UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE KERYX BIOPHARMACEUTICALS, INC., SECURITIES LITIGATION

13 Civ. 755 (KBF) &
13 Civ. 1307 (KBF)

OPINION & ORDER

KATHERINE B. FORREST, District Judge:

There is a significant public interest in the development of life-saving drugs. For every drug that succeeds, others do not. Clinical trials are phased into stages: some drugs never make it past the first stage, others never make it past the second stage, and so on. The costs of failure are high, but the rewards for success are also high. The relationship and ratio between the two determines whether, as a matter of economics, the costs of experimentation are worth it. Publicly traded pharmaceutical companies have the same obligations as other publicly traded companies to comply with the securities laws, but they take on no special obligations by virtue of their commercial sector. It would indeed be unjust—and could lead to unfortunate consequences beyond a single lawsuit—if the securities laws become a tool to second guess how clinical trials are designed and managed. The law prevents such a result; the Court applies that law here, and thus dismisses these actions.

Plaintiffs brought this purported class action on February 1, 2013 on behalf of all persons who purchased Keryx Biopharmaceuticals, Inc. ("Keryx" or the

"Company") common stock between June 1, 2009 and April 1, 2012 (the "Class Period"). Plaintiffs' claims are brought pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act (the "Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5.)

A related case containing substantially similar allegations, 13 Civ. 1307, was subsequently filed on February 26, 2013. By order dated June 10, 2013, the Court granted a motion to consolidate the two actions, and appointed lead plaintiff and lead counsel. (ECF No. 29.)[1] Plaintiffs then filed their consolidated amended complaint on July 10, 2013, and defendants moved to dismiss on August 26, 2013. Defendants' motion became fully briefed on November 12, 2013.

For the reasons set forth below, the motion to dismiss is GRANTED.

I. ALLEGATIONS IN THE CONSOLIDATED AMENDED COMPLAINT

For purposes of this motion, the Court assumes the truth of all well-pleaded factual allegations and construes them in plaintiffs' favor.

Corporate defendant Keryx is a biopharmaceutical company focused on the acquisition, development, and commercialization of medically important pharmaceutical products. (Consolidated Amended Complaint (hereinafter, "CAC") ¶¶ 2, 16, ECF No. 36.) Individual defendant Ronald Bentsur was the Company's chief executive officer ("CEO") at all relevant times and was appointed as a director on June 16, 2009. (Id. ¶ 17.) According to plaintiffs, as a senior executive and

[1] Unless otherwise noted, all "ECF No." references in this opinion correspond to the docket in 13 Civ. 755.

director, Bentsur was privy to confidential and proprietary information regarding Keryx's business, finances, products, markets, and present and future business prospects. (Id. ¶ 19.) Given his access to this information, plaintiffs allege Bentsur knew or recklessly disregarded that certain adverse facts were not disclosed to, or were being concealed from, the investing public. (Id.) As CEO, plaintiffs allege that Bentsur controlled or possessed the authority to control release of the Company's reports, press releases, and presentations to securities analysts. (Id. ¶ 20.) Plaintiffs also allege that Bentsur received stock options and shares linked to certain milestones, including achieving certain share prices, filing a "new drug application" with the U.S. Food and Drug Administration ("FDA"), and commercial sales of the drug perifosine. (Id. ¶ 138.) Perifosine was a drug being tested for its potential to treat metastatic colorectal cancer ("mCRC"). (Id. ¶ 3.) During the Class Period, plaintiffs allege that Bentsur sold common stock for total gross proceeds of $1,526,588. (Id. ¶ 141.)

Plaintiffs assert that, just prior to the commencement of the Class Period, the Company's assets and revenues were severely limited, its losses were substantial, an important drug trial had failed, and its stock faced de-listing by the NASDAQ. (Id. ¶ 28.) As a result, plaintiffs assert that the success of perifosine—which might be Keryx's next drug available to go to market—was critical to the Company's continued viability. (Id.)

Plaintiffs allege that perifosine had a checkered past—it had been the subject of clinical trials going back to 1998, which had shown "decidedly mixed results."

(Id. ¶ 29.) Through a licensing agreement, Keryx obtained rights to sell the drug in North America, but was also responsible for conducting all research and development necessary to obtain regulatory approvals. (Id. ¶¶ 30-31.)

During the Class Period, Keryx ran a "Phase 3" clinical trial of perifosine. (Id. ¶ 3.)[2] The CAC alleges defendants misled investors regarding the results of the Phase 2 trial for perifosine, repeatedly asserting that perifosine had demonstrated statistically significant positive results. (Id. ¶¶ 3-4.)

Plaintiffs assert that defendants' representations regarding the Phase 2 test results were misleading half-truths or falsehoods. (Id. ¶ 5.) According to plaintiffs, defendants knew or recklessly disregarded that their statements were false based on the design and analysis of the trial itself. (Id.) The crux of plaintiffs' claims in this regard relies on various omissions which are alleged to have rendered defendants' statements false or half-truths. For instance, plaintiffs assert that defendants' statements omitted the following material facts: that the Phase 2 trial involved multiple testing of different cancer treatments on a group of patients diagnosed with various types of cancer ("multiplicity"), included unplanned interim analyses of hypothesis-generating data from the testing, and other ad hoc, interposed steps that, under both regulatory guidance and the accepted statistical principles that underpin such guidance, required certain adjustments in the data

[2] Plaintiffs allege that, prior to the start of the Phase 3 trial and Class Period, Keryx announced the failure of a Phase 3 trial with respect to another drug, Sulonex. (Id. ¶ 22.) Plaintiffs allege that Keryx's revenues were at risk because "it had only its drugs, including perifosine, deep in the developmental pipeline." (Id.) Bentsur stated "[o]ur goal is to have Perifosine in a pivotal program this year . . . ." (Id.) In April 2008, the Company went through a restructuring which included laying off workers and terminating 12 of 20 early-stage clinical studies of perifosine. (Id. ¶ 23.)

that defendants failed to make when evaluating the statistical significance of the results. (Id.)

