UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MERIAM RATNER, Individually and On Behalf of All Others Similarly Situated Plaintiffs, v. OVASCIENCE, INC., MICHELLE DIPP, and CHRISTOPHER A. BLECK, Defendants.	)	CIVIL ACTION No. 14-12412-WGY

YOUNG, D.J. September 28, 2015

MEMORANDUM & ORDER

I. INTRODUCTION

This is a shareholder class action brought against OvaScience, Inc. ("OvaScience"), its Chief Executive Officer and President Michelle Dipp, and its Chief Commercial Officer and Vice President Christopher Bleck ("Individual Defendants"). Lead plaintiff Meriam Ratner brings this class action on behalf of herself and all other investors who purchased OvaScience securities between February 25, 2013 and September 10, 2013 (the "Class Period"). Consolidated Class Action Compl. ("Compl.") ¶ 1, ECF No. 30.

The shareholder plaintiffs (the "Plaintiffs") allege that throughout the Class Period, OvaScience and the Individual

Defendants (collectively, the "Defendants") omitted material information concerning the regulatory status and commercial prospects of OvaScience's first product candidate, a fertility treatment known as Autologous Germline Mitochondrial Energy Transfer ("AUGMENT"). Id. ¶¶ 44-50. They further assert that during the Class Period, OvaScience, in written public statements, expressed its belief that AUGMENT qualified for reduced regulatory oversight and stated it was enrolling patients in a human trial of AUGMENT without clearance from the FDA. Id. ¶¶ 5-7. As a result of OvaScience's statements and omissions, the Plaintiffs claim that OvaScience securities were trading at artificially inflated prices at the time the Plaintiffs purchased them. Id. ¶ 90.

A. Procedural History

The Plaintiffs initially filed an action against OvaScience for violations of federal securities laws on September 16, 2013. Class Action Compl., Ratner v. OvaScience, Case No. 1:13-cv-12286 (D. Mass. Sept. 16, 2013), ECF No. 1. On February 3, 2014, Ratner voluntarily dismissed the action. Pl.'s Notice Voluntary Dismissal Without Prejudice, Ratner v. OvaScience, Case No. 1:13-cv-12286 (D. Mass. February 3, 2014), ECF No. 24. Ratner later moved to vacate or withdraw her voluntary dismissal because, she asserted, the Plaintiffs had obtained new evidence through a FOIA request. Lead Pl.'s Mot. Vacate Or Withdraw

Voluntary Dismissal, Ratner v. OvaScience, Case No. 1:13-cv-12286 (D. Mass. May 9, 2014), ECF No. 25; Mem. Law Supp. Lead Pl.' Mot. Vacate Or Withdraw Voluntary Dismissal, Ratner v. OvaScience, Case No. 1:13-cv-12286 (D. Mass. May 12, 2014), ECF No. 26. The Court denied Plaintiffs' Motion to Vacate or Withdraw on May 29, 2014. Elec. Order, Ratner v. OvaScience, Case No. 1:13-cv-12286 (D. Mass. May 29, 2014), ECF No. 32.

The Plaintiffs subsequently initiated a new action in this Court on June 6, 2014. Class Action Compl., ECF No. 1. This Court approved the appointment of Ratner as lead plaintiff on September 25, 2014. Order, ECF No. 26. The Plaintiffs filed their Amended Consolidated Complaint on October 31, 2014. Compl. 1. In response, the Defendants moved to dismiss. Defs.' Mot. Dismiss Pls.' Am. Compl., ECF No. 31; Mem. Law Supp. Defs. OvaScience, Inc., Michelle Dipp, Christopher A. Bleck's Mot. Dismiss Pls.' Am. Compl. ("Defs.' Mem."), ECF No. 32. After both parties fully briefed their positions on the Defendants' motion, the Court heard oral argument on the motion on April 8, 2015. Elec. Clerk's Notes, ECF No. 48. In conjunction with the briefing, the Plaintiffs also requested this Court take judicial notice of certain documents, Req. Judicial Notice Supp. Pl.'s Opp. Defs.' Mot. Dismiss Am. Compl. ("Req. Judicial Notice"), ECF No. 41; the Defendants opposed the request, Defs.' Opp. Pl.'s Req. Judicial Notice, ECF No. 44.

