NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HENRY A. AND WILMA KELLEY, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

AERIE PHARMACEUTICALS, INC., et al.,

Defendants.

Civ. No. 15-3007

OPINION

THOMPSON, U.S.D.J.

INTRODUCTION

This matter is before the Court upon defendants Aerie Pharmaceuticals, Inc., Vicente Anido, Jr., Thomas A. Mitro, Richard J. Rubino, Brian Levy, and Anand Mehra's (together, "Defendants") motion to dismiss. (ECF No. 38). Plaintiffs City of Pontiac General Employees' Retirement System, City of Roseville Employees' Retirement System, and Wayne County Employees' Retirement System ("Plaintiffs") oppose. (ECF No. 46). The Court has decided the motion based on the written submissions of the parties and oral argument before the Court. For the reasons stated herein, Defendants' motion will be granted.

BACKGROUND

Aerie Pharmaceuticals, Inc. ("Aerie") is a clinical-stage pharmaceutical company that develops drugs to treat glaucoma and other eye diseases. (Pls.' Am. Compl. at ¶ 2, ECF No. 29). Aerie has not yet brought an FDA-approved product to market. (*Id.* at ¶

38). In recent years, Aerie has focused its development efforts on a glaucoma drug called Rhopressa. (*Id.* at ¶ 39). Plaintiffs allege that Defendants (Aerie and certain corporate officers and directors) defrauded investors by lying about or omitting material facts related to the development of Rhopressa. (*See id.* at ¶ 122).

Glaucoma is treated by lowering the levels of intraocular pressure in the eye. (*Id.* at ¶ 36). Currently, there are two generic drugs that are most frequently used to treat glaucoma: timolol and latanoprost. (*Id.* at ¶¶ 47-48). Plaintiffs allege that in order to become the "blockbuster drug" that Defendants hoped for, Rhopressa would need to offer an advantage beyond what latanoprost and timolol offered. (*Id.* at ¶ 45). Merely being "non-inferior" to the generic drugs would not be sufficient for Rhopressa to become a viable alternative in the marketplace. (*Id.*).

In 2012, Rhopressa entered its Phase 2 trials. (*Id.* at ¶ 56). Phase 2b was completed in May 2013. (*Id.* at ¶ 60). In the Phase 2b trial, Rhopressa and latanoprost were compared, and latanoprost was 1.1 millimeters of mercury ("mmHg") better at reducing intraocular pressure. (*Id.* at ¶ 59). Defendants noted that for a certain subset of patients, the two drugs were actually statistically equivalent. (*Id.* at ¶ 60). Plaintiffs allege that several of Defendants' subsequent positive comments about Rhopressa's performance compared to latanoprost were materially misleading to investors. (Pls.' Am. Compl. at ¶¶ 75, 84, 122, ECF No. 29).

Aerie went on to prepare for Rhopressa's Phase 3 trials. The first Phase 3 trial was named "Rocket 1" and was scheduled for 2015. (*Id.* at ¶ 67). Instead of comparing Rhopressa and latanoprost again, Rocket 1 was designed to compare Rhopressa and timolol. (*Id.* at ¶ 64). Plaintiffs allege that Aerie conveyed to investors that timolol was "an inferior drug that Rhopressa could easily match." (*Id.* at ¶ 65). To support this claim,

Defendants repeatedly referenced a Scandinavian study from the 1990s called the Hedman and Alm Study ("H&A Study"), which showed that timolol was 1 mmHg less effective than latanoprost. (*Id.*). Since Rhopressa had been approximately 1 mmHg less effective than latanoprost in its Phase 2b trial, Defendants believed Rhopressa would match timolol in Rocket 1. (*Id.* at ¶ 4). In one of several positive statements about Rhopressa's chances against timolol, Defendant Anido stated that because "timolol is known to be at least 1 mmHg less effective at lowering intraocular pressure than latanoprost is . . . there's strong expectation [sic] that Rhopressa will prove to be non-inferior to timolol in a Phase 3 Rhopressa trial." (Q2 2014 Earnings Call at 3, ECF No. 38-6). However, Rhopressa failed to meet its non-inferiority goal in Rocket 1. (Pls.' Am. Compl. at ¶ 99, ECF No. 29). Once the disappointing Rocket 1 results were released, Aerie's stock price dropped from $35.39 to $12.87. (*Id.* at ¶ 105).

