NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROY SAPIR, on behalf of himself and all other similarly situated, Plaintiff, v. PAUL AVERBACK and NYMOX PHARMACEUTICAL CORPORATION, Defendants.	Civil Action No.: 14-7331 (JLL) (JAD) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of the Motion to Dismiss the Amended Class Action Complaint (the "Amended Complaint" or "AC") filed by Defendants Paul Averback ("Averback") and Nymox Pharmaceutical Corporation ("Nymox" or "the Company") (collectively, "Defendants"). (ECF No. 32.) In this action, Lead Plaintiffs Harry Lattanzio, PRS, Inc., Network Accreditation Services, Inc., Andrew Silverman, and Rock 49th Restaurant Group (collectively "Lead Plaintiffs") allege claims under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Securities Exchange Act"), arising from alleged fraudulent misrepresentations about the design and conduct of two Phase 3 studies of Nymox's drug NX-1207. The proposed Class Period is from January 31, 2011 to November 2, 2014. (AC at 1.)

The Court has considered the parties' submissions and decides this matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, the Court grants the Motion to Dismiss.

FACTUAL BACKGROUND[1]

A. Company Background

Nymox is engaged in the research and development of therapeutics and diagnostics, with an emphasis on products for the unmet needs of the aging population. (AC ¶ 18.) The Company has two subsidiaries: the wholly-owned Nymox Corporation and the majority-owned Serex, Inc., both based in Hasbrouck Heights, New Jersey. (*Id.* ¶ 15.) Throughout its operating history, the Company's operations have primarily been funded through common stock private purchase agreements. (*Id.* ¶ 18.)

Dr. Paul Averback is Nymox's founder, has been the Company's President and a director since 1995, and has served as its Chairman of the Board since 2001. (*Id.* ¶ 19.) Dr. Averback is also the Company's largest shareholder. (*Id.*) At or near the commencement of the Class Period, he owned or controlled 13,115,395 shares (about 40.3%) of the Company's common stock, as well as 2,750,000 in vested and unexercised stock options. (*Id.*; *see also* ECF No. 32-4, Ex A. to Stroup Decl. ("2010 Form 20-F") at 41-42.) As of March 15, 2014, the number of common shares owned or controlled by Averback was 11,402,048. (AC ¶ 19.) According to the Amended Complaint, it was reported on August 6, 2014 that Averback sold 470,600 common shares in a private transaction for proceeds of $2.4 million. (*Id.*)

B. Facts Relevant to the Class Period Allegations

Since 2002, the Company has been developing a novel proprietary drug candidate, NX-1207, to treat benign prostatic hyperplasia (BPH), a condition found in older men whose

[1] This background is derived from Plaintiff's Amended Complaint, which the Court must accept as true at this stage of the proceedings, and "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice," such as SEC filings, press releases, and earnings call transcripts. *Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007); *Tellabs*, 551 U.S. at 322.

prostates have become enlarged. (*Id.* ¶ 1.) There are competing drugs for treatment of BPH already approved by the Food and Drug Administration (FDA),[2] but Nymox claims that NX-1207 is superior due to ease of administration (a single injection with minimal discomfort) and lack of serious side effects. (*Id.*)

Prior to the Class Period, Nymox successfully conducted Phase 1 and 2 clinical trials of NX-1207 in the U.S. (*Id.* ¶ 26.) Indeed, the Company stated that "[c]ompleted Phase 2 studies have shown that a single administration of NX-1207 resulted in symptomatic improvements which reached statistical significance compared to double-blinded placebo and study controls. . . . Follow-up studies have shown clinical efficacy effects lasting up to 7½ years after a single treatment." (ECF No. 32-7, Ex. D to Stroup Decl. ("2013 Form 20-F") at 15.)

In 2009, the Company began two large Phase 3 studies of NX-1207: NX02-0017 and NX02-0018 (collectively the "Phase 3 Studies"). (AC ¶ 26.) According the Company, the Phase 3 Studies specifically "incorporate[d] the specific protocol design recommendation provided to the [Company] by the FDA." (2013 Form 20-F at 15.) Both NX02-0017 and NX02-0018 were designed to include 500 men, who participated in their respective study for one year. (AC ¶¶ 26-27.) The Company completed patient enrollment for NX02-0017 in November 2012 and NX-0018 in May 2013. (AC ¶¶ 63, 68.)

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[2] The FDA is responsible for granting approval for new drugs. (AC ¶ 20.) In order to obtain approval, FDA regulations require the successful completion of three clinical trial phases, which assess the safety and efficacy of the drug. 21 C.F.R. § 312.21. Phase 1 studies are conducted generally on a group "rang[ing] [from] 20 to 80" healthy subjects and are designed mainly to test safety concerns. 21 C.F.R. § 312.21(a); ECF No. 32-27, Ex. X to Stroup Decl., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, *avail. at* www.fda.gov ("Ex. X"). Phase 2 studies largely attempt to evaluate the drug's efficacy by obtaining preliminary data on "no more than several hundred subjects" who have the condition under study. 21 C.F.R. § 312.21(b); Ex X. These studies typically compare patients receiving the drug to another group receiving a different treatment, or a placebo. *Id.* Phase 3 studies normally are expanded to "several hundred to several thousand subjects." 21 C.F.R. § 312.21(c); Ex X. Phase 3 studies also use a comparative framework and are intended to gather additional information about the drug's safety and efficacy. *Id.* Lead Plaintiffs allege that it is the generally accepted industry standard and consistent with industry best practice for a sponsor to unblind Phase 3 study results as soon as they are available upon completion of the study. (AC ¶ 24.)