B. Facts Alleged

OvaScience is a biotechnology company focused on the discovery, development, and commercialization of novel treatments for infertility. Compl. ¶ 2. OvaScience's patented technology identifies egg precursor cells in the ovaries "believed to have the potential to mature into fertilizable eggs." Id. The AUGMENT process involves removing mitochondria from a woman's egg precursor cells and injecting the mitochondria into one of the woman's eggs during in vitro fertilization ("IVF"). Id.

The regulatory process for a new medical product typically requires the completion and approval of an Investigational New Drug ("IND") application, supplemented by multiple phases of clinical trials in humans and animals demonstrating the safety and efficacy of the product. Id. ¶ 4. OvaScience wanted to bypass the IND process, claiming that AUGMENT qualified as a human cellular and tissue-based product ("HCT/Ps") exempt from regulation under section 361 of the governing statute ("361 HCT/P designation"). Id. ¶ 5. Under the Food and Drug Administration's ("FDA's") regulatory scheme, products receiving a 361 HCT/P designation can be tested and marketed without FDA licensure because they are considered low risk for disease transmission. Id. A product qualifies for the 361 HCT/P designation if:

> (1) it is minimally manipulated; (2) it is intended for homologous use as determined by labeling and advertising; (3) its manufacture does not involve combination with another article, with limited exceptions; (4) either (a) the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or (b) the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and (i) is for autologous use, (ii) is for allogenic use in a first or second degree blood relative, or (iii) is for reproductive use.

Id. ¶ 35. Companies can consult with a special FDA committee known as the Tissue Reference Group ("TRG") for guidance on whether a particular product falls within the 361 HCT/P designation. Id. ¶ 37.

In its December 2012 Annual Report ("2012 Annual Report"), OvaScience announced that the company had initiated a human clinical trial in late 2012 (the "AUGMENT Study") without filing an IND because OvaScience believed FDA premarket approval was not required. Id. ¶ 60. According to the 2012 Annual Report, OvaScience believed the FDA would regulate the HCT/Ps involved in the AUGMENT procedure as 361 HCT/Ps because the mitochondria taken from egg precursor cells and the fertilized eggs "(1) are minimally manipulated, (2) are intended for homologous use only, (3) do not involve the combination of cells or tissue with another article and (4) are dependent upon the metabolic activity of living cells for their primary function and are for reproductive use." Id. ¶ 58.

OvaScience made several more relevant statements in the 2012 Annual Report. It indicated that the company had not consulted with the TRG prior to initiating the AUGMENT Study, but that the FDA had contacted OvaScience regarding whether AUGMENT qualified for regulation as a 361 HCT/P. Id. ¶ 61. OvaScience disclosed that it "continue[s] to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree with our conclusion." Id. OvaScience anticipated generating revenues from AUGMENT in the second half of 2014, "assuming the final results of the AUGMENT Study are positive[.]" Id. ¶ 60.

On April 9, 2013, the FDA wrote a letter to OvaScience. Id. ¶ 46. The letter stated that a telephone conversation regarding AUGMENT had taken place between the FDA and Alison Lawton, OvaScience's Chief Operating Officer, on January 28, 2013. Id. "[F]ollow[ing] up" on that conversation, the April 2013 letter stated that, "based on the limited information available," the AUGMENT process (i.e., the "removal of mitochondria and introduction into other reproductive tissue") "appears to be more than minimal manipulation." Id. The FDA's letter ended with a follow-up statement: "For more information about applicable regulations or to schedule a pre-IND meeting, please contact [the relevant FDA contact.]" Id.

After the phone call referenced in the above letter (i.e., after January 28, 2013), Ovascience issued two quarterly reports in turn: one for the period ending March 31, 2013 ("March 2013 10-Q") and another for the period ending June 20, 2013 ("June 2013 10-Q"). See id. ¶¶ 64, 70. Next, the FDA wrote another letter to OvaScience, dated September 6, 2013. Id. ¶ 50. The letter indicated that Lawton and Dr. Patrick Riggins previously had spoken by phone on August 20, 2013. Id. During this call, Lawton had indicated that OvaScience was currently treating patients in the AUGMENT Study. Id. The letter informed OvaScience that an IND was required for the AUGMENT Study. Id. The FDA ended the letter with the same instruction as before (regarding whom to contact for more information or to schedule a meeting). Id.

