NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RANDY SMITH, Plaintiff, v. ANTARES PHARMA, INC., *et al.*, Defendants.	Civil Action No. 17-8945 (MAS) (DEA) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court upon Defendants Robert F. Apple, Fred M. Powell, and Leonard S. Jacob's (collectively, "Individual Defendants") and Antares Pharma, Inc.'s ("Antares" or the "Company") Motion to Dismiss pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act ("PSLRA"). (ECF No. 59.) Lead Plaintiff Serghei Lungu ("Plaintiff") opposed (ECF No. 61), and Individual Defendants and Antares (collectively, "Defendants") replied (ECF No. 33). The Court has carefully considered the parties' arguments and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth herein, Defendants' Motion to Dismiss is granted.

I. BACKGROUND[1]

Plaintiff seeks to represent a class of persons who purchased Antares common stock between December 21, 2016 and October 12, 2017, inclusive (the "Class Period"). (Consol. Second Am. Class Action Compl. ("SAC") ¶ 1, ECF No. 46.) Antares is a company that develops, manufactures, and commercializes therapeutic products using drug delivery systems. (*Id.* ¶¶ 2, 3.) Individual Defendants were executives at Antares during the Class Period. (*See id.* ¶¶ 27–29, 120.)

The action principally arises from statements that Defendants made during the Class Period relating to product safety. Plaintiff alleges that Defendants misled investors by downplaying and misstating the incidence of certain adverse events[2]—hypertension, suicidality, and depression—observed in two Phase 3 clinical studies[3] of Antares's lead product, QuickShot Testosterone ("QST"). (*Id.* ¶ 7.) QST is an auto injector product designed for testosterone replacement therapy ("TRT"). (*Id.* ¶ 4.) It is currently approved by the Food and Drug Administration ("FDA") and marketed as Xyosted. (*Id.* ¶¶ 4, 161.)

According to Plaintiff, "[u]nbeknownst to investors throughout the Class Period, but known at all relevant times within the Company, the incipient [QST] [New Drug Application

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[1] For the purpose of deciding the instant motion, the Court accepts all well-pleaded factual allegations as true. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). The Court also "consider[s] documents incorporated into the complaint and take[s] judicial notice of SEC filings." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 163 n.3 (3d Cir. 2014) (internal citations omitted).

[2] "Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 312.32.

[3] Phase 3 studies "are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c).

("NDA")] was facing serious risks in regard to (a) the clinically meaningful increase noted in blood pressure (*i.e.*, hypertension); and (b) the instance of suicidality [and] depression." (*Id.* ¶ 97.) Defendants knew of QST's hypertension risk, "yet consciously sought to downplay its significance instead of disclosing the direct link between QST and elevated blood pressure that the FDA would ultimately force the Company to acknowledge." (*Id.* ¶ 102.) Defendants also inaccurately reported the instances of suicide and depression. (*Id.* ¶ 105.) Plaintiff alleges that Antares, accordingly, "overstated the approval prospects for [QST]" (*id.* ¶¶ 130, 133, 137, 139, 141, 144, 150) and artificially inflated Antares share prices (*id.* ¶¶ 25, 182, 186–87).

The relevant facts begin in July 2014 when Antares initiated its first Phase 3 study of QST, QST-13-003 (the "003 Study").[4] (*Id.* ¶ 70.) In 2015, members of the Company's executive team met to discuss results from the 003 Study. (*Id.* ¶¶ 120–21.) The meetings were usually held biweekly. (*Id.* ¶ 120.) The executive team included, Individual Defendants Apple and Powell, the Vice President of Clinical and Medical Affairs Jonathan Jaffe, Plaintiff's confidential witness ("CW1"), and others. (*Id.* ¶ 120.) CW1 was the Senior Vice President of Pharmaceutical Development, responsible for the non-clinical development of the company's pipeline. (*Id.* ¶¶ 109, 113.)

According to CW1, Apple moderated these meetings. (*Id.* ¶ 121.) "At several different staff meetings in 2015, Jaffe reported that some patients in the [QST] study showed an elevation of blood pressure." (*Id.* ¶ 123.) "At the same group meetings early in [the] [QST] study. . . . multiple

[4] Plaintiff alleges that Defendants "beg[a]n reporting" the 003 Study results to the NIH on June 6, 2014 (SAC ¶ 72); however, Plaintiff also alleges that the 003 Study began in July 2014 (*id.* ¶ 70). Because it is implausible to report study results on a study that has not yet begun, the Court cannot consider this allegation that Defendants knew of any 003 Study results as early as June 2014 to be true.

suicide events occurred and were being investigated." (*Id.* ¶ 125.) CW1 alleges that Antares, aware of these adverse events, scrambled to conduct a second Phase 3 study.[5] (*Id.* ¶ 127.)

