *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000).

[4] Perrigo Company plc acquired Elan in 2013.

develop an Alzheimer's treatment that, unlike other drugs then on the market, would target the underlying causes of the disease. This joint venture produced bapineuzumab, which is designed to treat mild to moderate Alzheimer's. As required by Food and Drug Administration ("FDA") regulations, Wyeth and Elan launched clinical trials to assess the efficacy and safety of bapineuzumab in treating Alzheimer's.[5] In 2006, Wyeth and Elan completed Phase 1 trials of bapineuzumab and received Fast Track status from the FDA.[6] Before announcing Phase 1 results, Wyeth and Elan began the

[5] FDA regulations require three phases of clinical trials—which may overlap—to assess the efficacy and safety of potential new treatments. 21 C.F.R. § 312.21. Phase 1 tests the drug's efficacy and safety on a small number of patients. Phase 2 is a controlled clinical study in which various doses of the drug are tested on groups of up to several hundred patients to evaluate preliminary indicia of the drug's efficacy and safety. Phase 3 studies—randomized, multicenter trials on large patient groups over an extended period—aim to provide sufficient evidence of efficacy and safety to support FDA approval to market the drug.

[6] Fast Track status entitled the companies to priority oversight from the FDA, including an accelerated path to approval and more frequent communications with the FDA. *See Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review*, FDA, http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm (last visited June 4, 2014). Only drugs intended to treat serious or life-threatening diseases for which there is a significant unmet medical need qualify for Fast Track status.

Phase 2 trial, a controlled, double-blind study designed to measure the efficacy of bapineuzumab compared to a placebo. The companies measured bapineuzumab's efficacy using two tests, the Alzheimer's Disease Assessment Scale-Cognitive ("ADAS-cog") and the Disability Assessment Scale for Dementia ("DAD").

The Phase 2 trial was not scheduled for completion until 2008, and Wyeth and Elan said they did not expect to release any Phase 2 trial data until that time. The focus of the Funds' complaint is a joint press release issued on May 21, 2007 (the "May 2007 Release"), announcing the companies' decision to initiate a Phase 3 clinical trial, subject to FDA approval, in the second half of 2007. The May 2007 Release stated (emphasis added):

> Elan . . . and Wyeth . . . today announce the decision to initiate a Phase 3 clinical program of . . . Bapineuzumab. . . . This decision was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study, which remains blinded. *No conclusion about the Phase 2 study can be drawn until the study is completed and the final data are analyzed and released in 2008.* Phase 3 clinical trial design will be finalized with regulatory agencies, and *subject to regulatory approval*, it is intended for the trial to begin in the second half of 2007.

The Funds contend that at the time Wyeth issued the May

2007 Release the company knew—but did not disclose—that the Phase 2 interim results did not support the decision to initiate the Phase 3 trial.[7] The Funds' two confidential witnesses[8] allege the interim results showed bapineuzumab had failed pre-specified criteria for efficacy and revealed serious adverse safety risks. Wyeth disputes this allegation, arguing the Phase 2 results showed "statistically significant and clinically meaningful benefits" among an important patient subgroup—non-carriers of the Apolipoprotein E4 ("ApoE4") gene who are believed to make up 40 to 70 percent of Alzheimer's patients, or approximately 2 to 3.5 million Americans. Further, Wyeth contends CW1's statements confirm its interpretation of the subgroup data—CW1 noted the Phase 2 interim results were "interesting" and "warranted further testing" with regard to non-carriers of the ApoE4 gene but only as an additional Phase 2 trial, not as a Phase 3 trial. And Wyeth notes it had to obtain FDA

[7] The Funds also allege defendants Martin and Ruffolo profited from the concealment of the poor Phase 2 interim results by exercising and selling stock options on May 22, 2007.

[8] The Funds' confidential witnesses are former high-ranking Wyeth executives who performed extensive work related to the development of bapineuzumab during the Class Period. Confidential witness 1 ("CW1") was a member of Wyeth's Neuroscience Steering Committee and Bapineuzumab Steering Committee. Confidential witness 2 ("CW2") was a member of Wyeth's Research and Development ("R&D") Committee. The confidential witnesses provided their evidence through affidavits.

approval to initiate the Phase 3 trial,[9] on which the companies spent "millions of dollars of their own assets."

The Funds also argue the May 2007 Release was misleading in light of a prior statement made on October 5, 2006, by defendant Ruffolo, Wyeth's head of research, at the company's annual meeting for securities analysts. Ruffolo stated orally that the companies planned to conduct an interim review of the Phase 2 results at the end of 2006 in order to determine whether and how to proceed to a Phase 3 trial:

> Now, again, we don't have any results from this [Phase 2] study at all, but we have a planned interim look at the data at the end of the year. And, based on this interim look, we could do two things. One, depending on the data, we could advance directly into Phase III in the first half of 2007, but the results would have to be spectacular. We don't know what results we're going to get. Alternatively, we could complete the study and then move to the next interim look, which would be in the first half of 2007.