Plaintiffs allege that Rocket 1 and the H&A Study differed in multiple material ways, which Defendants were either aware of or recklessly disregarded. (*Id.* at ¶¶ 66, 79). These material differences apparently led to Rhopressa's surprisingly poor performance against timolol. (*See id.* at ¶ 79). Plaintiffs allege that because Defendants did not disclose the material differences between Rocket 1 and the H&A Study to investors, Defendants' optimistic statements about Rocket 1 were materially false and misleading. (*Id.*).

In addition to the allegedly misleading statements and omissions regarding Rhopressa's Phase 2b trial results and Rhopressa's likelihood of success in Rocket 1, Plaintiffs allege a third category of misleading statements. At various points in Rhopressa's development, Defendants referred to Rhopressa as a "blockbuster drug" or a drug with "blockbuster potential." (*Id.* at ¶¶ 76, 84). A "blockbuster drug" is understood

in the pharmaceutical industry to specifically mean a drug that has at least $1 billion in sales per year. (*Id.* at ¶ 37). Plaintiffs argue that Defendants misled investors by using the term "blockbuster drug," because Rhopressa allegedly could never become a blockbuster drug given its weak performances compared to timolol and latanoprost. (*Id.* at ¶¶ 60, 83, 86).

Lastly, Plaintiffs highlight the stock trades made by one of the defendants, Anand Mehra. Dr. Mehra is not an Aerie employee, but he serves on Aerie's board of directors. (*Id.* at ¶ 26). Prior to the class period, Dr. Mehra sold approximately 324,000 of his Aerie shares. (Mehra Forms 4, ECF No. 38-8). During the class period, Dr. Mehra sold approximately 2.5 million Aerie shares. (*Id.*). Plaintiffs allege that Dr. Mehra's trades "took advantage of the artificial inflation in Aerie's stock price caused by defendants' materially false and misleading statements and omissions." (Pls.' Am. Compl. at ¶ 32, ECF No. 29).

After the class period and the failure of Rocket 1, Aerie was able to design the second Phase 3 trial, Rocket 2, with more limited goals and a smaller patient population, such that Rhopressa was able to meet its goals. (Pls.' Br. at 14, ECF No. 46). However, Plaintiffs state that Rhopressa's failure in Rocket 1 has convinced analysts that any future financial success Rhopressa may have will be very limited. (*Id.*).

Six days after Aerie announced the results of Rocket 1, Plaintiffs filed a complaint against Aerie, its top executives, and Dr. Mehra. (ECF No. 1). Plaintiffs later amended their complaint. (ECF No. 29). Plaintiffs' amended complaint alleges that Defendants violated Section 10(b) of the Securities Exchange Act of 1934 and the corresponding SEC Rule 10b-5. (*Id.* at ¶¶ 119-29). Plaintiffs also allege that the individual defendants bear liability for the same violations under Section 20(a) of the Act. (*Id.* at ¶¶ 130-32). All

defendants moved to dismiss the amended complaint. (ECF No. 38). Their motion is presently before the Court.

LEGAL STANDARDS

In order to state a claim for securities fraud, a plaintiff must allege: "(1) a material misrepresentation or omission, (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." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). The Private Securities Litigation Reform Act of 1995 ("PSLRA") provides heightened pleading standards for private securities fraud complaints that allege false or misleading statements. *See id.* at 166. Plaintiffs must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Complaints must also "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).

The Third Circuit has identified three steps to follow when considering a motion to dismiss a Section 10(b) action. First, as with any motion to dismiss under Rule 12(b)(6), the Court must accept all of the factual allegations in the complaint as true. *Winer Family Trust v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007). Second, the Court must consider the complaint in its entirety, along with documents incorporated into the complaint by reference, and matters that a court may take judicial notice of. *Id.* Courts should inquire "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that

standard." *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007)). Third, when determining whether the facts in the complaint give rise to the required "strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u-4(b)(2), the Court "must take into account plausible opposing inferences." *Winer Family Trust*, 503 F.3d at 327 (quoting *Tellabs*, 551 U.S. at 323). The inference that the defendants acted with scienter need not be the most plausible inference, but it must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* (quoting *Tellabs*, 551 U.S. at 324).

ANALYSIS

Plaintiffs assert that the amended complaint (hereinafter "the complaint") alleges three categories of false and misleading statements that violate Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5: 1) that Rhopressa was a blockbuster drug; 2) that the H&A Study and Rhopressa's past equivalence to latanoprost "nearly guaranteed" that Rhopressa would do well against timolol in Rocket 1; and 3) that Rhopressa had performed well against latanoprost. (Pls.' Br. at 9, ECF No. 46). The Court will analyze each category separately.