A. Allegations Regarding the Flaws in the Phase 2 Trial

Plaintiffs allege that virtually all clinical trials involve multiplicity—multiple tests to assess intervention effects across multiple outcomes or endpoints. (Id. ¶ 34.) However, according to plaintiffs, literature shows that the probability of making a certain type of error (a "Type I error") increases as the number of tests that are performed. (Id. ¶¶ 35-36.) Literature states that "[g]iven the potential of multiplicity to inflate the Type I error rate of an experiment, it is critical to adjust the level of statistical significance when multiplicity is present in order to keep the overall probability of accepting any one of the alternative hypotheses, when all of the findings are due to chance, at the specified level." (Id. ¶ 37.) Failing to adjust for multiplicity may result in "believing" a research hypothesis "just because a P value is statistically significant." (Id. ¶ 39.) This can lead to errors in hypothesis generation. (Id. ¶¶ 38-44.)

Plaintiffs also allege that the Phase 2 trial was flawed due to "interim analysis" which occurred. (Id. ¶ 45.) The FDA defines "interim analysis" as "any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial." (Id.) According to plaintiffs, interim analysis "may also introduce bias and impact any purported statistical significance of a study's results when it is not planned and in advance and described

in the study's protocol." (Id.) Plaintiffs spend a number of paragraphs describing issues and potential issues with unplanned interim analysis. (Id. ¶¶ 46-48.)

According to plaintiffs, the Phase 2 trial for perifosine was affected by multiplicity, hypothesis generation, and interim analysis data comparisons—"yet, Keryx did not adjust the P-values it used to evaluate the statistical significance of the results." (Id. ¶ 49.) According to plaintiffs, the Company "then went on to tout the Phase 2 results as 'statistically significant' when, due to Keryx's failure to adjust the statistical evaluation of the Phase 2 results, such claims lacked any reasonable basis." (Id.)

B. Defendants' Public Statements

Plaintiffs' story regarding perifosine's Phase 2 clinical trial begins with a press release Keryx issued on June 1, 2009 when it announced positive FDA Phase 2 trial data. (Id. ¶ 77.) On August 12, 2009, Keryx filed a Form 10-Q with the SEC announcing its financial results for the fiscal quarter ending on June 30, 2009, which included statements regarding the statistical significance of the Phase 2 test results (statements identical to those in the June 1, 2009 press release.) (Id. ¶ 78.) Bentsur submitted certifications to the SEC in which he attested that the Form 10-Q "does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which the statements were made, not misleading with respect to the period covered by this report." (Id. ¶ 79.) Keryx then repeated or incorporated by

reference its statements regarding the Phase 2 clinical trial results on multiple occasions in 2009. (Id. ¶¶ 80-83.)

On January 25, 2010, the Company issued a press release reporting the updated results of the Phase 2 trial. (Id. ¶ 85.) The press release was entitled: "Keryx Reports Statistically Significant Benefit in Survival from Updated Results of a Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of KRX-0401 (Perifosine) in the Treatment of Advanced Metastatic Colon Cancer." (Id.)

During a conference call on January 28, 2010, Bentsur stated, "[w]e're excited about the dramatic advantages we saw across all key efficacy parameters . . . ." (Id. ¶ 86.) He also made public statements touting the "statistically significant" or "highly successful" Phase 2 results on at least eighteen different occasions over the next year and a half. (Id. ¶¶ 87-89, 92, 94, 97-98, 101-106, 109, 112-15.) Additionally, press releases and quarterly statements issued by Keryx on April 8, June 10, August 9, November 5, 2010, and March 9, 2011, stated essentially the same points. (Id. ¶¶ 93, 96, 99, 110.)

C. Keryx Announces a Phase 3 Trial

In February and April 2010, respectively, Keryx announced that it had a "Special Protocol Assessment" ("SPA")[3] agreement with the FDA for the conduct of a Phase 3 trial of perifosine—and an FDA "Fast Track" designation for the Phase 3 trial. (Id. ¶ 61.) The "Fast Track" program is designed to "facilitate the development and expedite the review of new drugs that are intended to treat

[3] The SPA process is a "procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application." (Id. ¶ 61.)

serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs." (Id.) Neither an SPA nor a Fast Track designation is tantamount to an FDA determination that a drug has demonstrated clinical efficacy. (Id. ¶ 62.)

In a press release dated April 8, 2010, Keryx announced that it had initiated the Phase 3 trial. (Id. ¶ 64.) Plaintiffs allege that, in this and other public statements regarding the Phase 3 trial, Keryx "emphasized how the purportedly positive results from the Phase 2 mCRC perifosine trial provided a 'strong' basis for expecting the Phase 3 results to be successful, with a marketable perifosine product for Keryx following immediately thereafter." (Id.)