[9] The FDA approves a Phase 3 trial, which typically includes far more subjects than a Phase 1 or Phase 2 trial, where there is "preliminary evidence suggesting effectiveness." 21 C.F.R. § 312.21(c). But the FDA retains the ability to suspend a clinical trial through a clinical hold, *id.* § 312.42, or to terminate a clinical trial if there is "convincing evidence that the drug is not effective for the purpose for which it is being investigated" or the trial poses "an unreasonable and significant risk of illness or injury," *id.* §§ 312.44(b)(1)(i), (b)(2)(i), (b)(2)(iii).

Despite defendants' explicit warning in the May 2007 Release that "[n]o conclusion about the Phase 2 study can be drawn" and that initiation of Phase 3 would be "subject to regulatory approval," the Funds allege Ruffolo's remarks led them to interpret the May 2007 Release's statement that the Phase 3 trial would commence early based in part on the Phase 2 interim results to mean those results were "spectacular."

On June 17, 2008, Wyeth and Elan issued a press release (the "June 2008 Release") disclosing "preliminary findings" from the Phase 2 study. The June 2008 Release reported that the Phase 2 trial failed to meet its objectives as to the entire study population and reported serious adverse events among both placebo- and bapineuzumab-treated patients. But it noted that based on "[p]ost-hoc analyses," bapineuzumab showed "statistically significant and clinically meaningful benefits" among non-carriers of the ApoE4 gene who are believed to make up 40 to 70 percent of Alzheimer's patients. Accordingly, the June 2008 Release announced the companies' conclusion that the results of the Phase 2 trial, as well as its safety findings, supported the decision to proceed with the Phase 3 trial.[10]

On July 29, 2008, Wyeth and Elan revealed the Phase 2 results through a joint press release, conference

[10] The Funds also alleged Wyeth and Elan committed securities fraud through factual omissions in the June 2008 Release. The District Court held the June 2008 Release was not actionable because defendants had no duty to disclose the allegedly omitted information, and the Funds do not challenge that determination on appeal.

presentation, and investor conference call. Despite the disclosure in the June 2008 Release that the Phase 2 trial had failed to meet its overall objectives, the Funds contend investors only learned for the first time on July 29 that the Phase 2 trial was nearly a complete failure—the results showed no efficacy and revealed serious safety concerns. According to CW1, the final Phase 2 results did not differ significantly from the Phase 2 interim results referenced in the May 2007 Release.

B.

The District Court granted defendants' first motion to dismiss on February 10, 2012, holding the Funds had not adequately alleged defendants made any materially false or misleading statements and defendants had no duty to disclose allegedly omitted details. On December 21, 2012, the District Court granted the Funds leave to file a second amended complaint. On April 22, 2013, the District Court again dismissed the Funds' claims, holding (1) the Funds failed to adequately allege defendants made any affirmatively false or misleading statements, (2) defendants had no duty to disclose additional information about the Phase 2 interim results, and (3) the Funds failed to sufficiently plead a predicate Exchange Act violation required to maintain their control person liability and insider trading claims.

On appeal, the Funds contend the District Court erred in dismissing their section 10(b) and Rule 10b-5 claims for failure to adequately plead falsity. The Funds also argue defendants' statements and actions triggered a duty to disclose full and complete material information to investors about the Phase 2 interim results. And the Funds challenge

the District Court's dismissal of their control person liability and insider trading claims.

We review *de novo* the District Court's decision to grant defendants' Rule 12(b)(6) motion to dismiss. *See In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010). We also exercise plenary review over the dismissal of a complaint for failure to satisfy the heightened pleading standards of the PSLRA and over the District Court's interpretation of federal securities laws. *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 251 (3d Cir. 2009). The PSLRA's heightened pleading standards require a private securities fraud complaint alleging false or misleading statements to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation . . . is made on information and belief, . . . state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); *see Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007). "This standard requires plaintiffs to plead the who, what, when, where, and how: the first paragraph of any newspaper story." *Institutional Investors Grp.*, 564 F.3d at 253 (internal quotation marks and citation omitted). A complaint must also "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); *Tellabs*, 551 U.S. at 321. We must evaluate "the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss," including documents incorporated into the complaint by reference and matters of which we may take judicial notice. *Tellabs*, 551 U.S. at 322 (citation omitted).

C.

This is not the first case in which the federal courts have adjudicated securities fraud allegations arising out the development of bapineuzumab. Three federal courts have considered and dismissed claims similar to those at issue in this case. *See Kleinman v. Elan Corp., plc*, 706 F.3d 145 (2d Cir. 2013); *In re Elan Corp. Sec. Litig.*, No. 08-cv-8761 (S.D.N.Y. June 23, 2011); *Philco Invs., Ltd. v. Martin*, No. 10-02785, 2011 WL 500694 (N.D. Cal. Feb. 9, 2010).

