UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

KEVIN L. DOUGHERTY, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,

Plaintiffs,

v.

ESPERION THERAPEUTICS, INC., ET AL.,

Defendants.
_____/

Case No. 16-10089

SENIOR U.S. DISTRICT JUDGE
ARTHUR J. TARNOW

U.S. MAGISTRATE JUDGE
R. STEVEN WHALEN

OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT [30]

Before the Court is a securities fraud class action against Esperion, a clinical stage pharmaceutical company, and its Chief Executive Officer, Tim M. Mayleben. Plaintiffs, a class of investors who purchased Esperion common stock between August 18, 2015 and September 28, 2015, allege that Defendants violated §§10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder. The underlying question that drives this dispute is whether FDA approval of ETC-1002, Esperion's lead product, requires Esperion to conduct a cardiovascular outcomes trial ("CVOT") to assess the drug's lipoprotein cholesterol-lowering efficacy in patients who suffer from certain types of cardiovascular problems.

Esperion allegedly made false statements to Plaintiffs about what occurred at an August 2015 meeting between Esperion and the U.S. Food and Drug

Administration ("FDA"), and failed to disclose material facts about the development of ETC-1002, a medication designed to lower elevated levels of lipoprotein cholesterol ("LDL-C"). Esperion's deceit regarding its business, according to Plaintiffs, operated as a fraud and caused Plaintiffs to transact in Esperion common stock at artificially inflated prices. Essentially, "[h]ad Plaintiffs . . . known the truth regarding the problems[1] that Esperion was experiencing, which Defendants did not disclose, Plaintiffs . . . would not have transacted in Esperion common stock." (Compl. ¶ 74).

Defendants argue that Plaintiffs' action is a "fraud by hindsight" case, exactly the kind that the Private Securities Litigation Reform Act ("PSLRA") was designed to prevent. They characterize this as a "knee jerk lawsuit by opportunistic plaintiffs whenever a company's stock price drops." (Dkt. 30, Defs.' Br. at Pg. ID 580). Defendants ask the Court to dismiss the Complaint for three reasons: 1) there can be no strong inference of scienter when Plaintiffs have not alleged that Defendants knew that any statements were materially false or misleading when made; 2) Plaintiffs have not specified why or how any statements were misleading when made; and 3) Defendants' statements were forward-looking and therefore immune from liability under the PSLRA.

[1] Plaintiffs do not specify what these problems are, but the Court will assume that Plaintiffs are referring to the fact that the FDA encouraged Esperion to initiate a CVOT.

The Court will **GRANT** Defendants' Motion to Dismiss. The PSLRA imposes strict pleading requirements that Plaintiffs have failed to satisfy. The Court finds that Plaintiffs have not stated with particularity any facts giving rise to a strong inference that Defendants acted with a knowing and deliberate intent to manipulate, deceive, or defraud. *See Frank v. Dana Corp.*, 646 F.3d 954, 959 (6th Cir. 2011). Furthermore, a reasonable person would conclude that the inference of scienter in this case is not as strong as the opposing inference of non-culpability. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 326 (2007); *Kuyat v. BioMimetic Therapeutics, Inc.*, 747 F.3d 435, 441 (6th Cir. 2014).

FACTUAL BACKGROUND

Because Defendants move to dismiss Plaintiffs' complaint under Federal Rule of Civil Procedure 12(b)(6), the Court sets forth Plaintiffs' non-conclusory allegations as fact. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009); *LULAC v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007) (explaining that the plaintiff's factual allegations, while "assumed to be true, must do more than create speculation or suspicion of a legally cognizable cause of action; they must show *entitlement* to relief) (emphasis in original).

The FDA regulates drugs and the drug development process under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Before a drug is marketed in the U.S., a drug sponsor, such as Esperion, must, among other things, complete nonclinical laboratory tests and submit a New Drug Application ("NDA") to the FDA. Navigating

the approval process requires the expenditure of substantial time and financial resources. The process is often complex, expensive, and uncertain, and, depending on how the development of the product advances, may be subject to delays, limits, or changes.

