NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE AMARIN CORP. PLC., SECURITIES LITIGATION	Civil Action No. 13-cv-6663 (FLW)(TJB) OPINION

WOLFSON, U.S. DISTRICT JUDGE:

Presently before the Court is a motion to dismiss the Consolidated Amended Class Action Complaint ("CAC") filed by Lead Plaintiff James L. Reiss ("Plaintiff") against Amarin Corp., PLC ("Amarin"), Joseph S. Zakrzewski ("Zakrzewski"), John F. Thero ("Thero"), and Steven Ketchum ("Ketchum") (Zakrzewski, Thero, and Ketchum known collectively as "the Individual Defendants") (Amarin and the Individual Defendants known collectively as "Defendants"). Plaintiff's lawsuit stems from alleged misrepresentations Defendants made about the progress of Amarin's ultimately unsuccessful application to the FDA to approve its drug Vascepa for the treatment of patients with high triglyceride levels. Also before the Court is Plaintiff's motion to strike certain references made in Defendants' reply brief to a document known as the Special Protocol Assessment ("SPA").

For the following reasons, Defendants' motion to dismiss is granted and Plaintiff's motion to strike is denied. Plaintiff's Complaint is dismissed without prejudice. Plaintiff is given thirty days to re-file his Complaint.

I. Background

The following allegations are taken as true for the purposes of this motion. Amarin is a biopharmaceutical company focused on the commercialization and development of therapeutics

to improve cardiovascular health. CAC ¶ 41. Vascepa is Amarin's primary product offering and, according to Amarin's SEC filings, "is an ultra-pure, EPA [ethyl eicosapentaenoic acid]-only omega-3 fatty acid product" for the treatment of patients with very high and high triglycerides. CAC ¶ 52. During the period from November 29, 2010 through October 16, 2013 (the "Class Period"), Amarin sought FDA approval to market Vascepa, based on a 12-week Phase III registration trial (the "ANCHOR study"), to treat patients with high trigylceride levels ("TGs") when co-administered with a statin[1] (a treatment purpose known as the "ANCHOR indication"). CAC ¶¶ 7, 64. According to Plaintiff, "Amarin's only prospect for profitability during the Class Period was the approval of Vascepa for the ANCHOR indication."[2] CAC ¶ 8. During the Class Period, defendants estimated that the potential patient population for the ANCHOR indication was 36 million patients.[3] *Id.* In support of this indication, during 2009–2010, Amarin conducted the ANCHOR study, which was a twelve-week, Phase III clinical trial that enrolled 702 patients, "to determine if administration of Vascepa to the patient population already optimized on statin therapy reduced TGs." CAC ¶¶ 11, 14.

In July 2008, senior officers of Amarin met with the FDA for the purpose of discussing the ANCHOR study for testing of Vascepa. CAC ¶ 12. Plaintiff alleges that "[a]t that meeting, the FDA expressed reservations to Amarin about approving Vascepa based only on the 12-week

[1] According to Plaintiff, "[s]tatins are a class of drugs that work in the liver to prevent the formation of LDL (bad) cholesterol, thus lowering the amount of cholesterol circulating in the blood." CAC at viii.

[2] However, Plaintiff does indicate that on July 12, 2012, Vascepa was approved by the FDA for the MARINE indication. CAC at viii. According to Plaintiff, "[u]nlike ANCHOR, the MARINE indication was intended to treat a much smaller and sicker patient population and to treat a different disease (pancreatitis rather than heart disease)." CAC ¶ 71.

[3] Amarin's ANCHOR study was based on a hypothesis that reducing TGs in patients, when co-administered with a statin, would lead to a statistically significant reduction in major adverse cardiac events ("MACE"). CAC ¶ 10.

ANCHOR trial, and in the absence of the completion of a long-term outcomes study that tested the reduction of MACE (major adverse cardiovascular events)."[4] CAC ¶ 13. Plaintiff alleges that the FDA advised Amarin at that meeting that two long-term outcomes studies, the ACCORD-Lipid and AIM-HIGH studies, were ongoing and were expected to test the hypothesis that reducing TGs would lead to fewer MACE. The FDA advised Amarin that it could proceed with the ANCHOR study, but that if the ACCORD and AIM-HIGH outcomes studies (which were then underway) failed to demonstrate a survival benefit, the FDA would be less likely to approve Vascepa based only on the ANCHOR trial. CAC ¶ 14. Plaintiff further alleges that the FDA's reservations with respect to approving Vascepa for the ANCHOR indication based only on a 12-week trial were reflected in written minutes of that meeting created by the FDA and provided to Amarin. CAC ¶ 15. Plaintiff also alleges that Amarin's future profitability at the time of that meeting was dependent on obtaining FDA approval to market Vascepa based on the ANCHOR study without first being required to conduct a long-term outcomes study.

[4] Specifically, Plaintiff alleges that according to the FDA's October 11, 2013 Briefing Document, the FDA informed Amarin in July 2008 as follows:

> During a pre-IND meeting with the applicant in July 2008 . . . the Division noted that there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk. The Division referenced trials ongoing at the time (e.g., AIM-HIGH, ACCORD-Lipid) that, while not able to assess the effect of specifically lowering non-HDL-C (or TG) on clinical outcomes, would be expected to provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy. It was stated that before an indication would be entertained for Ethyl-EPA as add-on to statin therapy in patients with elevated TG levels, the applicant at a minimum would have to provide results from a 12-week study with lipid endpoints as well as initiate an appropriately designed cardiovascular outcomes study.

CAC ¶ 13.

Both the ACCORD-Lipid and AIM-HIGH studies proved unsuccessful, with the test results for ACCORD-Lipid announced in March 2010, and the discontinuation of AIM-HIGH announced in May 2011. CAC ¶ 17. Plaintiff alleges that, "[n]otwithstanding Defendants' actual knowledge, initially, that the success of the ANCHOR trial was dependent on the success of the ACCORD-Lipid and AIM-HIGH trials, and subsequently, that the ACCORD-Lipid and AIM-HIGH trials had been unsuccessful, defendants intentionally failed to inform investors of the connections drawn by the FDA among the three studies." CAC ¶ 18. Rather, Plaintiff alleges that "Defendants misrepresented facts with respect to the likelihood of obtaining FDA approval for the ANCHOR indication without REDUCE-IT," Amarin's own long-term prospective cardiovascular outcomes study in high-risk patients on statin therapy that was not initiated until November 2011. CAC ¶ 19; CAC at viii.

According to Plaintiff, these misrepresentations were made "to induce Class Members to make in excess of $226 million of investments in Amarin securities through two secondary offerings – on January 6, 2011 – 13.8 million ADS at $7.60 per ADS, and on July 10, 2013 – 21.7 million ADS at $5.60 per ADS." CAC ¶ 19. Plaintiff additionally alleges that "Defendants were motivated to commit the fraud because they knew that Amarin was required to raise cash in public offerings to conduct the long-term REDUCE-IT study and that investors would be unwilling to buy Amarin ADSs in these public offerings if they knew that Amarin would be required to conduct the long-term REDUCE-IT study at an expense in excess of $100 million to get FDA approval." CAC ¶ 20. Further, "[t]he long-term REDUCE-IT study introduced an element of cost, risk, and delay that would have been unacceptable to public investors." CAC ¶ 21. Plaintiff alleges that "Defendants misrepresented facts with respect to the likelihood of obtaining FDA approval for the ANCHOR indication without REDUCE-IT to induce Class

Members to make in excess of $260 million of investments in Amarin securities through two secondary offerings – on January 6, 2011 – 13.8 million ADS at $7.60 per ADS, and on July 10, 2013 – 21.7 million ADS at $5.60 per ADS." CAC ¶ 22.

Plaintiff also alleges that Defendants "misrepresented facts concerning the [Japan Eicosapentaenoic acid (EPA) Lipid Intervention Study ("JELIS")] . . . study conducted in Japan . . . ." CAC ¶ 24. According to Plaintiff, the JELIS study, in which investigators "concluded that JELIS showed that the addition of EPA [very similar to the active ingredient in Vascepa, ethyl-EPA] to statin therapy provides additional benefit in preventing major coronary events," differed in two material ways from the ANCHOR study. CAC ¶¶ 120–25. However, Plaintiff alleges that Defendants held out the two studies as equivalent in their public statements to falsely indicate the efficacy of Vascepa for the ANCHOR indication. CAC ¶ 146(ii). Further, Plaintiff alleges that Defendants misrepresented "facts concerning . . . the use of mineral oil as a placebo in the ANCHOR study." CAC ¶ 24. Specifically, Plaintiff alleges that Defendants did not express concerns raised by Plaintiff's Confidential Witness A ("CWA") and the FDA about the viability of mineral oil as a placebo for the ANCHOR trial, because the mineral oil "may not be inert." CAC ¶¶ 72–85, 146(iii). Plaintiff asserts that due to these misrepresentations, "and unbeknownst to the investing public, Amarin securities traded at materially inflated prices throughout the Class Period." CAC ¶ 24.