In *Kleinman*, the Second Circuit affirmed the Rule 12(b)(6) dismissal of a suit against Elan, Pfizer, and two Elan executives for failure to allege any actionable false statements or omissions and failure to plead a predicate Exchange Act violation. *Kleinman*, 706 F.3d at 147. The plaintiff in *Kleinman* alleged the June 2008 Release misrepresented the Phase 2 results as "[e]ncouraging" and omitted key information about the lack of a dose response and analysis of the Phase 2 data. But the Second Circuit rejected those contentions, holding the June 2008 Release clearly stated the "[e]ncouraging" results were subgroup results and finding words like "encouraging" to be puffery. *Id.* at 153. And the court found the omitted information claim was not actionable because, although possibly of interest to a reasonable investor, its omission did not render the June 2008 Release false or misleading. *Id.* at 154–55.

In *In re Elan*, a district court dismissed claims against Elan for failure to allege any actionable false statements or omissions. The case challenged many of the same statements at issue in this case, including the May 2007 Release. The court rejected the allegation that the May 2007 Release was

false based on Ruffolo's "spectacular" statement. Transcript of Argument at 10:9–13, *In re Elan, Corp. Sec. Litig.*, No. 08-cv-8761 ("There's nothing about [the May 2007 Release] that says it's going to be spectacular. Everyone knows that in this business it's extraordinarily risky and . . . expensive, and lots of drugs have been stopped in phase 3, even though they had high hopes in phase 2."). The court described Ruffolo's "spectacular" statement as "puffery" and noted that the law does not provide that "an early puffery, if not corrected, continues to be a false statement every day of the year that follows." *Id.* at 15:20–23. And the court said Elan and Wyeth would not have agreed to proceed to Phase 3, given the millions of dollars the companies spent, unless Phase 2 showed at least some promising data. *Id.* at 18:5–19.

Finally, in *Philco Investments*, a district court dismissed claims against Elan and three of its executives for failure to adequately allege falsity and to plead a predicate Exchange Act violation. *Philco Invs.*, 2011 WL 500694, at *1. Plaintiffs challenged both the May 2007 Release and the June 2008 Release. The court found plaintiffs failed to allege Elan disclosed criteria by which it would judge the Phase 2 interim results, and, accordingly, plaintiffs failed to adequately allege the May 2007 Release was false. *Id.* at *6–7. The court also concluded plaintiffs failed to allege the June 2008 Release was false because, although it may not have included all the information a reasonable investor would have liked to have, it did not contain false or misleading information. *Id.* at *7–9.

II.

Section 10(b) of the Exchange Act prohibits the "use

or employ[ment], in connection with the purchase or sale of any security . . . [, of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). SEC Rule 10b-5 implements this provision by making it unlawful to, among other things, "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). The Supreme Court has implied a private cause of action from the text and purpose of section 10(b). *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1317 (2011).

To state a claim for securities fraud, plaintiffs must allege (1) a material misrepresentation or omission, (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. *Id.* at 1317–18; *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010).

The primary issue in this appeal is the first element, whether the Funds have adequately alleged defendants made a material misrepresentation or omission. The District Court concluded the Funds had failed to do so. But the Funds contend that conclusion was incorrect because the May 2007 Release contained affirmatively false and misleading statements about the Phase 2 interim results, and defendants' post-May 21 statements were also false or misleading. We agree with the District Court.

A.

We first analyze whether the May 2007 Release contained any affirmative false statements, and then we consider whether the May 2007 Release was misleading in light of defendant Ruffolo's October 2006 "spectacular" statement.

1.

Specifically, the Funds allege one statement in the May 2007 Release was affirmatively false—the decision to initiate the Phase 3 trial "was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study, which remains blinded." This statement was affirmatively false, the Funds contend, because Wyeth's decision to move to Phase 3 was not "based on" the Phase 2 interim results—it was made in spite of those results, which the Funds characterize as abysmal. Because their confidential witness statements demonstrate bapineuzumab failed the interim review, the Funds argue the Phase 2 interim results did not support defendants' decision to initiate Phase 3.[11]

[11] We apply the PSLRA's heightened pleading requirements to confidential witness allegations "by evaluating 'the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" *Institutional Investors Grp.*, 564 F.3d at 263

We agree with the District Court, however, that the Funds' allegations are insufficient to maintain a plausible claim of falsity regarding the May 2007 Release statement under the "[e]xacting pleading requirements" of the PSLRA. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007); *Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 263 (3d Cir. 2009) ("The PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter." (citation omitted)).

The Funds' own pleading demonstrates the accuracy of defendants' statement that the initiation of Phase 3 was based in part on the Phase 2 interim results. *See Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 156–58 (3d Cir. 2004) (finding plaintiffs failed to adequately plead falsity where information provided by their confidential witnesses was generally consistent with defendants' allegedly false and misleading public statements). Analyzing the phrase "based on" in the May 2007 Release under the PSLRA's heightened pleading standards, the Funds have failed "to specify . . . the reason or reasons why the statement is misleading" because the most cogent interpretation of that phrase is that defendants considered the Phase 2 interim results as one factor in their decision to initiate the Phase 3 trial. *See Tellabs*, 551 U.S. at 322. The Funds' confidential witness statements indicate defendants did analyze and consider those results in deciding whether to initiate Phase 3.

Moreover, the Funds' argument that the May 2007

(quoting *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004)).