In its short lifespan,[2] Esperion has focused exclusively on developing and commercializing ETC-1002, an oral, once-daily, small molecule designed to lower elevated levels of lipoprotein cholesterol ("LDL-C") and to avoid side effects associated with other LDL-C lowering medications on the market. Though most people use statins (cholesterol-lowering drugs) to reduce their LDL-cholesterol levels, statins are known to cause serious side effects and may interact adversely with other drugs.[3] Esperion estimates that "2-7 million U.S. adults are intolerant of statin therapy due to muscle pain or weakness associated with their use." (Dkt. 30-2, Defs.' Ex. A at Pg. ID 613). ETC-1002 is designed to provide an alternative treatment to statin-intolerant individuals, and may also be used as an add-on therapy for individuals who cannot reach their recommended LCL-cholesterol goals despite the use of a statin. *Id.* at Pg. ID 617.

[2] Esperion was incorporated in January 2008. Because it has devoted its resources to staffing the company and conducting research and development activities, it has not generated any revenue from product sales.

[3] "Statins interfere with the production of cholesterol in [the] liver. They lower bad cholesterol levels and raise good cholesterol levels. This can slow the formation of plaques in [the] arteries." MEDLINE PLUS, U.S. NATIONAL LIBRARY OF MEDICINE (Nov. 22, 2016), https://medlineplus.gov/statins.html.

I. August 17, 2015 Press Release and Conference Call.

Esperion met with the FDA after completing Phase 2b clinical trials for ETC-1002 in August 2015. It subsequently issued a press release on August 17, 2015, in which it provided updates on the ETC-1002 development program. The press release contained the following relevant statements:

- LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patient populations who have a high unmet medical need, including patients with heterozygous familial hypercholesterolemia ("HeFH")[4] or clinical atherosclerotic disease ("ASCVD")[5], who are already taking maximally tolerated statins yet require additional LDL-C reduction and where there is a positive benefit/risk ratio;
- **Based on feedback from the FDA**, approval of ETC- 1002 in the HeFH and ASCVD patient populations will not require **the completion** of a cardiovascular outcomes trial (CVOT).
- The Company continues to plan and **initiate** a CVOT prior to NDA ["New Drug Application"] filing **to pursue broader label indications related to cardiovascular disease reduction**.

The final section of the press release informed readers that "[f]orward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including . . . the risk that FDA may require additional studies or data prior to approval that might cause approval to be delayed."

[4] "Familial hypercholesterolemia is an inherited condition that causes high levels of LDL (low density lipoprotein) cholesterol levels beginning at birth, and heart attacks at an early age." *Learning About Familial Hypercholesterolemia*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Dec. 26, 2013), https://www.genome.gov/25520184/learning-about-familial-hypercholesterolemia/.

[5] "An elevated level of low-density lipoprotein cholesterol is directly associated with development of atherosclerotic cardiovascular disease, which may present as coronary heart disease, stroke, and peripheral arterial disease." Satyajeet Roy, *Atherosclerotic Cardiovascular Disease Risk and Evidence-based Management of Cholesterol*, NORTH AMERICAN J. OF MEDICAL SCIENCES, *available at* http://www.najms.org/temp/NorthAmJMedSci65191-8116681_223246.pdf.

(Dkt. 30-5, Defs.' Ex. D at Pg. ID 640). It also stated: "Esperion may need to change the design of its Phase 3 program once final minutes from the FDA meeting are received." *Id.*

Esperion held a conference call and webcast with investors on August 17, after issuing the press release, to discuss the contents of the press release and Esperion's meeting with the FDA. In his opening remarks, CEO Mayleben confirmed that the FDA had determined that "LDL cholesterol lowering remains an acceptable clinical surrogate endpoint for the potential approval of a therapy such as 1002." (Dkt. 30-6, Defs.' Ex. E at Pg. ID 644). He also assured participants that the company's commitment to conducting a cardiovascular outcomes trial . . . remains intact," both for commercial purposes and "for the broader label indications related to cardiovascular disease risk reduction that can be achieved." *Id.* at Pg. ID 645. He noted that Esperion "expect[s] to initiate the CVOT late next year or in early 2017 such that the CVOT will be underway by the time of our NDA submission." *Id.* Several minutes later, Mr. Mayleben stated, "[w]e know that 1002 will not require a CV outcomes trial to be completed prior to approval in patients with heterozygous FH and ASCVD, those patient populations that FDA considers to have an appropriate benefit/risk ration." *Id.* When discussing his thoughts about the Phase 3 program, Mayleben said that "the long-term potential here is the second step, which is to be able to complete and report out a positive CV outcomes trial." *Id.* at Pg. ID 649. Throughout the call, Mayleben emphasized that the company could not comment in

depth until it received the final minutes from the FDA; in response to one analyst's question, he said that Esperion has "zero interest in front running the FDA on this. The FDA's minutes are the only minutes that matter, and so we're going to wait for those minutes." *Id.* at Pg. ID 652.