Lead Plaintiffs claim that enrollment of 1000 men in the two Phase 3 Studies was a "very slow and difficult process" and allege that in order to "keep the market's interest in NX-1207 during the lengthy enrollment process and to obfuscate the problems with design and conduct of the two Phase 3 studies" Defendants "began a campaign to disseminate as much positive information about NX-1207, focusing on the two ongoing Phase 3 Studies and the results of prior, smaller, shorter Phase 2 studies of NX-1207." (AC ¶ 28.) Lead Plaintiffs allege that the misrepresentations were made "through the publication of News Releases and reporting on positive presentations at meetings of the American Urological Association made by 'friendly' doctors, as well as through SEC filings." (AC ¶ 28; *see* AC ¶¶ 29, 31, 34, 36, 38, 40, 42, 44, 46, 48, 49, 51, 53, 55, 57, 59, 61, 63, 65, 66, 68, 70, 71, 73, 74, 76.)

On Sunday, November 2, 2014, the Company issued a press release stating as follows:

> Nymox Pharmaceutical Corporation (NASDAQ: NYMX) announced today that the Company's two Phase 3 U.S. studies of NX-1207 for the treatment of BPH, NX02-0017 and NX02-0018, failed to meet their primary efficacy endpoints. Full results will be reported at a later date. The Company will hold a teleconference for shareholders on Monday, November 3, 2014 at 4:30 pm Eastern Time. . . .
>
> Nymox CEO, Paul Averback, said, "The two studies failed to meet the pre-specified efficacy endpoints. Drug safety was acceptable. Drug efficacy reached levels similar to earlier studies but was not statistically significant in comparison to the placebo control due to a higher placebo response than in earlier NX-1207 studies and in other placebo-controlled BPH studies. The compound remains promising for low grade localized prostate cancer where the Phase 2 results showed evidence that NX-1207 treatment had a positive effect on biopsy results and clinical and biochemical progression."

(AC ¶ 78.) On November 3, 2014, the Company's common stock price fell 82% to $0.93 per share on trading volume of 19.6 million shares. (AC ¶ 13.) Averback participated in the

conference call after the market closed on November 3, 2014. (*See* ECF No. 32-22, Ex. S to Stroup Decl., Certified Transcript of Nymox's Shareholder Teleconference dated November 3, 2014 ("Nov. 3, 2014 Tr.").)

Lead Plaintiffs allege that the factual reasons given for failure of the Phase 3 Studies by Averback on the November 3, 2014 conference call were all facts known to Defendants at the beginning of, and throughout the Class Period. (AC ¶ 9, 80.) In particular, the Amended Complaint alleges that, during the Class Period, Defendants knowingly failed to disclose or misrepresented in public statements that:

a. by November 2013, the drug had failed to show statistical significance in the first Phase 3 trial;

b. the design of the Phase 3 studies was faulty in that it would lead to the exclusion of those BPH patients with more serious conditions, thereby increasing the likelihood that the difference in effect between placebo and drug would be minimized and would cause significant if not overwhelming difficulties in patient enrollment and continued patient participation for the required year-long period causing substantial delays in the completion of the studies;

c. the design of the Phase 3 Studies would cause significant difficulties in accurately measuring the difference in effect of the drug and the placebo on the patients due to the highly subjective questionnaire each participant had to complete which was the end point, that is, the only measure of the drug's effect on the patient;

d. the design of the Phase 3 Studies, both of which relied solely on highly subjective questionnaires to be completed by the participants as the only end point, rendered

results from prior studies of NX-1207 inherently unreliable markers or predictors of results in the Phase 3 Studies; and,

e. the design of the Phase 3 Studies, in which the placebo was an injection of saline solution directly into the prostate, negated the standard role of a placebo in the Phase 3 Studies and increased the placebo effect, which presaged the failure of the drug in the Phase 3 Studies due to a higher placebo effect.

(AC ¶¶ 9, 80.)

PROCEDURAL BACKGROUND

This action was commenced on November 24, 2014. (ECF No. 1.) By Opinion and Order dated February 26, 2015, this Court appointed Lead Plaintiffs, Lead Counsel, and Liaison Counsel. (ECF No. 17.) In accordance with scheduling stipulations and Orders (ECF Nos. 24, 35): Lead Plaintiffs filed the Amended Complaint on June 9, 2015 (ECF No. 25); Defendants filed the instant motion to dismiss on August 10, 2015 (*see* ECF No. 32-1 ("Mov. Br.")); Lead Plaintiffs filed opposition on October 23, 2015 (ECF No. 36 ("Opp. Br.")); and Defendants replied on December 14, 2015 (ECF No. 41 ("Reply Br.")). The motion is now ripe for resolution.

LEGAL STANDARD

To withstand a motion to dismiss for failure to state a claim, "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)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

To determine the sufficiency of a complaint under *Twombly* and *Iqbal* in the Third Circuit, the court must take three steps: first, the court must take note of the elements a plaintiff must plead to state a claim; second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth; finally, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief. *See Connelly v. Lane Const. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (citations omitted). "In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of the public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010).

The Court's role is not to determine whether the non-moving party "will ultimately prevail" but whether that party is "entitled to offer evidence to support the claims." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). The Court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64.

ANALYSIS

A. Section 10(b) and Rule 10b–5 of the Securities Exchange Act

Section 10(b) of the Securities Exchange Act of 1934 prohibits the "use or employ[ment], in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Rule 10b–5, promulgated by the Securities and Exchange Commission, makes it unlawful

> (a) To employ any device, scheme, or artifice to defraud,
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b–5.

To state a claim under § 10(b) and Rule 10b–5, a plaintiff must allege that defendants: "[1] made a misstatement or an omission of material fact [2] with scienter [3] in connection with the purchase or the sale of a security [4] upon which plaintiff reasonably relied and [5] plaintiff's reliance was the proximate cause of their injury." *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 251 (3d Cir. 2009) (quoting *Winer Family Tr. v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007)). Furthermore, "[a] corporation is liable for statements by employees who have apparent authority to make them." *Id.* (quoting *Makor Issues & Rights, Ltd. v. Tellabs Inc. (Tellabs II)*, 513 F.3d 702, 708 (7th Cir. 2008)).

Additionally, Lead Plaintiffs must meet the heightened pleading requirements under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act

("PSLRA"). *See City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 168 (3d Cir. 2014). Rule 9(b) provides, in relevant part, as follows: "In alleging fraud . . . , a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Thus, at a minimum, "plaintiffs [must] support their allegations of securities fraud with all of the essential factual background that would accompany 'the first paragraph of a newspaper story'-that is, the 'who, what, when, where and how' of the events at issue." *In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 147 (3d Cir. 2004) (citation omitted).