In November 2015, pursuant to the FDA's recommendations, Antares began its second Phase 3 study of QST, QST-15-005 (the "005 Study"). (*Id.* ¶ 80.) The 005 Study excluded patients with baseline hypertension. (*Id.* ¶ 82.) In November 2016, the FDA informed Antares that the observed "increases in blood pressure" and "depression[,] . . . suicide, . . . cardiovascular[,] and cerebrovascular [adverse events] [in both the 003 and 005 Studies] [would] be review issue[s]." (*Id.* ¶ 91.) The FDA further advised that the adverse events "may prompt the need for an [advisory committee[6]]" and "may be included in [the product's] labeling." (*Id.* ¶ 91 (first alteration in original).)

At the beginning of the Class Period—December 21, 2016—Antares announced it submitted an NDA for QST ("the QST NDA") to the FDA. (*Id.* ¶¶ 4, 6.) "The price of Antares shares increased upon the announcement of the QST NDA." (*Id.* ¶ 129.) On the last day of the Class Period—October 12, 2017—Antares announced that the FDA sent a letter (the "October 11

[5] In dismissing the previous complaint, the Court steeply discounted CW1's allegations for failing to satisfy the PSLRA's stringent pleading requirements. *Smith v. Antares Pharma, Inc.*, No. 17-8945, 2019 WL 2785600, at *8–9 (D.N.J. July 2, 2019). Here, Plaintiff narrows down the 26-month period in which executives held these discussions on QST study results to 2015. (*See* SAC ¶¶ 120, 122–23.) Yet, deficiencies from the prior complaint remain in the Complaint. The allegation of reports of an "elevation of blood pressure" is still ambiguous. (*Id.* ¶ 124.) CW1 does not specify what, when, why, and how Antares and the Individual Defendants learned about these adverse events; when, why, and how CW1 learned of Jacob's concerns; what were Antares and Jacob's concerns; what were the FDA's concerns, if any; and what did Antares and Jacob know about the FDA's concerns. Furthermore, CW1 does not allege that Jacob or other executives believed the occurrence of these adverse effects rendered QST unsafe or would negatively affect QST's approval prospects.

[6] The FDA may convene an "advisory committee" of doctors and other scientists to consider whether a drug's health benefits outweigh its known risks and issue a recommendation to the FDA. *See* 21 CFR §§ 14.160, 14.171.

Letter") stating that the FDA had "identified deficiencies that preclude the continuation of the discussion of labeling and post[-]marketing requirements/commitments [for QST] at this time." (*Id.* ¶ 151.) "On the revelation of the . . . [October 11 Letter], Antares common stock fell 37.80%, or $1.41 per share, and closed at $2.32 per share on October 13, 2017." (*Id.* ¶¶ 15, 187.)

A week after the Class Period ended, Antares received a Complete Response Letter ("CRL") from the FDA, rejecting "the NDA in its present form." (*Id.* ¶¶ 14, 153.) The CRL identified two deficiencies relating to clinical data—"a clinically meaningful increase in blood pressure" and "the occurrence of depression and suicidality." (*Id.* ¶ 153.) On January 11, 2018, Antares disclosed a 12.7% rate of hypertension observed in the 003 Study. (*Id.* ¶ 158–59.) On April 5, 2018, Antares submitted a revised NDA (*id.* ¶ 160), which was approved on October 1, 2018 (*id.* ¶ 161). Xyosted's labeling includes a black boxed warning[7] for "blood pressure increases" and warnings and precautions[8] for the "[r]isk of [d]epression and [s]uicide." (*Id.* ¶¶ 161–62.) "On the heels of the revelation of approval with the requirement of a black box warning and risk of depression and suicide, Antares common stock fell 3%, or $0.10 per share." (*Id.* ¶ 18.)

Plaintiff's Consolidated Second Amended Class Action Complaint ("Complaint") asserts two causes of action: Count I alleges against all Defendants violations of Section 10(b) of the

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[7] On prescription drug labeling, "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box." 21 CFR. § 201.57(c)(1). This is called a "boxed warning" or "black box warning."