D. The October 2011 Disclosure

On October 5, 2011, Keryx issued a press release announcing the publication of a clinical manuscript in the Journal of Clinical Oncology ("JCO"). (Id. ¶¶ 6, 117.) In that press release, Keryx set forth data which "highlight[ed] the efficacy and safety data" of the Phase 2 trial on mCRC patients, and when used in combination with another drug, "demonstrated statistical significance with respect to median overall survival and median time to tumor progression." (Id. ¶¶ 6, 117.) Plaintiffs allege that "buried within the clinical manuscript was critical new information," and amounted to an "admission by Keryx" that "fatally undermined Keryx's claim of statistical significance in the results." (Id. ¶ 6.) The JCO manuscript stated, "[t]he P values were not adjusted for the unplanned interim analyses or for the multiple

comparisons . . . because of the exploratory nature of the study design with small sample size." (Id. ¶ 118.)

On October 19, 2011, a critique of the Phase 2 perifosine trial was published on the website TheStreet.com. (Id. ¶¶ 7, 119.) The critique stated that the design of the clinical trial was flawed, noting "certain unplanned, interim analyses and changes that Keryx had interposed into the original trial plan." (Id. ¶¶ 7, 119.) The critique concluded that the "p values are not real p values in the phase II study." (Id. ¶¶ 7, 119.) The critique also stated that the Phase 2 results were "uninterpretable" and provided "no basis to believe that the Phase 3 mCRC perifosine study results would be positive." (Id. ¶ 7.) The Keryx stock price dropped 6% on October 19, 2011 after a day of heavy trading. (Id. ¶ 120.)

Plaintiffs assert that, notwithstanding the critiques of the Phase 2 trial, the Company continued to insist that the Phase 2 results showed a statistically significant positive result and still provided a strong basis on which to expect a positive outcome for a Phase 3 trial. (Id. ¶ 70.) And, "despite having acknowledged that it had interposed numerous unplanned interim analyses and comparisons during Phase 2, Keryx never disclosed how many of these unplanned actions occurred, or what they involved, as would allow for independent assessment of their impact on the calculation of statistically significance of the Phase 2 data." (Id.)

During a November 3, 2011 earnings call, Bentsur tried to reassure the market and referred to the FDA's grant of the SPA for ongoing Phase 3 study. (Id. ¶ 71.) Plaintiffs claim that this was a misleading "sleight-of-hand" because an "SPA

does not equate with an FDA endorsement of claims of drug efficacy at trial." (Id. ¶ 73.) Bentsur also stated on the call that "it's hard to refute overall survival data from a double-blind randomized study, even if the study was relatively small." (Id. ¶¶ 8, 122.) According to plaintiffs, defendants responses to these critiques "raised irrelevancies and obfuscated the flaws in the Phase 2 trial—and the resultant risk as to the Phase 3 trial—that [the critiques] had identified." (Id. ¶ 9.)

In January and February 2012 presentations, Bentsur referred to the Phase 2 results as showing a "pretty dramatic difference" in "median overall survival." (Id. ¶¶ 125-26.) On March 2, 2012, Keryx's Form 10-K contained further statements regarding the statistical significance of the Phase 2 results. (Id. ¶ 128.)

E. The Phase 3 Trial Fails

Plaintiffs allege that the risk concealed by the misleading statements regarding Phase 2 materialized when Keryx announced the failure of Phase 3. (Id. ¶ 75.) On April 2, 2012, the Company announced that the Phase 3 trial "did not meet the primary endpoint of improving overall survival versus capecitabine + placebo." (Id. ¶¶ 10, 130.) In a press release issued by Keryx that day, Bentsur is quoted as saying, "[w]e are all extremely disappointed with the results of the study." (Id. ¶ 130.)

Plaintiffs allege that detailed test data released in June 2012 indicated how "disastrously" perifosine had performed in the Phase 3 trial." (Id. ¶ 10.) According to plaintiffs, properly interpreted, perifosine was shown to actually increase the risk of hastening patient death. (Id.) Plaintiffs assert that the Phase 3 failure was

"within the zone of risk created by the flawed Phase 2 study." (Id.) Between March 30, 2012 and April 2, 2012, the Company's share price declined by 65%. (Id.)

II. LEGAL STANDARDS

A. Motion to Dismiss Under Rule 12(b)(6)

On a motion to dismiss, this Court accepts as true all well-pleaded factual allegations, Ashcroft v. Iqbal, 556 U.S. 662, 678-80 (2009), and draws all reasonable inferences in plaintiffs' favor. See Famous Horse Inc. v. 5th Ave. Photo Inc., 624 F.3d 106, 108 (2d Cir. 2010). To withstand dismissal, however, the "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 556 U.S. at 678 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

"Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. Thus, while "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, . . . it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 678-79. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not shown—that the pleader is entitled to relief." Id. (internal punctuation omitted); see also Fed. R. Civ. P. 8(a)(2).

B. Liability Under Section 10(b) and Rule 10b-5

In Count I of the Consolidated Amended Complaint, plaintiffs allege that defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. (CAC ¶¶ 168-177.)