Release falsely conveyed that the Phase 2 interim results justified the initiation of Phase 3 fails because it is based on a selective reading of that document. *See id.* (instructing courts to consider complaints under the PSLRA in their entirety, including documents incorporated by reference). The May 2007 Release made no statement about the strength of the interim results. Instead, the May 2007 Release provided three bases for the move to Phase 3: (1) the seriousness of Alzheimer's disease, (2) the totality of what the companies learned from their immunotherapy programs, and (3) the Phase 2 interim results. A full reading of the May 2007 Release under the PSLRA's heightened pleading requirements, therefore, bolsters the District Court's conclusion that it contained no false statements. *See id.*; *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (noting we are to examine statements in the full context of the documents of which they are part). Most importantly, the May 2007 Release explicitly cautioned investors that "[n]o conclusion" could be drawn about the Phase 2 interim results until the completion of Phase 2.

A comparison with the Second Circuit's decision in *Kleinman* is instructive. In that case, plaintiff challenged allegedly false statements in the June 2008 Release. The June 2008 Release, unlike the May 2007 Release, did make affirmative characterizations about the Phase 2 results—it described the Phase 2 results as supportive of the decision to initiate Phase 3 because of the "statistically significant and clinically meaningful benefits" shown for the ApoE4 non-carrier subgroup. But the Second Circuit concluded plaintiff had not alleged anything in the June 2008 Release was literally false because the references to "[e]ncouraging" results could not have meant anything other than the positive

subgroup results. *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153 (2d Cir. 2013). Moreover, the Second Circuit held expressions such as "encouraging" constituted puffery. *Id.* Because the May 2007 Release offers no affirmative characterization of the Phase 2 interim results, *Kleinman* supports defendants' position that the May 2007 Release was not affirmatively false.

Even reading the May 2007 Release as conveying the message that the interim results supported the move to Phase 3 and assuming the truth of the Funds' confidential witness allegations, the Funds' allegations still fail to establish that defendants' May 2007 Release statement was affirmatively false. *See Institutional Investors Grp.*, 564 F.3d at 263 n.33 (noting that confidential witness allegations may be found adequately particularized under the PSLRA but may still "fail either to establish the falsity of a statement, or to give rise to a strong inference of scienter"). The Funds' confidential witnesses allege bapineuzumab failed the interim review because it did not achieve pre-defined p-values[12] Wyeth used to assess the statistical significance of bapineuzumab versus a placebo under the ADAS-cog and DAD tests. Specifically, CW2 alleges that unless the Phase 2 interim review met these specified p-values, Wyeth and Elan had agreed they would not proceed to Phase 3 based on the interim review. CW1 contends the Phase 2 interim results did not reveal any statistically significant difference between bapineuzumab-treated patients and placebo-treated patients with respect to

[12] A p-value, or probability value, is a measure of statistical significance. Relevant to the Funds' allegations, the companies did not disclose that achievement of any particular p-values were necessary to initiate a Phase 3 trial.

any of the pre-specified efficacy endpoints measured by the ADAS-cog and DAD tests. Nor did bapineuzumab show any "dose response," meaning higher doses of the drug were not associated with better results. Furthermore, the Phase 2 interim results showed serious safety concerns with bapineuzumab, including numerous side effects and three deaths (compared to no deaths in patients treated with placebo).

But the Funds point to no public disclosure by defendants of the specific p-values bapineuzumab was expected to achieve under the ADAS-cog and DAD tests, no public statements regarding a "dose response" or whether one would be expected, *see Kleinman*, 706 F.3d at 153–54, and no public comments about the safety metrics, including anticipated side effects, through which bapineuzumab would be evaluated. Because defendants never told investors bapineuzumab would only pass the interim review if specific p-values, dose responses, or safety metrics were achieved, the Funds' confidential witness allegations fail to establish with sufficient specificity that the challenged May 2007 Release statement—that the decision to initiate Phase 3 was based in part on the Phase 2 interim review—was false.

Moreover, CW1 noted that the results showed "circumstantial evidence of efficacy" for an important patient subgroup—non-carriers of the ApoE4 gene—consisting of approximately 40 to 70 percent of Alzheimer's patients. CW1 also stated that one of his superiors was upset about the decision to initiate Phase 3 testing and that the subgroup results justified further investigation through a Phase 2 "exploratory" trial, not a large scale Phase 3 "confirmatory" trial.

These allegations show a difference of opinion within Wyeth about whether the Phase 2 interim results—together with the seriousness of Alzheimer's disease and the totality of what the companies had learned from their immunotherapy programs—justified initiating a Phase 3 trial. Interpretations of clinical trial data are considered opinions. *See Kleinman*, 706 F.3d at 153; *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 567 (E.D. Pa. 2009). Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis. *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 166 (3d Cir. 2008); *Kleinman*, 706 F.3d at 153.