On September 10, 2013, OvaScience issued a press release announcing suspension of U.S. enrollment in the AUGMENT Study. Id. ¶ 51. Enrollment of patients outside of the U.S. would continue. Id. OvaScience "anticipate[d] having further discussions with the FDA to present details on AUGMENT and its qualifications as a 361 HCT/P, and to determine the appropriate path forward." Id. OvaScience "continue[d] to believe that AUGMENT qualifies as a 361 HCT/P." Id. Following the press release, OvaScience shares declined $3.325 per share, closing at

$10.95 per share on September 11, 2013, a decline of more than 23%. Id. ¶ 16.

Shortly thereafter, the Plaintiffs filed this class action alleging that the decline in market value of the company's securities was a result of the Defendants' wrongful acts and omissions (and that they had bought the securities at the earlier, artificially inflated prices), causing significant harm to the Plaintiffs. Id. ¶ 56.

II. ANALYSIS

A. Standard of Review

1. Rule 12(b)(6)

Under the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To survive a motion to dismiss under Rule 12(b)(6), a complaint must assert sufficient facts, that, if accepted as true, would "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). A "formulaic recitation" of the legal elements supported only by conclusory statements is insufficient to state a cause of action. Id. at 555 (internal citation omitted).

2. Heightened Pleading Standards under Rule 9(b) and the PSLRA

The Plaintiffs' claims are both premised on the Defendants having "engaged in . . . fraud and deceit," Compl. ¶ 86. This assertion triggers the heightened pleading standards of Federal Rule of Civil Procedure 9(b) and, because the claims if proven constitute securities fraud, those of the Private Securities Litigation Reform Act ("PSLRA"), Pub. L. No. 104-67, codified at 15 U.S.C. § 78u-4. See Lenartz v. Am. Superconductor Corp., 879 F. Supp. 2d 167, 180 (D. Mass. 2012).

Under Rule 9(b), a plaintiff alleging fraud "must state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). The PSLRA's pleading standards supplement those of Rule 9(b) in two ways. First, they add additional "heightened pleading requirements" with respect to plaintiffs claiming statements were false or misleading. Mississippi Pub. Empls.' Ret. Sys. v. Boston Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008). The plaintiff must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." Id. (quoting 15 U.S.C. § 78u–4(b)(1)) (alteration in original). This Court will "look at all of the facts alleged to see if they 'provide an adequate basis for believing that the defendants' statements were false.'" In re Cabletron Sys., Inc., 311 F.3d 11, 29 (1st Cir. 2002) (quoting

Novak v. Kasaks, 216 F.3d 300, 314 (2d Cir. 2000)). Second, PSLRA imposes more demanding requirements with regard to allegations that a defendant acted with the requisite scienter: "the complaint must, 'with respect to each act or omission [] state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Mississippi Pub. Empls.' Ret. Sys., 523 F.3d at 86 (quoting 15 U.S.C. § 78u–4(b)(2)) (alteration in original).

B. Rule 10b-5 Claim

The Plaintiffs' first claim is brought under Section 10(b) of the Exchange Act and Rule 10b–5, which was promulgated thereunder; this Court will follow convention in referring to it as a "10b–5 claim." See, e.g., Lenartz, 879 F. Supp. 2d at 180. To defeat a motion to dismiss, the Plaintiffs' 10b-5 claim must sufficiently allege "(1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." Mississippi Pub. Empls.' Ret. Sys., 523 F.3d at 85 (internal citation omitted). The Defendants contest only the first two elements in their motion to dismiss. See Defs.' Mem. 8.

1. Material Misstatement or Omission

The Plaintiffs assert that the Defendants made materially misleading statements or omissions in three separate documents:

the 2012 Annual Report, the March 2013 10-Q, and the June 2013 10-Q. Compl. ¶¶ 57-75. These three documents, and the allegedly misleading statements therein, will be discussed in turn.

a. The 2012 Annual Report

The Plaintiffs assert that three statements contained in the 2012 Annual Report each constitute a materially misleading misstatement or are materially misleading by omission. See id. ¶¶ 57-63.