[8] Prescription drug labeling also includes a "Warnings and Precautions" section. "This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (*e.g.*, avoiding certain concomitant therapy), and steps that should be taken if they occur (*e.g.*, dosage modification)." 21 CFR. § 201.57(c)(6)(i).

Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder (*id.* ¶¶ 180–89); and Count II alleges against Individual Defendants violations of Section 20(a) of the Exchange Act (*id.* ¶¶ 190–95).

II. LEGAL STANDARDS

A district court must conduct a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *See Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The Court must take note of the elements a plaintiff must plead to state a claim; review the complaint to strike conclusory allegations; and accept as true all of the plaintiff's well-pled factual allegations while "construe[ing] the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). The Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678).

Because Plaintiff alleges fraud, Plaintiff "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The PSLRA also imposes a heightened standard "to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

III. DISCUSSION

A plaintiff bringing an action under Section 10(b) and Rule 10b-5 must plead: "(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." *Matrixx, Inc. v.*

Siracusano, 563 U.S. 27, 37–38 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). "[T]he PSLRA imposes greater particularity requirements concerning alleged material misrepresentations and scienter." *Fan v. StoneMor Partners LP*, 927 F.3d 710, 714 (3d Cir. 2019).

A. Defendants' Statements[9]

Plaintiff alleges that Antares made the following material false or misleading statements.

1. Press Release dated December 21, 2016

Antares announced that it submitted the QST NDA to the FDA. Antares stated that "the study data demonstrated that [QST] can provide patients with physiologically normal and steady levels of testosterone over the course of therapy." (SAC ¶ 128.)

2. Press Release dated February 27, 2017

Antares announced that the FDA accepted the QST NDA and that the FDA would review the NDA by October 20, 2017. Antares remarked on QST's "physiologically normal" benefits and stated that it "continue[s] to believe QST could be an excellent treatment option for men with

[9] "Although generally a plaintiff is not required to attach documents to a complaint at the pleading stage, a plaintiff under the PSLRA must go beyond vague and generic descriptions of the documents upon which they rely, and instead describe those documents in specific detail." *Klein v. Autek Corp.*, 147 F. App'x 270, 276 (3d Cir. 2005) (internal citations omitted). This requirement includes providing the context of the documents and quoting from them. *Id.* at 276–77. With several statements, Plaintiff extracts isolated sentence fragments from the statement into the Complaint and without providing the necessary context for the statements. (*See, e.g.*, SAC ¶¶ 132, 138, 140.) Plaintiff further inserts commentary on what Plaintiff believes Defendants communicated. (*See, e.g.*, SAC ¶¶ 128 ("Defendant Apple touted the drug's prospects for approval and claimed . . . ."); 131 ("Defendant Apple again touted [QST's] prospects for approval and the alleged 'physiologically normal' *benefits* of [QST], as well as stating . . . ." (emphasis added)). Here, the Court includes Defendants' statements as quoted in the Complaint and, to the extent possible, omits Plaintiff's commentary. Any emphases were provided by Plaintiff. If Plaintiff chooses to amend the Complaint, Plaintiff shall address these deficiencies and remove any inaccuracies.

hypogonadism based upon *the positive pharmacokinetic and safety data* produced in the two phase three studies now." (*Id.* ¶ 132.)

3. Form 10-K dated March 14, 2017

Antares reported adverse events from the 003 Study:

> The most common adverse reactions *(incidence ≥5%)* in this phase 3 study were increased hematocrit, *hypertension*, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. *Serious adverse events (SAE's) reported included one case each of worsening depression, vertigo[,] and suicide.*

(*Id.* ¶ 134.) Apple and Jaffe furnished signed certifications in support of this Form 10-K. (*Id.* ¶ 135.) Jacob signed the Form 10-K. (*Id.* ¶ 136.)

4. Press Release dated April 3, 2017

Antares remarked on QST's "potential approval" and claimed "QST was found to be *safe*, well tolerated[,] and virtually pain free." (*Id.* ¶ 138.) Antares reported safety data:

> The most common adverse reactions *(incidence ≥5%)* in this phase 3 study were increased hematocrit, *hypertension*, increased PsA, [u]pper [r]espiratory [t]ract [i]nfection, sinusitis, injection site bruising[,] and headache. *Serious adverse events reported included one case each of worsening depression,* vertigo[,] *and suicide.*

(*Id.*)

5. Conference Call on May 9, 2017

Apple stated that "nothing unusual" had occurred with respect to the FDA review of QST. (*Id.* ¶ 140.)

