**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

TED DAVISON, WILLIAM GOULD, AND RAY LENCI, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

-against-

VENTRUS BIOSCIENCES, INC., DR. RUSSELL H. ELLISON, and DAVID J. BARRETT,

Defendants.

13 Civ. 3119 (RMB)

**DECISION & ORDER**

## I. Introduction

On September 17, 2013, lead plaintiffs Doris and Robert Alderson ("Plaintiffs") filed a Consolidated Amended Class Action Complaint ("Complaint") against Ventrus Biosciences, Inc. ("Ventrus" or "the Company"), a New York-based pharmaceutical company, and two of its officers, Dr. Russell H. Ellison ("Ellison") and David J. Barrett ("Barrett" and collectively, "Defendants").[1] Plaintiffs allege that Defendants violated the federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), Securities and Exchange Commission Rule 10b–5 ("Rule 10b–5"), and Section 20(a) of the Exchange Act, 15 U.S.C. § 78(t)(a) ("Section 20(a)"), by making materially false and/or misleading statements and omissions between December 17, 2010 and June 25, 2012 (the "Class

[1] Plaintiffs Ted Davison, William Gould, and Ray Lenci commenced this action by filing a complaint against Defendants on May 9, 2013. In an Order dated July 23, 2013, the Court consolidated this action with a substantially similar action brought by Michael Bartley against Defendants, entitled Bartley v. Ventrus Biosciences, Inc. et al., 13-cv-3429 (S.D.N.Y. 2013), and appointed Doris and Robert Alderson as lead plaintiffs in both actions. (See Order, dated July 23, 2013.)

Period") that concealed true, adverse facts about the efficacy of Ventrus leading drug candidate, VEN 309. (Consol. Am. Class Action Compl., dated Sep. 17, 2013 ("CAC") ¶ 32.) Plaintiffs bring their claims individually and on behalf of all those who purchased Ventrus stock during the Class Period.

At the core of the Complaint is the allegation that Defendants, as part of their efforts to raise capital for Ventrus, "touted" pre-2008 Phase II test results for VEN 309 conducted by the drug's patent holder, Sam Amer, "[d]espite the fact that the small testing groups and subjective endpoints used in Amer's studies could not produce a reliable gauge of the efficacy of VEN 309." (Id. ¶¶13–14). Plaintiffs allege that Defendants' misrepresentation of these Phase II test results—which were obtained during the second of three required stages of testing before a drug may obtain FDA approval—"misled investors as to VEN 309's previous testing success and anticipated FDA approval," and caused Plaintiffs to suffer economic loss when, on June 25, 2012, Ventrus disclosed that its Phase III clinical trial for VEN 309 "did not meet its endpoints" and that Ventrus would abandon its development of VEN 309. (Id. ¶¶ 35, 90–91.)

On November 22, 2013, Defendants filed a motion to dismiss the consolidated action pursuant to Rules 8, 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.") and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u–4(b), ("PSLRA"). Defendants argue that Plaintiffs fail to state a claim because, among other things, (1) the Complaint "fails to identify a single instance in which any reported fact [by Defendants] is demonstrably false or inaccurate"; and (2) Plaintiffs fail to plead the element of "scienter" because they do not allege facts sufficient to show a "strong inference" that defendants knew in advance that the Phase III trial would fail. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss Pls.' Consol. Am. Class Action Compl., dated Nov. 22, 2013 ("Def. Mem."), at 2–3.)

On December 23, 2013, Plaintiffs filed an opposition, arguing, among other things, that (1) "[t]he Complaint adequately alleges that Defendants made materially false and misleading statements and omissions that concealed true, adverse facts about, inter alia, the use of IPO proceeds for VEN 309, the efficacy of VEN 309, and its likelihood of FDA approval"; and (2) the Complaint pleads scienter because its "reliance on three [confidential witnesses], including the former Chief Medical Officer of Ventrus, adequately provides a basis for finding strong circumstantial evidence of conscious misbehavior or recklessness as to each Defendant," and because the Complaint alleges "significant concrete benefits realized by Defendants Ellison and Barrett resulting from their misleading statements or nondisclosures." (Pls.' Mem. of Law in Opp'n to Defs.' Mot. to Dismiss Pls.' Consol. Am. Class Action Compl., dated Dec. 23, 2013 ("Pl. Opp'n."), at 11, 14, 16.)

On January 17, 2014, Defendants filed a reply. (See Reply Mem. of Law in Supp. of Defs.' Mot. to Dismiss, dated Jan. 17, 2014 ("Def. Reply").) On April 24, 2014 the Court heard oral argument. (See Hr'g Tr., dated April 24, 2014.)