II. September 28, 2015 Press Release and Conference Call

Esperion received the FDA's End-of-Phase 2 final meeting minutes on September 28, 2015, and promptly issued a press release with an update on the ETC-1002 development program. Esperion declared "[the] FDA has **encouraged** the Company to **initiate** a cardiovascular outcomes trial promptly, which would be well underway at the time of the New Drug Application submission and review." (Dkt. 30-7, Defs.' Ex. F at Pg. ID 657) (emphasis added).

Esperion convened another conference call and webcast for investors later that day. CEO Mayleben began the call by telling participants that Esperion's "commitment to initiating a cardiovascular outcomes trial and having it well underway at the time of NDA submission remains intact." (Dkt. 30-8, Defs.' Ex. G at Pg. ID 663). Mayleben also cautioned,

> Historically and most recently, LDL has been an approval surrogate marker for LDL-cholesterol-lowering drugs. What happens in the future, I think is, it is something that we will find out along with the rest of the world as this dynamic therapeutic area continues to evolve.

Id. at Pg. ID 665.

In response to a question regarding the need for a completed cardiovascular outcomes trial prior to FDA approval, and the inconsistency in language between the two press releases, Mayleben explained, "we're trying to . . . balance the . . . history of using LDL-cholesterol as an accepted surrogate . . . with what the future may be given the fact that there are at least 4 CV outcomes trials ongoing now that will certainly read on whether LDL remains an accepted surrogate." *Id.* at Pg. ID 666. Mayleben also repeatedly emphasized that the development of ETC-1002 "is a very dynamic therapeutic area." *Id.* at Pg. ID 665.

The market reacted negatively in the days following Esperion's September 28 press release and conference call. The company's stock price fell from $35.09 per share to $18.33 per share; Plaintiffs say that this is a "one-day decline of 48% on massive volume of 9.9 million shares, or almost 8 times the average daily trading volume during the Class Period [August 18, 2015-September 28, 2015]." (Compl. at ¶ 52).

LEGAL STANDARD

"To survive a motion to dismiss, [plaintiffs] must allege 'enough facts to state a claim to relief that is plausible on its face.'" *Traverse Bay Area Intermediate Sch. Dist. v. Mich. Dep't of Educ.*, 615 F.3d 622, 627 (6th Cir. 2010) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court will "assume the veracity of [the plaintiff's] well-pleaded factual allegations and determine whether the plaintiff is entitled to legal relief as a matter of law." *McCormick v. Miami Univ.*, 693 F.3d 654,

658 (6th Cir. 2012) (citing *Iqbal*, 556 U.S. at 679; *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993)).

"Section 10(b) of the Securities and Exchange Act . . . and Rule 10b-5 prohibit fraudulent, material misstatements in connection with the sale or purchase of a security." *Zaluski v. United Am. Healthcare Corp.*, 527 F.3d 564, 570 (6th Cir. 2008) (internal quotations omitted). Securities cases demand heightened pleading requirements. In order to state a claim for securities fraud under Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter (3) a connection between the misrepresentation or omission and the purchase or sale of a security (4) reliance upon the misrepresentation or omission (5) economic loss and (6) loss causation." *Ind. State Dist. Council of Laborers & Hod Carriers Pension and Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 942 (6th Cir. 2009) (internal quotations omitted). Because §10(b) claims involve fraud, the strict pleading requirements of Fed. R. Civ. P. 9(b) apply. The Sixth Circuit has stated that fraud must be plead with particularity, and that the complaint must "(1) specify the statements that the plaintiff contends were fraudulent (2) identify the speaker (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* at 942-43. Furthermore, a plaintiff must "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." *See* 15 U.S.C. §78u-4(b)(1). Plaintiff must also "state with particularity facts giving rise to a

strong inference that the defendant acted with the required state of mind." *See Konkol v. Diebold, Inc.*, 590 F.3d 390, 396 (6th Cir. 2009) (citing 15 U.S.C. §78u-4(b)(2)).