6. Form 10-Q dated May 9, 2017

Antares reported safety data:

> The most common adverse reactions *(incidence ≥5%)* in this phase 3 study were increased hematocrit, *hypertension*, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising and headache. *Serious adverse events (SAE's) reported included one case each of worsening depression,* vertigo[,] *and suicide.*

(*Id.* ¶ 142.) Apple and Powell signed certifications in support of the Form 10-Q. (*Id.* ¶ 143.)

7. Conference Call on August 8, 2017

Apple stated, "anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted." (*Id.* ¶ 145.) Apple also stated, "I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate." (*Id.* ¶ 146.)

8. Form 10-Q dated August 8, 2017

Antares reported safety data:

> The most common adverse reactions *(incidence ≥5%)* in this phase 3 study were increased hematocrit, *hypertension*, increased prostate-specific antigen, upper respiratory tract infection, sinusitis, injection site bruising[,] and headache. *Serious adverse events (SAE's) reported included one case each of worsening depression,* vertigo[,] *and suicide.*

(*Id.* ¶ 148.) Apple and Powell furnished signed certifications in support of this Form 10-Q. (*Id.* ¶ 149.)

B. Falsity

First, the Court considers whether Defendants' statements are false or misleading. "[Section] 10(b) and Rule 10b–5 do not create an affirmative duty to disclose any and all material information. Disclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading." *Matrixx*, 563 U.S. at 44

(quoting 17 C.F.R. § 240.10b–5(b)). "[Defendants'] statements are only actionable if, when read in light of all the information then available to the market or a failure to disclose particular information, [Defendants] conveyed a false or misleading impression." *Fan*, 927 F.3d at 715 (internal citations and quotation marks omitted).

Under the PSLRA, a complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation . . . is made on information and belief, . . . state with particularity all facts on which that belief is formed." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 166 (3d Cir. 2014) (quoting 15 U.S.C. § 78u–4(b)(1)(B)). Plaintiff must plead "the who, what, when, where[,] and how: the first paragraph of any newspaper story." *Inst. Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009) (internal quotation marks and citation omitted).

"Interpretations of clinical trial data are considered opinions. Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Edinburgh*, 754 F.3d at 170 (internal citations omitted). A company's press release releasing "positive" study results is not misleading where the plaintiff fails to allege that the opinion lacked a reasonable basis. *See, e.g.*, *Biondolillo v. Roche Holding Ag*, No. 17-4056, 2018 WL 4562464, at *5 (D.N.J. Sept. 24, 2018); *cf. In re Merck & Co., Sec., Derivative, & ERISA Litig.*, 2011 WL 3444199, at *15 (D.N.J. Aug. 8, 2011) (finding alleged facts showed the company had no reasonable basis for and disbelieved its public characterization of the study results).

Plaintiff challenges the statements in the December 21, 2016 and February 27, 2017 press releases that QST demonstrated "physiologically normal" benefits. (SAC ¶¶ 128–33.) Plaintiff contends that these statements are false and misleading considering the adverse events observed in the clinical studies. (*Id.*) As an initial matter, Antares did not tout the "physiologically normal"

benefits of QST. Rather the company stated that QST could provide patients with "physiologically normal and steady *levels of testosterone*." (*Id.* ¶ 128 (emphasis added); *see also* Feb. 27, 2017 Press Release 1, Ex. 30 to Jacobsen Decl., ECF No. 59-32 ("[QST] can provide patients with physiologically normal and steady *levels of testosterone* over the course of therapy." (emphasis added)).) The term "physiologically normal" relates, therefore, to QST's ability to provide patients with "steady levels of testosterone" and not to QST's safety. Plaintiff does not allege why the occurrence of hypertension, depression, and suicidality, would render a statement about "physiologically normal" levels of testosterone false or misleading. Plaintiff, accordingly, fails to show that these statements are actionable.