The Funds have failed to adequately allege defendants did not honestly believe their interpretation of the interim results or that it lacked a reasonable basis. A company's failure to accurately disclose clinical trial data may be actionable under the securities laws, but the cases the Funds cite are distinguishable because they involve plausible allegations of affirmative false statements about a drug's efficacy and safety. *See, e.g.*, *In re Viropharma, Inc. Sec. Litig.*, No 02-1627, 2003 WL 1824914, at *6, *9 (E.D. Pa. Apr. 7, 2003); *In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 160 (D. Mass. 2004). In contrast, the May 2007 Release contains no affirmative statement about bapineuzumab's efficacy or safety. Moreover, the initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure. *See Kleinman*, 706 F.3d at 153.

Moreover, because the Phase 2 interim results showed

"circumstantial evidence of efficacy" for one important patient subgroup, the disagreement of some Wyeth employees with the company's interpretation of the interim results is not sufficient to show defendants' interpretation lacked a reasonable basis. The Funds present three pieces of evidence showing disagreement among Wyeth's employees about the decision to initiate Phase 3. CW2 noted that after presentation of the Phase 2 interim results to the company's four-member Elan Alliance Committee and approximately 100-member R&D Committee, he and two other members of the R&D Committee "expressed skepticism" at the decision to proceed with Phase 3 based on the interim results. CW1 revealed that one of his superiors was upset Wyeth decided to proceed, at Ruffolo's urging, with a "massive" Phase 3 study. And CW1 noted his own belief that Wyeth should have conducted another Phase 2 study to investigate the subgroup results, not a Phase 3 trial. But the disagreement of five employees within a large pharmaceutical company about the interpretation of clinical trial data and the critical strategic decision of initiating an expensive Phase 3 trial does not render defendants' decisions unreasonable or their statements false. *See Kleinman*, 706 F.3d at 153 (finding no basis for inferring defendants did not honestly believe their statements because the initiation of Phase 3 could only be made "after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests"); *In re Adolor*, 616 F. Supp. 2d at 567 (holding disagreements about the proper methodology and conduct of clinical studies are insufficient to establish falsity). At bottom, the Funds fail to plead sufficient facts to show defendants did not honestly believe initiating Phase 3 was appropriate or that defendants lacked a reasonable basis for that decision.

2.

We next evaluate whether the District Court correctly determined that the May 2007 Release was not misleading in light of defendants' prior statements. The Funds contend the May 2007 Release was misleading because defendant Ruffolo had assured investors in October 2006 that Wyeth would not commence Phase 3 early unless the Phase 2 interim results were "spectacular" in meeting specific efficacy criteria.[13] By telling investors they were moving to Phase 3 early based in part on the Phase 2 interim results, the Funds contend defendants misled the market by failing to disclose those poor results, leaving the impression they must have been "spectacular" or at least positive. The Funds argue this failure to disclose in fact misled the market, and they cite statements by stock analysts and point to the increase in Wyeth's stock price following issuance of the May 2007 Release.

We agree with the District Court that defendants' statements, taken in context, were not misleading. The May 2007 Release did not characterize or discuss the strength of the Phase 2 interim results. It only listed those results as one factor among three in the decision to initiate Phase 3, and it expressly cautioned investors not to draw conclusions about the Phase 2 study until its completion. The Funds' attempt to differentiate between conclusions regarding the interim and final results is unavailing in light of the May 2007 Release's

[13] Pre-class period statements may be used to ascertain the falsity and materiality of the challenged statements. *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 272 (3d Cir. 2005).

plain language. Defendants' explicit caution against drawing conclusions about the "Phase 2 study" by definition includes the interim results, which were part of the Phase 2 study.

The Funds also appear to misread Ruffolo's October 2006 statement. They interpret it to mean Wyeth would not commence Phase 3 early unless the Phase 2 interim results were "spectacular" in meeting specific efficacy criteria. But Ruffolo's statement was more narrow. He noted the companies "could advance directly into Phase III in the first half of 2007" if the results were "spectacular" or could complete the study and then move to the next interim look in the first half of 2007. As defendants correctly point out, the course of events Ruffolo envisioned in the "spectacular" scenario did not come to pass—the companies did not advance to Phase 3 in the first half of 2007. Instead, the May 2007 Release announced the initiation of Phase 3 in the *second half of 2007*. Accordingly, the May 2007 Release should have superseded any lingering impression left by the "spectacular" statement in the minds of reasonable investors. *See United States v. Schiff*, 602 F.3d 152, 170 (3d Cir. 2010); *Oran v. Stafford*, 226 F.3d 275, 286 (3d Cir. 2000).

Bolstering our conclusion is the nature of Ruffolo's prior statement. Ruffolo's 2006 "spectacular" statement was a forward-looking statement about a course of events that, as it turned out, did not come to pass. By using the conditional "could," Ruffolo did not bind the company to any particular course of action. Nor could he, because at the time he spoke initiation of Phase 3 still required FDA approval. Moreover, the adjective "spectacular" is the kind of "vague and general statement[] of optimism" that "constitute[s] no more than puffery and [is] understood by reasonable investors as such."