To state a claim under Section 10(b) and Rule 10b-5(b), plaintiffs must adequately allege the following: (1) the defendant made[4] a misstatement or omission of material fact; (2) the defendant did so with the requisite scienter; (3) the misstatement or omission was in connection with the purchase or sale of securities; (4) that one or more plaintiffs relied upon such misstatement or omission; and (5) that such reliance was the proximate cause of a plaintiff's loss. See Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005); In re IBM Sec. Litig., 163 F.3d 102, 106 (2d Cir. 1998);

Plaintiffs may also allege a claim for so-called "scheme" liability under Section 10(b) and Rule 10b-5(a) and (c). To state such a claim, plaintiffs must allege that the defendants: "(1) committed a deceptive or manipulative act,[5] (2) with scienter, that (3) the act affected the market for securities or was otherwise in connection with their purchase or sale, and that (4) defendants' actions caused the plaintiffs' injuries." In re Parmalat Sec. Litig., 376 F. Supp. 2d 472, 491-92 n. 90 (S.D.N.Y. 2005) (citing cases); see 17 C.F.R. §§ 240.10b-5(a), (c).

[4] In Janus Capital Group, Inc. v. First Derivative Traders, 131 S. Ct. 2296, 2302 (2011), the Supreme Court stated that, for Rule 10b-5 liability, the "maker" of a statement is the person or entity with ultimate control over the statement, including its content and whether and how to communicate it.
[5] Rule 10b-5(a) prohibits individuals from "employ[ing] any device, scheme, or artifice to defraud." 17 C.F.R. § 240.10b-5(a). Rule 10b-5(c) prohibits individuals from "engage[ing] in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. § 240.10b-5(c).

1. Falsity

Claims of actionable misstatements or omissions sound in fraud.[6] As a result, allegations supporting such claims must meet the requirements of both Rule 9(b) of the Federal Rules for Civil Procedure and the PSLRA. See Novak v. Kasaks, 216 F.3d 300, 306 (2d Cir. 2000); Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1128 (2d Cir. 1994). This pleading standard further requires that a plaintiff state with particularity not only the particular statements that the plaintiff asserts were fraudulent, but also the when and where the statements were made and why the statements were fraudulent. See 15 U.S.C. § 78u-4(b)(1); Novak, 216 F.3d at 306; In re Parmalat, 376 F. Supp. at 491.

The Second Circuit has repeatedly stated that plaintiffs must do more than say that statements were false and misleading—"they must demonstrate with specificity why that is so." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004) (emphasis added); accord Kleinman v. Elan Corp., plc, 706 F.3d 145, 152-53 (2d Cir. 2013). "A securities fraud complaint based on misstatements must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." ATSI Communications, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007).

[6] An omission is only actionable when the speaker has a duty to disclose the omitted facts. SEC v. DiBella, 587 F.3d 553, 563 (2d Cir. 2009). If a development renders a past statement misleading, a failure to correct the statement may be actionable. In re Time Warner Sec. Litig., 9 F.3d 259, 267-68 (2d Cir. 1993).

In Kleinman, the Second Circuit reviewed dismissal of a complaint under Rule 12(b)(6) for failure adequately to allege falsity as required by Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. In that case, the plaintiffs also alleged that positive statements regarding the results of a flawed Phase 2 drug trial were actionable. Id. at 148-49. Elan's CEO remarked that the results of Phase 2 clinically supported their decision to move to Phase 3. Id. at 149. In sum, the amended complaint in Kleinman alleged that the defendants "knowingly failed to disclose the full magnitude of overall negative Phase 2 trial results and duped [plaintiff] and other investors with the overly optimistic . . . press release." Id. at 152.

The Second Circuit found that these allegations failed as a matter of law. Id. Section "10(b) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information." Id. (citing Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1321 (2011)). Moreover, disclosure is not required simply because an investor might find the information relevant or of interest. Kleinman, 706 F.3d at 153 (citing Resnik v. Swartz, 303 F.3d 147, 154 (2d Cir. 2002)). That the plaintiffs in Kleinman would have preferred the defendants to have used a different drug trial methodology, or found the defendants' methodology to be lacking, was not sufficient to adequately allege falsity. Kleinman, 706 F.3d at 153-54. The court reasoned: "Kleinman (and others) may take issue with Defendants' researchers and scientists, but where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." (Id.)

The Kleinman court further explained:

> Kleinman's real complaint is that defendants were able to tout positive results only because they deviated from the established protocol (which called for a linear analysis) and changed the metrics by which data was analyzed. At bottom, Kleinman simply has a problem with using post-hoc analysis as a methodology in pharmaceutical studies. . . . Our job is not to evaluate the use of post-hoc analysis generally in the scientific community . . . . Instead, we look to see whether the statements made were misleading or rendered misleading due to an omission.

Id. at 154-55. Ultimately, the Kleinman court found that this was not a case in which positive predictions were made without qualification, as the statements were accompanied by a "note of caution." Id. at 155.

An actionable misstatement is not simply one that is false or incomplete; there must also be a substantial likelihood that a reasonable person would consider the fact misstated or omitted important in connection with a contemplated securities transaction. See Basic Inc. v. Levinson, 485 U.S. 224, 238 (1988); Azrielli v. Cohen Law Offices, 21 F.3d 512, 518 (2d Cir. 1994); In re Espeed, Inc. Sec. Litig., 457 F. Supp. 2d 266, 279 (S.D.N.Y. 2006). As a result, "rosy predictions," or statements that are loosely optimistic regarding a company's well-being have been found to be too vague and general to be actionable. See, e.g. Novak, 216 F.3d at 315 ("statements containing simple economic projections, expressions of optimism, and other puffery are insufficient"); see also Rombach, 355 F.3d at 174 (unfocused expressions of puffery and corporate optimism not actionable). In Kleinman, the Second Circuit found that words such as "encouraging" that are used in connection with the results of drug trials do not generally give rise to a securities law violation. Kleinman, 706 F.3d at 153 (citing Rombach, 355 F.3d at 174).

2. Scienter

Scienter is the mental state embracing an intent to deceive, manipulate, or defraud. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319, 323 (2007). When deciding a motion pursuant to Rule 12(b)(6), a court must decide whether all facts taken together—that is, collectively—give rise to a strong inference of scienter. Id. at 323. The question is not, therefore, whether any individualized statement in "scrutinized in isolation" meets this standard. Id. A plaintiff has adequately alleged scienter "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 324.

Facts giving rise to a strong inference of scienter can be alleged by (1) pleading motive and opportunity to commit the fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness. Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001); accord Novak, 216 F.3d at 311. Motive and opportunity require plausible allegations of concrete benefits that could be realized by the misstatement, and the likely prospect of achieving such benefits. See Shields, 25 F.3d at 1130. Allegations limited to the type of "corporate profit" motive possessed by most corporate directors and officers do not suffice. See Kalnit, 264 F.3d at 139. "[T]he 'motive' showing is generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 198 (2d Cir. 2009).

Assertions of conscious misbehavior or recklessness can also satisfy the scienter requirement of Section 10(b). Conscious misbehavior generally consists of deliberate, illegal behavior. Novak, 216 F.3d at 308. Recklessness requires allegations that a defendant's conduct was highly unreasonable and constituted an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it. See Rothman v. Gregor, 220 F.3d 81, 90 (2d Cir. 2000); Novak, 216 F.3d at 308; Chill v. Gen. Elec. Co., 101 F.3d 263, 269 (2d Cir. 1996) (recklessness can be found in instances of "[e]regious refusal to see the obvious, or to investigate the doubtful"). Plausible allegations that a defendant had facts at his disposal contradicting material public statements, but then ignoring such facts or proceeding despite them, can be sufficient to plead recklessness. See Novak, 216 F.3d at 308-309 ("Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information.").

"The Second Circuit has explicitly recognized that plaintiffs may rel[y] on post-class period [statements] to confirm what a defendant should have known during the class period." Lapin v. Goldman Sachs Grp., Inc., 506 F. Supp. 2d 221, 237 (S.D.N.Y. 2006) (internal quotation marks and citations omitted); Freudenberg v. E*Trade Fin. Corp., 712 F. Supp. 2d 171, 183-84 (S.D.N.Y. 2010); In re Vivendi Universal, S.A. Sec. Litig., 381 F. Supp. 2d 158, 181 (S.D.N.Y. 2003) (post-class period articles can be used to establish awareness of falsity of statements during

the class period; the opposite result would reward defendant for successful concealment efforts). Allegations in a complaint, including allegations about the knowledge defendants had or should have had, must be viewed together. See Freudenberg, 712 F. Supp. 2d at 197-98 (citing Tellabs, 551 U.S. at 323).

3. Loss causation

Pleading loss causation is an essential element of a Section 10(b) and Rule 10b-5 claim for private plaintiffs, but this requirement is not meant to impose a great burden. See Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 346-47 (2005). There is no heightened standard for pleading loss causation. See In re Bristol Myers Squibb Co. Sec. Litig., 586 F. Supp. 2d 148, 163 (S.D.N.Y. 2008). A short, plain statement that provides defendants with notice of the loss and some notion of the causal connection to the alleged misconduct is sufficient. Dura, 544 U.S. at 346-47.

To establish loss causation, a complaint must allege "that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security," Lentell, 396 F.3d at 173, but must do more than merely allege that a company's shares declined substantially in value after purchase. See Dura, 544 U.S. at 343. A plaintiff can make this showing "by alleging that the market reacted negatively to a 'corrective disclosure,' which revealed an alleged misstatement's falsity or disclosed that allegedly material information had been omitted." In re AOL Time Warner, Inc. Sec. Litig., 503 F. Supp. 2d 666, 677 (S.D.N.Y. 2007).

C. Control Person Liability Under Section 20(a)

In Count II of the Consolidated Amended Complaint, plaintiffs allege so-called control person liability by defendant Bentsur under Section 20(a) of the Exchange Act. (CAC ¶¶ 178-184.)

Section 20(a) provides:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). To sustain a claim of control person liability under Section 20(a), plaintiffs must allege plausible facts that (1) there was a primary violation by a controlled person, (2) the defendant controlled the primary violator, and (3) the defendant who is alleged to be the controlling person was, in some sense, a culpable participant in the controlled person's fraud. See ATSI, 493 F.3d at 108.

Although a defendant may not be held liable both for a primary violation of the Exchange Act under Section 10(b) as well as a control person violation under Section 20(a), alternative theories are allowed at the pleading stage. Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir. 1998).

III. ANALYSIS

The crux of plaintiffs' claim is that the design of the Phase 2 trial was flawed, and therefore the statistically significant results it generated were inherently unreliable; that defendants knew or recklessly disregarded that fact in their public

statements in order to keep Keryx's stock price inflated; and only when the results of the Phase 3 trial were announced did the public learn the truth. Put another way, by relying on a flawed study, defendants risked that the results from Phase 2 were misleading and knew when "they" made the statements at issue the results were in fact flawed. Finally, plaintiffs allege that the Phase 2 risks "materialized" when Phase 3 failed.

A case based on similar allegations—relating to the same drug, perifosine, against Keryx's co-developer, Aeterna Zentaris—was previously dismissed with prejudice by Judge P. Kevin Castel in this District last year. See Abely v. Aeterna Zentaris, No. 12 Civ. 4711, 2013 WL 2399869, at *1 (S.D.N.Y. May 29, 2013). In Abely, the plaintiffs alleged that Keryx's design for the Phase 2 trial was inherently flawed due to undisclosed multiplicity, that it failed to account for different hypotheses, and that flawed results emanating from this flawed study were reported publicly as "statistically significant." Id. at *2-3. The Abely plaintiffs also asserted that the defendants—Aeterna and three individual senior executives—were misleading about the prospects for the Phase 3 trial success, since they knew or should have known of the inherent flaws in Phase 2. Id. at *4. Judge Castel disagreed, finding that Abely plaintiffs had failed to adequately plead falsity or scienter. Id. at *14-17.

The allegations in the instant complaint are similarly deficient.

A. Falsity

At their core, plaintiffs' allegations as to falsity amount to a desire to have known aspects of the methodology used in the Phase 2 trial earlier than such details were fully disclosed (in October 2011). In substance, plaintiffs assert that, given the extent of the methodological flaws, defendants' statements regarding the Phase 2 results were actionable misstatement or half-truths. Plaintiffs are incorrect; these allegations fail as a matter of law.[7]

A false statement must be just that: false; in error; wrong. An actionable omission must be information that, in light of other statements made, defendants had a duty to disclose so as not to mislead. Here, if this Court were to determine that the statements defendants made were actionable, it would essentially be the "thin end of the wedge": it would be equivalent to a determination that if a researcher leaves any of its methodology out of its public statements—how it did what it did or was planning to do—it could amount to an actionable false statement or omission. This is not what the law anticipates or requires. "The Second Circuit has emphasized that in scrutinizing a section 10(b) claim, a court does not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading." Abely, 2013 WL 2399869, at *7 (citing Kleinman, 706 F.3d at 154-55); see also In re MELA Sciences, Inc. Sec. Litig., No. 10 Civ. 8774, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012) (positive statements about

[7] The Court does not, however, agree with defendants that this is a case in which they are left searching to decipher or divine which statement are at issue. (See Mem. at 9-10, ECF No. 38.) The issue, rather, is whether the statements that plaintiffs point to are false or misleading. The Court finds that they are not.

outcome of clinical trial, when viewed against defendants' criticisms of methodology, "are essentially no different than opinions"; in order to properly plead, "plaintiffs must allege with particularity provable facts demonstrating the statement of opinion is both objectively and subjectively false").

Kleinman and Abely are both useful and instructive here. In both, plaintiffs' claims were based on assertions that the methodology of a drug trial had not been sufficiently disclosed. In both, such claims were rejected as insufficient to support allegations of, inter alia, falsity. In Kleinman, the Second Circuit rejected an argument that the statements at issue were false because the defendants had not followed established statistical protocol and changed the metrics by which data was analyzed. 706 F.3d at 154. The Kleinman court declined to mold such criticisms into actionable securities fraud on the basis of false statements or omissions. See id. at 154-55. This Court declines to do so here as well.

Plaintiffs have surrounded their recitation of the statements regarding the "statistically significant" Phase 2 results with assertions as to why the underlying methodology was unsound. (See, e.g., CAC ¶¶ 50-59.) Specifically, plaintiffs assert that the methodology suffered from a failure to adjust "p-values" for "multiplicity" and led to errors in hypothesis generation, and also that interim analysis introduced bias. (Id. ¶¶ 32-49.)

Plaintiffs concede, however, that defendants disclosed the fact that p-values had not been adjusted in the JCO manuscript published on October 3, 2011 and referenced in the October 5, 2011 press release. (Id. ¶¶ 65-66, 117-18.) A critique of

the Phase 2 trial published in TheStreet.com a week later mentioned all of the issues that plaintiffs assert were hidden. (Id. ¶¶ 67, 119.) This October 2011 disclosure by Keryx, followed by the critique published in TheStreet.com, contain the very facts plaintiffs claim defendants should have disclosed earlier. See Ashland Inc. v. Morgan Stanley & Co., 652 F.3d 333, 337-38 (2d Cir. 2011) ("An investor may not justifiably rely on a misrepresentation if, through minimal diligence, the investor should have discovered the truth.") (citations omitted).

Plaintiffs also concede knowledge of the other types of risks of which they complain. Plaintiffs allege that "virtually all" clinical trials involve multiplicity and, because multiplicity can inflate the Type I error rate and result in flawed hypothesis generation, researchers must properly adjust for it. (CAC ¶¶ 34-41, 43, 49.) In essence, plaintiffs assert that the Phase 2 trial involved what "virtually all" clinical trials involve—multiplicity—but that defendants did not make proper adjustments on the back end and should have informed the world of this flawed methodology. This is not falsity; it is less disclosure than plaintiffs would have liked. Given the known "decidedly mixed results" of perifosine's prior clinical trials dating back to 1998 (id. ¶ 29), and the known use of multiplicity in "virtually all clinical trials" (id. ¶ 34), plaintiffs allegations reflect their awareness of the potential for known—not unknown or hidden—risks.

In terms of "interim analysis," plaintiffs assert that defendants never disclosed how many analyses or comparisons it performed, and thus never disclosed information that one could use to determine potential bias that may have been

introduced into the results. (Id. ¶¶ 55-58.) There is, however, no rule requiring this type of "deep dive" disclosure plaintiffs assert should have been made here. That plaintiffs would have preferred to have had more information regarding how the Phase 2 trial was performed and how the results were analyzed is irrelevant to a determination of actionable falsity. See In re Time Warner Sec. Litig., 9 F.3d 259, 267 (2d Cir. 1993) ("[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact.")

Though plaintiffs do not attach the full documents containing the statements they allege to be either materially false or half-truths to the CAC, a review of even the statements they chose to excerpt shows that many of them contain "notes of caution" concerning both the sample size of the Phase 2 trial and the need to confirm the Phase 2 results in a Phase 3 trial. For instance, in the June 1, 2009 press release that plaintiffs allege was quoted or otherwise incorporated by reference multiple times, Dr. Howard Burris states: "Although not a large sample size, the data here is very interesting and next steps should be considered." (CAC ¶ 77.) In the January 25, 2010 press release, Bentsur notes the "need to confirm these results in a Phase 3 setting." (Id. ¶ 85.) In a June 9, 2010 presentation at the Needham Healthcare Conference, Bentsur states: "One thing that's very important to mention. We would be the first ones to admit that this study was not a large Phase 2 study, [it] was 38 patients." (Id. ¶ 97.) In a October 22, 2010 presentation at BioCentury's NewsMakers in the Biotech Industry Conference, Bentsur again notes that "it wasn't a big Phase 2 study . . . ." (Id. ¶ 106.) These are precisely the

kinds of "notes of caution" that the Kleinman court viewed as balancing the defendants' positive statements about the clinical trials at issue in that case. See Kleinman, 706 F.3d at 156.

In sum, the Court holds that the allegations in the CAC fail to allege actionable falsity as a matter of law.

B. Scienter

Even if this Court accepts that defendants made a series of public statements that contained actionable misstatements or half-truths regarding the Phase 2 trial, the Court would also need to determine whether plaintiffs' allegations are sufficient to support a strong inference of scienter. The Supreme Court's decision in Tellabs requires the Court to weigh competing inferences as to a defendant's state of mind when making the alleged material misstatement or omission. Tellabs, 551 U.S. at 323 ("The strength of an inference [of scienter] cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts?"). Such an analysis here reveals the inadequacy of plaintiffs' scienter allegations.

Plaintiffs argue that defendants acted at least recklessly by stating half-truths and omitting material facts of which they were aware regarding the results of the Phase 2 trial. (Opp. at 18, ECF No. 40.) In particular, plaintiffs take issue with repeated statements by Bentsur that the Phase 2 results were "statistically significant." (Id.) Plaintiffs allege that the misleading nature of these results was hidden by defendants' failure to follow proper scientific methodology. Failure to

follow industry standards—without more—is not itself sufficient to support scienter. See Stevelman v. Alias Research Inc., 174 F.3d 79, 84 (2d Cir. 1999). Even accepting that such a failure occurred (which the Court must on this motion), it might as easily be due to mismanagement than conscious or reckless disregard of the truth. Id. at 85 ("Management's optimism that is shown only after the fact to have been unwarranted does not, by itself, give rise to an inference of fraud.").

Here, plaintiffs' allegations against the Company amount to no more than management problems: someone failed to adjust p-values, which led to increased chances of Type I errors and errors in hypothesis generation, and interim analyses may have introduced bias. The CAC does not, however, adequately plead that the statements the Company made regarding the Phase 2 trial were known to be false at the time they were made. Put another way, it is one thing to suggest that the scientists and analysts did their job poorly; it is another to suggest that the Company knew that they had done their job poorly, and nonetheless (either consciously or recklessly) made statements to hide those errors.

Plaintiffs attempt to plead around this issue in two ways. First, they include boilerplate allegations in the CAC that Bentsur, as CEO, "was privy to confidential and proprietary information concerning Keryx," and "[b]ecause of his possession of such information, Bentsur knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public." (CAC ¶ 19.) This is an insufficient allegation upon which to hang a claim of securities fraud. Plaintiffs ask this Court to make a number of

unsupported assumptions as to their allegations: (1) that Bentsur knew that the Phase 2 trial results had not been adjusted for multiplicity (something which even plaintiffs agree should routinely occur); (2) that Bentsur knew that failure to adjust for multiplicity had in fact resulted in hypothesis generation issues; and (3) that Bentsur knew of unplanned interim analyses (one or more) and that such analyses did in fact introduce bias into the results. There are no allegations with any specificity to support knowledge by Bentsur of any of these facts prior to the October 2011 disclosures.

Second, plaintiffs seem to suggest (though they do not argue it affirmatively) that Bentsur's stock-based compensation package and stock sales during the Class Period give rise to a strong inference of scienter. (See id. ¶¶ 138-141.) That Bentsur received Keryx stock as compensation (id. ¶¶ 138-140) is insufficient to give rise to such an inference; "[i]f scienter could be pleaded on that basis alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." Acito v. IMCERA Grp. Inc., 47 F.3d 47, 54 (2d Cir. 1995).

Similarly, that Bentsur sold small portions of his holdings during the Class Period also does not salavage plaintiffs' scienter allegations. Such insider sales of stock may be indicative of scienter, but only if the trades are unusual or suspicious in timing or amount. See, e.g., Glaser v. The9, Ltd., 772 F. Supp. 2d 573, 587 (S.D.N.Y. 2011). No such factors are present here. Plaintiffs allege that Bentsur sold shares of Keryx common stock on March 24, 2010, March 24, 2011, and

January 3, 2012. (Id. ¶ 141.)[8] In addition to being small sales when compared to Bentsur's overall holdings, the sales did not take place shortly before either the alleged corrective disclosure in October 2011 or the end of the Class Period in April 2012 (when the failure of the Phase 3 trial was announced). In fact, the relevant Form 4s that were filed by Keryx with the SEC for these sales by Bentsur indicate that the sales were executed to cover the tax withholding obligations due upon the vesting of shares of restricted stock. (See Jordak Decl. Exs. C, D, E, ECF No. 19.)[9] Such sales for tax reasons are not indicative of fraud. See, e.g., In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) ("While 'unusual' executive stock trading under some circumstances may give rise to an inference of fraudulent intent, executive stock sales, standing alone, are insufficient to support a strong inference of fraudulent intent.") (citations omitted).

Accordingly, the allegations contained in the CAC as to defendants' scienter with respect to making public statements regarding the Phase 2 trial results fail as a matter of law.

C. Loss Causation

Plaintiffs' failure to adequately plead loss causation for their Section 10(b) and Rule 10b-5 claim serves as an additional basis to grant defendants' motion to dismiss. Plaintiffs first allege that, following publication of the critique of the JCO

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[8] The Court notes that the total number of shares and the total gross proceeds from these three stock sales by Bentsur listed in Paragraph 141 of the CAC do not add up to the total number of shares and the total gross proceeds listed in the final sentence of that paragraph. This discrepancy, however it may be resolved, is immaterial to the Court's holding that plaintiffs have failed to adequately plead scienter.

[9] The Court may take judicial notice of disclosures made in publicly available SEC documents such as these. See, e.g., Finn v. Smith Barney, 471 F. App'x 30, 32 (2d Cir. 2012).

manuscript on TheStreet.com on October 19, 2011, "Keryx's common stock dropped approximately 6% to close at $2.75 per share that day." (CAC ¶ 148.) The disclosure by Keryx, however, occurred more than two weeks earlier; the JCO manuscript clearly stated, with respect to the Phase 2 trial, that "[t]he P values were not adjusted for the unplanned interim analyses or for the multiple comparisons . . . because of the exploratory nature of the study design with small sample size." (Id. ¶ 118.) As a result, this allegation of loss causation is insufficient as a matter of law. See In re Omnicom Group, Inc. Sec. Litig., 597 F.3d 501, 512 (2d Cir. 2010) ("A negative journalistic characterization of previously disclosed facts does not constitute a corrective disclosure of anything but the journalists' opinions.").

Plaintiffs next allege that the "risk concealed by Defendants' repeated misleading statements materialized on April 2, 2012 upon the Company's announcement of perifosine's failed Phase 3 results," and that Keryx's stock price dropped 73% from the Class Period high following this announcement. (Id. ¶ 152.) This allegation of loss causation fails for the same reason as the first—defendants disclosed their decision not to adjust the p-values for the Phase 2 trial nearly six months prior to the April 2, 2012 announcement regarding the Phase 3 results. Plaintiffs fail to allege that a concealed risk materialized and resulted in the loss, see Lentell, 396 F.3d at 173, and thus fail to allege loss causation in the CAC as a matter of law.

D. Control Person Liability for Bentsur

As set forth above, control person liability requires an underlying violation of Section 10(b) of the Exchange Act. See ATSI, 493 F.3d at 108. Having failed adequately to plead a claim under Section 10(b) and Rule 10b-5, plaintiffs' claim for control person liability by Bentsur also fails.

IV. LEAVE TO AMEND

At the end of their opposition, plaintiffs request leave to amend pursuant to Federal Rule of Civil Procedure Rule 15(a)(2) in order to cure any deficiencies the Court may find in the CAC. (Opp. at 23.) Though Rule 15(a)(2) provides that leave to amend "should be freely given when justice so requires," Fed. R. Civ. P. 15(a)(2), "[o]ne appropriate basis for denying leave to amend is that the proposed amendment is futile." Lucente v. Int'l Bus. Machines Corp., 310 F.3d 243, 258 (2d Cir. 2002). The Court notes that, in addition to the three rounds of pleading in Abely concerning substantially similar allegations, plaintiffs have had the benefit of two rounds of pleading in the instant action. (ECF Nos. 1, 36.)

If, in light of the deficiencies identified by the Court herein, plaintiffs believe that amending the complaint would not be futile, they shall submit a memorandum setting forth what new allegations they would include in a consolidated second amended complaint to cure these deficiencies within **14 days** of the date of this order. Plaintiffs shall also attach a copy of a proposed consolidated second amended complaint to their memorandum that is blacklined against the current CAC.

If plaintiffs submit such a memorandum and proposed consolidated second amended complaint, defendants may submit any opposition within **7 days** of plaintiffs' submission.

V. CONCLUSION

For the reasons set forth above, defendants' motion to dismiss the Consolidated Amended Complaint is GRANTED.

The Clerk of Court is directed to terminate the motions at ECF No. 37 in 13 Civ. 755 and ECF No. 17 in 13 Civ. 1307, and to terminate both actions.

SO ORDERED.

Dated: New York, New York
February 14, 2014

K. B. Forrest

KATHERINE B. FORREST
United States District Judge