I. Rhopressa is a Blockbuster Drug

Plaintiffs' brief highlights a number of allegedly false and misleading statements regarding Rhopressa's blockbuster status:

> "[O]ur products have blockbuster potential."
>
> "I am also very excited about the blockbuster potential for both Rhopressa and Roclatan."
>
> "We think that on the back of the two blockbuster drugs that we have, Rhopressa and Roclatan, we should be able to do that."

"[W]e believe we are well on our way to developing two potential blockbuster products."

(Pls.' Br. at 11-12, ECF No. 46). Defendants argue that all of these statements are forward-looking and covered by both of the PSLRA's safe harbor provisions. (Defs.' Br. at 13, ECF No. 38-1).

The PSLRA contains two safe harbors for forward-looking statements. 15 U.S.C. § 78u-5(c). Defendants are shielded from liability for any forward-looking statement if: 1) the statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement;" or 2) if the plaintiff fails to prove that the statement "was made with actual knowledge by that person that the statement was false or misleading." *Id.*

Plaintiffs argue that neither safe harbor protects Defendants' statements. Plaintiffs first argue that Defendants' statements were not forward-looking. (Pls.' Br. at 26-31, ECF No. 46). Plaintiffs argue that the statements were not forward-looking because at least one of them refers to Rhopressa as a blockbuster in the present tense, and because the statements were premised on Defendants' misleading representations of historical facts, such as how Rhopressa previously performed compared to latanoprost. (*Id.*).

The Court finds that Defendants' statements calling Rhopressa a "blockbuster" or "potential blockbuster" were forward-looking. Plaintiffs themselves note that in the pharmaceutical industry, the term "blockbuster drug" means a drug that generates over $1 billion in sales per year. (Pls.' Br. at 1, ECF No. 46). Rhopressa has no sales, as it is still being developed, so any statement about its earnings is inherently forward-looking. Calling Rhopressa a "blockbuster drug" is equivalent to saying that Rhopressa will make

more than $1 billion in sales per year in the future. The Third Circuit has repeatedly held that statements about future revenues are forward-looking statements. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 281 (3d Cir. 2010) ("Statements about future profitability and assumptions underlying management's expectations about the future fall squarely within the definition of forward-looking statement."); *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 255 (3d Cir. 2009) (noting that the PSLRA defines forward-looking statements "broadly" and that they include projections of future revenue.). Plaintiff correctly notes that statements that are mixed present and future statements are not fully protected by the safe harbor provisions, however, only the part of the statement that refers to the present is unprotected. *Institutional Inv'rs Grp.*, 564 F.3d at 255.

Defendants argue that both of the PSLRA's safe harbors apply. (Defs.' Br. at 13, ECF No. 38-1). The first safe harbor requires that Defendants accompanied their statements with "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i). While the cautionary statements need to directly relate to the alleged misrepresentations, they need not literally accompany the misrepresentations. *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004). The cautionary statements must be "extensive and specific;" mere boilerplate disclaimers that warn generally of risks are insufficient to meet the requirements of the first safe harbor. *Id.* (citations omitted). "To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions . . . which the plaintiffs challenge." *Id.* (citations omitted).

Defendants offer many examples of written and oral cautionary statements. (Defs.' Br. at 15-16, ECF No. 38-1). Besides general language about unspecified risks

that "could cause actual results to differ materially from those contemplated by the [forward-looking] statements," (Clinical Trial Update at 2, ECF No. 38-6), Aerie warned:

> • that "[i]n most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of [a] drug," and that Aerie's business "is substantially dependent on [its] ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner." (2013 10-K at 23, 33, ECF No. 38-3; 2014 10-K at 21, 30, ECF No. 38-5).
>
> • that Aerie's application for regulatory approval for Rhopressa might be rejected in the event of Aerie's "inability to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols," or in the event of "unfavorable or inconclusive results of clinical trials . . . , including unfavorable results regarding effectiveness of product candidates during clinical trials," and that, in those circumstances, Aerie's "business will be materially harmed." (2013 10-K at 35, ECF No. 38-3; 2014 10-K at 31-32, ECF No. 38-5.)
>
> • that "[a] failure of one or more clinical trials can occur at any stage of testing for a variety of reasons," that "[f]laws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced," that Aerie had "limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval," and that "[i]f the results of our clinical trials for our current product candidates or clinical trials for any future product candidates do not achieve the primary efficacy endpoints . . . the prospects for approval of our product candidates will be materially adversely affected." (2013 10-K at 37, ECF No. 38-3; 2014 10-K at 33-34, ECF No. 38-5).