**For the reasons stated below, Defendants' motion to dismiss is granted.[2]**

## II. Background

For purposes of this motion, the allegations of the Complaint are taken as true. See Slayton v. Am. Express Co., 604 F.3d 758, 766 (2d Cir. 2010). The Court is also entitled to consider documents incorporated by reference in the Complaint. See Rothman v. Gregor, 220 F.3d 81, 88 (2d Cir. 2000) ("[F]or purposes of a motion to dismiss, we have deemed a complaint

[2] Any issues raised by the parties not specifically addressed herein were considered by the Court on the merits and rejected.

to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference . . . .").

Ventrus is a New York-based pharmaceutical company specializing in the development of late-stage prescription drugs for gastrointestinal disorders, including hemorrhoids, anal fissures, and fecal incontinence. (CAC ¶ 28.) During the Class Period, Defendant Ellison was Ventrus' CEO and Chief Medical Officer, and Defendant Barrett was the Company's CFO and Accounting Officer. (Id. ¶¶ 29–30.)

Ventrus began its operations in April 2007 when it acquired the licenses to two drugs, VEN 307 and VEN 308. (Id. ¶ 6.) In March 2008, Ventrus acquired the license to "iferanserin ointment," or VEN 309, as a treatment of hemorrhoids, from Sam Amer, Ph.D ("Amer"), a former director of research and development at Bristol-Myers Squibb Company. (Id. ¶¶ 7–8, 71.) As of March 2009, Ventrus was "limping along and could not begin any drug trials because the Company did not have any money." (Id. ¶ 7.)

Plaintiffs allege that VEN 309 "provided the perfect conduit to infuse capital into a stagnant company." (Id. ¶ 8.) Unlike the prescription drugs commonly used in the United States to treat hemorrhoids, VEN 309 was created to address the underlying medical cause, as opposed to the mere symptoms, of hemorrhoids. (Id.). Thus, an "enormous" marketing opportunity existed during the Class Period (and still exists) for an FDA-approved drug of this type. (Id.) Moreover, although VEN 309 had not been approved by the FDA at the time it was licensed to Ventrus in 2008, the drug had previously undergone clinical testing "up through a Phase II study," which meant that "all Ventrus would need to do is perform a Phase III study before submitting its new drug application . . . with the FDA." (Id. ¶ 97.) According to Plaintiffs,

"[t]hese characteristics made VEN 309 a perfect lure for investors to infuse capital into the . . . company." (Id.)

**Pre-2008 Phase II Studies of VEN 309**

FDA regulations, as noted, require that pharmaceutical companies engage in three phases of clinical trials—with each successive phase growing in complexity and size—before a drug is presented to the FDA for approval. See 21 C.F.R. § 312.21. Phase I studies typically involve twenty to eighty volunteers, and are designed to determine the safety of the drug and, if possible, early evidence of effectiveness. Id. § 312.21(a). Phase II studies include "controlled clinical studies conducted to evaluate the effectiveness of the drug," and are "conducted in a relatively small number of patients, usually involving no more than several hundred subjects." Id. § 312.21(b). Phase III clinical trials "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained" and usually include "several hundred to several thousand subjects." Id. § 312.21(c).

At the time Ventrus acquired the license to VEN 309 in March 2008, the drug had undergone three hundred and fifty (350) Phase I and seven (7) Phase II studies. (CAC ¶¶ 12, 57.) The Phase II studies involved a total of three hundred and fifty-nine (359) patients. (Id. ¶¶ 38–39.) Plaintiffs' allegations focus upon one of these seven Phase II studies, called the "Phase IIB" trial conducted by Amer in Germany in 2003 (the "German Study").[3] While Defendants'

[3] The German Study concluded that, "compared with placebo, iferanserin ointment significantly reduced bleeding, itching and pain ($P < 0.05$) by day 3" and that "57% of iferanserin-treated patients has cessation of bleeding versus only 20% of placebo-controlled patients ($P = 0.0001$)." (Form 424B4 Prospectus, filed Dec. 17, 2010 ("12/17/10 Prospectus") (Ex. A to Decl. of Ryan E. Blair, dated Nov. 22, 2013 ("Blair Decl.") at 6); CAC ¶ 75.) Additionally, the German Study found "no clinically significant adverse findings for either iferanserin or the placebo ointment. (Id.)