Plaintiff also challenges a statement in the February 27, 2017 press release that the Phase 3 studies have produced "positive safety data." (SAC ¶¶ 131–33.) Plaintiff contends that the statement is false and misleading considering the adverse events observed in those trials. (*Id.* ¶ 133.) Here, the press release offers an interpretation of the clinical trial data and is considered an opinion. *See Edinburgh*, 754 F.3d at 170. Because Plaintiff fails to plead facts that show Defendants did not honestly believe the studies produced positive safety data and lacked a reasonable basis for this opinion, *see also supra* note 5, Plaintiff fails to show that this statement is actionable.

Plaintiff similarly challenges the April 3, 2017 press release stating that "QST was found to be safe." (*Id.* ¶ 138.) Plaintiff contends the statement is false and misleading, considering the incidence of hypertension, suicidality, and depression and that QST demonstrated a much higher hypertension rate than comparable approved TRTs. (*Id.* ¶ 139.) Plaintiff does not allege that Defendants were aware of this comparative risk data when they made the statement and that this data would render QST unsafe. *See also supra* note 5. Because Plaintiff again fails to plead that

Defendants did not believe QST was "safe" and had no reasonable basis for this opinion, Plaintiff has not demonstrated that this statement is actionable.

Plaintiff challenges four statements in which hypertension was included among the "most common adverse reactions (incidence ≥ 5%)." (*Id.* ¶¶ 134, 138, 142, 148.) Plaintiff argues that the statement is misleading given the true risk of hypertension observed in the 003 Study. (*Id.* ¶¶ 137, 139, 144, 150.) Here, the statement is not false, and Plaintiff has not pleaded facts that show the statement is misleading (*e.g.*, that Defendants knew the 12.7% hypertension rate observed in the 003 Study was significantly higher than the other six common adverse events). Section 10(b) and Rule 10b-5 do not impose a duty to disclose all material information. *Matrixx*, 563 U.S. at 44. Here, Antares informed the public that hypertension was a common adverse event observed in the 003 Study and was not duty bound to disclose the exact statistical risk of any adverse events. Plaintiff, therefore, fails to show that these statements are false or misleading.

Plaintiff challenges the same four statements as falsely stating the observed incidence of suicides and depression cases in *both* Phase 3 studies. (SAC ¶¶ 137, 139, 144, 150.) These statements, however, only purport to disclose the adverse events of *a single* Phase 3 study. (*See id.* ¶¶ 134 ("Antares stated, with respect to QST-13-003 . . . ."), 138 ("in the phase 3 study"),[10] 142 ("in this phase 3 study"),[11] 148 ("in this phase 3 study")[12].) Plaintiff, accordingly, fails to

[10] The press release does not identify whether the adverse reactions were observed in the 003 or 005 Study. Nonetheless, the press release refers to a singular Phase 3 study. (*See* April 3, 2017 Antares Press Release 1–2, Ex. 32 to Jacobsen Decl., ECF No. 59-34.)

[11] The excerpt refers to the 003 Study. (*See* May 9, 2017 Antares Form 10-Q 20, Ex. 15 to Jacobsen Decl., ECF No. 59-17.)

[12] The excerpt refers to the 003 Study. (*See* Aug. 8, 2017 Antares Form 10-Q 22, Ex. 16 to Jacobsen Decl., ECF No. 59-18.)

demonstrate how these statements misrepresent the observed incidence of suicides and depression in this *one* Phase 3 study.

Plaintiff alleges that Antares omitted the increased risk of hypertension and suicidality in QST as compared to other TRTs. (*E.g.*, SAC ¶¶ 128, 131–32, 134, 138, 140, 142, 148; *see also* Pl.'s Opp'n Br. 20, ECF No. 61.) Here, Plaintiff neither contends that Antares is duty bound to disclose this information nor that Antares had disclosed some other comparative safety data that would render this omission misleading. "Silence, absent a duty to disclose, is not misleading . . . ." *Edinburgh*, 754 F.3d at 174. Plaintiff, accordingly, has not demonstrated that Antares's omission of the increased risk of hypertension and suicidality in QST as compared to other TRTs is actionable.

Plaintiff next challenges Apple's statement during the May 9, 2017 investor call. (SAC ¶ 140.) Plaintiff alleges that "Apple claimed, in response to an analyst question, that 'nothing unusual' had occurred with respect to the FDA review of [QST]."[13] (*Id.* ¶ 140.) This is an opinion for which Plaintiff fails to allege that Defendants did not honestly believe and lacked a reasonable basis to make. *See also supra* note 5. Thus, Plaintiff has not demonstrated that this statement is false or misleading.