On October 11, 2013, the FDA released its briefing document for the Endocrinologic and Metabolic Drugs Advisory Committee ("AdCom") meeting scheduled for October 16, 2013 ("the Briefing Document"). CAC ¶ 26. According to Plaintiff, the Briefing Document revealed that "Amarin had been informed by the FDA in July 2008 that the FDA's willingness to approve Vascepa for use by a 36 million patient population based only on a 12-week trial, was dependent

on the ACCORD and AIM-HIGH test results, and further that those test results had been unsuccessful." CAC ¶ 27. Plaintiff also asserts that "the Briefing Document called into question whether Vascepa offered any meaningful clinical benefit to patients with high triglyceride levels." CAC ¶ 28. Upon the release of the Briefing Document, Amarin's shares declined by $1.28 per share – from $6.37 to $5.09 – over 20% -- on volume of over 37.9 million shares. CAC ¶ 29. On October 16, 2013, the AdCom voted 9 to 2 against approval of Vascepa for the ANCHOR indication citing, among other matters, concerns regarding the failure of recent cardiovascular outcomes trials (including ACCORD-Lipid and AIM-HIGH) to demonstrate meaningful cardiovascular benefit from reduction in triglyceride levels. CAC ¶ 30. Plaintiff asserts that "[o]n this news, Amarin shares declined an additional $3.16 per share–over 61% on volume of over 105.6 million shares." CAC ¶ 31. Plaintiff further asserts that "Individual Defendants, and other senior Amarin executives, with knowledge of the undisclosed facts, exercised stock options and sold Amarin ADSs to unsuspecting investors on the open market, garnering unlawful profits of excess of $15 million." CAC ¶ 32.

On November 1, 2013, Plaintiff filed this lawsuit. Plaintiff alleges in Count One of the CAC that Defendants' actions amounted to securities fraud and a violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder ("Rule 10b-5"). In Count Two, Plaintiff asserts a claim pursuant to Section 20(a) of the Exchange Act against the Individual Defendants. On July 29, 2014, the Court consolidated the various securities actions against Amarin into this single case and appointed Plaintiff as Lead Plaintiff. Thereafter, Defendants moved to dismiss the CAC. Specifically, Defendants assert that Plaintiff's claims must fail because (1) Plaintiff has not alleged that Defendants made a false statement or omission

and (2) Plaintiff fails to allege particularized facts giving rise to a strong inference that the individual defendants acted with scienter.[5]

[5] On March 12, 2015, Plaintiff moved to strike portions of Defendants' reply brief in support of Defendants' motion to dismiss, arguing that Defendants' references to the special protocol assessment ("SPA") governing the ANCHOR trial "that are outside plaintiff's Class Action Complaint and unsupported by the factual record" should be stricken. Pl.'s Mot. to Strike at 2. Plaintiff indicates that the SPA "is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase 3 [ANCHOR] trial." CAC ¶ 130. Plaintiff argues that Defendants' references to the SPA are inappropriate because "without the actual SPA, amendments to the SPA, and the text of communications between the FDA and Amarin, including minutes of those communications, the public record is ambiguous whether the SPA concerned the criteria for *filing* of the NDA [new drug application] or whether it concerned the criteria for *approval* of the NDA." *Id.* at 6.

Whether to grant a motion to strike is within the district court's sound discretion. *McElroy v. Sands Casino*, 593 Fed. App'x 113, 116 (3d Cir. 2014) (citing *Meditz v. City of Newark*, 658 F.3d 364, 367 n.1 (3d Cir. 2011)).

As a threshold matter, motions to strike are brought in federal court pursuant to Rule 12(f) of the Federal Rules of Civil Procedure. FED. R. CIV. P. 12(f). Rule 12(f) states in relevant part that "[t] he court may strike from a *pleading* an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." *Id.* (emphasis added).

Here, the Court denies Plaintiff's motion, because Plaintiff does not move to strike any statements from a pleading; rather, Plaintiff seeks to strike statements made in a reply brief. *See, e.g., In re Schering-Plough Corp./Enhance Sec. Litig.*, No. 08-CV-397 (DMC), 2009 WL 1410961, at *2 (D.N.J. May 19, 2009); *cf. United States v. Coney*, 689 F.3d 365, 379 & n.5 (5th Cir. 2012); 5C CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 1380 & n.8.50 (3d ed. 2012) ("Rule 12(f) motions only may be directed towards pleadings as defined by Rule 7(a); thus motions, affidavits, briefs, and other documents outside of the pleadings are not subject to Rule 12(f)."); *see also* FED. R. CIV. P. 7(a).

In the alternative, Plaintiff argues that in the event that Defendants attached the SPA in their opposition brief, "the Court 'must' convert the motion to a motion for summary judgment pursuant to Fed. R. Civ. P. 12(d) and allow Plaintiff plenary discovery." Pl.'s Br. at 9. However, Defendants did not provide the SPA to the Court; thus, Plaintiff's alternative request is denied as moot.

Finally, I note that Defendants' reply brief does not materially rely on the substance of the SPA. Rather, Defendants make limited references to the SPA, mostly to argue that Plaintiff failed to allege that the SPA stated that the success of the ACCORD, AIM-HIGH and IMPROVE-IT studies was a condition to approving the ANCHOR indication. Defs.' Reply Br. at 5–6. Given the several substantive references to the SPA that Plaintiff himself makes in his Complaint, *see* CAC ¶¶ 69, 79, 99, 129, 130, 143, 194, 198, 199, 211–13, 215, 233, 249, 260, 262, 282, 286, 322, the Court does not find Defendants' references to the SPA to be inappropriate on its face. In any event, the Court will of course examine Defendants' arguments under the Rule 12(b)(6) standard discussed *infra*, which assumes Plaintiff's factually supported allegations to be true unless explicitly contradicted in documents which (1) are integral to, or

II. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the [complaint] in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the [complaint], the plaintiff may be entitled to relief."[6] *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court clarified the Rule 12(b)(6) standard: the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Id.* at 555. As the Third Circuit has stated, "[t]he Supreme Court's *Twombly* formulation of the pleading standard can be summed up thus: 'stating ... [a] claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 127 U.S. at 555); *see also Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. The pleading standard is not akin to a probability requirement; to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citations omitted)).

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relied upon, in Plaintiff's Complaint and (2) publicly available, attached to the parties' moving briefs, or indisputably authentic. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (Courts may consider "exhibits attached to the complaint, matters of public record, [or] undisputedly authentic documents if the complainant's claims are based upon these documents."); *see also, e.g.*, *Cichonke v. Bristol Twp.*, No. CIV.A. 14-4243, 2015 WL 1345439, at *7 (E.D. Pa. Mar. 25, 2015).

[6] Though Defendants did not attach the SPA to their briefs, they do attach 27 other exhibits. The Court will only consider, when relevant, the attached documents that are integral to, or relied upon, in Plaintiff's Complaint and will note when it does so. *In re Burlington Coat Factory*, 114 F.3d at 1426.

In affirming that *Twombly*'s standards apply to all motions to dismiss, the Supreme Court explained several principles. First, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Second, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." *Fowler v. U PMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009). However, "a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings . . . [although a] limited exception exists for documents that are integral to or explicitly relied upon in the [complaint]." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 97 n.6 (3d Cir. 2010) *cert. denied*, 132 S.Ct. 98 (2011) (citation and internal quotation marks omitted).

The Third Circuit has reiterated that "judging the sufficiency of a pleading is a context-dependent exercise" and "[s]ome claims require more factual explication than others to state a plausible claim for relief." *Id.* at 98. That said, the Rule 8 pleading standard is applied "with the same level of rigor in all civil actions." *Id.* (quoting *Iqbal*, 556 U.S. at 684).

"Independent of the standard applicable to Rule 12(b)(6) motions," Rule 9(b) of the Federal Rules of Civil Procedure requires a heightened pleading standard for claims sounding in fraud or mistake. *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002); *see also* FED. R. CIV. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.").

In addition to Rule 9(b)'s heightened pleading requirements, Congress enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA") 15 U.S.C § 78u *et seq.* to require an even higher pleading standard for plaintiffs bringing private securities fraud actions. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006). The purpose of requiring particularized pleadings is to prevent abusive securities litigations. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) ("Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law"); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81 (2006) (identifying "ways in which the class-action device was being used to injure the entire U.S. economy" and listing examples such as "nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests, and manipulation by class action lawyers of the clients whom they purportedly represent . . . ") (internal quotes and citations omitted).

The PSLRA provides two distinct pleading requirements, both of which must be met in order for a complaint to survive a motion to dismiss. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). First, under 15 U.S.C. § 78u–4(b)(1), the complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity." *Winer Family Trust v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007) (construing 15 U.S.C. § 78u–4(b)(1)). Second, the complaint must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2).[7]

[7] The PSLRA states, in pertinent part:

Both provisions of the PSLRA require facts to be pled with "particularity." *Avaya,* 564 F.3d at 253. This particularity language "echoes precisely FED. R. CIV. P. 9(b)." *In re Advanta Corp. Sec. Litig.,* 180 F.3d 525, 534 (3d Cir. 1999); *see* FED. R. CIV. P. 9(b) ("[A] party must state with particularity the circumstances constituting fraud or mistake."). Indeed, although the PSLRA replaced Rule 9(b) as the pleading standard governing private securities class actions, Rule 9(b)'s particularity requirement "is comparable to and effectively subsumed by the requirements of [§ 78u–4(b)(1) of] the PSLRA." *Avaya,* 564 F.3d at 253 (citations omitted). This standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *Advanta,* 180 F.3d at 534 (internal quotation marks omitted).