First, the Plaintiffs challenge the following statement (hereinafter, the "Qualification Statement"):

> We believe that the FDA will regulate the HCT/Ps involved in the AUGMENT procedure as 361 HCT/Ps. This is because, in our view, both the mitochondria taken from egg precursor cells and the eggs into which those mitochondria are injected during IVF (1) are minimally manipulated, (2) are intended for homologous use only, (3) do not involve the combination of cells or tissue with another article and (4) are dependent upon the metabolic activity of living cells for their primary function and are for reproductive use.

Id. ¶ 58. The Plaintiffs assert that the Qualification Statement was misleading because AUGMENT does not in fact qualify for a 361 HCT/P designation, and because the Defendants had received notice from the FDA in January 2013[1] that the FDA would not grant it 361 HCT/P status. Id. ¶ 59.

[1] The 2012 Annual Report was filed on February 25, 2013. Compl. ¶ 57.

Neither reason renders the Qualification Statement misleading. The Plantiffs' first ground fails, as OvaScience's statement of belief in a future outcome, especially accompanied as it was by a disclaimer,[2] was not misleading. See Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 772 (1st Cir. 2011) (noting that cautionary statements are relevant to analysis when the statements at issue are "forward-looking") (internal citation and quotation marks omitted). The Plaintiffs' invocation of a January 2013 phone call between the FDA and OvaScience is similarly unavailing: the Plaintiffs assert simply that there was a phone call between OvaScience and the FDA, after which the FDA wrote a follow-up letter. Compl. ¶ 46. Without more, this allegation fails to render the Qualification Statement misleading.[3]

[2] "Our current business plan assumes that the FDA will regulate AUGMENT as a 361 HCT/P rather than as a new drug or biologic and, therefore, AUGMENT will not be subject to premarket review and approval." Decl. Amy D. Roy Supp. Mem. Law Supp. Defs.' Mot. Dismiss Plf.'s Am. Compl., Ex. 1, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934 for Fiscal Year Ended Dec. 31, 2012 ("2012 Annual Report") 45, ECF No. 33-1.

[3] This is especially so in light of the fact that OvaScience did disclose that it had "been contacted by the FDA regarding the AUGMENT Study, and a number of other matters relating to AUGMENT, including whether it qualifies for regulation as a 361 HCT/P." Compl. ¶ 61.

The Plaintiffs next challenge the following statement: (hereinafter, the "AUGMENT Study Statement"):

> In late 2012, we initiated a study of AUGMENT in the United States in up to 40 women aged 38 to 42 who have failed two to five IVF cycles to assess both safety and effectiveness. . . . [A]ssuming the final results of the AUGMENT Study are positive, [we] plan to begin generating revenues from AUGMENT in the second half of 2014. . . . We do not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States or certain other countries.

Id. ¶ 60. The third challenged statement reads as follows (hereinafter, the "FDA Contact Statement"):

> We have not consulted the TRG. We have, however, been contacted by the FDA regarding the AUGMENT Study, and a number of other matters relating to AUGMENT, including whether it qualifies for regulation as a 361 HCT/P. [OvaScience] continue[s] to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree.

Id. ¶ 61.

The Plaintiffs allege that these two statements were misleading for five reasons. Id. ¶ 62. The first two reasons are identical to those discussed regarding the Qualification Statement, and are unpersuasive for the same reasons (that in light of the disclosures elsewhere in the document the statements were not misleading). Their third argument is that the FDA's having "raised numerous other regulatory concerns regarding AUGMENT" renders the FDA Contact Statement misleading by omission. Id. Yet the Statement itself provides that