[13] Defendants argue that "Plaintiff cannot sustain a claim by misquoting disclosures." (Defs.' Moving Br. 31, ECF No. 59-1.) In reviewing the transcript, the Court does not find Plaintiff "misquoted" Apple's statement. When questioned on the progress of the FDA's review of QST, Apple responded, "We really haven't provided that much update or exactly on where we are with the file, the status, because the FDA – it's kind of a rolling situation where as they go through areas they might raise questions and so forth. . . . So I would say nothing unusual at this point in any regards." (May 9, 2017 Antares Earnings Call Tr. 8, Ex. 40 to Jacobsen Decl., ECF No. 59-42.) Although Plaintiff failed to provide a verbatim quote of Apple's complete statement, the Court does not find that Plaintiff fabricated Apple's statement.

Plaintiff challenges Apple's statement during the August 8, 2017 conference call that "anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted." (SAC ¶ 145.) Apple also stated, "I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate." (*Id.* ¶ 146; *see also* Aug. 8, 2017 Antares Earnings Call Tr. 12, Ex. 39 to Jacobsen Decl., ECF No. 59-41.) Here, the Court finds that these statements could be misleading considering hypertensive patients are excluded from the 005 Study, but Plaintiff, nonetheless, fails to show that these statements are actionable. *See infra* Section III.C.

Plaintiff lastly alleges that seven of Defendants' statements overstated QST's approval prospects, by either omitting or misrepresenting study safety results. (SAC ¶¶ 130, 133, 137, 139, 141, 144, 150.) To the extent Plaintiff makes broad allegations tying QST's safety to its approval, Plaintiff cannot do so in a conclusory fashion. Plaintiff must allege specific facts that show how the incidence of these adverse events necessarily precluded FDA approval. *See Kovtun v. VIVUS, Inc.*, No. 10-4957, 2012 WL 4477647, at *8 (N.D. Cal. Sept. 27, 2012), *aff'd sub nom. Ingram v. VIVUS, Inc.*, 591 F. App'x 592 (9th Cir. 2015). Moreover, Antares only addressed the prospects of QST's approval in one of the statements. (*Id.* ¶ 138.) In the April 3, 2017 press release, Antares mentioned QST's "potential approval." (*Id.*; *see also* Apr. 3, 2017 Press Release 1, Ex. 32 to Jacobsen Decl., ECF No. 59-34 ("We will continue to work with the FDA during the regulatory review process toward a potential approval.").) Because Antares only mentioned the "potential approval" of QST, even if the prospect of approval were tied to the rate of hypertension or incidence of other adverse events, Antares cannot be said to have overstated QST's approval prospects. Moreover, Plaintiff has failed to plead there is no way QST could have been approved. For these reasons, Plaintiff fails to show that Antares overstated QST's approval prospects.

C. Materiality

Even if Plaintiff could show that Defendants' statements are false or misleading, Plaintiff fails to plead that Defendants' statements were "misleading as to a material fact." *Matrixx*, 563 U.S. at 38. "[T]o fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (citing *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)) (internal quotation marks omitted); *In re Aetna Inc. Sec. Litig.*, 617 F.3d 272, 283 (3d Cir. 2010).

"Assessing the materiality of adverse event reports is a fact-specific inquiry that requires consideration of the source, content, and context of the reports." *Matrixx*, 563 U.S. at 43 (internal citation and quotation marks omitted). Nevertheless, "complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so unimportant that courts can rule them immaterial as a matter of law at the pleading stage." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

"Material representations must be contrasted with statements of subjective analysis or extrapolations, such as opinions, motives[,] and intentions, or general statements of optimism . . . ." *Aetna*, 617 F.3d at 283 (citation omitted). "[V]ague and general statements of optimism . . . are not material [because] a reasonable investor would not base decisions on such statements." *Fan*, 927 F.3d at 716.

Here, Defendants' statements that "QST was found to be safe," that QST showed "positive . . . safety data," and that "nothing unusual" had occurred with respect to the FDA's review (SAC ¶¶ 132, 138, 140) are vague and general statements of optimism and are, accordingly, not material. *Fan*, 927 F.3d at 716. The statements also cannot be read in a vacuum. "[W]hen

considering whether an alleged misstatement is material, [the Court] pay[s] particular attention to whether or not Defendants sufficiently disclosed facts and information that would render the alleged misrepresentation[] not misleading." *Id.* Here, a reasonable investor would understand Defendants' statements on QST's safety in light of the disclosure of adverse events and would not, accordingly, find a vague statement on QST's safety material. (*See* SAC ¶ 138.)