Plaintiffs argue that these statements are "mere boilerplates." (Pls.' Br. at 11-12, ECF No. 46). However, considering Aerie's cautionary statements in the context of other relevant cases in this Circuit, the Court finds that Aerie's warnings were sufficient to meet the requirements of the first PSLRA safe harbor. In *Institutional Investors Group v. Avaya, Inc.* the Third Circuit held that the defendant's cautionary statements were sufficiently extensive and specific to fall under the PSLRA's first safe harbor. *Institutional Inv'rs Grp.*, 564 F.3d at 257. The Third Circuit described the defendant's statements in some detail:

> Avaya's SEC filings contain a detailed list of specific factors and uncertainties that could affect its future economic performance. . . . These documents explicitly warned that Avaya's forward-looking statements "may turn out to be wrong" because "[t]hey can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties." *Id.* at 44. Avaya included in a list of these "risks and uncertainties" the very "price and product competition" Shareholders assert was responsible for Avaya's missing its projections. *Id.*; *see also id.* at 47-48 ("We face intense competition from our current competitors and . . . may face increased competition from companies that do not currently complete [sic] directly against us. . . . Competitors with greater resources also may be able to offer lower prices. . . ."). Avaya also warned about uncertainties related to its marketing strategy, stating that "if we do not successfully execute our strategy to expand our sales in market segments with higher growth rates, our revenue and operating results may continue to be adversely affected."

Id. Aerie's warnings were at least as extensive and detailed as the warnings described in *Institutional Investors Group*. Aerie's cautionary statements also compare favorably to the statements in *In re NutriSystem, Inc. Securities Litigation*, where the defendant "included warnings that a pharmaceutical competitor perceived as easier to use than the NutriSystem program could negatively impact results and harm the company's competitive position." 653 F. Supp. 2d 563, 579-80 (E.D. Pa. 2009). The Court held that these cautionary statements were sufficient under the PSLRA's first safe harbor. *Id.*

Defendants did more than just warn about a competitor's success being able to harm their bottom line: they described what trials Rhopressa needed to succeed in, what would happen if Rhopressa underperformed, and stated that Rhopressa could fail to perform for a number of reasons, including Aerie's own lack of experience in designing trials. These warnings are much more detailed than mere boilerplate statements that simply recite that an "investment has risks." *Institutional Inv'rs Grp.*, 564 F.3d at 256 (citation omitted). Therefore, Defendants' "blockbuster" statements are protected by the

PSLRA's first safe harbor, and Plaintiffs' allegations based on these statements must be dismissed.

Since the statements are protected by the first safe harbor, the Court will not analyze the requirements of the second safe harbor. However, Defendants' state of mind will be discussed at length in the following sections.

II. Rhopressa Would Do Well Against Timolol in Rocket 1

A significant portion of Plaintiffs' complaint, brief, and oral arguments focuses on Defendants' statements about how Rhopressa would perform in its first Phase 3 trial, "Rocket 1." Specifically, Plaintiffs argue that Defendants misleadingly used the H&A Study to convince investors that Rhopressa was almost guaranteed to meet its goals in Rocket 1.[1] (Pls.' Br. at 20-26, 40, ECF No. 46). The Court will therefore briefly describe Rocket 1, and the apparent reasons for Rhopressa's disappointing performance.

Prior to Rocket 1, Aerie performed a Phase 2b trial that showed Rhopressa to be 1.1 mmHg less effective than latanoprost at reducing intraocular pressure. (Pls.' Am. Compl. at ¶ 59, ECF No. 29). Aerie shared this information with investors. (*Id.* at ¶ 60). In Rocket 1, instead of comparing Rhopressa to latanoprost, Aerie chose to compare Rhopressa to timolol, the other leading generic glaucoma drug. (*Id.* at ¶ 64). Aerie allegedly depicted timolol as an "inferior drug that Rhopressa could easily match." (*Id.* at ¶ 65). In support of this claim, Aerie referenced the H&A Study, which showed that

[1] Plaintiffs argue that Defendants also mischaracterized how Rhopressa had previously performed against latanoprost in order to mislead investors about Rhopressa's likelihood of success in Rocket 1. (Pls.' Br. at 20, ECF No. 46). However, since Plaintiffs address Defendants' statements about the H&A Study separately from Defendants' statements about Rhopressa's previous performance against latanoprost, the Court will address the two categories of statements in separate sections.

timolol was itself 1 mmHg less effective than latanoprost. (*Id.*). The goal of Rocket 1 was simply to show that Rhopressa was non-inferior to timolol. (*Id.* at ¶ 4).