Similarly, as per the PSLRA, a plaintiff must satisfy heightened pleading requirements and "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313, 321 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12 (1976), and citing 15 U.S.C. § 78u–4(b)(1), (2)). First, with regard to misleading statements and omissions of material fact, a plaintiff must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omissions is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u–4(b)(1). Further, the statement must have been misleading at the time it was made, as "liability cannot be imposed on the basis of subsequent events." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002). Additionally, "when assessing the sufficiency of allegations made on information and belief pursuant to 15 U.S.C. § 78u–4(b)(1)," "plaintiffs need only plead with particularity *sufficient* facts to support those beliefs." *California Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146 (3d Cir. 2004) (adopting *Novak v.*

Kasaks, 216 F.3d 300 (2d Cir. 2000)). In other words, the facts alleged must be "sufficient to support a reasonable belief as to the misleading nature of the statement or omission." *Id.*

As to the second requirement of scienter—the intent to deceive, manipulate, or defraud investors—"each act or omission alleged to violate [Section 10(b)], [must] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u4(b)(2).[3] In evaluating whether a complaint meets this requirement, a court is required to consider inferences urged by the plaintiff as well as "competing inferences rationally drawn from the facts alleged." *Tellabs*, 551 U.S. at 314. A "strong" inference is "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent. . . . The inference . . . need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" *Id.* at 314, 324. A court must consider the entirety of a complaint in determining "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets this standard." *Tellabs*, 551 U.S. at 322; *see also Avaya,* 564 F.3d at 273. The Third Circuit permits a plaintiff to satisfy this requirement with allegations of strong circumstantial evidence of either conscious behavior or recklessness. *S.E.C. v. Infinity Grp. Co.*, 212 F.3d 180, 192 (3d Cir. 2000); *see also In re Radian Sec. Litig.*, 612 F.Supp.2d 594, 607 (E.D. Pa. 2009) (noting that although in *Tellabs* the Supreme Court specifically reserved the question of whether recklessness could give rise to civil liability under 10b–5, "every court of appeals to consider the issue has held that a plaintiff can meet the scienter requirement by showing that a defendant acted intentionally or recklessly.") In this context,

[3] To the extent that the PSLRA's scienter pleading requirements conflict with those of Federal Rule of Civil Procedure 9(b), the PSLRA supersedes the latter as it relates to Rule 10b–5 actions. *See Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir.2009); *see also Alpharma*, 372 F.3d at 148.

recklessness is "highly unreasonable [conduct], involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *S.E.C. v. Infinity Grp. Co.*, 212 F.3d at 192. Additionally, although motive or opportunity "may no longer serve as an independent route to scienter," *Avaya*, 564 F.3d at 277-78, "personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325.

Aside from the two requirements pertaining to the facts surrounding the alleged violation and scienter, the PSLRA imposes additional burdens with respect to allegations involving forward-looking statements. The PSLRA's Safe Harbor provision, 15 U.S.C. § 78u-5(c), "immunizes from liability any forward-looking statement, provided that: the statement is identified as such and accompanied by meaningful cautionary language; or is immaterial; or the plaintiff fails to show the statement was made with actual knowledge of its falsehood." *Avaya*, 564 F.3d at 254.[4] However, a "'mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present.'" *Id.* at 255 (quoting *Tellabs II*, 513 F.3d at 705). If the statement is forward looking, cautionary language must be extensive yet specific and touch upon the subject matter of the alleged misrepresentation in order for the safe harbor to apply. *See Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000) ("[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary

[4] The Court also notes that the "bespeaks caution" doctrine is relevant to interpreting the PSLRA safe harbor. *Avaya*, 564 F.3d at 254-56; *see also In re Anadigics, Inc., Sec. Litig.*, Civil Action No. 08-5572, 2011 WL 4594845, at *10 n.4 (D.N.J. Sept. 30, 2011) (noting that the Third Circuit Court of Appeals has "incorporated much of the [bespeaks caution] doctrine into its analysis of the PSLRA") (citing *Nat'l Junior Baseball League v. Pharmanet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 533-34 (D.N.J. 2010))).

statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge.") (quoting *In re Trump Casino Sec. Litig.*, 7 F.3d 357, 371-72 (3d Cir.1993)); *see also Avaya, Inc.*, 564 F.3d at 256 (3d Cir. 2009) (reiterating same). Thus, boilerplate language that merely warns readers of the risks associated with investing is generally insufficient. *Id.* Cautionary language in SEC filings "may be incorporated by reference" into the document containing the forward-looking statement, and need not be contained within the same document as the forward-looking statement itself. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 282 (3d Cir. 2010) (quoting *In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 273 n.11 (3d Cir. 2005)).

Defendants generally do not dispute that the following elements of the cause of action are properly pleaded: materiality, reliance, loss causation, and damages. Falsity, loss causation, and scienter are disputed. The Court sets forth the arguments for each below, but analyzes scienter only because the Court concludes that that the Amended Complaint fails to satisfy the heightened scienter pleading requirements under the PSLRA.