III. Analysis

Defendants argue that Plaintiff fails to state a claim for securities fraud because Plaintiff does not sufficiently allege that Defendants (1) made a materially false statement or omission or (2) acted with scienter. "To state a claim under Section 10(b) of the Exchange Act and SEC Rule 10b–5, the plaintiff must prove: '(1) a material misrepresentation or omission by the defendant;

(b) Requirements for securities fraud actions

(1) Misleading statements and omissions

In any private action arising under this chapter in which the plaintiff alleges that the defendant-

(A) made an untrue statement of a material fact; or

(B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading; the complaint shall 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 omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

(2) Required state of mind

In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

15 U.S.C.A. § 78u–4(b)(1), (2).

(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.'" *Universal Am. Corp. v. Partners Healthcare Solutions Holdings, L.P.*, 61 F. Supp. 3d 391, 395 (D. Del. 2014) (quoting *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, —— U.S. ——, 133 S.Ct. 1184, 1191–92 (2013)).

a. Whether Plaintiff Has Alleged that Defendants Made a False Statement or Omission

Defendants argue that Plaintiff has failed to allege that Defendants made a materially false statement or omission. The CAC asserts that Defendants made three sets of false statements or omissions, and the Court will examine each set in turn.

1. First Set of Statements – Importance of the ACCORD and AIM-HIM Studies

First, Plaintiff asserts that "on no fewer than nine occasions,[8] Defendants misrepresented that

[8] The nine statements at issue in the first set of allegedly false statements or omissions are as follows. The first three statements pre-date the Class Period.

(1) On September 11, 2009, Amarin held a conference call in which it stated, "And we're also in discussion with the FDA about – over the long-term this is not required for approval, but a CV outcome study to demonstrate the reduction in cardiovascular risk." CAC ¶ 127 n.10.

(2) On May 13, 2010, Amarin issued a press release stating, in relevant part, that "[t]he results of an outcome study are not required for FDA approval of the broader indication." CAC ¶ 127 n.10.

(3) On August 10, 2010, Amarin issued a press release stating, in relevant part, that "[o]utcomes study are not required for FDA approval of this broader [ANCHOR] indication for VASCEPA." CAC ¶ 127 n.10.

(4) On January 6, 2011 Amarin issued a Prospectus Supplement on Form 424B5 for an offering of 12 million American Depositary Shares at a price to the public of $7.60 per ADS which stated in relevant part:

> In order to obtain a separate indication for Vascepa based on the ANCHOR trial results, the Food and Drug Administration, or FDA, requires that we have a clinical "outcomes study" substantially underway at the time of filing a New Drug Application, or NDA. If we elect to seek this separate indication in our initial NDA filing and commence an outcomes study, we will need to seek additional financing, through a commercial partner or otherwise. The results of an outcomes study are not required for FDA approval of the broader indication, and an outcomes study is not required for the indication being studied in the MARINE trial.

CAC ¶ 158.

(5) "On March 16, 2011, Amarin filed its Form 10-K for the period ending December 31, 2010. CAC ¶ 162. The Form 10-K stated, '[i]n order to obtain a separate indication for Vascepa based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The results of an outcomes study are not required for FDA approval of the broader indication.'" CAC ¶ 163. "In further describing the ANCHOR trial, the Form 10-K reiterated, '[i]n order to seek approval of this potentially expanded indication, we will be required to have substantially enrolled subjects in a medical outcomes study at the time of our NDA submission. We are in the process of defining the clinical trial design for the outcomes study. We do not anticipate initiating the outcomes study until after the ANCHOR trial is complete. The results of this outcomes study are not required for approval of the indication studied in the ANCHOR trial; the only requirement is that the outcomes study is substantially underway.'" CAC ¶ 164.

(6) "On April 18, 2011, prior to the opening of the U.S. securities markets, Amarin released results from the ANCHOR trial . . . ." CAC ¶ 171. "The April 18, 2011 press release contained the . . . statement that 'the results of an outcomes study are not required for FDA approval of the broader [ANCHOR] indication . . . .'" CAC ¶ 174.

(7) "During the First Quarter 2011 earnings call, Zakrzewski . . . went on to discuss plans for submitting the MARINE NDA and referenced ANCHOR stating that "[a]n outcomes study must be substantially enrolled, but results are not required in order to secure approval of an indication based on the ANCHOR trial results." CAC ¶ 186–87.

(8) On February 29, 2012, Amarin filed its Annual Report on Form 10-K for year ended December 31, 2011. The company stated that "[b]ased upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial." CAC ¶ 213 (internal quotation marks omitted).

(9) "In its Form 10-K for fiscal 2012, filed with the SEC on February 28, 2013, Amarin reiterated its prior misrepresentations and omissions with respect to the ANCHOR study. The Form 10-K stated that:

the long-term REDUCE-IT study was *not* required to be completed for FDA approval of the ANCHOR indication, when Defendants knew that such a study was likely to be required, per Amarin's July 2008 meeting with the FDA[9] in which the FDA indicated that the outcomes of the

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> Based on communications with the FDA, we believe that we are required to be "substantially underway" with a cardiovascular outcomes study at the time of the submission of our sNDA [supplemental new drug application] seeking approval of the ANCHOR indication. We believe that we achieved this requirement prior to submitting the sNDA. However, there can be no assurance that the FDA will agree with our assessment or that they will accept our sNDA for the ANCHOR indication. We do not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication.

CAC ¶ 261.

[9] Plaintiff filed his complaint by relying on the FDA's October 16, 2013 Briefing Document, which was prepared in advance of the Endocronolic and Metabolic Drugs Advisory Committee Meeting at which the FDA brought the supplemental application for Vascepa to the Advisory Committee. The Briefing Document was made publicly available in October 2013. The Briefing Document stated, in relevant part, that

> During a pre-IND meeting with the applicant in July 2008 . . . the Division noted that there was a lack of prospective, controlled clinical trial data demonstrating that pharmacological reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk. The Division referenced trials ongoing at the time (e.g., AIM-HIGH, ACCORD-Lipid) that, while not able to assess the effect of specifically lowering non-HDL-C (or TG) on clinical outcomes, would be expected to provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy. It was stated that before an indication would be entertained for Ethyl-EPA as add-on to statin therapy in patients with elevated TG levels, the applicant at a minimum would have to provide results from a 12-week study with lipid endpoints as well as initiate an appropriately designed cardiovascular outcomes study. This outcomes study, known as REDUCE-IT, is ongoing and is investigating whether the addition of AMR1014 g daily ameliorates residual cardiovascular risk among patients at high CV risk who have moderate hypertriglyceridemia at LDL-C goal on statin therapy. The study designs for both ANCHOR and REDUCE-IT were agreed to by the Division under special protocol assessments.

CAC ¶ 13; *see also* FDA October 16, 2013 Briefing Document at 37.

long-term ACCORD and AIM-HIGH trials[10] would provide "important information," and both trials were ultimately unsuccessful. *See* CAC ¶¶ 127; 158; 163; 164; 168–69; 174; 187; 213; 261; 281–84 Defendants attach the FDA's Meeting Minutes to their motion and contend that their alleged non-disclosure of the FDA's 2008 comments is not actionable because (1) they had no duty to disclose the FDA comments and (2) the statements Defendants did make were not false or misleading.

In response, Plaintiff argues that "[t]he FDA's statements to Amarin regarding the importance of the ACCORD and AIM-HIGH studies[]were essential to any discussion of approval of Vascepa, and thus Defendants had a duty to reveal that information." Pl.'s Opp. Br. at 13–14.

Defendants also attach to their motion the July 2008 FDA meeting minutes, which are not publicly available and were not available to Plaintiff at the time he filed his Complaint. The meeting minutes indicate that the FDA stated, in relevant part, that:

> Although levels of non-HDL-C correlate with risk for CVD in some studies, we are not aware of any prospective, controlled clinical trial data demonstrating that pharmacological reduction of non-HDL-C (or TG) with a second drug in patients with elevated TG levels at LDL goal on statin therapy significantly reduces the residual risk for CVD. The AIM-HIGH, ACCORD, and IMPROVE-IT studies, while not designed to address this specific gap in knowledge, will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy.
>
> Thus, before we would entertain granting Ethyl-EPA an indication as add-on to statin therapy in patients with elevated TG levels, Amarin would at a minimum have to provide us with the results from a 12-week study similar to what you have proposed with Study B, and you would have to initiate an appropriately-designed cardiovascular outcomes study such that the trial was well under way at the time we reviewed the results from Study B.

July 14, 2008 FDA Pre-IND Meeting Notes at 9–10. The Court finds that the Meeting Minutes are integral to Plaintiff's Complaint, and, accordingly, may consider the document without converting this motion into a motion for summary judgment. *In re Burlington Coat Factory*, 114 F.3d at 1426.

[10] According to Defendants, the results from the third long-term study referenced in the Meeting Minutes, the IMPROVE-IT study, were not released until November 17, 2014; Defendants assert that the IMPROVE-IT study was successful. Defs.' Br. at 1.

Plaintiff acknowledges that the FDA did not state "that the success of the two trials was a 'condition' to approval.'" Pl.'s Opp. Br. at 10 n.8. However, Plaintiff argues "that the failure of the trials was 'important information' that made it 'substantially less likely' that Amarin would obtain approval."[11] *Id.*

Section 10(b) and Rule 10b–5 "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, —— U.S. ——, 131 S.Ct. 1309, 1321 (2011). Rather, "'[d]isclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Id.* (quoting 17 C.F.R. § 240.10b–5(b)); *see also City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410 (3d Cir. 1997) ("[P]ossession of material nonpublic information alone does not create a duty to disclose it.").