Latanoprost and timolol lower intraocular pressure in different ways. Timolol reduces the amount of acqueous humor the eye produces. (*Id.* at ¶ 48). Latanoprost diverts acqueous humor away from the trabecular meshwork, the eye's primary drain, which functions less well in glaucoma patients. (*Id.* at ¶ 47). Rhopressa has its own mechanism for lowering intraocular pressure, which is to increase the drainage that is possible through the trabecular meshwork. (*Id.* at ¶ 52).

The differences in how the different drugs operate was apparently a primary driver of Rhopressa's inability to prove non-inferior to timolol in Rocket 1. At the time of the H&A Study, approximately twenty years ago, very few (if any) patients had used a prostaglandin analogue ("PGA") drug. (*Id.* at ¶ 65). PGAs divert acqueous humor away from the trabecular meshwork. (*Id.*). This diversion damages the trabecular meshwork over time. (*Id.* at ¶ 51). However, by the time Rocket 1 was conducted, many patients had used PGA drugs that could damage their trabecular meshworks over time. (*Id.* at ¶ 67). Because Rhopressa works by increasing drainage through the trabecular meshwork, it could not work as well in patients with damaged trabecular meshworks. (*Id.* at ¶ 79(a)). Since timolol works by simply reducing the amount of acqueous humor the eye produces, it is able to work relatively well in patients with damaged trabecular meshworks. (*Id.*). Therefore, while timolol and Rhopressa may have performed equally well back when the H&A Study was conducted, by the time Rocket 1 was conducted with a significant number of patients who had used PGAs and likely damaged their trabecular meshworks, timolol had a material advantage over Rhopressa. (*See id.*). Plaintiffs allege that Defendants knew about this advantage, but failed to disclose it. (*Id.*). Instead, Defendants

allegedly used the H&A Study in a misleading fashion to suggest that Rhopressa would likely achieve non-inferiority to timolol in Rocket 1. (*Id.*).

Plaintiffs highlight a few of other differences between the H&A Study and Rocket 1 that allegedly contributed to Rhopressa's failure in Rocket 1, and which Defendants did not highlight for investors. The H&A Study lasted six months, while Rocket 1 only lasted three months. (*Id.* at ¶ 79(b)(i)). Plaintiffs assert that latanoprost continues to reduce intraocular pressure over time, while timolol plateaus or loses effectiveness over time. (*Id.*). Therefore, timolol would perform better in the shorter Rocket 1 trial than it had in the H&A Study. (*Id.*). Additionally, the types of glaucoma and levels of intraocular pressure included in Rocket 1 differed from those in the H&A Study, again in a way that allegedly led to timolol performing better in Rocket 1 than it had performed in the H&A Study. (*Id.* at ¶ 79(b)(ii) and (iii)).

While the H&A Study and the above information about Rocket 1 were available to the public, Plaintiffs argue that Defendants failed to articulate the material differences between the H&A Study and Rocket 1, and failed to warn investors that these differences could have a material effect on the outcome of Rocket 1. (Pls.' Br. at 24, ECF No. 46). Therefore, Plaintiffs argue, Defendants' use of the H&A Study to predict that Rhopressa would do well in Rocket 1 was materially misleading in violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. (*See id.* at 21).

In order to pursue their claims, Plaintiffs must allege six elements: "(1) a material misrepresentation or omission, (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." *City of Edinburgh Council*, 754 F.3d at 167. The Court will follow the three steps the Third

Circuit articulated in *Winer Family Trust v. Queen* to evaluate Plaintiffs' claims. 503 F.3d at 327. First, as with any motion to dismiss under Rule 12(b)(6), the Court accepts all of the factual allegations in the complaint as true. *Id.* Second, the Court has considered the complaint in its entirety, along with documents incorporated into the complaint by reference. *Id.* Third, the Court will now review whether the pleaded facts collectively have met the PSLRA's "strong inference" standard for scienter.[2]

The PSLRA provides heightened pleading standards for Plaintiffs' claims. *See id.* at 166. In order to successfully allege scienter, Plaintiffs must state with particularity "the facts evidencing scienter, *i.e.*, the defendant's intention to 'deceive, manipulate, or defraud.'" *Tellabs*, 551 U.S. at 323 (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194 n.12 (1976)). Vague or unspecific allegations of scienter that might ordinarily suffice under Rule 12(b)(6) are not sufficient. *See In re Digital Island Sec. Litig.*, 357 F.3d 322, 328 (3d Cir. 2004). The Third Circuit has held that the scienter requirement can be met by showing a defendant acted either intentionally or recklessly, with recklessness defined as "highly unreasonable (conduct), involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, . . . which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *United States S.E.C. v. Infinity Grp. Co.*, 212 F.3d 180, 192 (3d Cir. 2000) (quoting *McLean v. Alexander*, 599 F.2d 1190, 1197 (3d Cir. 1979)) (alteration in original).

[2] Defendants argue that their statements regarding Rhopressa's likelihood of success in Rocket 1 are also protected by the PSLRA's safe harbors (Defs.' Br. at 17-20, ECF No. 38-1). However, since Plaintiffs present a mixed discussion of forward-looking and backward-looking statements in relation to Rocket 1, the Court will not address the safe harbors here. *See Institutional Inv'rs Grp.*, 564 F.3d at 255 (noting that mixed present/future statements are not fully protected by the PSLRA's safe harbors).

A plaintiff must plead particular facts that give rise to a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2)(a). The strength "cannot be decided in a vacuum," rather courts "must consider plausible nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Winer Family Trust v. Queen*, 503 F.3d at 327 (quoting *Tellabs*, 551 U.S. at 323). To survive a motion to dismiss, the inference of scienter must be "cogent and at least as compelling as any opposing inference [a reasonable person] could draw from the facts alleged." *Id.*

Plaintiffs cannot meet this bar. Plaintiffs offer three lines of argument in order to demonstrate Defendants' scienter:

> 1) Aerie was extremely knowledgeable about glaucoma drugs since Rhopressa was its core product, so Defendants must have understood or recklessly disregarded the material differences between Rocket 1 and the H&A Study;
>
> 2) The executive defendants were motivated to deceive investors because their compensation and performance awards depended on them initiating and completing clinical trials, even if the trials were not successful; and
>
> 3) Aerie board member Anand Mehra sold off significant amounts of Aerie stock prior to the announcement of the Rocket 1 results, therefore he and the other defendants must have known that Rhopressa would do poorly in Rocket 1.

(Pls.' Br. at 37-45, ECF No. 46).

The core of Plaintiffs' first argument is that Defendants "knew or recklessly disregarded" the fact that many Rocket 1 patients had taken PGA drugs (unlike the patients in the H&A Study), and that Defendants "knew or were reckless in not knowing the effects prior PGA use would have on Rhopressa patients." (*Id.* at 38-39). The presence of former PGA users in Rocket 1 was apparently a primary cause of Rhopressa's failure to prove non-inferior to timolol. (*See* Pls.' Am. Compl. at ¶ 79(a), ECF No. 29). However, while Aerie had presumably studied glaucoma drug development very closely,

Plaintiffs offer nothing besides bare allegations that Defendants "knew or recklessly disregarded" the allegedly crucial differences between the H&A Study and Rocket 1. The PGA-related explanation for Rhopressa's failure came from Aerie's CEO, Defendant Anido, in a conference call after the disappointing Rocket 1 results were released. (April 23, 2015 Conference Call at 4, ECF No. 38-7). The explanation appears to be an initial post-mortem, not a fact that would have been obvious to any party prior to Rocket 1:

> Now we've been taking a look at [the results] . . . We think that one likely explanation is that some of these patients . . . could actually have had glaucoma for quite a while. And so if they were on for example latanoprost or any other prostaglandin ["PGA"] where a lot of the [acreage humor] was being shunted away from a trabecular meshwork that may have led to further fibrosis occurring at the trabecular meshwork to the point where a drug like ours that works primarily on the Rho-kinase inhibition and increasing the outflow through trabecular meshwork, if it's basically extremely fibrotic or drug may not work, so -- and probably most like won't work, so that could be a possible explanation.

(*Id.*). Since Plaintiffs do not plead with particularity any facts that demonstrate Defendants' intentional or reckless failure to predict the effect of including past PGA users in Rocket 1, this basis for scienter fails.

Plaintiffs' second proposed basis for scienter is the executive defendants' financial motivations to continue Rhopressa's development and convince the market that Rhopressa would be a successful drug. (Pls.' Br. at 40-42, ECF No. 46). Plaintiffs point to Defendants' allegedly high compensation, as well as the fact that they "were eligible for performance compensation by simply initiating and completing a clinical trial" regardless of the results. (*Id.*). These allegations are insufficient to support the requisite inference of scienter. "[M]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this fraud." *GSC Partners CDO Fund v.*

Washington, 368 F.3d 228, 237 (3d Cir. 2004) (citations omitted). Executives are generally compensated and wish their core products to continue their development. These motivations therefore are insufficient to establish an inference of scienter.

Plaintiffs' third proposed basis for scienter is Defendant Mehra's allegedly suspicious sales of Aerie stock during the class period. (Pls.' Br. at 42-45, ECF No. 46). Dr. Mehra is not an Aerie employee, but he serves on Aerie's board of directors. (*Id.* at ¶ 26). During the class period, Dr. Mehra sold:

- 1 Million Shares for approximately $24 per share on July 9, 2014
- 800,000 Shares for $26 per share on November 25, 2014
- 425,000 Shares for $33-$34 per share on April 14-15, 2015

(Mehra Forms 4, ECF No. 38-8). Dr. Mehra's April sales occurred a little over a week before the disappointing Rocket 1 results came out. Plaintiffs allege that by April 13, 2015, the Rocket 1 data was available to Aerie. (Pls.' Am. Compl. at ¶ 34, ECF No. 29). Plaintiffs argue that "Mehra's suspiciously timed massive stock dump can only be explained by the fact that he knew that negative news was coming." (Pls.' Br. at 3, ECF No. 46). Defendants respond by noting that Dr. Mehra sold stock consistently over a period of months, including an additional sale of 323,932 Shares for just $16 per share outside of the class period on May 22, 2014. (Defs.' Br. at 41-42, ECF No. 38-1).

Plaintiffs' allegations are insufficient to support a strong inference of scienter. First, the Court notes that there are no allegations that any of the executive defendants, who occupied the top positions at Aerie, sold any stock during the class period. It has been unclear throughout this litigation what exactly Plaintiffs believed Defendants' fraudulent scheme was, but the fact that no other defendants engaged in a "stock dump" weighs against an inference of scienter for all defendants. *In re PDI Sec.*, No. 02-211,

2006 WL 3350461, at *16 (D.N.J. Nov. 16, 2006) ("This Court fails to perceive what possible *concrete and personal* benefits Defendants were trying to obtain by fraudulently inflating PDI's stock price if Defendants were not selling their shares."); *see also Ronconi v. Larkin*, 253 F.3d 423, 436 (9th Cir. 2001) ("One insider's well timed sales do not support the 'strong inference' required by the statute where the rest of the equally knowledgeable insiders act in a way inconsistent with the inference that the favorable characterizations of the company's affairs were known to be false when made."). Second, the Court does not find Dr. Mehra's trades to be particularly suspicious. Dr. Mehra sold off his holdings over the course of a year, so that they appear to be largely unconnected to Rocket 1. *See In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 313 (D.N.J. 2001) ("A broad temporal distance between stock sales and a disclosure of bad news defeats any inference of scienter."). Dr. Mehra's one arguably suspiciously timed sale, where he sold stock at a much higher price per share shortly before the Rocket 1 results were announced, was his smallest sale of the class period. This trading pattern simply does not support a strong inference that Defendants' use of the H&A Study was part of an intentional or reckless plan to deceive investors.

Lastly, the Court notes that after Rocket 1 failed, Aerie designed Rhopressa's next trial, Rocket 2, with more limited goals and a smaller patient population so that Rhopressa was able to meet its goals. (Pls.' Br. at 14, ECF No. 46). When considering "plausible nonculpable explanations for the defendant's conduct," *Winer Family Trust*, 503 F.3d at 327, it seems extremely plausible that Defendants did their best in designing Rocket 1, reasonably relied on the H&A Study for its conclusions about timolol, were unpleasantly surprised by the results of Rocket 1, and adjusted their goals accordingly so Rhopressa could succeed in its next trial. Plaintiffs' allegations, taken collectively, do not lead to an

inference of scienter that is "cogent and at least as compelling" as this nonculpable explanation. *Id.* Therefore, Plaintiffs' allegations based on Defendants' use of the H&A Study fail to state a claim, and will be dismissed.

III. Rhopressa Previously Performed Well Against Latanoprost

Plaintiffs' last category of allegedly misleading statements is Defendants' statements that Rhopressa had performed well against latanoprost. As with the previous category of statements, Plaintiffs are unable meet the PSLRA's high bar for scienter.

In its Phase 2b trial, Rhopressa was compared to latanoprost. (Pls.' Compl. at ¶ 58, ECF No. 29). Rhopressa was 1.1 mmHg less effective than latanoprost overall, though for patients who had an intraocular pressure ("IOP") of 26 mmHg or below, Rhopressa was only 0.1 mmHg less effective. (*Id.* at ¶ 59; Sept. 10, 2014 Investor Day Slide Show at 23, ECF No. 38-4). Plaintiffs argue that several of Defendants' statements about these results were used to materially mislead investors. (Pls.' Br. at 19, ECF No. 46). In particular, Plaintiffs highlight the following statements:

> • "And certainly for IOP's below 26, then that would be ideal for Rhopressa. Because as you saw in the Phase 2 results, Rhopressa did exceptionally well versus latanoprost . . . in its Phase 2 trial." (June 25, 2014 Conference Call with Analysts at 7, ECF No. 38-6).
>
> • "[W]e're as good, if not better, than latanoprost." (Sept. 10, 2014 Investor Day Conference Call at 9, ECF No. 38-7).
>
> • "We believe Rhopressa™ may be prescribed by eye-care professionals as an initial therapy for patients with low to moderately elevated baseline IOPs of 26 mmHg or below at the time of diagnosis, representing approximately 80% of glaucoma patients. At these IOP levels, we believe the amount of IOP reduction achieved by Rhopressa™ would be equal to or exceed that of all currently marketed PGA and non-PGA products." (Form 10-K for the fiscal year ended December 31, 2014 at 3, ECF No. 38-5).
>
> • "We believe the ability of Rhopressa™ to maintain a consistent IOP-lowering effect on baseline IOP will place Rhopressa™ in a favorable

> competitive position relative to current PGA and non-PGA products because a significant majority of glaucoma patients have baseline IOPs of 26 mmHg or below at the time of diagnosis." (Form 10-K for the fiscal year ended December 31, 2014 at 10, ECF No. 38-5).

In the first statement, Plaintiffs chose to only to highlight the portion of the quote where Defendant Mitro said "Rhopressa did exceptionally well versus latanoprost . . . in its Phase 2 trial." (Pls.' Br. at 19, ECF No. 46). However, placed in context, Defendant Mitro was clearly only describing Rhopressa's performance in the lower IOP range where Rhopressa performed comparably to latanoprost. Moreover, his statement assumes that the sophisticated analysts he is speaking to already saw the Phase 2b results. (June 25, 2014 Conference Call with Analysts at 7, ECF No. 38-6 ("Because *as you saw in the Phase 2 results*, Rhopressa did exceptionally well versus latanoprost.")) (emphasis added). While Defendant Mitro unsurprisingly wishes to put a positive spin on his product's performance, there are no pleaded facts that reflect an intention to "deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 323.

The lack of any deceptive intent or recklessness is clearer when the statements are viewed collectively. The second highlighted statement, which called Rhopressa "as good, if not better, than latanoprost" was accompanied by a slide showing the actual results of the Phase 2b trial, which was then described in detail approximately five minutes after the statement was made. (Sept. 10, 2014 Investor Day Conference Call at 10, ECF No. 38-7). Later on during that same call, Defendants once again accurately described Rhopressa's performance compared to latanoprost: "when we compared at the normal baselines of all-comers in the Phase IIb, if you recall, we were 1 millimeter or Rhopressa was 1 millimeter less effective than latanoprost. But when we lowered the baselines, they then came out to be equivalent." (*Id.* at 15). These material representations are what matter in a securities

fraud complaint; opinions and "general statements of optimism" are understood by reasonable investors to be mere puffery. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d at 283.

The third and fourth statements highlighted by Plaintiffs only appear suspicious in Plaintiffs' brief, where Plaintiffs omitted the portions of Defendants' statements that refer to the lower IOP range, thereby making Defendants' statements appear broader than they actually were. (Pls.' Br. at 19-20, ECF No. 46). These statements express optimism about Rhopressa's prospects, but Plaintiffs do not plead any facts that suggest there was any deceptive intent or recklessness behind the statements. Moreover, a chart that accurately displayed Rhopressa's performance compared to latanoprost was included in the very same document, in relatively close proximity to both statements. (Form 10-K for the fiscal year ended December 31, 2014 at 8, ECF No. 38-5).

Since Plaintiffs do not plead with particularity any facts that suggest the above statements were made with a wrongful state of mind, and Plaintiffs' other arguments for scienter in the previous section were unavailing, Plaintiffs cannot meet the bar for scienter. Therefore, Plaintiffs' allegations based on Defendants' statements about Rhopressa's past performance against latanoprost fail to state a claim, and will be dismissed.

CONCLUSION

For the reasons above, the Court grants Defendants' motion to dismiss. An appropriate Order accompanies this Opinion.

/s/ Anne E. Thompson
ANNE E. THOMPSON, U.S.D.J.

Date: June 20, 2016