OvaScience had been contacted by the FDA "regarding . . . a number of other matters[;]" it is not misleading. The Plaintiffs' fourth ground, that "the FDA indicated that [the Defendants] should schedule a pre-IND meeting," id. ¶ 62, is based on a letter that post-dates the submission of the 2012 Annual Report, compare id. ¶ 46 (discussing April 9, 2013 letter) with id. ¶ 57 (asserting the 2012 Annual Report was filed on February 25, 2013). Thus it fails to suggest the statement was false or misleading at the time it was made. The Plaintiffs' final ground is that the FDA Contact Statement was misleading because in fact the Defendants would not generate their predicted sales revenue due to the FDA's regulatory concerns. Id. ¶ 62. This ground fails in light of the disclaimers in the Statement and the clear indication that the projection was based on assumptions, see, e.g., id. ¶ 60 ("assuming the final results of the AUGMENT Study are positive"). See Plumbers' Union Local No. 12 Pension Fund, 632 F.3d at 772 (noting "[c]autionary statements" can negate reliance on "forward-looking" statements). The plaintiffs have failed adequately to allege any materially false or misleading statements or omissions in the 2012 Annual Report.

b. The First Quarterly Report of 2013

Plaintiffs next assert that certain statements contained in the March 2013 10-Q were false or misleading. Compl. ¶¶ 64-68. The Plaintiffs target two statements.

The first is the AUGMENT Study Statement, apparently reproduced verbatim from the 2012 Annual Report. Compare id. ¶ 65 with id. ¶ 62. The second is the FDA Contact Statement, again apparently copied verbatim from the 2012 Annual Report, compare id. ¶ 67 with id. ¶ 61. The Plaintiffs essentially recycle their previously discussed reasons that these statements are misleading, and to the extent they are the same, this Court remains unpersuaded.

The Plaintiffs, however, purport to explain how both statements, even if true in the 2012 Annual Report, were misleading when they were made in the March 2013 10-Q: OvaScience received a letter from the FDA in the interim, id. ¶ 46.[4] The FDA's letter to OvaScience stated that "[t]he removal of mitochondria and introduction into other reproductive tissue appears to be more than minimal manipulation." Id. (emphasis added). The FDA qualified this statement as "based on the limited information available[.]" Id. The Plaintiffs thus

[4] OvaScience filed the March 2013 10-Q on May 15, 2013. Compl. ¶ 64. The relevant FDA letter to OvaScience was dated April 9, 2013. Id. ¶ 46.

argue that this undisclosed statement renders misleading by omission two statements in the March 2013 10-Q: both the AUGMENT Study Statement's assertion that "[OvaScience] do[es] not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States," Compl. ¶ 65, and the FDA Contact Statement's assertion that "[OvaScience] continue[s] to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree[,]" id. ¶ 67. Whether these two forward-looking statements were misleading by omission presents a close question.

"[T]here is no per se rule that a company immediately disclose receipt of any correspondence with the FDA." Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc., 778 F.3d 228, 243 n.9 (1st Cir. 2015) (internal citation omitted). The April 2013 Letter was an informal one outside the FDA's hierarchy of regulatory correspondence, not a Warning Letter or Untitled Letter.[5] Yet the FDA's perspective on whether AUGMENT involved more than "minimal manipulation" and thus would fail to qualify

[5] Untitled Letters are a step below Warning Letters in "the FDA's enforcement hierarchy[,]" and address alleged regulatory violations that do not meet the threshold for regulatory significance warranting a Warning Letter. Fire & Police Pension Ass'n of Colorado, 778 F.3d at 234. A Warning Letter "communicates that the FDA believes the regulated entity has committed a violation of regulatory significance but does not commit the FDA to taking enforcement action." Id. (internal citation omitted).

for 361 HCT/P status is closely tied to OvaScience's professed "belie[fs.]" Compl. ¶ 65. As such, noting the hypothetical possibility that "the FDA could disagree[,]" Compl. ¶ 45, without mentioning that the FDA had sent a letter indicating its initial (tentative) disagreement, especially in the context of a company's first product,[6] id. ¶ 4, does not save OvaScience. As to the two statements expressing OvaScience's "belie[f]" about whether it would receive the FDA's approval, Compl. ¶¶ 65, 67, the Plaintiffs adequately state a claim of a material omission rendering two statements in the March 2013 10-Q misleading.

c. The Second Quarterly Report of 2013

Finally, Plaintiffs assert that certain statements contained in the June 2013 10-Q were false or misleading. Compl. ¶¶ 64-68. The Plaintiffs again target two statements, the AUGMENT Study Statement[7] and the FDA Contact Statement, that appear in the June 2013 10-Q as they did in the March 2013 10-Q

[6] The drop in stock value of more than twenty-three percent when OvaScience revealed that the FDA asked the company to file an IND before continuing the AUGMENT Study indicates the importance to investors of regulatory issues with AUGMENT. See Compl. ¶ 16.