Class Period statements indicated that the German Study and other Phase II trials had achieved positive results, Plaintiffs contend that the German Study "could not produce a reliable gauge of the efficacy of VEN 309," because "[o]nly 121 patients were studied for the German[] Phase IIB tests." (Id. ¶ 13.) Plaintiffs allege that the data obtained from the six other Phase II studies were "woefully inconclusive due to the small sample sizes used in [the] studies." (Id. ¶ 58.) Plaintiffs cite in their Complaint a confidential witness ("CW1"), the former Chief Medical Officer of Ventrus, who allegedly expressed concern (at times which are unspecified by Plaintiffs) over the small number of participants in the German Study. (Id. ¶ 98.)

**Ventrus' 2011-2012 Phase III Trial of VEN 309**

Between February 2008 and July 2011, Defendants engaged in discussions with the FDA regarding the methodology and procedure for an anticipated Phase III trial of VEN 309. (See 12/17/10 Prospectus (Ex. A to Blair Decl. at 6, 23); CAC ¶¶ 59, 61, 63, 65.) These discussions included Ventrus' plans for a "special protocol assessment" ("SPA"), a procedure by which a drug developer can obtain advance FDA approval of its testing protocol. (CAC ¶¶ 14, 44.) Ventrus ultimately decided not to complete the SPA process, but agreed to implement several changes to its anticipated Phase III trial protocol that were proposed by the FDA. (Id. ¶ 55.) And, in July 2011, Ventrus began its Phase III trial of VEN 309. (Form 424B4 Prospectus, filed May 30, 2012 (Ex. T to Blair Decl. at 263–264) ("We filed the protocol to our existing IND with the FDA in July 2011 and began enrolling and dosing patients in August 2011 . . . .).)

In an effort to raise capital while its discussions with the FDA and its Phase III trial of VEN 309 were going on, Ventrus undertook three public offerings of its common stock. On December 17, 2010, Ventrus commenced an initial public offering ("December 2010 IPO"), by

filing a prospectus with the SEC ("December 2010 Prospectus").[4] (Id. ¶ 10.) On July 14, 2011, Ventrus filed a second prospectus in connection with the sale of 4.5 million additional shares of the Company's common stock ("July 2011 Prospectus"). (Id. ¶15.) And, on May 30, 2012, Ventrus filed a third prospectus, which accompanied an offering of 948,378 shares of common stock to the public ("May 2012 Prospectus"). Ventrus' three public offerings raised over $70 million for the Company. (Id.)

**June 25, 2012 Announcement of Phase III Results**

On June 25, 2012, Ventrus issued a press release announcing that the Phase III trial of VEN 309 "did not meet its endpoints." (Id. ¶ 90.) The press release stated that the trial "failed to demonstrate an improvement for therapy, in either treatment arm, over placebo for the primary and secondary endpoints" and that "[c]onsequently, Ventrus has no immediate plans to continue development of VEN 309 . . . ." (Id. ¶¶ 90–91.) Plaintiffs allege that this announcement "eviscerated the value of Ventrus stock," which declined by 59 percent on the day of the press release. (Id. ¶ 93.)

**Alleged Misstatements and Omissions**

Defendants' alleged misstatements can be divided into four categories: (1) statements regarding the results of the Phase II studies of VEN 309; (2) statements regarding the progress of Ventrus' Phase III trial of VEN 309; (3) statements relating to Ventrus' plans to seek FDA approval of an SPA; and (4) statements regarding Ventrus' intended use of the proceeds from its December 2010 IPO.

[4] Through its December 2010 IPO, Ventrus raised approximately $16.1 million. (CAC ¶ 11.)

1. Phase II Studies

Plaintiffs allege that throughout the Class Period Ventrus falsely informed investors that the Amer's Phase II studies, and in particular the German Study, had achieved positive results and that "VEN 309 was ready for its Phase III trial due to its 'successful' Phase IIB studies . . . in Germany." (Id. ¶¶ 9, 13.) These misrepresentations are alleged to have occurred on several occasions, beginning with Ventrus' December 2010 IPO and ending with its third public offering in May 2012. Plaintiffs cite the December 2010 Prospectus, which stated that "Phase II studies consistently demonstrate that iferanserin treatment significantly reduces hemorrhoidal symptoms of bleeding, itching and pain . . . ." (Id. ¶ 36.). Plaintiffs contend that similar statements were made in Ventrus' July 2011 and May 2012 Prospectuses, and in several press releases. (See, e.g. id. ¶ 57 ("Seven clinical studies of VEN 309 have been completed, and five of these studies demonstrated that VEN 309 significantly improved and in many cases eliminated the pain, bleeding and itching associated with hemorrhoids versus placebo ointment."); id. ¶ 75 ("In the German Phase [IIB] study, it was determined that 57% of iferanserin-treated patients has cessation of bleeding versus only 20% of placebo-controlled patients (P = 0.0001).")) Plaintiffs contend that these statements were false because "Defendants knew and/or recklessly disregarded that Phase IIB clinical trials in Germany were completely inconclusive due to the small number of participants in the study." (Id. ¶ 54; see also id. ¶¶ 35, 37, 39, 41, 58, 62. 64, 72, 74, 76, 78, 80, 82, 86.)