1. Falsity

The Amended Complaint contains a section entitled "Class Period Statements" which sets forth in block quotations the particular statements (press releases, public filings, etc.) alleged to contain misstatements or omissions of material fact. (*See* AC at 16-54, ¶¶ 29, 31, 34, 36, 38, 40, 42, 44, 46, 48, 49, 51, 53, 55, 57, 59, 61, 63, 65, 66, 68, 70, 71, 73, 74, 76.)[5] Lead Plaintiffs assert that, in essence, their claims are that "Defendants knew, at the outset of the Phase 3 trials,

[5] As an initial matter, the Court agrees with Lead Plaintiffs that the Amended Complaint satisfies Rule 9 and PSLRA's particularity requirements. Even though the block quotations utilized by Lead Plaintiffs do not identify the precise language at issue, the quotations are followed by explanatory paragraphs that explain why Lead Plaintiffs believe the particular statement is false or misleading.

that significant obstacles existed to a successful outcome from the start, but chose to conceal these obstacles." (Opp. Br. at 14.) Upon review of the Amended Complaint, the Court agrees with Defendants that the claims generally fall into two buckets surrounding the Phase 3 Studies: design and conduct. With respect to "design," the thrust of Lead Plaintiffs' claims is that the Company knew or should have known that the Phase 3 Studies were destined to fail due to the design of the studies: fulfilling enrollment was difficult because of the one-year enrollment and requirement that the subjects not undergo any additional treatment; prior studies did not provide "reliable markers" for the Phase 3 Studies given the reliance in Phase 3 on subjective questionnaires; and the placebo effect was significantly higher than in previous studies. (*See* AC ¶¶ 29, 31, 34, 36, 38, 40, 42, 44, 46, 48, 49, 51, 53, 55, 57, 59, 61, 65, 66.) With respect to "conduct," the general allegations are that Defendants stalled in releasing the Top-Line results from the Phase 3 Studies so that they could be manipulated in a way to make it appear that the studies were a success. (*See* AC ¶¶ 5, 63, 68, 70, 71, 73, 74, 76.) Defendants argue that Lead Plaintiffs have failed to adequately allege falsity due to application of the Safe Harbor and because of failure to establish that any of the statements were actually false or misleading when made.

Defendants first move to dismiss the Amended Complaint on grounds that the challenged statements fall within the Safe Harbor for forward-looking statements. (Mov. Br. at 10-15.) Specifically, Defendants contend that the statements notified investors about the existence of forward-looking statements and the inherent risks of drug development and incorporated by reference the detailed Risk Factors in the Company's periodic filings. (*Id.*) As an example, Defendants point to two Risk Factors set forth in the Company's filings, entitled "Our Clinical

Trials for Our Therapeutic Products, Such as NX-1207, May be Delayed, Making it Impossible to Achieve Anticipated Development or Commercialization Timelines" and "Our Clinical Trials for Our Therapeutic Products in Development, Such as NX-1207, May Not Be Successful and We May Not Receive the Required Regulatory Approvals Necessary to Commercialize These Products." (*Id.* at 13-14.)[6] Defendants claim that in light of these "substantive and specific warnings (plus, subsequent disclosures), any statements regarding the 'design and conduct of the two Phase 3 Studies' that Plaintiff could have identified in the press releases block-quoted in the Amended Complaint (but did not), are forward-looking statements shielded by the Reform Act's safe harbor." (*Id.* at 15.)

In opposition, Lead Plaintiffs assert that that the statements in question were not forward-looking because the risks being warned of had already come to pass at the time the statements were made, such that the Safe Harbor is inapplicable. (Opp. Br. at 15-18.) Lead Plaintiffs contend that Defendants' reliance on Risk Factors that "may" occur is misplaced because the allegations contained in the Amended Complaint focus on misleading and incomplete statements containing information already existing and already known to Defendants. (*Id.* (citing *In re Cell Pathways, Inc. Secs. Litig.*, 2000 U.S. Dist LEXIS 8584 (E.D. Pa. June 20, 2000).) According to Lead Plaintiffs, the issues acknowledged by Averback on the November 3, 2014 conference call—*i.e.*, heightened placebo effect, difficulty achieving enrollment (including exclusion of "sicker" patients), and subjective questionnaires—demonstrate that the statements in question were not forward-looking. (*Id.* at 17-18.)

Defendants also argue that the Amended Complaint should be dismissed because of a

[6] For the full extent of the Risk Factors, *see* 2010 Form 20-F at 5; ECF No. 32-5, Ex B. to Stroup Decl. ("2011 Form 20-F") at 5; ECF No. 32-6, Ex C. to Stroup Decl. ("2012 Form 20-F") at 5; 2013 Form 20-F at 5; ECF No. 32-9, Ex F. to Stroup Decl. ("2014 Form 20-F") at 5.)

failure to plead facts showing that any statement was materially false or misleading when made. (Mov. Br. at 15-23; Reply Br. at 2-7.) With respect to the "design"-related statements, Defendants contend that Lead Plaintiffs are essentially trying to plead fraud by hindsight since the Amended Complaint lacks particularity and instead states only in conclusory fashion that Defendants knew of the design flaws of the Phase 3 Studies. (Mov. Br. at 15-17.) In fact, according to Defendants, the full, certified transcript of the November 3, 2014 conference call undermines the allegations in the Amended Complaint. (Mov. Br. at 17-18.) Furthermore, Defendants argue that the securities laws do not permit second-guessing of the design methodology of a clinical trial, and that any such claims are nothing more than a plaintiff's criticism and personal opinion of how it should have been different. (Mov. Br. at 19-20 (citing *In re Keryx Biopharmaceuticals, Inc. Securities Litigation*, Nos. 13-755 and 13-1307, 2014 WL 585658 (S.D.N.Y. Feb. 14, 2014).) With respect to "conduct"-related statements (*i.e.*, that Defendants stalled in releasing the Top-Line results), Defendants point to multiple public filings and the transcript of the November 3, 2014 conference call to discredit these claims. (Mov. Br. at 20-22, 23.) Additionally, Defendants dispute Lead Plaintiffs' statement that it is "generally accepted industry standard and consistent with industry best practice" to unblind Top-Line Phase 3 study results as soon as they are available. (Mov. Br. at 22.)

In opposition, Lead Plaintiffs argue that the Amended Complaint sufficiently pleads that Defendants' Class Period statement were false when made. (Opp. Br. at 19-21.) In essence, Lead Plaintiffs assert that the Amended Complaint alleges that highly material information, that would have significantly reduced public expectations that the Phase 3 Studies would yield successful results, was repeatedly omitted from Class Period statements. (*Id.*) For example,

Lead Plaintiffs state that Class Period statements were false and misleading when made because they failed to mention the following, all of which increased the likelihood of clinical failure: that using a procedure of directly injecting saline into the prostate as a placebo would increase the placebo effect (*id.* at 19); that a one-year study that simultaneously prohibited alternative treatments would be difficult to fill and would reduce the number of "sicker" patients in the studies (*id.* at 19-20); that reliance on highly subjective questionnaires increased the likelihood of increased placebo effect (*id.* at 20); and that the Phase 3 Studies were qualitatively different from earlier trials (*id.*). In sum, Lead Plaintiffs "agree that Defendants were free to design any kind of study they wanted" but state that Defendants "were not free to . . . make positive statements about the drug and the progress of those Phase 3 studies, yet at the same time omit material adverse information about the severe impairment to any chance of Phase 3's success due to factors inherent in the studies' design." (*Id.* at 21.) Lead Plaintiffs assert that the "factual reasons" given by Averback on the November 3, 2014 conference call for the failure of the Phase 3 Studies "were all facts known to, or recklessly disregarded by defendant Averback and Nymox through the Class Period, as Averback effectively admitted on the conference call, but which Defendants intentionally chose to conceal and misrepresent throughout the Class Period." (*Id.* at 5 (citing AC ¶¶ 9, 79).)

Although the Court has serious doubts as to whether Lead Plaintiffs have sufficiently pled falsity, because the Court finds that the Amended Complaint fails to satisfy the heightened scienter pleading requirements under the PSLRA and that dismissal is warranted on that basis, it need not address the falsity arguments.

2. Loss Causation

The Amended Complaint alleges that the price of Nymox common stock "fell precipitously, declining an aggregate 82%" on November 3, 2014, as a "direct result" of the disclosures on November 2, 2014 (press release) and November 3, 2014 (conference call). (AC ¶¶ 85, 87.) However, the Amended Complaint acknowledges that the November 3, 2014 conference call occurred after the market had closed, such that disclosures made during the conference call could not have affected the price of the stock during market hours on November 3, 2014. (*Id.* ¶ 79.)

In a fraud on the market case (as pled here), "a plaintiff may establish the element of loss causation simply by showing that he or she purchased a security at a market price that was artificially inflated due to a fraudulent misrepresentation." *Semerenko v. Cendant Corp.*, 223 F.3d 165, 184 (3d Cir. 2000) (citing *Scattergood v. Perelman*, 945 F.2d 618, 624 (3d Cir. 1991)). However, "[b]ecause a plaintiff in an action under § 10(b) and Rule 10b–5 must prove that he or she suffered an actual economic loss, . . . an investor must also establish that the alleged misrepresentations proximately caused the decline in the security's value to satisfy the element of loss causation." *Semerenko*, 223 F.3d at 185.

Defendants argue that loss causation cannot be established for the disclosures made during the November 3, 2014 conference call because the conference call occurred after the market had closed. (Mov. Br. at 29-30.) Defendants accordingly request that "all allegations pertaining to the purported 'misrepresentations and omissions' about the Phase 3 studies that were 'revealed to investors and the market' during the November 3, 2014 conference call should be dismissed." (*Id.* at 30.)

In opposition, Lead Plaintiffs contend that they have sufficiently alleged loss causation since the statements made by Averback on the November 3, 2014 conference call merely "shed light" on the misstatements made during the Class Period. (Opp. Br. at 29-30.) In other words, Lead Plaintiffs assert that the explanations given on the conference call as to why the Phase 3 Studies failed do not negate their core allegations that they purchased Nymox common stock at an inflated price due to the misrepresentations made during the Class Period regarding the Phase 3 Studies. (*Id.*)

Again, because the Court finds that the Amended Complaint fails to satisfy the heightened scienter pleading requirements under the PSLRA and that dismissal is warranted on that basis, it declines to address this issue.

3. Scienter

Defendants move to dismiss the Amended Complaint on grounds that Lead Plaintiffs have failed to adequately plead scienter. (Mov. Br. at 23-29; Reply Br. at 7-11.) First, Defendants argue that the Amended Complaint fails to adequately allege motive and opportunity, since neither operational funding nor Averback's stock sales demonstrate a sufficient motive. (Mov. Br. at 24-27.) Second, Defendants contend that the competing inference of non-fraudulent intent is more compelling than an inference of scienter. (Mov. Br. at 27-29 (citing *Tellabs*, 551 U.S. at 314).)

In opposition, Lead Plaintiffs argue that the Amended Complaint, when viewed holistically, adequately pleads allegations of scienter. (Opp. Br. at 21-29.) Specifically, Lead Plaintiffs contend that Defendants were at least reckless for not disclosing the heightened placebo effect resulting from an injectable placebo and subjective questionnaires, and that

enrollment difficulties were skewing the results by reducing the number of "sicker" participants in the Phase 3 Studies. (Opp. Br. at 22-24.) Lead Plaintiffs assert that the "core operations doctrine" allows the Court to impute knowledge of these alleged defects to senior management. (*Id.* at 24.) Additionally, Lead Plaintiffs argue that when accepting the Amended Complaint as true, the Court can infer scienter from Defendants' allegedly stalling the release of the Phase 3 Tope-Line results. (*Id.* at 25.) Furthermore, Lead Plaintiffs concede that although "goals and aspirations" to maintain a high stock price are insufficient in and of themselves to establish scienter, they contend that this case is different because the very viability of the Company was dependent on maintaining a high stock price, and thus ensuring the success of the Phase 3 Studies. (*Id.* at 26-28.) Finally, Lead Plaintiffs argue that the strong inference of scienter is at least as compelling as any other inference. (*Id.* at 28-29.)

As noted, "each act or omission alleged to violate [Section 10(b)], [must] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind [*i.e.*, scienter]." 15 U.S.C. § 78u4(b)(2). Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). In evaluating whether a complaint meets this requirement on a Rule 12(b)(6) motion, a court must accept all factual allegations in the complaint as true, consider the complaint in its entirety and other documents properly before the court, and compare "plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs*, 551 U.S. at 322-24. "The inference . . . need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the 'most plausible of competing inferences,'" but it "must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other

explanations." *Id.* at 324. "The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts?" *Id.* Again, a court must consider the entirety of a complaint in determining "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets this standard." *Tellabs*, 551 U.S. at 322; *see also Avaya,* 564 F.3d at 273. Ultimately, a complaint will survive "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*, 551 U.S. at 324.

The Third Circuit permits a plaintiff to demonstrate with allegations of strong circumstantial evidence of either conscious behavior or recklessness. *S.E.C. v. Infinity Grp. Co.*, 212 F.3d 180, 192 (3d Cir. 2000); *see also In re Radian Sec. Litig.*, 612 F.Supp.2d 594, 607 (E.D. Pa. 2009) (noting that although in *Tellabs* the Supreme Court specifically reserved the question of whether recklessness could give rise to civil liability under 10b–5, "every court of appeals to consider the issue has held that a plaintiff can meet the scienter requirement by showing that a defendant acted intentionally or recklessly.") In this context, recklessness is "highly unreasonable [conduct], involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *S.E.C. v. Infinity Grp. Co.*, 212 F.3d at 192. Additionally, although motive or opportunity "may no longer serve as an independent route to scienter," *Avaya*, 564 F.3d at 277-78, "personal financial gain may weigh heavily in favor of a scienter inference." *Tellabs*, 551 U.S. at 325.

The Court finds that, when considered holistically, the Amended Complaint fails to give rise to a strong inference that Defendants acted with scienter. In essence, Lead Plaintiffs' theory is that Defendants knew all along that the Phase 3 Studies were unlikely to succeed but concealed this information in order to prolong the viability of the Company. In contrast, Defendants suggest that the facts point to a more benign explanation: that Defendants designed the Phase 3 Studies with input from the FDA in a manner they thought was appropriate; that they kept the market abreast of the studies' progress through press releases and other filings; and that Defendants immediately revealed the disappointing results of the Phase 3 Studies when they became available. The Court finds that when comparing the competing inferences, the opposing inference of non-fraudulent intent is more compelling than an inference of scienter. In other words, when viewing all of the facts collectively, a reasonable person would not deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged. *See Tellabs*, 551 U.S. at 324.

First, the Court notes that Amended Complaint fails to cite a single document or witness that corroborates allegations of scienter. Although, admittedly not necessary to state a claim, the Court is cognizant that "'omissions and ambiguities count against inferring scienter' under the PSLRA's particularity requirements." *Avaya*, 564 F.3d at 263 (quoting *Tellabs*, 551 U.S. at 326).

Second, the Court is not convinced that allegations surrounding the design and conduct of the Phase 3 Studies necessarily support an inference of scienter. For example, with respect to allegations that Defendants "must have" withheld the Phase 3 Top-Line results, Lead Plaintiffs rely on two press releases. Specifically, Lead Plaintiffs point to a November 28, 2012 press

release in which the Company announced completion of enrollment for the NX02-0017 study and that they "expected" Top-Line results in "late 2013." (AC ¶ 63.) Similarly, Lead Plaintiffs rely on a May 3, 2013 press release in which the Company announced completion of enrollment for the NX02-0018 study and that they "expected" Top-Line results in "early 2014." (AC ¶ 68.) The Amended Complaint concludes that Defendants "must have" received the Top-Line results in these "expected" time frames, and that they withheld the results in defiance of "industry standard" and best practice," which demonstrates scienter according to Lead Plaintiffs. (*See* AC ¶¶ 7, 24.)

As an initial matter, it is not clear that withholding the Top-Line results supports an inference of scienter. Although Lead Plaintiffs allege that it is "industry standard" and "best practice" to immediately unblind Phase 3 study results as soon as they are available (AC ¶ 24), Defendants correctly point out that Lead Plaintiffs fail to support this allegation with any relevant FDA regulation. Furthermore, the Court is not convinced that a general allegation that a defendant violated industry standard and best practice, without more, can support a securities fraud claim. *See In re Milestone Sci. Sec. Litig.*, 103 F. Supp. 2d 425, 470 (D.N.J. 2000) (allegations that Defendants acted with scienter because they violated generally accepted accounting principles insufficient).

More significantly, the allegations that Defendants withheld the results are undermined by other documents properly before the Court, leading the Court to conclude that the inference of scienter is far less compelling than the opposing, non-fraudulent inference. Although on the one hand courts generally must "accept all factual allegations in the complaint as true," *Tellabs*, 551 U.S. at 322, in the Third Circuit, allegations that are "no more than conclusions," as here, "are

not entitled to the assumption of truth." *See Connelly v. Lane Const. Corp.*, No. 14-3792, --- F.3d ---, 2016 WL 106159, at *4 (3d Cir. Jan. 11, 2016) (citations omitted). This is especially true when the allegations are directly contradicted by "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice," such as SEC filings, press releases, and earnings call transcripts. *See Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007) (citing *Tellabs*, 551 U.S. at 322). Indeed, as this Court has previously held, "[w]hen allegations contained in a complaint are contradicted by the document it cites, the document controls." *In re PDI Sec. Litig.*, No. 02-0211, 2005 WL 2009892, at *21 (D.N.J. Aug. 17, 2005). In sum, for purposes of the comparative scienter inquiry, the Court takes into consideration "*all* of the facts alleged, taken collectively"—including whether allegations are contradicted by other documents properly before the Court. *Tellabs*, 551 U.S. at 322.

Putting aside whether the Company's expectations about when they would receive the Top-Line results are forward-looking statements, Lead Plaintiffs' allegations that Defendants "must have" withheld the Top-Line results are contradicted by other documents properly before the Court, specifically subsequent public filings (of which the Court may take judicial notice) and the November 3, 2014 conference call transcript (which is explicitly incorporated into the Amended Complaint by reference). As noted, Lead Plaintiffs rely on press releases dated November 28, 2012 and May 3, 2013 to support their conclusion that Defendants withheld the Phase 3 Top-Line results. (AC ¶¶ 63, 68.) However, as late as August 11, 2014, Defendants publicly disclosed in a Form 6-K filed with the SEC that they were still awaiting the Phase 3 Top-Line results:

> In June 2009, Nymox started the first of two pivotal double blind placebo controlled Phase 3 trials for NX-1207 that incorporated

> specific protocol design recommendations provided by the FDA. The two pivotal Phase 3 studies for NX-1207 were conducted at well-known investigational sites across the U.S. with a total enrollment of approximately 1,000 patients. Patient enrollment and participation was completed in December 2013 for the NX02-0017 study and in May 2014 for the NX02-0018 study. Data verification and auditing procedures are in progress for these studies with unblinding and top line analysis of efficacy and safety data to follow once these procedures have been concluded.

(ECF No. 32-8, Ex. E to Stroup Decl. ("Q1'2014 Form 6-K") at 1; *see also* ECF No. 32-20, Ex. Q to Stroup Decl. ("Jan. 28, 2014 News Release") ("unblinding and data analyses of the two [Phase 3 Studies] will commence at the appropriate time in Q2 2014 with top line results being reported expeditiously when available").)[7] Additionally, on the November 3, 2014 conference call, Averback repeatedly stated that the Company had only received the Top-Line results a few days prior:

> the top-line data was made available to use for the first time at the end of last week. And, of course, as soon as we hand unblended data for the very first time, we immediately put out the top-line data to be – get it out as soon as possible to the public. And so we have not done the in-depth analysis that would answer some of the questions like what you just asked about the effect on skewing. And we just received the top-line from arm's length analysis and we've reported it in a dutiful immediate fashion. So that's an important background.

Nov. 3, 2014 Tr. 8:19-9:11; *see also id.* at 13:21-22 ("We just got the top-lines[.]"); *id.* at 39:9-40:4 (reiterating that the Company received the top-line results a few days prior, that they released them right away, and that they could not have gotten the results sooner); *id.* at 58:17-21 ("Our purpose today is to communicate to the public the top-line as soon as we get it and we just got it and that's as far as we know."); *id.* at 91:4-6 ("[W]e've communicated [the top-line data]

[7] The SEC filings and press releases are subject to judicial notice. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002). However, the Court makes clear that it is not relying on them for the truth of their contents, but only for their existence. *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000). In other words, what these documents state, regardless of truth, is relevant to the Court in considering scienter. *Tellabs*, 551 U.S. at 322.

as quickly as we could."); *id.* at 110:23-24 ("We only got [the top-line data] a couple of days ago[.]") In light of this, Lead Plaintiffs' conclusory allegations that Defendants "must have" withheld the Phase 3 Top-Line results do not support an inference of scienter.

Additionally, with respect to the design of the Phase 3 studies, the November 3, 2014 conference call also undermines Lead Plaintiffs' allegations that Defendants knew of design flaws all along but chose to conceal them. For example, with respect to the placebo effect:

> Q: And it sounds like the placebo level, you were really -- it sounds like you were kind of blindsided. Just from what you've said and what I've inferred from your tone, that you -- you were pretty shocked at the results, I guess; right.
>
> A: Yeah. I could -- I could tell you in a hundred different ways how shocked we are.

(Nov. 3, 2014 Tr. at 69:9-20.)

> Q: [D]o you have an idea of why the placebo behaved differently in this trial than it did in the Phase 2s, and in retrospect, is there something you could have done in designing the trial that would have dampened down the effect?
>
> A: [T]here are a number of approaches that people take to try and dampen placebo effect . . . . We had never encountered any problems before and we didn't want to further complicate our studies because it took long enough to do. Nobody has ever successfully enrolled a thousand people for an injectable prostate study where you had to do placebos before and the more barriers you put in, the more difficulty there would have been to enroll such a large number of people. In the U.S., I'm referring. So yes, there -- there are things that one could try with -- to dampen it, as you say, but none had been identified before and there's no guarantee that they would have helped, but some of the placebos responses are clearly troublesome that were so off the dial that it's hard to imagine that -- that there's any validity to them, but this -- this will be things that we'll be examining in-depth starting right away. . . .
>
> Q: Do you know why [the heightened placebo effect] happened in

these Phase 3 trials when it didn't seem to happen in the Phase 2's?

A: At this point, I can't give you an answer to that. We just got the top-lines and we'll be looking into that and hopefully we'll find something.

(*Id.* at 11:12-13:24.)

Unfortunately, we didn't beat the placebo on it and so we're trying to do a little postmortem here, trying to understand what went wrong and we're making hypothesis, but we can't be sure and we certainly don't want to be perceived as saying that the measuring stick was unfair or that there's anything like that. We didn't beat it and we didn't beat it. That's all there is to it. Now, trying to understand it, we will work hard on that and the goal for that will be to see, can we design something that won't be quite as susceptible to these types of -- of random risks? But you can talk to 50 urologists, they'll all tell you that the symptom score is very subjective and half of them don't believe in it, but that's just the lay of the land. There's nothing better.

(*Id.* at 81:10-82:9.) When asked about the use of a subjective questionnaire, Dr. Averback continued:

Well, there's all kinds of errors and limitations in the field, but we can't change that. These are the standard accepted ways, at least right now, that this is how it's done. And the authorities want standard things for good reasons. They want to compare them to what other modalities have done in the past.

(*Id.* at 34:4-35:8.). In addressing the design of the Phase 3 Studies, Averback stated:

[NX-1207] had undergone U.S. studies in the past using many of the same investigational sites and using the same formulations and using the same -- very similar protocol. So we -- you know, our goal was to just take what we'd done before and just repeat it in larger numbers and then it was all agreed that if it -- if it did that we would have a good dossier for approval. Unfortunately, we did repeat it, but the placebo did better than what we'd seen before and, in fact, did much better that we've seen in other studies as well and that's -- that's the long and short of it.