Here, the Court does not find that Defendants had a duty to disclose the FDA's full comments from the 2008 meeting. The Briefing Document and the Meeting Minutes characterize the FDA's position as: "the trials ongoing at the time (e.g., AIM-HIGH, ACCORD-Lipid) . . . , while not able to assess the effect of specifically lowering non-HDL-C (or TG) on clinical outcomes, would be expected to provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy."[12] CAC ¶ 13; *see also* FDA October 16, 2013 Briefing Document at 37; Oct. 16, 2013 AdCom Testimony of Mary Roberts ("Specifically, the sponsor was told the AIM-HIGH, ACCORD, and [IM]PROVE-IT studies will provide important

[11] Plaintiff's characterization of the FDA's position in his opposition brief shifted slightly from his position in the Complaint, in which Plaintiff asserted that "the success of the ANCHOR trial was dependent on the success of the ACCORD-Lipid and AIM-HIGH trials." CAC ¶ 18.

[12] Similarly, the FDA July 2008 meeting minutes state that "[t]he AIM-HIGH, ACCORD, and IMPROVE-IT studies, while not designed to address this specific gap in knowledge, will provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy." July 14, 2008 FDA Pre-IND Meeting Notes at 9–10.

information to the incremental benefit of adding a second lipid active drug to statin therapy."). Meanwhile, Defendants' statements indicate that while the FDA would require an outcomes study to be completed before entertaining an application for a more specific indication than the ANCHOR indication, such a study was not required to be completed to obtain approval for the ANCHOR indication itself.[13] *See* CAC ¶¶ 127 n.10, 158, 163, 164, 174, 187, 213, 261.

Plaintiff argues that even though the FDA did not require the outcomes studies to be completed, Defendants had a duty to disclose the fact that the FDA considered the results of the outcomes studies that were underway to be important, and failure to do so, constitutes a misleading statement or omission such that would sustain a securities fraud action. However, the case law does not support Plaintiff's assertion.

The Third Circuit's recent decision in *City of Edinburgh* is instructive. In that securities litigation case, which involved Pfizer's statements made to investors in connection with the FDA approval process involving an experimental Alzheimer's drug, the plaintiffs argued that the "defendants had a duty to speak fully and truthfully about the [experimental drug's] Phase 2 interim results because they put the subject 'in play' by discussing those results publicly. Instead of concealing material information about the poor Phase 2 interim results, the Funds allege defendants should have either disclosed those poor results or admitted they had changed their criteria for initiating the Phase 3 trial." *City of Edinburgh*, 754 F.3d at 174. However, the Third Circuit found that "[n]one of these statements [at issue] characterized or made affirmative claims

[13] According to the July 2008 Meeting Minutes, Amarin met with the FDA to discuss potential development plans for *two* indications: (1) "[a]s an adjunct to diet to reduce triglyceride (TG) levels in adult patients with very high TG levels" (the ANCHOR indication) and (2) "[a]s an adjunct to diet to reduce TG levels in adult patients with high TG levels not controlled by diet and HMG CoReductase (statin) therapy" (an unnamed and more specific indication than the ANCHOR indication, which Amarin apparently abandoned). *See* July 14, 2008 FDA Pre-IND Meeting Notes at 4, 9–10.

about the Phase 2 interim results" and, thus, "defendants did not have a duty to disclose additional information because they mentioned the Phase 2 interim results as one factor in their decision to initiate Phase 3." *Id.* at 174–75. Similarly, here, as pled, none of Defendants' statements affirmatively characterized the importance of the outcomes studies; Defendants are merely alleged to have stated, correctly, that the studies were not required to be completed in order for the ANCHOR indication application process to continue, though they would have to be completed if Amarin wished to apply for a new, more specific, indicator. *See also Oran v. Stafford*, 226 F.3d 275, 285 (3d Cir. 2000) (finding that the defendant "did not make any 'affirmative characterization' that the FDA's approval was based on a complete review of every piece of relevant medical information . . . . [but r]ather . . . made a simple (and accurate) factual assertion that the FDA had found that Redux had an 'acceptable safety profile' following a 'thorough review of more than 17 clinical trials'"); *The Winer Family Trust v. Queen*, No. CIV.A. 03-4318, 2004 WL 2203709, at *7 (E.D. Pa. Sept. 27, 2004) *aff'd sub nom. Winer Family Trust v. Queen*, 503 F.3d 319 (3d Cir. 2007) ("Rule 10b-5 . . . prohibits only misleading and untrue statements, not statements that are incomplete. Often, a statement will not mislead even if it is incomplete or does not include all relevant facts.") (quoting *Brody v. Transitional Hopsitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)) *cf. In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose.").

Plaintiff relies on *In re Viropharma Inc. Securities Litigation*, 21 F.Supp. 3d 458 (E.D. Pa. 2014), in which the district court examined, in relevant part, the defendants' statements "that based on the changes to [their drug's] label, the Company expected to reap record sales on their

exclusivity-protected" drug. *Id.* at 470. The district court in that case found that the plaintiffs had adequately alleged that defendants' omissions regarding the FDA's conclusions regarding deficiencies in a pharmaceutical study were material because the FDA's conclusions "bore directly on the exclusivity issue." Specifically, the plaintiffs alleged that "the FDA told Defendants that the studies upon which Defendants based their new label did not and could not meet the QI Act standards for exclusivity." *Id.* at 470. However, *Viropharma* is distinguishable. In that case, the defendants made affirmative representations about the probability that their new label would be approved in spite of the FDA's conclusion that the study that defendants wanted to use in support of their label changes "was not adequate and well controlled." *Id.* at 469 (internal citations and quotation marks omitted). Here, however, the FDA did not issue any conclusions about the studies at issue, nor did they make any requirements about how far along or successful the studies had to be in order for the FDA to consider approving the ANCHOR indication. Rather, as pled by Plaintiff, the FDA merely commented that the studies would provide important information. Such a comment does not transform defendants' statements into material omissions as in *Viropharma*.[14]

[14] On April 13, 2015, Plaintiff submitted a supplemental letter to the court, arguing that the Supreme Court's March 2015 decision in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S.Ct. 1318 (2015) supports its position that Defendants made materially false or misleading statements regarding the importance of the ACCORD and AIM-HIGH studies. In *Omnicare*, the Supreme Court examined Section 11 of the Securities Act of 1933, which provides a private right of action for any person acquiring security in a company making a public offering and whose registration statement, "when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). The Supreme Court considered how opinion statements made in the registration statement should be treated under Section 11 and found that (1) "a sincere statement of pure opinion is not an 'untrue statement of material fact,'" though an insincere statement of opinion or a statement supplying an underlying untrue fact may be; and (2) "if a registration statement omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and if those

Therefore, Plaintiff fails to allege that the first set of statements were materially false or misleading,[15] and, thus, the first set of statements, as pled, do not support at 10b-5 action.[16]

2. Second Set of Statements – Mineral Oil Placebo in ANCHOR trial

Second, Plaintiff asserts that "Defendants suppressed concerns regarding the use of mineral oil as the placebo in the ANCHOR trial." *See* CAC ¶¶ 72–85; 143; 249. Specifically, Plaintiff alleges that Defendants stated, on numerous occasions, that "(i) the use of mineral oil as a placebo did not raise any specific concerns with respect to the anticipated approval of the ANCHOR sNDA [supplemental new drug application] by late 2013, (ii) that the ANCHOR study

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facts conflict with what a reasonable investor would take from the statement itself, then § 11's omissions clause creates liability." *Omnicare*, 135 S.Ct. at 1326, 1329.

While the Court noted that the principles considered in *Omnicare* "inhere, too, in much common law respecting the tort of misrepresentation," *id.* at 1330, I do not find that *Omnicare* changes my analysis in this case. Here, assuming, without deciding, that *Omnicare* applies in the Section 10(b) context, I find that the omitted fact in Defendants' opinion statements at issue—that the FDA commented that the ACCORD and AIM-HIGH studies' outcomes would produce "important information"—does not conflict with what a reasonable investor would take from the statements themselves. Again, Defendants merely stated that a long-term outcomes study, which was already underway, was not required to be completed for the ANCHOR indication to be approved; that the completion of any other such studies underway would provide important information does not conflict with those statements.

[15] Defendants also separately argue that their first set of statements is not materially false or misleading because Plaintiff "does not identify any statement rendered false or misleading by the information Amarin actually omitted." Defs.' Br. at 12–13. The Court does not view this argument as separate from Defendants' underlying argument that there was no duty to disclose the FDA's comment that the outcomes studies would provide important information. Because "'[d]isclosure is required . . . only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading," *Matrixx*, 131 S.Ct. at 1321, Defendants had no duty to disclose here because the statements they made on the subject were not misleading; inherent in that conclusion is the notion that Plaintiff "does not identify any statement rendered false or misleading by the information Amarin actually omitted." Defs.' Br. at 12.