[7] Although a few words are changed, the essential ones are not: the defendants state that "assuming the results of the AUGMENT Study are positive, [we] plan to begin generating revenues from AUGMENT in the second half of 2014. . . . We do not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States or certain other countries." Compl. ¶ 71.

and 2012 Annual Report. The Plaintiffs make the same arguments as before, but assert one more fact: this time, it arises from a letter the FDA sent to OvaScience on September 6, 2013, referencing a prior phone call. Id. ¶ 50. The letter mainly operates to inform OvaScience that "an IND is required," but in doing so it references prior communications between the two parties:

> [f]rom the August 20, 2013 phone call between you and Dr. Patrick Riggins, of [the FDA], it appears you are treating subjects under your clinical study protocol, even though you have not submitted an IND.
> We are taking this opportunity to advise you that an IND is required for this study. Further, we are writing to express additional concerns based on our review of the protocols, Investigator's Brochure, and informed consent document that you submitted to the [redacted] for your AUGMENT study. These documents were collected during our inspection of [redacted].

Id. The referenced phone conversation occurred on August 20, 2013, yet the June 2013 10-Q was filed before that, on August 13, id. ¶ 70, thus the failure to disclose the as-yet-unmade phone call could not constitute a misleading omission.[8]

For the same reasons discussed in the prior section, see supra section II-B-1-b, the Complaint again adequately states a claim that two statements in the June 2013 10-Q were misleading.

[8] The remainder of the FDA's letter to the Defendants in September 2013 is irrelevant to the Plaintiffs' claims for the same reason: it post-dates all statements the Plaintiffs assert are false or misleading.

Other than that ground, the remaining assertions regarding statements made in the June 2013 10-Q lack merit.

2. Scienter

Having found that all but two of the Plaintiffs' claims of false statements or omissions of material facts fail to state a cognizable claim (the only still-viable one arising from two statements expressing OvaScience's "belie[f]" that AUGMENT would qualify as a 361 HCT/P, both made in the March 2013 10-Q and in the June 2013 10-Q), this Court moves to the Defendants' second ground for dismissing the Plaintiffs' complaint: a failure adequately to plead the required element of scienter. See Defs. Mem. 13-20. Scienter is a "mental state embracing intent to deceive, manipulate, or defraud." Mississippi Pub. Empls.' Ret. Sys., 523 F.3d at 85 (citing Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976); ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 57 (1st Cir. 2008)). Here, the remaining statements were forward-looking,[9] thus the PSLRA requires the

[9] The relevant portion of the first statement at issue is: "[A]ssuming the final results of the AUGMENT Study are positive, [we] plan to begin generating revenues from AUGMENT in the second half of 2014. . . . We do not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States or certain other countries." Compl. ¶¶ 65 (statement in March 2013 10-Q), 71 (statement in June 2013 10-Q) (emphasis supplied). The second statement reads: "[OvaScience] continue[s] to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree[,]" id. ¶ 67 (statement in March 2013 10-Q), 73 (statement in June 2013 10-Q).

Plaintiffs adequately to allege a scienter of "actual knowledge." Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1324 n.14 (2011) (quoting 15 U.S.C. § 78u–5(c)(1)(B)). The complaint must not simply allege knowledge, but must assert facts sufficient to create a "strong" inference that the defendant acted with the requisite scienter. Id. at 1324.

