Jeffrey W. Herrmann
COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
Park 80 Plaza West – One
Saddle Brook, New Jersey 07663
(201) 845-9600

Lester L. Levy
Robert C. Finkel
Natalie M. Mackiel
WOLF POPPER LLP
845 Third Avenue, 12th Floor
New York, New York 10022
(212) 759-4600

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STEVEN SKLAR, on behalf of himself and all others similarly situated, Plaintiff, vs. AMARIN CORPORATION PLC and JOSEPH S. ZAKRZEWSKI, Defendants.	Civil Action No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Steven Sklar (hereinafter, "Plaintiff"), by his attorneys, alleges the following upon information and belief, except for those allegations that pertain to Plaintiff, which are based on Plaintiff's personal knowledge:

NATURE OF THE ACTION

1. Plaintiff brings this action as a class action on behalf of himself and all other persons or entities who purchased shares of Amarin Corporation plc ("Amarin") common stock on the open market, or pursuant to Registration Statements filed with the Securities and Exchange Commission, during the period July 9, 2009 through October 15, 2013 to recover

damages caused by Defendants' violations of the federal securities laws.

JURISDICTION AND VENUE

2. This action arises under Sections 10(b) (15 U.S.C. § 78j(b)) and 20(a) (15 U.S.C. § 78t(a)) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a et seq. (the "Exchange Act"), and Rule 10b-5 (17 C.F.R. § 240.10b-5) promulgated there under by the SEC, and is brought on behalf of investors who purchased publicly traded shares of Amarin on the NASDAQ Stock Exchange Global Market ("NASDAQ") in the United States.

3. In connection with the acts alleged herein, the Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including the United States mails and facilities of a national exchange.

4. Jurisdiction is conferred upon this Court by Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §§ 1331 and 1337. This action arises out of the laws of the United States and the Courts of the United States have exclusive jurisdiction of claims brought under the Exchange Act under 15 U.S.C. § 78aa.

5. This Court has personal jurisdiction over the Defendants pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) because Defendants have sufficient contacts with the United States through their regular and substantial transaction of business therein and exercising jurisdiction over those Defendants is reasonable.

6. Venue is proper in this District because Amarin maintained offices in this District during the class period and many of the acts and transactions constituting the violations of law herein complained of occurred within this District, including the preparation and dissemination of materially false and misleading financial statements and corporate documents.

7. In connection with the acts alleged herein, the Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including the United States mails and facilities of a nation securities exchange.

PARTIES

8. Plaintiff Steven Sklar is a citizen of the State of New York and resides at 2000 Broadway, New York, New York. Plaintiff purchased 2000 shares of Amarin common stock on September 18, 2013 at $6.41 per share.

9. Defendant Amarin is a British corporation, headquartered in Dublin, Ireland, with U.S. offices at 1430 Route 206, Suite 200, Bedminster, New Jersey 07921, conducting business within New Jersey and this Judicial District. Amarin stock trades on the NASDAQ under the symbol AMRN.

10. Amarin is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Vascepa® (icosapent ethyl) is Amarin's first FDA approved product and is available in the United States by prescription.

11. Defendant Joseph S. Zakrzewski ("Zakrzewski" or "Individual Defendant") is the Chairman and Chief Executive Officer of Amarin, having joined Amarin in January 2010. Zakrzewski was appointed CEO effective November 10, 2010. Zakrzewski, as Amarin's CEO, had actual knowledge or supervision over Amarin's communications with the FDA and the true (undisclosed) facts concerning the FDA approval process.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

12. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."), on behalf of all persons or entities who purchased shares of Amarin common stock on the open market, or pursuant to Registration Statements filed with the SEC, during the period July 9, 2009 through October 15, 2013, (the "Class Period") and were damaged thereby. Excluded from the Class are the Defendants herein, officers and directors of Amarin, members of the immediate family of Defendant Zakrzewski, and affiliates of the corporate Defendant (the "Class").

13. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes there are hundreds of members of the Class. Amarin's common stock was actively traded on the NASDAQ Exchange throughout the Class Period.

14. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to further ensure such protection; he is a member of the Class; his claims are typical of the claims of all Class members; and he does not have interests antagonistic to, or in conflict with, those of the Class.

15. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since a multiplicity of actions could result in an unwarranted burden on the Court system and could create the possibility of inconsistent judgments. Moreover, a class action will allow redress for many persons whose claims would otherwise be too small to litigate individually. There will be no difficulty in the management of this action as

a class action.

16. There are numerous questions of law and fact which are common to the Class and which predominate over any questions affecting individual members of the Class, including:

(i) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(ii) whether the Defendants misrepresented or omitted material facts concerning the FDA approval process for Vascepa; and

(iii) whether members of the Class were damaged by virtue of their investments in Amarin common stock during the Class Period, and if so, the appropriate measure of damages.

SUBSTANTIVE ALLEGATIONS

A. Background

17. According to Amarin's Form 10-K for fiscal 2012 (at 2), Amarin is "a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health."

18. On July 26, 2012, Amarin received approval from the U.S. Food and Drug Administration ("FDA") to market and sell its lead product Vascepa capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride ("TG") levels in adult patients with severe (TG ≥ 500mg/dL) hypertriglyceridemia. This indication for Vascepa is sometimes referred to as the MARINE indication.

19. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. Triglycerides are fats in the blood.

20. Vascepa became commercially available in the United States by prescription in January 2013, when Amarin commenced sales and shipments to its network of U.S.-based wholesalers. On January 28, 2013, Amarin commenced its full commercial launch of Vascepa in the United States for the MARINE indication.

21. Amarin is also developing Vascepa for the treatment of patients with high (TG greater than 200 mg/dL and less than 500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which is referred to as mixed dyslipidemia. This second proposed indication for Vascepa is sometimes referred to as the ANCHOR indication. The ANCHOR study is a 12-week test of approximately 700 patients to determine if administration of Vascepa to the patient population reduces TGs.

22. In December 2011, Amarin announced commencement of patient dosing in a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial). REDUCE-IT is a multi-year test of approximately 8000 patients that is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy [the same patient population as ANCHOR].

23. According to Amarin's Form 10-K for fiscal 2012 (at 2-3), the market for the ANCHOR indication is approximately ten times larger than the market for the MARINE indication: "It is estimated that over 40 million adults in the United States have elevated triglyceride levels greater than 200mg/dL and approximately 4.0 million people in the United States have severely high (TG ≥500mg/dL) triglyceride levels, commonly known as very high triglyceride levels."

24. Amarin's future profitability is dependent on obtaining FDA approval to market Vascepa for the ANCHOR indication.

25. Amarin has estimated that it would cost over $100 million to conduct the REDUCE-IT study.

26. Accordingly, Amarin's future profitability was not only dependent on getting approval to market Vancepa for the ANCHOR indication, but also to getting that approval without having to complete the REDUCE-IT study.

B. The FDA Informs Amarin that Results From Two Pending Pivotal Trials On Other Drugs Are Significant to the FDA's Willingness to Approve the ANCHOR Application Prior to Completion of the REDUCE-IT Study

27. Amarin met with the FDA in July 2008 to discuss the ANCHOR study, including whether Amarin would be required, prior to FDA approval of the ANCHOR indication, to complete a comprehensive clinic trial (the REDUCE-IT study) to determine whether Vancepa was effective in reducing major cardiovascular events in the ANCHOR population.

28. According to the FDA's "Clinical Review" to the Endocrimologic and Metabolic Drugs Advisory Committee for its October 16, 2013 meeting with respect to Vascepa, the FDA informed Amarin in July 2008 that "there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk" and that the results of two ongoing drug tests – AIM-HIGH and ACCORD-Lipid -- "would be expected to provide information on the incremental benefit of adding a second lipid-active drug to statin therapy":

> During a pre-IND meeting with the applicant in July 2008 … the Division noted that there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated

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

29. By virtue of this meeting with the FDA, Amarin knew that even if Vascepa was effective in reducing TGs in the ANCHOR study, that "there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction" of TG "significantly reduces residual cardiovascular risk," and that if the AIM-HIGH and ACCORD-Lipid failed to demonstrate effectiveness in reducing major cardiovascular events, FDA was substantially less likely to approve the ANCHOR indication prior to completion of the REDUCE-IT study.