[16] Defendants further allege that the first set of statements were not materially false or misleading because (1) Amarin's statements are protected by the safe harbor for forward-looking statements, (2) the allegedly false statements are inactionable puffery, and (3) the truth on the market doctrine bars Plaintiff's claims. Because I have found that the statements are not materially false or misleading, I need not consider Defendants' alternative arguments.

achieved its primary and secondary endpoints, and (iii) that Amarin anticipated approval of the ANCHOR sNDA without completing an outcomes study," all of which was materially false and misleading,[17] because "[a]ccording to the FDA's statements at the Advisory Committee Meeting, the FDA's [concerns] with the use of mineral oil as placebo was shared with Amarin prior to the AdCom."[18] CAC ¶ 143(iii). Defendants argue that their alleged omissions about the mineral oil

[17] Plaintiff alleges that Defendants made statements to this effect at least thirty times, on the following occasions: (1) the November 29, 2010 press release, (2) the December 16, 2010 press release, (3) the January 6, 2011 Prospective Supplement, (4) the 2010 Form 10-K, (5) the March 17, 2011 conference call, (6) the April 18, 2011 press release announcing the ANCHOR trial results, (7) the April 18, 2011 conference call, (8) the May 10, 2011 press release announcing first quarter 2011 operating results, (9) the May 10, 2011 conference call, (10) the August 9, 2011 press release, (11) the August 10, 2011 earnings call, (12) the November 7, 2011 press release, (13) the November 8, 2011 earnings call, (14) the January 3, 2012 letter to shareholders, (15) the 2011 Form 10-K, (16) the February 29, 2012 press release, (17) the February 29, 2012 conference call, (18) the May 8, 2012 conference call, (19) a conference call following the July 26, 2012 announcement that Amarin had received approval for the MARINE indication, (20) the August 8, 2012 press release announcing second quarter 2011 operating results, (21) the August 8, 2012 earnings call, (22) the November 8, 2012 conference call, (23) the February 26, 2013 press release, (24) the February 28, 2013 press release, (25) the February 28, 2013 conference call, (26) the 2012 Form 10-K, (27) the May 9, 2013 press release, (28) the May 9, 2013 conference call, (29) the June 19, 2013 announcement of an Advisory Committee for the ANCHOR sNDA, (30) the July 10, 2-013 Prospectus Supplement, and (31) the August 8, 2013 press release and conference call. CAC ¶ 146(ii); *see also* CAC ¶¶ 146–147, 149, 153, 158, 162–164, 168–169, 172, 174–175, 180, 181, 183–187, 194–198, 201–202, 204–208, 211–213, 215–217, 220–222, 224, 231–234, 240, 241, 243–245, 249, 256–261, 266, 268, 274, 275, 281, 286–288.

[18] Plaintiff's specific allegations about the viability of mineral oil as a placebo are detailed below. The ANCHOR trial utilized mineral oil as a placebo. CAC ¶ 74. "The ANCHOR study demonstrated adverse lipid test results on placebo compared to baseline statin therapy – including an increase in LDL-C of 8.8% and TGs of 5.9% -- raising the possibility that mineral oil was not inert and had an adverse impact on absorption of the statin." CAC ¶ 76. "Moreover, the treatment arm (Vascepa plus statin) resulted in a 1.5% increase in LDL-C over baseline. Therefore, in absolute terms, Vascepa did not decrease the reading of LDL-C in the ANCHOR study, but rather only decreased the reading relative to placebo." CAC ¶ 77.

> In September 2011, Confidential Witness A ["CWA"], a senior director of clinical research and medical affairs at Amarin who reported to Paresh Soni, Senior Vice President, Head of Development, was concerned that the mineral oil placebo was not inert and had an adverse impact on the absorption of the statin, which resulted in the

placebo used in the ANCHOR trial are not materially false or misleading because (1) "[a] company has no duty to disclose "internal debate" regarding its trials (especially so when the position management has taken is consistent with a negotiated protocol approved by the FDA)

> 8.8% increase in LDL-C and 5.9% increase in TG readings in the control arm. Soni informed [CWA] that he too was concerned that mineral oil was not inert and had discussed his concerns with defendant Zakrzewski.

CAC ¶ 78.

> Because of his concern with mineral oil as the placebo, [CWA] recommended to [] Soni and Rene Braeckman (Head of Development Operations) that Amarin conduct a . . . study to compare mineral oil placebo to corn oil and olive oil to determine if there were effects on results [and potentially modify the newer REDUCE-IT study]. Other similar studies of drugs with similar viscosity and taste to Vascepa at the time were using olive oil or corn oil placebos. Soni and Braeckman rejected any potential study or modifications to the REDUCE-IT protocol because the SPA had been approved by the FDA and the ANCHOR study had been conducted with mineral oil as the placebo. Zakrzewski told [CWA] that he would not allow any change to REDUCE-IT and that this study would meet a budget number and not to answer a scientific question and that Amarin 'was not moving backwards.' Zakrzewski told [CWA] that he was not changing any studies that would affect the time line of when Amarin could file the sNDA with the FDA for the ANCHOR indication.

CAC ¶ 79.

"As stated . . . in the [FDA's] October 11, 2013 Briefing Document to the Advisory Committee and at the Advisory Committee meeting itself, the FDA shared [CWA's] concern that mineral oil was not inert and stated that it had met with Amarin to discuss the issue in advance of the Advisory Committee hearing – thus confirming plaintiff's allegations that Defendants' had actual knowledge of the risk that mineral oil was not inert and misrepresented the true facts to investors." CAC ¶ 83; *see also* CAC ¶ 313 (Plaintiff's allegations quoting an FDA official's testimony at the AdCom meeting in which the official allegedly stated, "we discussed our concerns with the sponsor and asked that they task the REDUCE-IT data monitoring committee with evaluating the accruing lipid data with this concern in mind"). Therefore, according to Plaintiff, "Defendants knew that the ANCHOR test results indicated that mineral oil may not be biologically inert, refused to conduct further tests, and misrepresented the truth with respect to the ANCHOR results to investors." CAC ¶ 84.

However, Plaintiff does not specify in the CAC when Defendants allegedly became aware of the FDA's concerns. *See generally* CAC.

The credibility of CWA's allegations is examined *infra* in the Court's discussion of scienter.

and (2) "Plaintiffs also fail to allege that any affirmative statement was rendered misleading by the alleged omission." Defs.' Br. at 18–19.

At the outset, to the extent that the more than thirty statements highlighted by Plaintiff indicated "that Amarin anticipated approval of the ANCHOR sNDA without completing an outcomes study," such statements are opinions which do not contain underlying untrue facts and are thus not materially false or misleading unless Defendants knew them to be false or misleading at the time they were made. *See, e.g.*, *Dutton v. Harris Stratex Networks, Inc.*, 270 F.R.D. 171, 178 (D. Del. 2010).

Here, the Court does not find Defendants' statements about the progress and likelihood of success of the ANCHOR trial to be materially false or misleading at the time they were made, for multiple reasons. First, Plaintiff does not plead that any FDA concerns about the mineral oil placebo were so serious as to place the ANCHOR trial and, thus, FDA approval of the ANCHOR indication, in jeopardy; in fact, Plaintiff indicates that the FDA approved the use of mineral oil as a placebo in its SPA with Amarin. *See* CAC ¶ 79. Because Plaintiff fails to plead that the FDA's concerns were so concrete or serious as to derail the ANCHOR trial or indication,[19] Plaintiff fails to plead that Defendants' statements expressing optimism about the ANCHOR trial's progress were materially false or misleading so as to require the disclosure of those concerns. *See, e.g.*, *In re Sanofi Sec. Litig.*, No. 13 CIV. 8806 PAE, 2015 WL 365702, at *18 (S.D.N.Y. Jan. 28, 2015) (finding that defendants' omissions regarding FDA concerns about a clinical trial to not be materially false or misleading statement because "[d]espite the concerns the FDA had expressed about the design of the clinical trials, it allowed those trials to proceed."); *cf. In re MedImmune,*

[19] Indeed, the July 2008 Meeting Minutes indicate that any FDA concerns expressed at that time regarding the mineral oil placebo were resolved at the meeting. *See* July 14, 2008 FDA Pre-IND Meeting Notes at 7–8.

Inc. Sec. Litig., 873 F. Supp. at 966 ("Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process . . . . Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions."). Moreover, Plaintiff fails to plead when the FDA expressed its concerns to Amarin about the mineral oil placebo. *See generally* CAC. Therefore, even if the Court were to conclude that positive statements about the trial in the wake of such concerns were materially false or misleading, I would be unable to determine which statements were made after the concerns were expressed.

Therefore, the Court finds that Plaintiff has failed to plead that Defendants' second set of statements are materially false or misleading so as to sustain a 10b-5 action.

3. Third Set of Statements – JELIS Trial

Plaintiff states that "Defendants repeatedly miscited JELIS[20] as support for the efficacy of Vascepa, despite their actual knowledge of critical distinctions between JELIS and ANCHOR and REDUCE-IT." *See* CAC ¶¶122–25; ¶ 146(ii), 165; 202; 288. Specifically, Plaintiffs allege that on two occasions, Defendants "represented that the JELIS study was indicative of efficacy of Vascepa for the ANCHOR indication," which was "materially false and misleading because

[20]"The Japan Eicosapentaenoic acid (EPA) Lipid Intervention Study, or JELIS study, was the first large-scale, prospective, randomized trial of combined treatment with a statin and an omega-3 fatty acid originally derived from fish, eicosapentaenoic acid (EPA). The study tested the effects of long-term use of EPA in addition to a statin in Japanese patients with hypercholesterolemia." CAC ¶ 120. "The JELIS investigators concluded that JELIS showed that the addition of EPA to statin therapy provides additional benefit in preventing major coronary events, apparently through lipid-independent mechanisms." CAC ¶ 121.