To create an inference that is "strong," scienter "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314 (2007). This Court must consider the totality of the circumstances in evaluating scienter, and not examine each alleged omission or misstatement in isolation. See In re Cabletron Sys., Inc., 311 F.3d at 40; cf. Tellabs, 551 U.S. at 323 ("The strength of an inference cannot be decided in a vacuum."). Specifically, this Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Tellabs, 551 U.S. at 310; see ACA Fin. Guar. Corp., 512 F.3d at 59 (noting PSLRA mandates that courts weigh competing inferences from facts). If there are equally strong inferences for and against scienter, the tie goes to the plaintiff. ACA Fin. Guar. Corp., 512 F.3d at 59 (internal citation omitted).

The Plaintiffs, in arguing that the statements were made with knowledge of their falsity in both the March 2013 10-Q and in the June 2013 10-Q, principally rely on the April 2013 letter from the FDA to OvaScience. That letter adequately supported a claim that the statements were materially misleading by omission. To aid the Plaintiffs in adequately pleading the required element of scienter, however, they must establish the requisite strong inference that the Defendants knew the FDA would not grant AUGMENT 361 HCT/P designation. They fail to do so.

The Defendants' alternative explanation for the AUGMENT Study Statement is that OvaScience "honestly believed that AUGMENT met the criteria for regulation as a 361 HCT/P, [and] believed that [the] FDA ultimately would agree with its conclusion," even after receipt of the April 2013 Letter. Defs.' Mem. 15. That such belief was ultimately incorrect ex-post does not, without more, support a "strong inference" that ex-ante it was knowingly false. Cf. Kuyat v. BioMimetic Therapeutics, Inc., 747 F.3d 435, 442 (6th Cir. 2014) (affirming dismissal where the defendant company "may have ultimately been mistaken" in its belief about the FDA's eventual approval of its procedures because "there are no facts suggesting the company knew this at the time its representatives spoke."). Instead, OvaScience asserts that its statements must be evaluated in

context. Specifically, that it is using "new technology . . . present[ing] a matter of first impression for the FDA[.]" Decl. Amy D. Roy Supp. Mem. Law Supp. Defs.' Mot. Dismiss Plf.'s Am. Compl., Ex. 1, Form 10-K, Annual Report Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934 for Fiscal Year Ended Dec. 31, 2012 ("2012 Annual Report") 46, ECF No. 33-1. Thus OvaScience "could not reliability predict rejection[]" as a result of the FDA's preliminary statement that AUGMENT appeared, "based on limited information[,]" to involve more than minimal manipulation. Reply Mem. Further Supp. Defs.' Mot. Dismiss 7, ECF. No. 43.

OvaScience's nonculpable explanation for its actions suggests the company believed that AUGMENT might qualify for 361 HCT/P status even after receipt of the April 2013 Letter. The April 2013 Letter was not an Untitled Letter, but an informal letter based on the "limited information available" to the FDA, Compl. ¶ 46. OvaScience was not silent about the company's regulatory exchanges with the FDA: OvaScience informed shareholders that the company had been contacted by the FDA regarding AUGMENT's qualification for 361 HCT/P status in both the March 2013 10-Q, id. ¶ 67, and in the June 2013 10-Q, id. ¶ 73. These disclosures, although they omitted the FDA's preliminary notice of disagreement with OvaScience, preclude a strong inference of scienter. See Abiomed, 778 F.3d at 244

(stating that company's "substantial disclosures about its correspondence with the FDA. . . . undercut any inference of scienter.").[10]

The Plaintiffs argue that additional asserted facts, when combined with the April 2013 letter, create the requisite strong inference of knowledge of falsity, but this argument fails because they add nothing of consequence. The Plantiffs argue that this case is similar to Abrams v. MiMedx Group Inc., 37 F. Supp. 3d 1271 (N.D. Ga. 2014), in which the court found that shareholder plaintiffs adequately stated a claim that a pharmaceutical company had acted with the requisite scienter because previously-issued FDA guidance made clear that the product would not qualify as 361 HCT/P.[11] Here, however, unlike the relevant FDA guidance in Abrams, the FDA guidance at issue

[10] The same reasoning applies to OvaScience's subsequent action: four days after receiving a more definitive statement that AUGMENT could not bypass the IND process, OvaScience issued a press release to investors. Compl. ¶¶ 50, 51.