Similarly, Apple's statements that "anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for Xyosted" and that "there isn't any particular patient population . . . we think is a better candidate" are not actionable. They are vague and general statements of optimism and are "not material [because] a reasonable investor would not base decisions on such statements." *Fan*, 927 F.3d at 716. In conclusion, Plaintiff has not pleaded with particularity as to the materiality of Defendants' statements.

D. Scienter

Plaintiff also fails to plead scienter as to the Company and the Individual Defendants. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud," *Matrixx*, 563 U.S. at 48 (citing *Tellabs*, 551 U.S. at 319), encompassing reckless or conscious behavior, *Avaya*, 564 F.3d at 267. To plead a "knowing or reckless state of mind" in the securities context, Plaintiff must plead "an extreme departure from the standards of ordinary care." *Id.* at 252, 267 n.2.

"[T]he plaintiff's pleadings [must] conjure a 'strong inference' that the defendant[s] acted with the . . . intent to defraud shareholders." *Fan*, 927 F.3d at 717–18 (quoting 15 U.S.C. § 78u-4(b)(2)(A)). A court "must analyze the complaint holistically" and "not whether any individual allegation, scrutinized in isolation, meets that standard.'" *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Tellabs*, 551 U.S. at 323). A plaintiff only clears

the high hurdle imposed by the PSLRA if "a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Tellabs*, 551 U.S. at 326.

Plaintiff argues that, at all relevant times, QST was Antares's lead product; Antares gambled heavily on the product; and Antares knew and "lied" about the instances of hypertension, suicidality, and depression "because admitting [them] . . . would have doomed Antares as a public company and left it tens of millions of dollars in debt." (Pl.'s Opp'n Br. 3–4, 9, 29–37.) Here, Plaintiff does not allege particularized facts to support this theory. As the Court detailed earlier, CW1's allegations about what Antares executives knew in 2015 are ambiguous. *Supra* note 5. Although Plaintiff alleges that the FDA had informed Defendants certain adverse events would be "review issues," may prompt the need for an advisory committee, and may result in change in product labeling (SAC ¶ 91), Plaintiff does not allege that the FDA thought or communicated to Defendants the occurrence of adverse events threatened or would delay QST's approval. To the contrary, the alleged facts suggest that Antares informed investors of the delay in approval immediately after receiving the FDA's October 11 Letter.

Plaintiff also argues that excluding hypertension patients from the 005 Study supports a finding of scienter. (Pl.'s Opp'n Br. 30.) Plaintiff pleads, however, that "Antares finalized and submitted the [005 Study] protocol . . . and enrolled patients [in the study] . . . pursuant to the FDA's recommendations." (SAC ¶ 80.) The FDA, therefore, approved the study design and would presumably approve QST on the data from this study. Indeed, QST was ultimately approved, albeit with a black box warning and an additional warning and precaution. The exclusion of certain patients from the 005 Study does not, therefore, support a finding of scienter.

Nor does Plaintiff's allegation that Defendants' significant financial motives, including Antares's possible NASDAQ delisting, support a strong inference of scienter. (Pl.'s Opp'n

Br. 34–35.) First, the out-of-circuit cases to which Plaintiff cites are factually distinguishable. *See In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 813 (C.D. Cal. 2011) (finding the company's "short-term need to keep their stock price above $6.50 per share provides a plausible motive for Defendants' actions[] and supports a finding of scienter"); *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 31 (D. Mass. 2004) (finding that the FDA's "extremely strict stance against even the faintest possibility of cardiac side effects in any new antihistamines," that the company was burning cash at a high rate, and that the company was dependent on its products as the most promising drug in its pipeline supported scienter); *In re Cabletron Sys.*, 311 F.3d 11, 39 (1st Cir. 2002) (finding numerous allegations, including that the company's cofounder was forced out of management due to the magnitude of the company's issues, showed "the executives' careers and the very survival of the company were on the line" and added to the strong inference of scienter). Second, Plaintiff's conclusory allegation that Antares's delisting from the NASDAQ stock exchange threatened the Company's survival is not supported by particularized facts. Plaintiff's pleadings do not conjure a strong inference that Antares acted with the intent to defraud investors. For these reasons, the Court finds Plaintiff has not sufficiently pleaded scienter for the Company.