Plaintiff identifies the differences between the JELIS trial and the ANCHOR trial as follows: (1) "the ANCHOR trial was double-blind (neither participants nor researchers were aware of which treatment each participant was receiving), whereas JELIS was open-label (both participants and researchers knew which treatment was being administered)," and (2) "whereas over 90% of the patients in the ANCHOR trial were on medium to high doses of statins, by design, all of the patients in the JELIS study were on low doses of statin." CAC ¶¶ 123, 125.

they failed to disclose material distinctions with respect to JELIS. Defendants were aware of the distinctions between [the] JELIS and ANCHOR [trials] and knew that the results of the JELIS study (high LDL-C at baseline and low statin administration) were not indicative of efficacy of Vascepa for the ANCHOR indication."[21] CAC ¶ 146(ii). Defendants, however, argue that "Amarin . . . never represented that the studies were identical or that the JELIS trial could serve as a proxy for a Vascepa outcome study." Defs.' Br. at 20. Defendants further argue that "Plaintiffs' claim is also barred by the truth-on-the-market doctrine because the information

[21] Specifically, Plaintiffs point to the following statements:

(1) The 2010 Form 10-K "discussed JELIS as establishing a successful outcomes study for the ANCHOR indication of Vascepa:

> Among the reasons why Phase II trials were not conducted or required is that the active ingredient in Vascepa, ethyl-EPA of not less than 96% purity with no DHA, has been approved by regulatory authorities in Japan and marketed by Mochida Pharmaceutical Co. for over a decade. In Japan, ethyl-EPA is marketed under the product name of Epadel and is indicated for hyperlipidemia and peripheral vascular disease and which we understand has 2009 revenues in Japan that exceed $500 million per year. Clinical data from Japan shows that Epadel is effective in reducing TGs. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study (JELIS) study, which study consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of patients with triglyceride levels of 150 mg/dL (average 269 mg/dL at entry) and HDL-C <40 mg/dL."

CAC ¶ 165.

(2) At the August 8, 2013 conference call, "Defendant Steven B. Ketchum, AMRN's head of R&D sought to downplay any risk to the approval of Vascepa for the ANCHOR indication based on the outcomes of recent studies: . . . . 'While we believe we do not need the REDUCE-IT study to be completed for approval of the ANCHOR indication, we do believe that this study is positioned for success. (inaudible) EPA and the JELIS study, albeit in a Japanese population demonstrated significant reduction in cardiovascular events over statin therapy alone . . . .'" CAC ¶ 288.

Plaintiffs allege was omitted was part of the total mix of information available to the market." *Id.* at 21.

Upon review of Plaintiff's allegations, the Court concludes that, as a matter of law, Defendants' statements regarding the JELIS trial were not materially false or misleading. The first statement merely notes the existence of the JELIS trial and its successful outcome, without comparing the JELIS trial to the ANCHOR trial. *See* CAC ¶ 165. The second statement is not even pled as a complete statement, and the portion that was audible and transcribed in the Complaint merely states that the JELIS study "demonstrated significant reduction in cardiovascular events over statin therapy alone," again without making comparisons or highlighting similarities between the JELIS and ANCHOR studies. CAC ¶ 288. Indeed, the second statement actually notes a distinction between the two studies: that the JELIS study tested a Japanese population. *Id.* Therefore, as pled, Defendants' statements regarding the JELIS trial are not materially false or misleading as to sustain a 10b-5 action.[22]

Because the existence of a materially false or misleading statement is an essential element of a 10b-5 action, and I have found that none of the statements identified by Plaintiff qualify, Plaintiff's Complaint is dismissed without prejudice for failure to state a claim.

b. Whether Plaintiff Has Alleged Particularized Facts Giving Rise to a Strong Inference that the Individual Defendants Acted with Scienter

Plaintiff's Complaint also fails to state a claim because Plaintiff fails to allege that the Individual Defendants acted with scienter, another essential element of a 10b-5 action. "[I]n determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must

[22] Defendants further argue that their statements about the JELIS study are protected by the "truth on the market" doctrine. Because I find that Defendants' statements regarding JELIS are not materially false or misleading, I need not reach this issue.

take into account plausible opposing inferences . . . . A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323–29 (2007) (emphasis in original). "While we will aggregate the allegations in the complaint to determine whether it creates a strong inference of scienter, plaintiffs must create this inference with respect to each individual defendant in multiple defendant cases."[23] *Winer Family Trust v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007) (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 603 (7th Cir. 2006) *rev'd on other grounds*, 551 U.S. 308 (2007)).

Plaintiff alleges that the following facts that, according to Plaintiff, support a strong inference that the Individual Defendants acted with scienter: (1) Vascepa is Amarin's "core" business, supporting a strong inference that the Individual Defendants knew what transpired at the July 2008 meeting; (2) financial motives of the individual defendants support a strong inference of scienter; (3) key senior employees left Amarin soon before the FDA ruling on the sNDA for

[23] Defendants argue that Plaintiff has failed to plead that the Individual Defendants acted with scienter. Regarding corporate scienter, also known as collective scienter, in which "a plaintiff . . . plead[s] an inference of scienter against a corporate defendant without raising the same inferences required to attribute scienter to an individual defendant," the Third Circuit has "neither . . . accepted nor rejected the doctrine of corporate scienter in securities fraud actions." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246 (3d Cir. 2013) (internal citation omitted). Plaintiff argues that the doctrine should be used here because the Third Circuit acknowledged that other Circuits have adopted the concept of corporate scienter and indicated a willingness to adopt the concept as well. Pl.'s Opp. Br. at 36. However, the Court reads *Rahman* as neutral, not positive, towards the corporate scienter doctrine. *See Rahman*, 736 F.3d at 246.

Nevertheless, in his Complaint, Plaintiff does not plead any specific facts raising a strong inference of scienter against Amarin; at most, Plaintiff states general, conclusory allegations that both Amarin and the Individual Defendants acted with scienter. *See* CAC ¶¶ 327–380. Instead, Plaintiff raises specific corporate scienter allegations for the first time in his opposition to Defendants' motion to dismiss by alleging that Amarin (1) had knowledge of the July 2008 FDA meeting and (2) was economically motivated to commit fraud. It is axiomatic that a plaintiff may not amend his Complaint through an opposition brief. *Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988). Therefore, the Court will not consider Plaintiff's allegations of corporate scienter.

ANCHOR; and (4) CWA confirmed that Defendants were aware of but chose to ignore concerns with the outcomes trials. CAC ¶¶ 327–80. While the Court will examine the totality of the inferences supporting and opposing scienter to make its final determination, I will examine the allegations regarding Defendants' motive and opportunity before proceeding to allegations regarding Defendants' conscious misbehavior or recklessness. *See Institutional Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 268 (3d Cir. 2009).

1. Motive and Opportunity

The Court will first examine Plaintiff's contention that the Individual Defendants acted with scienter because they had financial motive and opportunity. While the Third Circuit recognizes that "'motive and opportunity' may no longer serve as an independent route to scienter" in the wake of *Tellabs*'s instructions to consider the complaint in its entirety, particularized allegations regarding motive and opportunity may, in combination with other allegations, support a strong inference of scienter. *Avaya*, 564 F.3d at 268; *see also Tellabs*, 551 U.S. at 323–29. In that connection, Plaintiff alleges that (1) Defendants Zakrzewski and Thero were "financially motivated to commit the fraud and artificially inflate the market price of Amarin stock, [because w]hile in possession of material, nonpublic information regarding the prospects for approval of Vascepa for the ANCHOR indication, [they] sold substantial Amarin ADSs at artificially inflated prices, reaping huge profits."[24] CAC ¶¶ 343, 346. "Stock sales unusual in time and scope may give rise to an inference of scienter." *In re Urban Outfitters, Inc. Sec. Litig.*, No. CIV.A. 13-5978, 2015 WL 2069222, at *12 (E.D. Pa. May 4, 2015) (citing *Avaya*, 564 F.3d at 279). Put another way, "insider trading in suspicious amounts or at suspicious times" giving rise to an inference that the trader engaged in wrongdoing, may be also inferred to the company as well.

[24] As to Defendant Ketchum, Plaintiff does not allege that Ketchum sold any stock.

Advanta, 180 F.3d at 540; *see also Urban Outfitters*, 2015 WL 2069222, at *12. "Whether a sale is 'unusual in scope' depends on factors such as 'the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved.'" *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 277 (3d Cir. 2006) (quoting *Wilson v. Bernstock*, 195 F.Supp. 2d 619, 635 (D.N.J. 2002)). "Other factors relevant to scope and timing are whether the sales were 'normal and routine,' and whether the profits were substantial relative to the seller's ordinary compensation." *Id.* (quoting *In re Burlington Coat Factory*, 114 F.3d at 1423).

Here, Plaintiff alleges that, "[a]s part of Zakrzewski's remuneration, he was granted an option on December 21, 2009 to purchase 1,170,000 ordinary shares under the Amarin 2002 Stock Option Plan (the options were to vest in four equal installments over four years). On November 11, 2010, Zakrzewski was granted options to purchase an additional 1,750,000 shares under the same Plan (also to vest over four years in equal installments). During 2011, 730,000 of his shares became exercisable and he sold 460,000, or 63% of his total shares available to sell. During 2012, another 730,000 of his shares became exercisable and he sold 610,000, or 84% of his total shares available to sell. In sum, from February 22, 2011 through October 1, 2012, Zakrzewski sold 1,070,000 shares of Amarin ADSs for total net proceeds of $11,898,553." CAC ¶¶ 344–45. However, none of these facts suggest that Zakrzewski sold his stocks at unusual times or in unusual amounts; Zakrzewski sold his stocks at prices well below Amarin's high of $19.50, sold them in increments throughout 2011 and 2012, sold them well before the October 2013 Briefing Document was released, and still retained hundreds of thousands of Amarin shares. *See* CAC ¶ 4. Further, Zakrzewski's stock options were a portion of his salary, and, thus, it is not unusual for him to have exercised his stock options when they became available. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 541 (3d Cir. 1999) ("A large number of today's

corporate executives are compensated in terms of stock and stock options. It follows then that these individuals will trade those securities in the normal course of events.") (quoting *Burlington Coat Factory*, 114 F.3d at 1424); *see also In re Astea Int'l Inc. Sec. Litig.*, No. CIV.A. 06-1467, 2007 WL 2306586, at *14 (E.D. Pa. Aug. 9, 2007); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 176 (3d Cir. 2014). ("The mere fact that [the defendants] sold stock is insufficient to establish scienter.").

Similarly, Plaintiff alleges that, "[a]s part of Thero's remuneration, he was granted an option on December 21, 2009 to purchase 900,000 ordinary shares under the Amarin 2002 Stock Option Plan (under which the options were to vest in four equal installments over four years). On November 10, 2010, Thero was granted an option to purchase an additional 1,200,000 ordinary shares under the Amarin 2002 Stock Option Plan (also to vest over four years in equal installments). During 2012, 625,000 of his shares became exercisable and he sold 451,852, or approximately 72% of his total shares available to sell. In sum, from April 9, 2012 through July 27, 2012, Thero sold 451,852 shares of Amarin ADSs for total net proceeds of $4,901,434." CAC ¶¶ 347–48. However, the same reasoning applies to Plaintiff's allegations about Thero's motive and opportunity. Thero sold his stocks at prices well below Amarin's high of $19.50, sold them in increments throughout 2012, sold them well before the October 2013 Briefing Document was released, and still retained several hundreds of thousands of shares. Further, Thero's stock options were a portion of his salary, and, thus, it is not unusual for him to have exercised his stock options when they became available. *See In re Advanta Corp.*, 180 F.3d at 541; *see also In re Astea Int'l Inc.*, No. CIV.A. 06-1467, 2007 WL 2306586, at *14.

Plaintiff further alleges that Zakrzewski, Thero, and Ketchum also received bonuses, additional stock options, and high salaries. Specifically, "[a]ll three defendants were paid, in the

aggregate, from 2010-12, in excess of $24.5 million of executive compensation–an enormous sum considering that the company had hardly any revenue and little to no prospect of success on getting FDA approval for Vascepa based on the ANCHOR indication, without conducting the 'bet the ranch' $100 plus million REDUCE-IT test." CAC ¶ 360. However, this fact simply reveals a generic corporate motive to continue Amarin's success, which is insufficiently supportive of scienter. *See GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237-38 (3d Cir. 2004) (finding insufficient the plaintiffs' allegations that "the defendants' motive to commit fraud was that Washington 'would not have been able to acquire [the target company] without the successful issuance of the Notes,' and would not have been able to sell any of the notes at or near the price sought 'had the true financial condition of the [target company] been revealed'"). Courts have found even more specific pecuniary motivations, such as the possibility of receiving performance-related bonuses or underwriting fees on behalf of the company, to fall short of demonstrating scienter. *Id.* (underwriting and financial advisory fees); *California Pub. Employees' Ret. Sys. v. Chubb Corp.*, No. CIV. NO. 00-4285 (GEB, 2002 WL 33934282, at *22 (D.N.J. June 26, 2002) (a higher salary and bonus). Nor is it sufficient to allege a general desire to inflate, increase, or maintain the stock price. *Nat'l Junior Baseball League*, 720 F. Supp. 2d at 551-52; *In re Bio-Technology General Corp. Sec. Litig.*, 380 F. Supp. 2d 574, 595 (D.N.J. 2005).

Therefore, Plaintiff has failed to allege that Defendants had motive and opportunity, or engaged in sock sales unusual in time or scope, such that would support a strong inference of scienter.

2. Conscious Misbehavior or Recklessness

I next turn to Plaintiffs' scienter allegations regarding Defendants' alleged conscious misbehavior or recklessness. "The standard for 'conscious misbehavior or recklessness' requires

misrepresentations to be 'so recklessly made that the culpability attaching to such reckless conduct closely approaches that which attaches to conscious deception.'" *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 622 (E.D. Pa. 2009) (quoting *In re Digital Island Sec. Litig.*, 357 F.3d 322, 332 (3d Cir. 2004)). "Conscious misbehavior involves 'intentional fraud or other deliberate illegal behavior.'" *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 613 (E.D. Pa. 2009) (quoting *In re Advanta*, 180 F.3d at 535). Recklessness involves "not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and 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." *In re Advanta*, 180 F.3d at 539.

In that connection, Plaintiff alleges that (1) Vascepa is Amarin's "core" business, and, therefore, "it is simply not plausible that Amarin's most senior management, including those directly responsible for overseeing, managing and reporting on its financial state, were not privy to the internally known adverse facts disclosed to the Company by the FDA in July 2008," CAC ¶ 331; (2) "two key senior employees with knowledge of Amarin's communication with the FDA" left Amarin soon before the FDA ruling on the sNDA for ANCHOR, CAC ¶ 361; and (3) CWA confirmed that Defendants were aware of but chose to ignore concerns with the outcomes trials.

I will first address Plaintiff's "core business" allegation. "While it is true that false or misleading statements by key executives regarding a company's lead product or core business practices will weigh in favor of finding a strong inference of scienter, [courts] will not make such an inference 'absent particularized allegations showing that defendants had ample reason to know of the falsity of their statements.'" *City of Roseville Employees' Ret. Sys. v. Horizon Lines, Inc.*, 686 F. Supp. 2d 404, 423 (D. Del. 2009). In that connection, Defendants argue that the

Individual Defendants joined Amarin years after the 2008 Meeting, and, thus, Plaintiffs do not sufficiently allege that the Individual Defendants knew about the FDA's comments regarding the ACCORD and AIM-HIGH trials. Defs.' Br. at 23. The Court agrees. *See Nat'l Junior Baseball League*, 720 F. Supp. 2d at 556 ("[I]t is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question."); *see also In re Bio–Technology General Corp. Sec. Litig.*, 380 F.Supp.2d 574, 596 (D.N.J.2005); *In re Advanta*, 180 F.3d at 539 ("[A]llegations that a securities-fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading are precisely the types of inferences which courts, on numerous occasions, have determined to be inadequate to withstand Rule 9(b) scrutiny."). Here, that the FDA expressed its opinion at one point that the results of the ACCORD and AIM-HIGH studies would be "important information" with respect to the ANCHOR indication is not even a specific enough statement to qualify as a fact that was important to Amarin's business; even if it were, Plaintiff has not adequately alleged that the individual defendants had knowledge of the FDA's comment. Thus, Plaintiff's allegations that Vascepa is Amarin's core business are insufficient to support a strong inference of scienter.

Next, I examine Plaintiff's argument that two key employees with knowledge of the FDA's July 2008 comments left Amarin before the FDA ruled on the ANCHOR sNDA. "[A] defendant's resignation could constitute a 'piece to the scienter puzzle' if the resignation both takes place within a couple of months of the announcement of the errors committed and is accompanied by an extraordinary corporate punishment measure, e.g., denial of severance payment." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 347 (D.N.J. 2007); *see also City of*

Roseville Employees' Ret. Sys. v. Horizon Lines, Inc., 442 Fed. App'x 672, 679 (3d Cir. 2011).

Here, Plaintiff alleges that Paresh Soni, Amarin's Senior Vice President and Head of Development since September 2008, left in August 2013, two months before the Briefing Document was released, "reflecting his lack of confidence in Amarin's ability to get FDA approval of Vascepa for the ANCHOR indication." CAC ¶ 368. Further, Plaintiff alleges that Paul Duff, who joined Amarin in February 2011 as Chief Commercial Officer and was thereafter promoted to Senior Vice President, "resigned from Amarin without public comment in July 2013, prior to the AdCom Hearing, reflecting his significant lack of confidence in Amarin's ability to get FDA approval of Vascepa for the ANCHOR indication."[25] CAC ¶ 377. Neither Soni nor Huff are named as Individual Defendants in Plaintiff's Complaint.

Here, though Soni and Huff did resign just a few months before the Briefing Document was released, in which it was "revealed" that the FDA had concerns about the studies underpinning Vascepa's ANCHOR sNDA, Plaintiff does not allege that any extraordinary corporate punitive actions were taken against Soni or Huff, nor any other specific facts that suggest that they resigned because they feared fallout from Amarin's false or misleading statements about Vascepa. Based on Plaintiff's allegations, is more plausible that Soni and Huff resigned for various other reasons, such as to pursue other opportunities, for family reasons, etc., than it is that they resigned due to knowledge that Amarin's false or misleading statements were soon to be exposed. *See Tellabs*, 551 U.S. at 323–29. Thus, those executives' resignations, without more,

[25] The CAC also alleges that in 2011, Soni sold 200,000 of his 400,000 stock shares that became exercisable and that in 2012, Huff sold 100% of his restricted stock units that vested, as well as an unspecified percentage of his stock options that also vested. To the extent that Plaintiff alleges these facts to suggest that Soni and Huff lacked confidence in the possibility that Vascepa would be approved for the ANCHOR indication, such a suggestion must fail, for the same reasons discussed *supra* regarding Plaintiff's scienter allegations about the Individual Defendants' exercise of their stock options.

are insufficient to support a strong inference of scienter. *See, e.g.*, *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 347 (D.N.J. 2007); *see also City of Roseville Employees' Ret. Sys.*, 442 Fed. App'x at 679.

Finally, Plaintiff also alleges that scienter may be inferred from the fact that CWA confirmed that Defendants were aware of but chose to ignore concerns with the outcomes trials. *See* CAC ¶¶ 378–80. Defendants argue that the majority of CWA's allegations pertain to the use of mineral oil as a placebo and "establish the highly credible non-fraudulent inferences that Amarin was comfortable with the mineral oil placebo, and resistant to running new trials using a new placebo 'because the SPA had been approved by the FDA and the ANCHOR study had been conducted with mineral oil as the placebo.'" Defs.' Br. at 26 (quoting CAC ¶ 79). Defendants further argue that "CWA's allegations regarding Zakrzewski's disagreement with an unspecified Senior Director of Investor Relations likewise fail to raise any inference of scienter, instead bolstering the notion that Zakrzewski believed Vascepa would be approved for the ANCHOR Indication," in part because Plaintiff has not alleged that Zakrzewski did not believe his own statements. Defs.' Br. at 26–27.

The Third Circuit has counseled that when examining the allegations of confidential sources, district courts should examine "the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Calif. Public Employees' Retirement Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004). "If, after that assessment, 'anonymous source allegations are found wanting with respect to these criteria . . . courts must discount them steeply." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 244 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 261). "We explained in *Avaya* that such a

discount 'is consistent with *Tellabs*'s teaching that omissions and ambiguities count against inferring scienter under the PSLRA's particularity requirements,' but if 'a complaint's confidential witness allegations are adequately particularized, we will not dismiss them simply on account of their anonymity.'" *Id.* (quoting *Avaya*, 564 F.3d at 261).

Here, Plaintiff has identified CWA as "a senior director of clinical research and medical affairs at Amarin who reported to Paresh Soni, Senior Vice President, Head of Development . . . ." CAC ¶ 78. The Court finds that CWA's sources of knowledge (his clinical research position at Amarin and his conversations with senior executives at the company), the reliability of the sources (high, by virtue of his position at Amarin), the corroborative nature of other facts alleged (fairly corroborative, given that Amarin made no changes to placebo used in the ANCHOR trial and the FDA stated it had expressed concerns about the placebo as well) and the coherence and plausibility of the allegations (high, by virtue of the FDA's similar concerns and his position at Amarin), are not wanting; thus, the Court will not discount CWA's allegations simply because he is anonymous. *See Calif. Public Employees' Retirement Sys.*, 394 F.3d at 147; *Rahman*, 736 F.3d at 244.

However, the Court finds that CWA's allegations do not support a strong inference of scienter. CWA's allegations state that (1) Zakrzewski was open about wanting to sell Amarin at a high price, (2) the Senior Director of Investor Relations and Communications "would tell CWA that he tried to get Zakrzewski to be less optimistic in public statements" and that CWA tried to do the same, and (3) "the Senior Director told CWA that the Senior Director was 'at the end of his rope,'" and "[t]he Senior Director left Amarin in March 2013." CAC ¶ 379. "CWA also said that he has spoken to two different Medical Science Liaisons (the "MSLs") who worked with Amarin, and specifically defendant Ketchum, in advance of the October 16, 2003 AdCom. The

MSLs told CWA that defendant Ketchum knew he would receive questioning from the AdCom on the use of mineral oil on placebo and the relevance of ACCORD-LIPID and AIM-HIGH to approving Vascepa for the ANCHOR indication without an outcomes trial and was concerned that he would be unable to satisfy the FDA's and the AdCom's concerns." CAC ¶ 380. However, these statements—even coupled with Plaintiff's statements earlier in the Complaint about Amarin senior executives rejecting any changes to their studies because the SPA had been approved and Amarin "was not moving backwards"—merely create the inference that Zakrzewski and other executives were optimistic about the success of Vascepa and about Amarin's success, despite some concerns raised about the mineral oil placebo. The statements do not indicate that Zakrzewski or any other executive did not believe the statements Amarin made about Vascepa were false. *See* CAC ¶¶ 78–79; 378–80. Therefore, CWA's statements do not raise the strong inference of scienter.[26]

[26] Finally, to the extent that allegations by Confidential Witness B ("CWB") are raised in support of scienter, Defendants argue that the allegations "are so speculative and attenuated as to have no credibility." Defs.' Br. at 27.

"[CWB] was a Senior Medical Science Liaison for Amarin based in a mid-Atlantic state. [CWB] was employed by Amarin from July 2012 to October 2013. Confidential Witness B reported to Sephy Philip, Senior Director of Medical Affairs, and to Christina Copeland, Medical Director." CAC ¶ 294. Plaintiff "has confirmed [CWB's] job description and employment with Amarin on LinkedIn." CAC ¶ 298 n.11. "When [CWB] attended the prep session for the FDA meeting, he was under the impression that Dr. Christie Ballantyne, the principal investigator on the ANCHOR study, would be presenting the results of the study and speaking on behalf of Amarin at the FDA meeting. A week before the FDA meeting, however, [CWB] learned that Ballantyne had declined to participate and was not going to present the data or speak on behalf of Amarin." CAC ¶ 301. "Ballantyne's decision surprised [CWB] because principal investigators usually are willing to present their data and speak on behalf of the company at FDA meetings." CAC ¶ 302. "'I found that odd,' [CWB] said. 'I'm sure it's happened before but not in my 20 years in the industry. It clearly raised a red flag for me.'" CAC ¶ 303.

Assuming without deciding that CWB's allegations should not be discounted due to the witness's confidential status, the Court finds that CWB's allegations do not create a strong inference of scienter. Plaintiff does not allege that Dr. Ballantyne chose not to testify because he knew Amarin's public statements about Vascepa were materially false or misleading, and CWB

Further, reading Plaintiff's allegations of scienter holistically, no strong inference of scienter may be imputed, either. None of Plaintiff's allegations individually raise a strong inference of scienter, and, even when combined, Plaintiff fails to "plead facts rendering an inference of scienter *at least as likely* as any plausible opposing inference." *Tellabs*, 551 U.S. at 323–29. Rather, it is more plausible to infer from the totality of Plaintiff's allegations that, at most, Amarin executives were simply overly optimistic about the success of the ANCHOR trial and the likelihood of FDA approval for the ANCHOR indication. *See Rahman*, 736 F.3d at 247. Therefore, Plaintiff's 10b-5 claim fails as a matter of law for failure to sufficiently allege scienter.[27]

Because Plaintiff's 10b-5 claim fails to sufficiently allege either a material false or misleading statement or that Defendants acted with scienter, Count One of the CAC must be dismissed for failure to state a claim.[28]

c. Count Two

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himself acknowledges that he's "sure it's happened before" that a principal investigator would not present his or her study's results before the AdCom.

[27] Defendants also argue that their risk disclosures negate an inference of scienter. *See* Defs.' Br. at 24–25. However, Defendants do not cite to any cases in this circuit for that proposition, and the Court is unable to find authority within the circuit addressing the existence and content of risk disclosures in connection with scienter analysis. Rather, case law in this circuit appears to address risk disclosures in the context of the applicability of the safe harbor to forward-looking statements. *See, e.g.*, *In re Anadigics, Inc., Sec. Litig.*, No. CIV.A. 08-5572 MLC, 2011 WL 4594845, at *24 n.7 (D.N.J. Sept. 30, 2011) *aff'd sub nom. In re Anadigics, Inc. Sec. Litig.*, 484 F. App'x 742 (3d Cir. 2012); *Bldg. Trades United Pension Trust Fund v. Kenexa Corp.*, No. CIV.A. 09-2642, 2010 WL 3749459, at *14 (E.D. Pa. Sept. 27, 2010). Therefore, the Court will not consider this argument.

[28] In a footnote of their moving brief, Defendants also argue that Plaintiff fails to plead loss causation, another essential element of a 10b-5 action, as to Defendants' allegedly misleading statements about the JELIS study. *See* Defs.' Br. at 20 n.6. However, the Court need not reach this issue, as I have already found that Plaintiff's claim is deficient as to two of the required elements of a 10b-5 action and because the parties do not adequately argue the issue.

In Count Two, Plaintiff alleges a violation of Section 20(a) of the Exchange Act against the Individual Defendants. "[S]uch liability 'is derivative of an underlying violation of Section 10(b) by the controlled person.' Inasmuch as there cannot be Section 10(b) liability here, the individual defendants cannot be liable" under Section 20(a). *Rahman*, 736 F.3d at 247 (quoting *Avaya*, 564 F.3d at 252). Therefore, because the Court finds that Plaintiff fails to state a claim under Section 10(b), Count Two must also be dismissed for failure to state a claim.

IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is granted and Plaintiff's motion to strike is denied. Plaintiff's Complaint is dismissed without prejudice. Plaintiff is given thirty days to re-file his Complaint.

Dated: June 26, 2015

/s/ Freda L. Wolfson
United States District Judge