[11] The Plaintiffs argue that the FDA's communication with the public about the 361 HCT/P designation provided OvaScience with effective notice that its product would not receive said designation. Their argument initially appears similar to that successfully made by the plaintiff in Abrams, 37 F. Supp. 3d 1271. In ruling that the shareholders had adequately pled scienter, that court relied in part on the fact that the "FDA had stated that products that destroy original characteristics or are made from amniotic fluid are generally not 361 HCT/Ps," and that the defendant's products "[fell] squarely into a category the FDA had previously announced would not be exempt from regulation." Id. at 1278.

does not create a strong inference that OvaScience knew that AUGMENT would not qualify for 361 HCT/P status. The Plaintiffs' proffered 2002 FDA guidance discusses ooplasm transfers, which involve transfer of cellular material from a third-party egg to a mother's unfertilized egg. See Req. Judicial Notice, Ex. D, BRMAC Briefing Document for Day 1, May 9, 2002.[12] AUGMENT, on the other hand, involves transfer of cellular material from a woman's egg precursor cells into one of her own unfertilized eggs. Compl. ¶ 29. Further, the fact that the FDA was having an Advisory Meeting in October 2013 to discuss mitochondrial manipulation technologies like AUGMENT, Compl. ¶ 3, supports OvaScience's claim that the FDA's rejection of AUGMENT as a 361 HCT/P was not inevitable. In fact, the FDA's advisory meeting suggests that the issue of whether mitochondrial manipulation fell within the 361 HCT/P designation was still an open question. After all, if FDA guidance from more than a decade

[12] In considering this claim, this Court thus GRANTS the Plaintiffs' request for judicial notice of certain of its proposed documents, ECF No. 41. See In re Vertex Pharm. Inc., Sec. Litig., 357 F. Supp. 2d 343, 352 (D. Mass. 2005) (Saris, C.J.) (taking judicial notice of FDA policy published on its website when deciding motion to dismiss securities claim); see also OrbusNeich Med. Co., BVI v. Boston Scientific Corp., 694 F. Supp. 2d 106, 111 (D. Mass. 2010) (Tauro, J.) ("The public filing of this document with a regulatory agency also makes it a proper subject of judicial notice, at least with regard to the fact that it contains certain information, though not as to the truth of its contents.").

earlier clearly answered this question, there would be little reason to hold an advisory committee meeting on the topic.

This Court thus holds as matter of law that the Plaintiffs have failed adequately to plead facts raising the requisite "strong inference" of "actual knowledge" required by PSLRA when challenging forward-looking statements. Matrixx Initiatives, Inc., 131 S. Ct. at 1324, 1324 n.14 (internal citation omitted).

Whether a statement was materially misleading, and whether it was made with the requisite scienter, are two separate inquiries. See id. at 1323-25 (analyzing the issue of whether shareholders "adequately pleaded the element of a material misrepresentation or omission[]" before separately evaluating the issue of scienter). Here, although the Plaintiffs' 10b-5 claim adequately pled that two of OvaScience's statements were misleading, it cannot survive the Defendants' motion to dismiss because it does not allege sufficient facts to meet the demanding scienter requirement for forward-looking statements.

B. Section 20(a) Claims

Section 20(a) of the Exchange Act allows for investors to sue "control persons" under Section 11. 15 U.S.C. §§ 77k, 77o. The Plaintiffs allege that the Individual Defendants acted as control persons within this definition and are thus liable as direct participants in the fraud. Compl. ¶¶ 94-99.

Claims under section 20(a) of the Exchange Act "are derivative of [Rule] 10b-5 claims[,]" therefore liability under the former can attach only when there is a predicate violation of the latter. Hill v. Gozani, 638 F.3d 40, 53 (1st Cir. 2011). Since this Court dismisses the 10b-5 claims against OvaScience, no Section 20 liability can be assigned to the Individual Defendants.

III. CONCLUSION

This Court **GRANTS** the Defendants' motion to dismiss the Plaintiffs' complaint in its entirety, ECF No. 31. This Court also **DENIES** the Plaintiffs' boilerplate request for leave to amend their complaint, ECF No. 40.[13]

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE

[13] The Court does so for substantially the same reasons as articulated by the First Circuit in Fire and Police Pension Ass'n of Colorado, 778 F.3d at 247.