ANALYSIS

Defendants set forth the following arguments in their Motion to Dismiss:

- The PSLRA's heightened pleading standard applies to Plaintiffs' claims;
- Plaintiffs' complaint does not allege facts giving rise to any inference of scienter;
- Plaintiffs failed to plead any actionable misstatements or omissions; and
- Plaintiffs' Section 20(a) claim fails.

Both parties agrees that the PSLRA's heightened pleading standard governs this case. The Court will address each of Defendants' remaining arguments in turn.

I. The Inference of Scienter

Plaintiffs claiming a violation of the PSLRA "shall, with respect to each act or omission alleged . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" in violating the securities laws. 15 U.S.C. § 78u-4(b)(2)(A); *see also Tellabs*, 551 U.S. at 314. "A strong inference of scienter 'must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent.'" *Doshi v. General Cable Corp.*, 823 F.3d 1032, 1039 (6th Cir. 2016) (citing *Tellabs*, 551 U.S. at 314). As the *Tellabs* Court advised, "[t]he strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts?" *Tellabs*, 551

U.S. at 323. Courts evaluating a plaintiff's allegations of scienter "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

The Sixth Circuit has held that scienter includes a "knowing and deliberate intent to manipulate, deceive, or defraud, and recklessness." *Ley v. Visteon Corp.*, 543 F.3d 801, 809 (6th Cir. 2008), *abrogated on other grounds by Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48-50 (2011). "Recklessness is . . . highly unreasonable conduct which is an extreme departure from the standards of ordinary care" and requires more than negligence; it is "akin to conscious disregard." *Frank*, 646 F.3d at 959. "Before drawing an inference of recklessness, courts typically require 'multiple, obvious red flags,' demonstrating 'an egregious refusal to see the obvious, or to investigate the doubtful.'" *Doshi*, 823 F.3d at 1039 (quoting *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 686-87, 695 (6th Cir. 2004), *abrogated on other grounds by Matrixx*, 563 U.S. at 48-50)).

Courts in this circuit use nine factors to holistically review a plaintiff's allegations for securities fraud:

> (1) insider trading at a suspicious time or in an unusual amount; (2) divergence between internal reports and external statements on the same subject; (3) closeness in time of an allegedly fraudulent statement or omission and the later disclosure of inconsistent information; (4) evidence of bribery by a top company official; (5) existence of an ancillary lawsuit charging fraud by a

> company and the company's quick settlement of that suit; (6) disregard of the most current factual information before making statements; (7) disclosure of accounting information in such a way that its negative implications could only be understood by someone with a high degree of sophistication; (8) the personal interest of certain directors in not informing disinterested directors of an impending sale of stock; and (9) the self-interested motivation of defendants in the form of saving their salaries or jobs.

Helwig v. Vencor, Inc., 251 F.3d 540, 552 (6th Cir. 2001) (en banc). This list is not intended to be exhaustive, but rather is helpful in evaluating the sufficiency of securities fraud pleadings. *Id.* Moreover, the fact that Plaintiff does not mention allegations with respect to all nine of the *Helwig* factors is not dispositive. *See, e.g.*, *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 684-86 (6th Cir. 2005); *In Re Hayes Lammerz Int'l, Inc. Equity Sec. Litig.*, 271 F. Supp. 2d 1007, 1014-17 (E.D. Mich. 2003).

Kuyat v. BioMimetic Therapeutics, Inc., a similar Sixth Circuit case from 2014, is on point. There, the plaintiffs alleged that Defendant BioMimetic made materially false statements when it spoke optimistically about FDA-approval prospects for its lead product, Augment, even though the company knew of multiple deficiencies in Augment's clinical trials. 747 F.3d 435, 440 (6th Cir. 2014). They further argued "that the FDA had privately communicated that it expected BioMimetic to obtain statistically significant results based on an analysis of the ITT [intent-to-treat] population, but that the company characterized those results as less important than the analysis of the mITT [modified-intent-to-treat] population." *Id.* at 441. The plaintiffs identified numerous statements made by the company that shed a favorable light on

Augment's clinical trials; the company told investors that it "characterized the study as producing positive top line results," for example, and "referred to the mITT population as the pre-specified primary study population." *Id.* (internal quotations omitted). The plaintiffs argued that such statements were false because BioMimetic knew that mITT was not the FDA-approved study population.

The Sixth Circuit concluded that the plaintiffs' allegations did not give rise to a strong inference of scienter. A holistic review of the pleadings convinced the court that "a reasonable person would conclude that the inference of scienter in this case is not as strong as the opposing inference. BioMimetic could legitimately believe that the . . . results it achieved based on an analysis of the mITT population would be sufficient to obtain approval by the FDA." *Id.* The court found that the May 2007 and September 2010 letters, upon which the plaintiffs relied, were simply ambiguous rather than fraudulent, and that "nothing in [either letter] indicates that the FDA told BioMimetic to use an ITT population for the primary effectiveness analysis." *Id.* at 442. Furthermore, the court held, "the complaint did 'not allege any facts showing that, **at the time Defendants made their forward-looking statements**, FDA compliance problems existed, Defendants actually knew of the[] problems, or that the[] problems would preclude FDA approval.'" *Id.* at 443 (quoting *Yanek v. Staar Surgical Co.*, 388 F.Supp. 2d 1110, 1126 (C.D. Cal. 2005) (emphasis added)). The plaintiffs provided no facts as to what BioMimetic "did or did not know at the time

the allegedly misleading statements were made," and therefore, the complaint did not support a strong inference of scienter. *Id.* at 442.

Likewise, here, Plaintiffs have not adequately pled a strong inference of scienter because they have not alleged with particularity facts showing what Esperion and/or Mayleben did or did not know on August 17, 2015, when the allegedly misleading statements were made. Plaintiffs have neither pointed to anything in the record to suggest that Esperion or Mayleben knew that they were mistaken in their August 17 communications, nor have they identified facts demonstrating that Esperion actually understood the FDA's communications in a way that was different than what was publicly disclosed.

Plaintiffs argue that even if Defendants did not operate with a knowing and deliberate intent to defraud, their actions constituted "absolute recklessness." (Mot. Hr'g Tr. 35). The Court disagrees. Defendants' statements were made based on their knowledge that the FDA has never before required a company seeking approval of a drug that claims to lower cholesterol levels to conduct a CVOT. (Dkt. 30-4, Defs.' Ex. C, at Pg. ID 637). That Defendants did not accurately predict that the FDA would deviate from its normal practices with respect to the need to conduct a CVOT for this purpose hardly constitutes an "egregious refusal to see the obvious, or to investigate the doubtful." *PR Diamonds, Inc.*, 364 F.3d at 693. Additionally, although Esperion may have ultimately been mistaken about the scope of the CVOT – in terms of whether the trials were necessary to measure ETC-1002's ability as to both lowering

cholesterol levels and improving overall heart health – "there are no facts suggesting the company knew this at the time its representatives spoke." *Kuyat*, 747 F.3d at 442. Defendants did not engage in such "highly unreasonable conduct which an extreme departure from the standards of ordinary care." *PR Diamonds, Inc.*, 364 F.3d at 681. Moreover, the Court finds that "[i]t is hard to imagine that [Defendants] would risk the [FDA's] ire" by lying about the steps in the development process with which it was required to comply. *Kuyat*, 747 F.3d at 442.

II. Material Misrepresentation or Omission

Plaintiffs seeking recovery under § 10(b) and Rule 10b-5 must show both an omission or misstatement and its materiality. A misrepresentation or omission is material if there is a "substantial likelihood that the disclosure of the omitted fact would have been viewed by a reasonable investor as having significantly altered the total mix of information made available." *See Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). The Sixth Circuit has said that when a company speaks, it must "provide complete and non-misleading information." *Omnicare, Inc.*, 583 F.3d at 943; *see also Rubin v. Schottenstein, Zox & Dunn*, 143 F.3d 263, 268 (6th Cir. 1998). It is important to recognize, though, that "liability does not attach to mere corporate puffery or statements of corporate optimism." *Omnicare, Inc.*, 583 F.3d at 943. Moreover, there is a safe-harbor that excuses liability for specific statements made by a defendant, including "projections, statements of plans and objectives, and estimates of future economic performance." *Helwig*, 251 F.3d at 547-48 (citing 15 U.S.C. §

78u-5(i)(1)). A plaintiff may defeat the safe-harbor only "if the statement was material; if defendants had actual knowledge that it was false or misleading; and if the statement was not identified as 'forward-looking' or lacked meaningful cautionary statements." *Helwig*, 251 F.3d at 548 (citing 15 U.S.C. § 78u-5(c)(1)).

A. August 17 Statements

Plaintiffs claim that Defendants' August 17, 2015 statements were false or misleading, and that there are material differences between the August 17 and the September 28 statements. Plaintiffs first point to Esperion's August 17 press release, which states:

> Based on feedback from the FDA, approval of ETC-1002 in the HeFH and ASCVD patient populations **will not require the completion of a cardiovascular outcomes trial.**

In the following sentence, Esperion indicates:

> The Company continues to plan and **initiate a CVOT** prior to NDA [New Drug Approval] filing **to pursue broader label indications related to cardiovascular disease reduction**.

Esperion set forth two goals: the first and primary goal was to obtain FDA approval for ETC-1002 as a drug that effectively lowers LDL cholesterol. The second, broader goal, that would hopefully occur at a later stage of development, was to seek FDA approval for ETC-1002 as a drug that can reduce the likelihood of heart disease and improve heart health overall. (Mot. Hr'g Tr. 6-7).

Plaintiffs note that during the August 17 conference call, Defendant Mayleben "made it clear that based on the information from the FDA, the Company had 'a clear

regulatory path forward' for ETC-1002 use with HeFH and ASCVD patients,'" meaning that *completing* a CVOT to assess ETC-1002's LDL-cholesterol lowering abilities was unnecessary. (Dkt. 32, Pls.' Br. at Pg. ID 713). This is true: Mayleben told investors on the call that:

> We know that 1002 will not require a CV outcomes trial to be **completed** prior to approval in patients with heterozygous FH and ASCVD.

(Dkt. 30-6, Defs.' Ex. E at Pg. ID 645).

Mayleben also said:

> Our commitment to conducting a cardiovascular outcomes trial **for commercial reasons** remains intact . . . [w]e will be working closely with the FDA on the design of the CVOT for 1002, **not only for commercial purposes but also for the broader label indications related to cardiovascular disease risk reduction that can be achieved**.

Id. (emphasis added).

Mayleben's comments during the August conference call suggest two things: first, that it was Esperion's understanding that it would not be required by the FDA to *complete* a CVOT prior to approval in HeFH and ASCVD patients as to the drug's ability to lower LDL-C levels; and second, that Esperion still intended, at some point, to *initiate* a CVOT to determine whether ETC-1002 could be used to improve an individual's overall heart health and reduce the risk of cardiovascular disease. Mayleben also emphasized to participants that Esperion expected "to **initiate** the CVOT late next year or in early 2017 such that the CVOT will be underway by the time of our NDA submission." *Id.*

B. September 28 Statements

Esperion followed up on its prior statements regarding the development of ETC-1002 on September 28, 2015, after receiving the final meeting minutes from the FDA. Plaintiffs argue that it was at this time that they discovered that Defendants' earlier statements were false and misleading. In its press release, Esperion declared that the "FDA encouraged the Company to **initiate** a cardiovascular outcomes trial promptly, which would be well underway at the time of the New Drug Application submission and review, since any concern regarding the benefit/risk assessment of ETC-1002 could necessitate a completed cardiovascular outcomes trial before approval." (Dkt. 30-7, Defs.' Ex. F at Pg. ID 657) (emphasis added). During the conference call later that day, Mayleben reiterated Esperion's "commitment to **initiating** a cardiovascular outcomes trial and having it well underway at the time of NDA submission." (Dkt. 30-8, Defs.' Ex. G at Pg. ID 663) (emphasis added). Mayleben also acknowledged Esperion's desire to "signal[] a dual strategy . . . not only looking to add on to statin opportunity and the ASCVD and heterozygous FH patients retaining that opportunity there . . . but also . . . focus[ing] on statin-intolerant patients." *Id.* at Pg. ID 664. One analyst on the conference call noted the inconsistency in language between the August and September press releases, and pointed out that "previously, [Esperion] would outline a path to market without outcome data, at least in these sort of higher-risk patients." *Id.* at Pg. ID 666. Mayleben responded:

> [W]hat it reflects is . . . the dynamic nature of this therapeutic area . . . what we're trying to do just with that language is to balance the . . . history of using LDL cholesterol as an accepted surrogate . . . with what the future may be given the fact there are at least 4 CV outcomes trials ongoing now that will certainly read on whether LDL remains an accepted surrogate.

Id.

C. Comparison of the August and September Statements

Plaintiffs argue that Defendants made false and misleading statements and omissions "by representing the future prospects for Esperion's drug ETC-1002 and engaging in a scheme to deceive the market." (Compl. ¶ 53). The Court finds no evidence supporting Plaintiffs' claims. It is certainly true that on August 17, Esperion represented that FDA approval of ETC-1002, as to its effectiveness in lowering levels of LDL-C in HeFH and ASCVD patient populations specifically, would not require the completion of a CV outcomes trial, and that on September 28, Esperion said that the FDA was in fact interested in getting a CVOT underway. *See* Dkt. 30-5, Defs.' Ex. D at Pg. ID 639; Dkt. 30-6, Ex. E at Pg. ID 645; Dkt. 30-8, Ex. G at Pg. ID 663. It is also true, however, that throughout the class period, Esperion consistently maintained that it planned to conduct a CVOT. In its August 17 press release, Esperion revealed that it "**continues to plan and initiate a CVOT** prior to NDA filing to pursue broader label indications related to cardiovascular disease reduction." During the conference call later that day, Mayleben told participants that Esperion's "commitment to conduct a CVOT for commercial reasons remains intact" and that Esperion hoped "to be able to complete and report out a positive CV outcomes trial" during Phase III of the

program. (Dkt. 30-6, Defs.' Ex E. at Pg. ID 645, 649). Esperion and Mayleben repeated these representations on September 28. *See, e.g.*, Dkt. 30-8, Defs.' Ex. G at Pg. ID 663 ("Our commitment to conducting a CVOT and having it well underway at the time of the NDA submission remains intact."). Though Plaintiffs are correct in pointing out that Defendants' statements were made in reliance on information previously conveyed to them by the FDA, the Court concludes that such statements fall squarely within the PSLRA safe harbor provision because they served as "the basis for the later forward-looking statements, thus qualifying as an 'assumption underlying' a forward looking statement." *Miller v. Champion Enters., Inc.*, 346 F.3d 660, 677 (6th Cir. 2003) (quoting 15 U.S.C. § 78u-5(i)(1)(D)).

The fact that Esperion consistently communicated the risks of drug development and the inherently dynamic nature of the FDA approval process is also worthy of mention. Both the August and September press releases include the following language: "This press release contains forward-looking statements that are made pursuant to the safe-harbor provisions of the federal securities laws . . . **forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, the risk that FDA may require additional studies or data prior to approval that might cause approval to be delayed**." (Dkt. 30-5, Defs.' Ex. D at Pg. ID 640; Dkt. 30-7, Defs.' Ex. F at Pg. ID 658). Esperion "disclosed the exact risk that [seems to have] occurred in this situation:" Esperion, based on the

encouragement of the FDA, decided to move forward with an additional outcomes trial that may delay the approval of ETC-1002. *See Miller*, 346 F.3d at 678. Defendants' allegedly problematic statements were "accompanied by meaningful cautionary language." *Id.* at 677. Moreover, through its Form 10-K, the Prospectus Supplement, and in nearly every communication with investors, Esperion highlighted the risks related to the clinical development and commercialization of ETC-1002. Esperion took care to caution investors that "the FDA may delay, limit or deny approval of ETC-1002 for many reasons, including, among others . . . [a requirement] that we conduct additional clinical studies, such as a cardiovascular outcomes study." (Dkt. 30-1, Defs.' Ex. A at Pg. ID 622; Ex. B at Pg. ID 630).

Plaintiffs' arguments are unavailing. They have not set forth sufficient evidence to bypass the protection of the safe harbor provision. In addition to the fact that these statements are protected and non-actionable, Plaintiffs have failed to show that the defendants had actual knowledge that these statements were false or misleading. *See* O*mnicare, Inc.*, 583 F.3d at 943.

III. Section 20(a) Claim

Section 20(a) of the 1934 Act states:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regularity thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a) (2006). "Section 20(a) claims are predicated upon at least one underlying violation committed by a controlled party." *Ley*, 543 F.3d at 818. Moreover, "[w]hen a primary violation of securities law is shown, that provision imposes joint and several liability on 'controlling persons.'" *Omnicare, Inc.*, 583 F.3d at 948.

Because the Court will **GRANT** Defendants' Motion to Dismiss Plaintiffs' § 10(b) and Rule 10b-5 claims, dismissal of Plaintiffs' claims under § 20(a) is also proper.

Accordingly,

IT IS ORDERED that Defendants' Motion to Dismiss the Amended Complaint [30] is **GRANTED**.

SO ORDERED.

s/Arthur J. Tarnow
Arthur J. Tarnow
Dated: December 27, 2016 Senior United States District Judge