(*Id.* at 55:23-56:17.) These passages undermine Lead Plaintiff's inference of scienter, and in fact

lend support to the competing non-fraudulent inference. Rather than showing that Defendants knew all along that the Phase 3 Studies were destined to fail, the transcript demonstrates that Averback's comments were grounded in "20/20 hindsight." (*Id.* 49:15.)[8]

Third, allegations concerning Averback's stock sales and the Company's need for continued operational funding do not convince the Court that Defendants possessed the requisite state of mind. Although not explicitly framed as indicative of scienter, the Amended Complaint notes that Averback "reduc[ed] his investment in the Company" during the Class Period. (AC ¶ 19.) When taking stock options into consideration, Averback sold less than 5.9% of his available shares during the three-plus year Class Period. Stock he sold for $4.4 million would have been worth only $767,000 immediately after the Phase 3 failure; at the same time his retained shares lost over $62.8 million in value immediately after the Phase 3 failure. Stock sales that are "unusual in scope or timing . . . may support an inference of scienter." *In re Advanta*, 180 F.3d at 540 (citing *In re Burlington Coat Factory*, 114 F.3d at 1424) (internal citations and punctuation marks omitted); *see also In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 152 (3d Cir. 2004) (reviewing complaint for allegations that stock sales were "unusual in scope (*e.g.*, compared to their total level of compensation or the size of previous sales) or timing (*e.g.*, compared to the timing of past trades)"). Here, he Amended Complaint does not specifically allege that Averback's sales were unusual in scope or timing, and there is nothing to suggest to the Court that they were, considering that Averback retained a large percentage of his holdings, and that he is compensated mainly in stock.

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[8] Additionally, although it did not factor into the present analysis, the Court notes that some judges are skeptical of allowing securities claims that are essentially premised on the design of clinical trials. *See In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, No. 13-1307, 2014 WL 585658, at *1 (S.D.N.Y. Feb. 14, 2014) ("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.").

Additionally, generalized motivations, such as maintaining a high stock price in order to fund operations, are insufficient to establish scienter. *See In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 284 (D.N.J. 2007) ("a plaintiff may not rely on facts indicating that the defendant had certain goals or aspirations (or sought to engage in the industry practices) common to the law-abiding business community, since such goals or practices cannot amount to a valid motive for the purposes of showing scienter.") (citing *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004). To be sure, it is relevant to the Court that NX-1207 is alleged to be the centerpiece of the Company. *In re Vicuron Pharm., Inc. Sec. Litig.*, No. 04-2627, 2005 WL 2989674, at *8 (E.D. Pa. July 1, 2005) ("[W]e note that anidulafungin was [defendant's] lead product in development, which in itself supports a finding of scienter for alleged misrepresentations as to it.") However, the Company's focus on NX-1207 must be balanced with the more generalized motivation for FDA approval. *See Koncelik v. Savient Pharm., Inc.*, No. 08-10262, 2010 WL 3910307, at *6 (S.D.N.Y. Sept. 29, 2010) *aff'd*, 448 F. App'x 154 (2d Cir. 2012) (holding that "the alleged motive to maintain the perception of [a] drug's approvability simply rises to a generalized motivation, and is not sufficiently concrete for purposes of inferring scienter.") (internal quotation marks and citation omitted). When viewing the operational funding component in light of the Amended Complaint in its entirety, the Court is not convinced that NX-1207's prominence within the Company's strategy is enough to infer scienter. Accordingly, the Court finds that Lead Plaintiffs' allegations that Defendants had "strong motive to obfuscate and forestall timely disclosure of the adverse material facts concerning the two Phase 3 Studies and the adverse results of those two Phase 3 Studies" in order to "fund ongoing operations" (AC ¶¶ 10, 12) do not support an inference of scienter.

In sum, when considering the Amended Complaint holistically and in a light most favorable to Lead Plaintiffs, the Court concludes that the competing inference of non-fraudulent is more compelling than an inference of scienter. Accordingly, the Court finds that Lead Plaintiffs have failed to state a claim under Section 10(b) and Rule 10b–5 of the Securities Exchange Act.

B. Control Person Claim Against the Officer Defendants under § 20(a) of the Securities Exchange Act

Section 20(a) of the Securities Exchange Act of 1934 creates a cause of action against individuals who exercise control over a "controlled person," including a corporation, that has committed a violation of Section 10(b). 15 U.S.C. § 78t(a); *In re Suprema*, 438 F.3d at 284. Accordingly, liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person. *Avaya*, 564 F.3d at 252; *In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 153 (3d Cir. 2004) ("[P]laintiffs must prove not only that one person controlled another person, but also that the 'controlled person' is liable under the Act.") (internal quotation marks omitted).

Because the Court has found Lead Plaintiffs have failed to state a claim for a violation of Section 10(b) and Rule 10b–5 of the Securities Exchange Act, it likewise finds that Lead Plaintiffs have failed to state a claim for control liability under Section 20(a). *See In re NUI Sec. Litig.*, 314 F. Supp. 2d 388, 418 (D.N.J. 2004). Accordingly, the Court will grant Defendants' Motion to Dismiss this claim.

DISMISSAL WITH OR WITHOUT PREJUDICE

Rule 15(a)(2) provides that leave to amend "should be freely given when justice so requires." Fed. R. Civ. P. 15(a)(2). However, "a court may deny leave to amend when such amendment would be futile"—*i.e.*, "the amended complaint would not survive a motion to dismiss for failure to state a claim." *Budhun v. Reading Hosp. & Med. Ctr.*, 765 F.3d 245, 259 (3d Cir. 2014) (citations omitted).

In light of the deficiencies identified by the Court in this Opinion, the Court believes that amendment may well be futile. However, in the interests of justice, if Lead Plaintiffs believe that amending the complaint would not be futile, they shall file a motion in accordance with the Local Rules for leave to amend within 14 days of the date of this Opinion and Order. Such motion shall set forth precisely what new allegations they would include in a consolidated second amended complaint to cure the deficiencies identified by the Court, and shall also include a copy of a proposed second amended complaint that is blacklined against the current Amended Complaint. Accordingly, dismissal shall be without prejudice at this time.

CONCLUSION

For the reasons above, the Court grants the Motion to Dismiss. An appropriate Order accompanies this Opinion.

DATED: February 10, 2016

JOSE L. LINARES
UNITED STATES DISTRICT JUDGE