In re Advanta Corp. Sec. Litig., 180 F.3d 525, 538 (3d Cir. 1999), *abrogated on other grounds by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), *as recognized in Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 276 (3d Cir. 2009); *see also* Transcript of Argument at 15, *In re Elan Corp. Sec. Litig.*, No. 08-cv-8761 (S.D.N.Y. June 23, 2011); *Philco Invs., Ltd. v. Martin*, No. 10-02785, 2011 WL 500694, at *6 (N.D. Cal. Feb. 9, 2011). Furthermore, although the May 2007 Release did not offer any specific characterization of the Phase 2 interim results, it did caution that no conclusion could be drawn about the Phase 2 data until the completion of the study. Had the interim results been "spectacular," it is reasonable to assume the companies would have trumpeted that fact in the May 2007 Release—or at least given some indication the data were positive.

Moreover, Ruffolo never said bapineuzumab was required to meet specific efficacy criteria to advance to Phase 3. That remark was made by Elan's CEO at a January 9, 2007, healthcare conference. Defendants cannot be held responsible for statements they did not make. *See Schiff*, 602 F.3d at 168, 170–71. Although the Funds' confidential witnesses stated that bapineuzumab was required (and failed) to achieve certain p-values in Phase 2 and showed no dose response and numerous safety concerns, the Funds fail to allege any public statements by defendants regarding specific p-values, dose responses, or safety metrics bapineuzumab would be expected to achieve in order to advance to Phase 3.

Accordingly, we conclude the District Court correctly determined the Funds failed to adequately allege defendants made any affirmatively false or misleading statements in the May 2007 Release.

B.

The Funds also contend defendants made six false or misleading public statements following issuance of the May 2007 Release. The Funds allege these statements failed to disclose the efficacy and safety problems revealed in the Phase 2 study, as well as that the Phase 2 interim results showed bapineuzumab did not meet pre-established criteria and Phase 2 testing was nearly a complete failure. We concur with the District Court and reject these allegations.

The Funds first challenge defendant Ruffolo's May 22, 2007, remarks at the Citigroup Healthcare Conference. When asked to discuss which aspects of the Phase 2 interim review justified the early initiation of the Phase 3 trial, Ruffolo said he "cannot comment and will not comment on the Interim look" because he "cannot do anything to destroy the blind in that study." Because Ruffolo only referred attendees to the May 2007 Release and refused to comment on how the interim review justified the initiation of Phase 3, he made no false or misleading statement.

Next, the Funds contend statements made by Wyeth investor relations representative Justin Victoria and defendant Poussot during earnings calls on July 19, 2007, and April 22, 2008, that described the Phase 2 interim results as one factor in the "composite decision" to move to Phase 3 were false and misleading. But those statements are consistent with the May 2007 Release and accurately convey that the interim results were one factor defendants considered in deciding to initiate Phase 3. Moreover, Victoria confirmed to investors and analysts on the April 22, 2008, call that Wyeth had not yet disclosed the strength of the Phase 2 results and needed to

complete the analysis of the Phase 2 data to make that determination. As a result, we find the July 19 and April 22 statements were not false or misleading.

The Funds also challenge statements made by Wyeth executives Dr. Joseph Camardo and Joseph M. Mahady. At the January 8, 2008, J.P. Morgan Healthcare Conference, Camardo described bapineuzumab as a potential "breakthrough" drug for Alzheimer's, and at the March 19, 2008, Lehman Brothers Global Healthcare Conference Mahady mentioned bapineuzumab as an example of a drug offering "opportunities for transformational growth of the company." But these statements are not actionable because they are vague, non-specific, and forward-looking. *See In re Advanta*, 180 F.3d at 538; *Philco Invs.*, 2011 WL 500694, at *6. Both speakers were also cautious—Camardo noted the companies still faced risks establishing bapineuzumab's efficacy and safety, and Mahady reminded the audience that the final results of the Phase 2 study were not yet available. Furthermore, Camardo's statement that Wyeth and Elan "learned a lot in Phase II" is true based on the statements from the Funds' own confidential witnesses. Accordingly, the Funds' allegations that these statements were false or misleading lack merit.

Finally, the Funds allege defendant Poussot's statements on Wyeth's July 23, 2008, 8-K and earnings call were false and misleading because he described the Phase 2 results as "encouraging and supportive of our prior decision to initiate Phase 3." Unlike the other post-May 21 statements, Poussot did characterize the *final* Phase 2 results as positive. But he only repeated conclusions Wyeth had disclosed six days before in the June 2008 Release. The District Court held

the June 2008 Release was not actionable because defendants were under no duty to disclose information the Funds alleged was omitted from that document, and the Funds do not challenge that determination on appeal. Accordingly, we concur with the District Court that because the June 2008 Release is not false or misleading, Poussot's statements cannot be the basis of liability here.

Based on the foregoing analysis, we hold the District Court correctly determined the Funds failed to sufficiently allege defendants' post-May 21 statements were false or misleading.

III.

In addition to alleging defendants' statements were affirmatively false or misleading, the Funds contend those statements triggered a duty to disclose full and complete material information regarding the Phase 2 interim results. A duty to disclose under federal securities laws may arise when a statute requires disclosure, insider trading occurs, or there is an inaccurate, incomplete, or misleading prior disclosure. *Oran v. Stafford*, 226 F.3d 275, 285–86 (3d Cir. 2000). The Funds urge us to impose a duty to disclose on each of these grounds because (1) defendants chose to speak about a material subject to investors, (2) defendants Ruffolo and Martin allegedly engaged in insider trading, and (3) disclosure was necessary to make defendants' prior statements not misleading. We agree with the District Court that defendants were under no duty to disclose the allegedly omitted information.

A.

The Funds first argue defendants had a duty to speak fully and truthfully about the Phase 2 interim results because they put the subject "in play" by discussing those results publicly. Instead of concealing material information about the poor Phase 2 interim results, the Funds allege defendants should have either disclosed those poor results or admitted they had changed their criteria for initiating the Phase 3 trial.

Section 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011). "Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b-5(b)). "Silence, absent a duty to disclose, is not misleading under Rule 10b-5." *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988). "[C]ompanies can control what they have to disclose under these provisions by controlling what they say to the market." *Matrixx*, 131 S. Ct. at 1322.

The May 2007 Release made no affirmative statement about the strength of the Phase 2 interim results nor characterized those results in any manner. *See Oran*, 226 F.3d at 285 (finding no material misrepresentation or omission where defendants did not make any "affirmative characterization" that FDA approval was based on a complete review of all relevant medical information as alleged by plaintiffs). Accordingly, Wyeth did not place the strength or nature of the Phase 2 interim results "in play," so it was under no duty to provide additional details about those results.

Wyeth was also not obligated to disclose whether it had changed its criteria for initiating Phase 3, since that fact was likewise not "in play." Significantly, Wyeth never disclosed that particular p-values would have to be met in order to commence Phase 3. Nor did it ever reveal the specific rationale or formula it was using to decide whether to initiate Phase 3.

The Funds' attempt to analogize this case to *Matrixx* is unavailing. In *Matrixx*, the Supreme Court evaluated whether a drug company's failure to disclose reports of a possible link between its product and anosmia, the loss of the sense of smell, rendered the company's statements relating to revenues and product safety misleading. *Matrixx*, 131 S. Ct. at 1313–14. The company stated, among other things, that reports linking its product to anosmia were "completely unfounded and misleading" and that the safety and efficacy of the drug were well established. *Id.* at 1323. The evidence showed, however, that the company had documentation of a biological link between the drug and anosmia and had conducted no studies of its own to disprove that connection. *Id.* In finding the company's actions rendered its statements misleading, the Court determined it was substantially likely a reasonable investor would regard the omitted information as material. *Id.*

Here, by contrast, the central issue is whether the Funds have adequately alleged falsity, not materiality. And, unlike *Matrixx*, the challenged statements in this case do not characterize or make affirmative claims about the Phase 2 interim results. The May 2007 Release noted only that Wyeth and Elan decided to initiate the Phase 3 trial "based on the seriousness of the disease and the totality of what the

companies have learned from their immunotherapy programs, including a scheduled Interim look at data from an ongoing Phase 2 study, which remains blinded." Subsequent statements only reiterated the May 2007 Release statement, discussed bapineuzumab's potential to be a "breakthrough" drug for Alzheimer's, and noted bapineuzumab as an example of a drug offering "opportunities for transformational growth" of Wyeth. None of these statements characterized or made affirmative claims about the Phase 2 interim results.[14]

Accordingly, *Matrixx* is inapposite to this case, and defendants did not have a duty to disclose additional information because they mentioned the Phase 2 interim results as one factor in their decision to initiate Phase 3.

B.

The Funds next argue defendants were under a duty to disclose because defendants Ruffolo and Martin allegedly engaged in insider trading.[15] "[A] corporate insider must

[14] Defendant Poussot's July 23, 2008, statement describing the Phase 2 results as "encouraging and supportive" of the decision to initiate Phase 3 did characterize the *final* Phase 2 results. But, as noted previously, this statement only repeated conclusions Wyeth had previously disclosed in the June 2008 Release, which the District Court found was not actionable—a determination the Funds do not challenge on appeal.

[15] Specifically, the Funds contend that on May 22, 2007, Ruffolo exercised options and sold 130,436 Wyeth shares at $58.33 per share, for a net gain of approximately $2.36 million. The same day, Martin sold 200,500 shares at $57.97 per share, for a net gain of approximately $283,000. By May

abstain from trading in the shares of his corporation unless he has first disclosed all material information known to him." *Chiarella v. United States*, 445 U.S. 222, 227 (1980); *Deutschman v. Beneficial Corp.*, 841 F.2d 502, 506 (3d Cir. 1988). The Funds' theory is Ruffolo and Martin knew the negative Phase 2 interim results, concealed them from investors, and reaped the benefit of that concealment by trading on Wyeth's artificially inflated stock.

But the Funds have failed to adequately plead an insider trading violation under section 20A of the Exchange Act because they have failed to adequately plead a predicate section 10(b) violation. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 541 (3d Cir. 1999), *abrogated on other grounds by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), *as recognized in Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 276 (3d Cir. 2009). Section 20A, which provides an express private cause of action for insider trading against contemporaneous traders, requires the alleged insider trader to have committed an independent violation of the Exchange Act or SEC rules and regulations promulgated under that law. 15 U.S.C. § 78t-1(a). The Funds have not adequately alleged that Martin and Ruffolo committed such an independent violation.