But Plaintiffs concede that the December 2010 Prospectus (and several other filings by Defendants during the Class Period) disclosed the size of the German Study (121 patients) and the total number of patients involved in the drug's pre-2008 Phase II studies (359). (Pl. Opp'n. at 19–20; see 12/17/10 Prospectus (Ex. A to Blair Decl. at 6); Form 424B4 Prospectus, filed July

14, 2011 ("7/14/11 Prospectus") (Ex. D to Blair Decl. at 103); Form 10-K, filed Mar. 14, 2012 (Ex. C to Blair Decl. at 53); Hr'g Tr., dated April 24, 2014 at 6:24–7:9 (The Court: "[I]s it also true . . . that the sample size was fully disclosed?" Plaintiffs' Counsel: "They disclosed the sample size included 121 participants . . . yes, your Honor, they did disclose [the] sample size.").)

Plaintiffs also contend that Ventrus made statements during the Class Period touting a positive correlation between the results of the pre-2008 Phase II studies of VEN 309 and Ventrus' 2011–2012 Phase III trial. (See, e.g. CAC ¶ 79 ("We have modeled the potential performance of the primary and secondary endpoints which were proposed by the FDA [for the Phase III trial] . . . using data from the German Phase IIB trial, because the principal elements of the German Phase IIB trial are substantially similar to our first Phase III trial."). Plaintiffs allege that such statements were false because "the endpoints of the Phase III trial were far more stringent than those of the German Phase IIB trial." (Id. ¶ 80.)

2. Ventrus' Phase III Trial

Plaintiffs identify representations made by Defendant Ellison in Ventrus' SEC filings in late 2011 stating that the "data quality [of the Phase III trial of VEN 309] is good," that "no serious severe adverse events related to the drug have been seen to date," and that the Phase III trial was "progressing well with respect to data quality and GCRP (Good Clinical Research Practices)." (Id. ¶¶ 67, 69.) Plaintiffs contend that these statements were false because, at the time they were made, "Defendants either knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints." (Id. ¶70.) In support of this contention, Plaintiffs cite a confidential witness who was an employee of one of the third-party contractors conducting the

trial ("CW2"), who stated that she "engaged in update calls with [Defendant] Ellison regarding the drug's trials." (Id. ¶ 68.)

3. Ventrus' Plans to Seek an SPA

Plaintiffs identify several Class Period statements regarding Ventrus' plans to seek FDA approval of an SPA for its anticipated Phase III trial. (See id. ¶¶ 44, 55.) They point to the December 2010 Prospectus, which stated that Ventrus "expect[s] to complete the SPA process by the end of the first quarter of 2011." (Id. ¶ 44.) And, on June 22, 2011, Defendant Ellison was quoted in a press release as stating that Ventrus' discussions regarding an SPA had "been very productive." (Id. ¶ 55.) Plaintiffs allege that these statements were false because Ventrus never intended to proceed with an SPA and, in fact, "abandoned its SPA application by July 2011." (Id. ¶ 45.) The purpose of Defendants' misrepresenting Ventrus' SPA process, according to Plaintiffs, was "to lure investors" to the Company because "investors would misinterpret the SPA as an indication that the FDA would approve VEN 309." (Id.)

4. Use of IPO Proceeds

Plaintiffs allege that Ventrus (mis)stated in its IPO Prospectus that it intended to "use the proceeds from this financing to . . . conduct the first of the two required Phase III clinical trials with VEN 309 . . . ." (CAC ¶ 46.) Plaintiffs allege that this statement was false because "[t]he primary purpose of the IPO was to repay the Company's creditors, pay Defendants Ellison and Barrett large salaries and bonuses, and continue Ventrus as a going concern . . . ." The Complaint states that "[a]lthough some proceeds were spent on the VEN 309 trials, Defendants were careful not to spend very much money on these trials." (Id. ¶ 47.)