Next, the Court considers whether the Complaint alleges scienter for each Individual Defendant. *See Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007) (abolishing group pleading doctrine in post-PSLRA private securities actions). The Complaint fails to allege scienter as to Apple and Powell. That Apple and Powell signed the certifications supporting Antares's SEC filings "cannot establish the requisite strong inference of scienter unless the [C]omplaint asserts facts indicating that, at the time of certification, [the] [D]efendants knew or consciously avoided any meaningful exposure to the information that was rendering their [Sarbanes-Oxley] certification[s] erroneous." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 355 (D.N.J. 2007).

Even if Plaintiff had successfully pleaded statements in the Company's SEC filings were material and false, Plaintiff fails to plead that Apple and Powell individually knew or consciously avoided information that rendered their certifications erroneous. Plaintiff, accordingly, fails to satisfy the requisite strong inference of scienter as to Apple and Powell.

Next the Court considers Plaintiff's allegation that Jacob sold 230,000 shares of Antares stock on October 9, 2017—just two days before the FDA's October 11 Letter informing Antares that certain deficiencies in the NDA precluded the FDA's continued discussion on QST. (SAC ¶¶ 14–16, 185.) Stock sales that are "unusual in scope or timing . . . may support an inference of scienter." *Avaya*, 564 F.3d at 279 (internal citations omitted). To support a finding of scienter on this basis, the plaintiff "must provide sufficient 'information as to whether the trades were normal and routine for [the] executive.'" *Lovallo v. Pacira Pharm., Inc.*, No. 14-6172, 2015 WL 7300492, at *13 (D.N.J. Nov. 18, 2015) (quoting *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000)). Relevant to this inquiry would be Jacob's total stock holdings, the amounts of his base compensation compared to trading proceeds, whether his trading practices remained consistent year-over-year, whether he retained a large percentage of common stock holdings in the Company, whether the stock sales were unusual compared to the timing of past trades, and whether he made his trades automatically under a Rule 10b5-1 trading plan. *Id.* Here, Plaintiff does not plead any information as to whether Jacob's trade was "normal and routine." Plaintiff, therefore, fails to allege scienter with particularity as to Jacob.

E. Economic Loss and Loss Causation

Lastly, Plaintiff fails to plead economic loss and loss causation. It is not enough to allege an "artificially inflated purchase price" as an economic loss. *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005). To plead economic loss, Plaintiff must show Defendants'

"misrepresentation[s] (or other fraudulent conduct) proximately caused [P]laintiff's economic loss." *Id.* at 346. To plead loss causation, "the plaintiff must show that the defendant[s] misrepresented or omitted the very facts that were a substantial factor in causing the plaintiff's economic loss." *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 426 (3d Cir. 2007).

Here, Plaintiff alleges an artificially inflated purchase price, which alone cannot plead economic loss. *Dura*, 544 U.S. at 347. Furthermore, Plaintiff fails to plead loss causation. Plaintiff alleges that the Company's stock price fell after the Company disclosed the October 11 Letter. (SAC ¶ 15.) The October 11 Letter, however, did not disclose the reasons for delaying review of the QST NDA. (*Id.* ¶ 14.) The drop in Antares's stock price on October 12—the last day of the Class Period—cannot, accordingly, be attributed to the release of QST's safety data. It was not until October 20 when the public became aware of the FDA's safety concerns. (*Id.* ¶ 153.) The Complaint does not allege if and how Antares's stock price dropped upon the disclosure of the safety issues in the FDA's CRL. For these reasons, Plaintiff has not adequately pleaded economic loss and loss causation.

F. Section 20(a) Claim

Liability under Section 20(a) "is derivative of an underlying violation of Section 10(b) by the controlled person." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 252). Where no Section 10(b) violation has been successfully pled, a Section 20(a) violation must fail as well. *Id.* Because Plaintiff's Section 20(a) claim requires a predicate violation of the Exchange Act and because the Court dismisses Plaintiff's Section 10(b) claim, the Court dismisses Plaintiff's Section 20(a) claim.

IV. CONCLUSION

For the foregoing reasons, the Complaint has not stated claims under Exchange Act Sections 10(b) and 20(a) and Rule 10b-5. The Court grants Plaintiff leave to amend the Complaint. The Court will issue an Order consistent with this Memorandum Opinion.

/s/

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE