NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE AMARIN CORPORATION PLC SECURITIES LITIGATION	Case No. 3:19-cv-06601 (BRM) (TJB) **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before the Court are three motions: (1) a Motion to Dismiss filed by Amarin Corporation, PLC ("Amarin"), Craig B. Granowitz, Steven Ketchum, John F. Thero, and Joseph S. Zakrzewski (collectively, "Defendants"), seeking to dismiss Gaetano Cecchini, as Trustee of the Gaetano Cecchini Living Trust, and Dan Kotecki's (collectively, "Plaintiffs") Amended Class Action Complaint ("Amended Complaint") (ECF No. 51); (2) Plaintiffs' Motion to Strike exhibits attached to Defendants' Motion to Dismiss (ECF No. 52); and (3) Plaintiffs' Motion to Strike exhibits attached to Defendants' reply (ECF No. 63). Plaintiffs' Amended Complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against Amarin, John F. Thero, Steven Ketchum, and Craig Granowitz (individuals collectively, the "Officer Defendants") and a violation of Section 20(a) of the Exchange Act against John F. Thero, Steven Ketchum, Craig Granowitz, and Joseph S. Zakrzewski (collectively, the "Individual Defendants"). (*See* ECF No. 43 ¶¶ 194–208.) Plaintiffs filed an opposition to Defendants' Motion to Dismiss (ECF No. 53), and Defendants filed a reply to Plaintiffs' opposition. (ECF No. 58.) Further, Defendants filed oppositions to Plaintiffs' Motions to Strike (ECF Nos. 56, 64), and Plaintiffs filed replies to Defendants' oppositions (ECF Nos. 57, 65). Pursuant to Federal Rule of Procedure 78(a), the Court heard Oral Argument on September 9, 2020. (ECF No. 81.) For the reasons set forth below and

for good cause shown, Plaintiffs' Motions to Stay are **DENIED** and Defendants' Motion to Dismiss is **GRANTED without prejudice.**

I. BACKGROUND

A. Factual Background[1]

Amarin is a pharmaceutical company that has, since 2008, focused exclusively on testing and marketing Vascepa, a drug intended to treat heart disease. (ECF No. 43 ¶ 1.) The company is traded on the NASDAQ Global Market under the ticker "AMRN." (*Id.*) Amarin undertook three trials to demonstrate the drug's efficacy. (*Id.* ¶ 2.) The first two trials—the MARINE and ANCHOR trials—were conducted to demonstrate how Vascepa could lower patients' triglyceride levels. (*Id.*) The third and longest trial—the REDUCE-IT trial—was conducted to show Vascepa could reduce patients' major adverse cardiac events. (*Id.*)

The REDUCE-IT trial concluded in the summer of 2018 and while it appeared to show positive results, the trial featured two issues that may have impacted data: (1) the placebo used did not appear to be acting as an inert placebo and (2) the trial data could not explain how the drug was actually reducing negative cardiac events. (*Id.* ¶ 3.) Amarin decided to publish the REDUCE-IT trial's apparently positive results while keeping both issues with the trial a secret. (*Id.* ¶ 5.) At a conference call following the trial, Defendants stated the trial's results exceeded expectations and were "the single most, significant advance in preventive cardiovascular drug therapy since the advent of statin therapy" while also priding it was "an overall robust study result." (*Id.* ¶ 5.) As a result of this announcement, Amarin's share price rose 433% over the course of two days. (*Id.*)

[1] For the purposes of this Motion to Dismiss, the Court accepts the factual allegations in the Amended Complaint as true and draws all inferences in the light most favorable to Plaintiffs. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008).

Following this price spike, "Amarin's top officers seized on the opportunity to sell an unprecedented number of shares." (*Id.* ¶ 6.) But when the issues with the REDUCE-IT trial were disclosed at an American Heart Association ("AHA") conference on November 10, 2018, where top health experts noted the placebo "may have helped overstate Vascepa's true effect," share prices dropped 27% over the course of a few days. (*Id.* ¶ 7.) Plaintiffs and other Class members seek to recover the damages they suffered as a result of "Defendants' fraudulent acts and omissions." (*Id.* ¶ 8.)

The Court has jurisdiction over this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331. (*Id.* ¶ 9.) Lead Plaintiff Gaetano Cecchini, as Trustee of the Gaetano Cecchini Living Trust, purchased Amarin American Depository Shares ("ADS") during the Class Period, and was damaged as a result. (*Id.* ¶ 13.) Defendant Amarin is a biotechnology company with its headquarters in Dublin, Ireland and its U.S. office at 1430 Route 206, Bedminster, New Jersey 07921. (*Id.* ¶ 14.)

Plaintiffs allege the Individual Defendants, "as senior executive officers and directors of Amarin, were privy to confidential and proprietary information concerning Amarin, its operations, product, finances, financial condition, and present and future business prospects." (*Id.* ¶ 20.) According to Plaintiffs, "[b]ecause of their possession of such information, the Officer Defendants knew or recklessly disregarded that the adverse facts contradicting their misrepresentation and relating to their omissions had not been disclosed to, and were being concealed from, the investing public."[2] (*Id.*)

[2] Plaintiffs spend several pages describing heart disease in general, Vascepa's function, the MARNIE trial, the ANCHOR trial, and the REDUCE-IT trial (ECF No. 43 ¶¶ 25–46.) Plaintiffs detail other information in its Amended Complaint as well, including: FDA rejection of expanded approval of Vascepa based on the ANCHOR trial (*id.* ¶¶ 47–63); a previous securities class action based on Amarin shares (*id.* ¶¶ 64–68); and the conclusion of the REDUCE-IT trial (*id.* ¶¶ 69–71.)

On September 24, 2018, "the Class Period began when Amarin announced the results of the REDUCE-IT trial." (*Id.* ¶ 71.) Defendants reported the REDUCE-IT trial showed using Vascepa, when compared to a placebo, resulted in a 25% reduced risk of major adverse cardiovascular events. (*Id.*) They noted the trial showed "that pure EPA Vascepa at 4 grams/day can provide additional cardiovascular risk reduction benefit on top of LDL-C control with standard care statin therapy in studied patients." (*Id.*) During a conference call that same day, Amarin officers further touted the "truly remarkable" results of the REDUCE-IT study, emphasizing the risk reduction the drug offered, which was "supported by robust demonstrations of efficacy across multiple secondary endpoints." (*Id.* ¶ 72.) Defendants stated the results "represent[ed] a greater reduction than demonstration on top of statin therapy for any other drug" and "positions Vascepa to be first to market in addressing a large unmet medical need." (*Id.*) During the conference, Defendants "indicated that they had reviewed the entire data set, but explained that they were withholding the remaining results for the forthcoming AHA Conference presentation." (*Id.* ¶ 73.)

Plaintiffs allege the statements made by Defendants were misleading when made in the context of the FDA's prior concerns with the mineral oil placebo in the ANCHOR trial, the FDA's rejection of the ANCHOR supplemental new drug application ("sNDA"), the FDA's direction to Amarin to monitor the placebo arm in the REDUCE-IT trial, the allegations in the *Sklar* Action regarding the use of mineral oil as a placebo, Regulation 21 C.F.R. 201.302(G)(a) (2018), and recent failed cardiovascular studies of omega-3 products. (*Id.* ¶ 83.) Plaintiffs allege these statements were misleading because Defendants omitted several facts from these communications. (*Id.*)

These omissions include not disclosing that the mineral oil used as a placebo "may have interfered with patients' cholesterol-lowering statins" which impacted the relative risk reduction

of Vascepa. (*Id.*) Plaintiffs allege omissions were made about the mineral oil that affected various aspects of the patient's studied metrics—that is, the mineral oil raised various metrics across groups in the REDUCE-IT trial, making Vascepa seem more effective in comparison to the placebo arm of the study. (*Id.*) According to Plaintiffs, even though Defendants were aware of the issues with the REDUCE-IT trial, they "decided to conceal [that] information from the market to drive up Amarin's share price and keep it inflated." (*Id.* ¶ 84.)

Plaintiffs allege "publicizing only the efficacy results that claimed a 25% reduction of major adverse cardiovascular events on top of statin therapy was false and misleading." (*Id.* ¶ 139.) Relatedly, Plaintiffs assert as of September 24, 2018, when Defendants announced the REDUCE-IT trials' results, they "had already analyzed the full REDUCE-IT trial data and thus knew that publicizing the results without important caveats would likely mislead investors." (*Id.* ¶ 140.) Further, "Amarin and the Officer Defendants' public statements confirm that the Company had the full data when Amarin announced the results on September 24, 2018." (*Id.* ¶ 143.) Plaintiffs point to statements where Amarin's CEO and CSO, who both had access to the full data set before it was released to the public, said they were not going to disclose additional details or "talk too much about the results of the REDUCE-IT study because" they were saving those further details for presentation at the AHA Conference. (*Id.* ¶¶ 144–48.) According to Plaintiffs, Defendants, knowing the full results of the REDUCE-IT trial, mislead investors by choosing not to "provide the necessary qualifications" before the full results were released at the AHA Conference. (*Id.* ¶ 151.) Even if Defendants had not reviewed the full dataset "about which they spoke during the Class Period, they were deliberately reckless in making statements about such data when they could have easily reviewed it in the database to which they had access." (*Id.* ¶ 152.)

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