Plaintiffs contend that Defendants Barrett and Ellison benefited personally from the alleged misrepresentations in two ways. First, Plaintiffs claim that Barrett and Ellison were able to attract investors to the Company and, consequently, received incentive bonuses of $250,000. (Id. ¶ 17.) Second, because Ventrus' three public offerings during the Class Period "kept [Ventrus] afloat and infused tens of millions of dollars into Ventrus, Ellison and Barrett were able to pay themselves huge annual salaries of $375,000 and $250,000 respectively and large annual performance bonuses." (Id. ¶ 102.)

## III. Legal Standards

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. 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. "[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. at 678–679 (internal punctuation omitted); see also Fed. R. Civ. P. 8(a)(2).

To maintain a private damages action under § 10(b) and Rule 10b–5,

> a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.

Stoneridge Inv. Partners, LLC v. Scientific–Atlanta, Inc., 552 U.S. 148, 157 (2008) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341–42 (2005)).

Plaintiffs must meet the heightened pleading standards of Fed. R. Civ. P. 9(b) and the PSLRA by "specify[ing] each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Kleinman v. Elan Corp., plc, 706 F.3d 145, 152 (2d Cir. 2013) (quoting 15 U.S.C. § 78u–4(b)(1)(B)); see Fed. R. Civ. P. 9(b) (The "circumstances constituting fraud" must be "state[d] with particularity."). Plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004).

In order adequately to plead scienter, "the pleaded facts must give 'rise to a strong inference' of fraudulent intent." Kleinman, 706 F.3d at 152 (quoting 15 U.S.C. § 78u–4(b)(2)(A)). This burden is met "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." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007).

## IV. Analysis

In their motion, Defendants set forth the following two alternative grounds for dismissing Plaintiffs' securities fraud claims: (1) Plaintiffs have failed to allege any false statements by Defendants; and (2) Plaintiffs have failed to plead the element of scienter. The Court agrees with Defendants as to both grounds.[5]

[5] Although the Court addresses both arguments, Plaintiffs' Complaint may be dismissed on either ground. See In re Keryx Biopharm., Inc. Sec. Litig., 13-cv-755, 2014 WL 585658, at *10–13 (S.D.N.Y. Feb. 14, 2014) (dismissing securities fraud claim on alternative grounds of failure to plead falsity and scienter).

**A. Falsity**

As explained below, Plaintiffs fail to allege facts demonstrating that Defendants' Class Period statements were false or misleading.

1. Phase II Studies

Plaintiffs argue that Defendants' representations regarding the results of the German Study and other Phase II studies and, even more broadly, Defendants' expressions of optimism regarding VEN 309 based upon those studies, were misleading because "Defendants[] fail[ed] to disclose the inconclusiveness and unreliability of the results generated from [the German Study] . . . due to the small sample size."[6] (Pl. Opp'n. at 20.) This argument fails.

"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 v. Aeterna Zentaris Inc., 12-cv-4711, 2013 WL 2399869, at *7 (S.D.N.Y. May 29, 2013) (citing Kleinman, 706 F.3d at 154–55). In Kleinman v. Elan Corp., plc, a case very much on point, the Court held that plaintiffs' criticism of the methodology used in defendants' "post-hoc analysis" of a Phase II drug trial did not support a securities fraud claim because defendants had not made misleading statements regarding that methodology. Kleinman, 706 F.3d at 154–55. The Court 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

[6] Plaintiffs concede that Defendants accurately and repeatedly disclosed the size of the German Study to investors during the Class Period. (Pl. Opp'n. at 19–20; H'rg Tr., dated April 24, 2014 at 6:24–7:9).) Plaintiffs contend Defendants failed to disclose that the German Study was "inconclusive[] and unreliab[le]" **because of** its limited size.

> 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.

Here, as in Kleinman, Plaintiffs do not allege that Defendants' Class Period statements misrepresented any facts regarding the German Study, including its size or any other facts about its methodology, but, instead, criticize the study's methodology as unreliable. Under Kleinman, this is plainly insufficient to plead falsity in a securities fraud case. See id.; In re Keryx, 2014 WL 585658, at *11 (allegations that defendants' Phase II methodology "suffered from a failure to adjust 'p-values' for 'multiplicity'" was insufficient to support a securities fraud claim where "defendants disclosed the fact that p-values had not been adjusted"); In re MELA Sciences, Inc. Sec. Litig.,10-cv-8774, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012) (allegation of "unsound statistical analysis" in a clinical study insufficient to support securities fraud claim, and "are essentially no different than opinions."); In re Rigel Pharm., Inc. Sec. Litig., 697 F.3d 869, 879 (9th Cir. 2012) ("Because Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results.").

Plaintiffs' characterizations of the Phase II studies as "woefully inconclusive" (CAC ¶ 86), "not significant" (id. ¶ 78), and "not helpful" (id. ¶ 80) reflect Plaintiffs' subjective interpretation or opinion of those studies and cannot support their claims. Plaintiffs do not contest the data actually obtained in the German Study—i.e., that "it was determined that 57% of iferanserin-treated patients has cessation of bleeding versus only 20% of placebo-controlled patients." (Id. ¶ 75.) They contend only that these data are "not helpful." (Id. ¶ 80.) But where,

as here, "a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement." Kleinman, 706 F.3d at 154; see In re Sanofi–Aventis Sec. Litig., 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011) ("Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [defendants] chose to interpret the results.").

In fact, the allegations in the Complaint strongly suggest that the German Study was scientifically legitimate and statistically significant. The Complaint acknowledges, for example, that the clinical results of the German Study were published in the peer-reviewed journal Clinical Therapeutics, (CAC ¶ 75; see Form 8-K, filed Jan. 13, 2012 (Ex. E to Blair Decl. at 112)), and does not contest Defendants' statement that "[i]n the German Phase 2b study, it was determined that 57% of iferanserin-treated patients had cessation of bleeding versus only 20% of placebo-controlled patients (P = 0.0001)."[7] (CAC ¶ 75.) And, Plaintiffs' allegation that the 121-patient size of the German Study undermined its results ignores the FDA's regulations which state that "**Phase 2 studies are typically . . . conducted in a relatively small number of patients, usually involving no more than several hundred subjects.**" 21 C.F.R. § 312.21(b) (emphasis added).

Plaintiffs also allege that Defendants falsely stated in March 2012 that "the principal elements of the German Phase IIB trial are substantially similar to [the 2011–2012] Phase III trial." (CAC ¶ 79.) Plaintiffs contend that this statement was false because "the endpoints of the [2011–2012] Phase III trial were far more stringent than those of the German Phase IIB trial." (Id. ¶ 80.) But Defendants' public statement made no mention of the "endpoints" used in the

[7] "Statistical significance is determined by reference to the p-value" (David H. Kaye and David A. Freedman, Reference Guide on Statistics in Reference Manual on Scientific Evidence 211, 241 (Federal Judicial Center ed., 3d ed. 2011).) "If p is smaller than 5%," or .05, "the result is statistically significant." (Id. at 291.) **As noted, Plaintiffs do not contest Defendants' statement that the German Study achieved a p-value of 0.0001.**

German Study, and stated only that the "principal elements" of the German Study and the Phase III trial were similar. Thus, even assuming, arguendo, that the Phase II and III endpoints differed, Plaintiffs fail to "demonstrate with specificity" why Defendants' March 2012 statement, which made no comparison between the endpoints, was false. Rombach, 355 F.3d at 174; see In re Austl. & N.Z. Banking Grp. Ltd. Sec. Litig., No. 08-cv-11278, 2009 WL 4823923, at *14 (S.D.N.Y. Dec. 14, 2009) (finding statements not false or misleading where the "[alleged] fraud consisted of ANZ's misrepresentation of its 'equity finance practices'" but "[t]hose practices . . . are not the subject of the representations cited in the Complaint").

2. Ventrus' Phase III Trial

Plaintiffs allege that in 2011 Defendants made false statements regarding the progress of Ventrus' Phase III trial of VEN 309, including statements that the "data quality [of the Phase III trial of VEN 309] is good," that "no serious severe adverse events related to the drug have been seen to date," and that the Phase III trial was "progressing well with respect to data quality and GCRP (Good Clinical Research Practices)." (CAC ¶¶ 67, 69.) Plaintiffs allege that these statements were false because, at the time they were made, "Defendants either knew or recklessly disregarded that VEN 309's Phase III testing would not meet its endpoints." (Id. ¶70.)

The Complaint's allegations are conclusory. It fails to allege facts (even remotely) suggesting that Defendants knew in 2011 that the Phase III trial, which ended in June 2012, would not meet its endpoints. Novak v. Kasaks, 216 F.3d 300, 309 (2d Cir. 2000) ("Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information."). In their opposition, Plaintiffs argue that "Defendants had access to information that undermined the Company's [2011] statements," and refer—again—to the alleged unreliability of the Phase II studies. (Pl. Opp'n. at 18.) But, as

noted above, Plaintiffs have not alleged plausibly that the Phase II studies were objectively unreliable. (See supra at 15.) Plaintiffs' allegation that CW2 "engaged in update calls with [Defendant] Ellison regarding the drug's trials" (CAC ¶ 68) is also insufficient to plead falsity because the Complaint does not specify what, if any, information was discussed during these calls. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 ("Allegations that are conclusory or unsupported by factual assertions are insufficient.").

3. Ventrus' Plans to Seek an SPA

Plaintiffs allege that Defendants falsely stated in the December 2010 Prospectus that Ventrus "expects to complete the SPA process by the end of the first quarter of 2011." (Id. ¶ 44.) Plaintiffs contend that this statement was false because "Ventrus did not, in fact, expect to complete the SPA process by the end of the first quarter of 2011" and "abandoned its SPA application by July 2011." (Id. ¶ 45.) But as Defendants correctly point out, the Complaint is devoid of any facts demonstrating that Ventrus did not intend to complete an SPA at the time of the alleged misstatements. (Def. Mem. at 19.) And, that Ventrus ultimately decided in 2011 to forego an SPA is plainly insufficient to plead falsity with respect to Defendants 2010 statements. Novak, 216 F.3d at 309 ("[W]e have refused to allow plaintiffs to proceed with allegations of 'fraud by hindsight.'").

Plaintiffs also allege that Defendants' June 22, 2011 statement that Ventrus' SPA-related discussions with the FDA had "been very productive" was false. (Id. ¶ 55.) Defendants' use of the phrase "very productive" in this way amounts to "commercial puffery," which is not actionable under the Exchange Act. ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 206 (2d Cir. 2009) (holding inactionable "statements [that] are too general to cause a reasonable investor to rely upon them"); Nasik Breeding & Research

Farm, Ltd. v. Merck & Co., Inc., 165 F. Supp. 2d 514, 530 (S.D.N.Y. 2001) ("Terms like 'very high productive traits,' which do not set forth a concrete representation as to the company's future performance, are in the nature of commercial puffery and cannot form the basis for a fraud claim here.").[8]

4. Use of IPO Proceeds

Plaintiffs allege that Defendants' statement in the December 2010 Prospectus that they intended to "use the proceeds from this financing to . . . conduct the first of the two required Phase III clinical trials with VEN 309" was false because "[t]he primary purpose of the IPO was to repay the Company's creditors, pay Defendants Ellison and Barrett large salaries and bonuses, and continue Ventrus as a going concern . . . ." (CAC ¶¶ 46–47.) The Complaint also states that "[a]lthough some proceeds were spent on the VEN 309 trials, Defendants were careful not to spend very much money on these trials." (Id. ¶ 47.)

Plaintiffs' allegations are wholly conclusory and unsupported by specific facts. In any event, they are contradicted by Ventrus' public SEC filings which demonstrate that Ventrus did spend a significant amount of money on development of VEN 309. See Rapoport v. Asia Elec. Holding Co., Inc., 88 F. Supp. 2d 179, 184 (S.D.N.Y. 2000) (when publicly filed documents on which a complaint relies contain statements that contradict the allegations in the complaint, "the documents control"); ATSI Commc'ns, 493 F.3d at 98 (When ruling on a motion to dismiss, a court "may consider . . . documents incorporated into the complaint by reference [and] legally required public disclosure documents filed with the SEC . . . ."). Between October 7, 2005 and March 31, 2012 Ventrus spent over $36 million on the development of VEN 309, far more than

[8] And, Plaintiffs have not alleged any facts demonstrating that Ventrus' discussions with the FDA were not productive.

was spent by Ventrus on its other drug candidates. (Form 10-Q, filed May 9, 2012 (Ex. S to Blair Decl. at 258). Over the three-month period between January and March 2012 (when the Phase III trial of VEN 309 was taking place), Ventrus spent over $5.8 million on its development of VEN 309. (Id.) The Complaint concedes that, "from the Company's inception to December 31, 2011, Ventrus had allocated six times more resources to VEN 309 than its other drug candidates." (CAC ¶ 104.) Plaintiffs' unsupported allegation that "Defendants were careful not to spend very much money on [the Phase III trial]" is plainly insufficient. See Rombach, 355 F.3d at 174.

**B. Scienter**

Dismissal of Plaintiffs' securities fraud claims is also appropriate because Plaintiffs have failed to allege facts that, "taken collectively, give rise to a strong inference of scienter," or "fraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 323 (2007); Kleinman, 706 F.3d at 152. Plaintiffs may plead scienter either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001) (internal quotations marks and citation omitted). Plaintiffs' allegations fall short as to both theories.

Plaintiffs argue that they have alleged "significant concrete benefits realized by Defendants Ellison and Barrett resulting from their misleading statements or nondisclosures," (Pl. Opp'n. at 14.) Specifically, they contend that Ellison and Barrett were motivated to mislead investors regarding VEN 309 "in order to finance the development of VEN 307 and VEN 308 and continue Ventrus as a going concern" and to receive incentive bonuses tied to Ventrus' market capitalization. (Id. at 15; CAC ¶¶ 100–01). These alleged motives—i.e., to keep the

Company afloat and to increase its officers' compensation—are no different than those generally possessed by most corporate directors and officers, and thus "do not suffice" to demonstrate scienter. Kalnit, 264 F.3d at 139 (citing Novak, 216 F.3d at 307–08); see id. ("Insufficient motives, we have held, can include (1) the desire for the corporation to appear profitable and (2) the desire to keep stock prices high to increase officer compensation."); Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1130 (2d Cir. 1994) ("To allege a motive sufficient to support the inference [of fraudulent intent], a plaintiff must do more than merely charge that executives aim to prolong the benefits of the positions they hold."); In re Cross Media Mktg. Corp. Sec. Litig., 314 F. Supp. 2d 256, 265 (S.D.N.Y. 2004) (where allegations that defendants were motivated by a desire to raise capital or benefited by raising capital were insufficient to establish motive and opportunity).

To survive dismissal under a "conscious misbehavior" theory, Plaintiffs must allege that Defendants engaged in "reckless conduct," or "conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care." In re Carter–Wallace, Inc. Sec. Litig., 220 F.3d 36, 39 (2d Cir. 2000) (citation omitted). Allegations that Defendants had "knowledge of facts or access to information contradicting their public statements" may suffice to plead conscious misbehavior. Novak, 216 F.3d at 308.

Plaintiffs argue that the testimony of their confidential witnesses, CW1 and CW2, supports a "strong inference of conscious misbehavior or recklessness."[9] (Pl. Opp'n. at 9.)

[9] In their motion, Defendants argue that Plaintiffs' allegations relating to a third confidential witness, "CW3", are "irrelevant" because CW3 "had no involvement in the VEN 309 program and is not alleged to have spoken with anyone at Ventrus." (Def. Mem. at 14.) Plaintiffs do not contest this argument in their opposition. In re UBS AG Secs. Litig., 07-cv-11225, 2012 WL 4471265, at *11 (S.D.N.Y. Sept. 28, 2012) (a party "concedes through silence" arguments by its opponent that it fails to address).

These witnesses merely repeat the Complaint's (unpersuasive) falsity allegations. For example, CW1 "expressed concern over the small number of participants in the German Phase IIB study." (CAC ¶ 98.) Plaintiffs' bare-bones allegation regarding CW1's concern is similar to the conclusory assertion that the German Study was "not helpful" in that they are premised upon the opinion that 121-patient drug trials are inherently unreliable. (See supra at 14–15.)

CW2 states that Ventrus was "cheap" in the way it conducted its Phase III trial of VEN 309. (CAC ¶ 18.) This assertion, even assuming, arguendo, that it were true (but see supra at 18–19), has no obvious connection to Plaintiffs' fraud allegation that Defendants wilfully lied about past results and future prospects of VEN 309. Tellabs, 551 U.S. at 324 (scienter is only sufficiently pled "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.").

### C. Section 20(a) Control-Person Liability

Because the Complaint does not allege a primary violation of the Exchange Act, Plaintiffs' claim of control-person liability under Section 20(a) is also dismissed. See Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir. 1998) ("In order to establish a prima facie case of liability under § 20(a), a plaintiff must show . . . a primary violation by a controlled person . . . .").

## V. Conclusion

For the reasons stated herein, Defendants' motion to dismiss [#46] is hereby granted, and Plaintiffs' Complaint is dismissed with prejudice.[10]

[10] By letter dated October 7, 2013, Defendants informed Plaintiffs of their anticipated grounds for moving to dismiss the Complaint. (See Letter from Jonathan Bach to Hon. Richard M. Berman, dated Oct. 7, 2013, Dkt. # 39.) During the October 21, 2013 conference, the Court

The Clerk of Court is respectfully requested to close this case.

Dated: New York, New York
May 5, 2014

RMB

**RICHARD M. BERMAN, U.S.D.J.**

gave Plaintiffs the opportunity to amend the Complaint in light of the anticipated arguments presented by Defendants and also informed Plaintiffs' counsel that Defendants' motion would, if successful, be "with prejudice." (Hr'g Tr., dated Oct. 21, 2013 at 2:18–3:18.) Plaintiffs declined to amend their Complaint, and acknowledged that dismissal would be with prejudice. (Id. at 3:13 (Plaintiffs' Counsel: "[W]e're happy to stand on [] this Complaint.").)