Nor are the Funds' insider trading allegations sufficient to meet the heightened pleading standards for scienter under the PSLRA. The PSLRA requires the Funds to allege facts giving rise to a "strong inference" of scienter, which "must be more than merely plausible or reasonable—it

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22, 2007, Martin had exercised every profitable option available to him.

must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). The mere fact that Martin and Ruffolo sold stock is insufficient to establish scienter. *See In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 152 (3d Cir. 2004), *abrogated on other grounds by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), *as recognized in Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 484 (3d Cir. 2012).

For these reasons, there is no duty to disclose based on alleged insider trading.

C.

The Funds also allege defendants had an ongoing duty to disclose throughout the Class Period each time they spoke about the Phase 2 interim results or the decision to initiate the Phase 3 trial to avoid misleading disclosures. *See Oran*, 226 F.3d at 285–86. The Funds contend because defendants previously told the market the interim results would need to be "spectacular" to justify early initiation of Phase 3, defendants had an ongoing duty to disclose that the interim results were not supportive of the move to Phase 3. We conclude the District Court properly refused to find defendants had an ongoing duty to disclose.

As noted above, the course of events outlined in Ruffolo's October 2006 "spectacular" statement did not come to pass. The companies only advanced to Phase 3 in the second half of 2007, not in the first half of 2007 as Ruffolo had said they might if the interim results proved to be "spectacular." Accordingly, defendants had no duty to update

the "spectacular" statement. *See United States v. Schiff*, 602 F.3d 152, 170 (3d Cir. 2010); *Oran*, 226 F.3d at 286. Moreover, we have held that a duty to update applies only in "narrow circumstances" involving more fundamental corporate changes such as mergers, takeovers, or liquidations, as well as when subsequent events produce an "extreme" or "radical change" in the continuing validity of the original statement. *See Schiff*, 602 F.3d at 170 (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1433–34 (3d Cir. 1997)). Those elements are not present here. Furthermore, there is no duty to update vague and general statements such as "spectacular." *See In re Advanta*, 180 F.3d at 538 ("[V]ague and general statements of optimism constitute no more than puffery and are understood by reasonable investors as such." (internal quotation marks and citations omitted)); *Philco Invs., Ltd. v. Martin*, No. 10-02785, 2011 WL 500694, at *6 (N.D. Cal. Feb. 9, 2011).

Even if we determined defendants had a duty to update the October 2006 "spectacular" statement, the May 2007 Release would have cut off any such duty. Its explicit caution that investors should draw no conclusion about the Phase 2 interim results tempered any impression made by the "spectacular" statement. Had the Phase 2 interim results been spectacular, it is reasonable to assume Wyeth would have trumpeted that fact.

Accordingly, defendants were under no duty to disclose the allegedly omitted information.

IV.

The Funds also appeal the District Court's dismissal of

their control person liability and insider trading claims. We conclude the District Court correctly dismissed those claims for failure to adequately plead a predicate Exchange Act violation.

Section 20(a) of the Exchange Act creates a cause of action against individuals who exercise control over a "controlled person," including a corporation, who has committed a section 10(b) violation. 15 U.S.C. § 78t(a); *see also Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). Because the Funds have failed to adequately plead a predicate section 10(b) violation, their section 20(a) claim must be dismissed. *See Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (citing *Institutional Investors Grp.*, 564 F.3d at 252).

Similarly, section 20A of the Exchange Act provides that a corporate insider who trades stock "while in possession of material, nonpublic information" is liable to any person who traded contemporaneously with the insider, provided there is an independent Exchange Act violation. 15 U.S.C. § 78t-1(a). Because the Funds have failed to adequately plead a predicate Exchange Act violation, their section 20A claim must also be dismissed. *See In re Advanta*, 180 F.3d at 541 (citations omitted); *In re Cendant Corp. Litig.*, 60 F. Supp. 2d 354, 378 (D.N.J. 1999).[16]

[16] The Funds also allege the District Court erred in relying on two other bases to dismiss their section 10(b) claims—the May 2007 Release's use of cautionary language and the District Court's purported finding that the May 2007 Release statement was immaterial. The Funds contend the District Court misapplied either the PSLRA Safe Harbor provision, 15

V.

For the foregoing reasons, we will affirm the judgment of the District Court granting defendants' Rule 12(b)(6) motion to dismiss.

U.S.C. § 78u-5(c), or the "bespeaks caution" doctrine, *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 873 (3d Cir. 2010), in finding the May 2007 Release statement to be cautious. But the District Court applied neither doctrine and only invoked defendants' use of cautionary language in analyzing whether the plain language of the May 2007 Release was false or misleading. Nor did the District Court make any findings on materiality—the court based its ruling on the Funds' failure to plead falsity, not on the materiality of the statements. Accordingly, the Funds' contentions the District Court erred in relying on the May 2007 Release's cautionary language and in making materiality determinations lack merit.