C. Defendants Misrepresent the FDA's Position on Approval of the ANCHOR Trial and Fail to Disclose the FDA's Misgivings that Reducing Levels of Triglycerides Will Reduce Major Cardiovascular Events

30. Throughout the Class Period, beginning on July 9, 2009, Amarin misrepresented to investors that, pursuant to a Special Protocol Assessment Agreement ("SPA") agreed to between Amarin and the FDA, the FDA would approve Vascepa based only on the ANCHOR protocol, so long as the REDUCE-IT study "was substantially underway."

31. Although Amarin ultimately clarified that the SPA only specified that the FDA would accept a New Drug Application ("NDA") (rather than approve Vascepa) for the ANCHOR indication if the REDUCE-IT study was "substantially underway," at no time did Amarin disclose that the FDA had also expressed reservations about approving VASCEPA in the absence of the completion of the long-term REDUCE-IT study – and especially if the ACCORD-

Lipid and AIM-High studies were unsuccessful (as they were) in demonstrating a reduction in major cardiovascual events.

32. The statements alleged to be false and misleading were not forward looking statements because they misrepresented existing facts based on historical communications with the FDA with respect to the approval process.

1. The July 9, 2009 Press Release

33. On July 9, 2009, Amarin issued a press release entitled "Amarin Received Special Protocol Assessment Agreement From the FDA for Phase 3 Trial In Mixed Dyslipidemia." The press release announced that Amarin had reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for its planned Phase 3 [ANCHOR] clinical trial of AMR101 (ethyl-EPA) in patients with mixed dyslipidemia…. The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase 3 trial.

34. The July 9, 2009 press release continued:

> The primary endpoint in the trial is the percentage change in triglyceride level from baseline to week 12.
>
> This trial is expected to enroll approximately 650 patients and will be conducted in centers throughout the United States. The Company plans to use the results of this Phase 3 trial as a basis for potentially broadening the label for AMR101 beyond treatment for very high triglycerides to include treatment for high triglycerides.

35. The July 9, 2009 press release created the materially false and misleading impression that merely achieving the primary endpoint of the ANCHOR study (reducing TG levels) was sufficient to obtain FDA approval for the ANCHOR indication. The press release failed to disclose that the REDUCE-IT study would have to be substantially underway prior to submission of the NDA for the ANCHOR study, and that even then, depending on the results of

other studies (including the AIM-HIGH and ACCORD-Lipid studies), that the FDA was not likely to approve Vascepa for the ANCHOR indication prior to completion of the REDUCE-IT study.

2. The May 13, 2010 Press Release

36. On May 13, 2010, in a press release reporting Amarin's first quarter 2010 operating results, Declan Doogan, Amarin's Interim Chief Executive Officer, acting on behalf of Amarin, was quoted as saying: "Elevated triglycerides are increasingly being recognized as an important independent risk factor for cardiovascular disease."

37. Doogan's statement was materially false and misleading inasmuch as the FDA had informed Amarin in July 2008 that "there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk." No study had been released in the interim between July 2008 and May 2010 that justified Doogan's statements, without the clarification that Amarin understood that the FDA disagreed with that position.

3. The August 10, 2010 Operating Press Release

38. On August 10, 2010, Amarin announced its second quarter 2010 operating results. The press release stated:

> In order to potentially obtain a broader indication for AMR101 based on the ANCHOR trial results, the Company's SPA for the ANCHOR trial requires that the Company has a cardiovascular Outcomes study [REDUCE-IT] substantially underway at the time of the NDA filing…. Importantly, the results of an Outcomes study are not required for FDA approval of this broader [ANCHOR] indication for AMR101.

39. The August 10, 2010 press release was materially false and misleading in that the FDA had only agreed in the SPA that the minimum requirements for filing the NDA did not require the completion of the Outcomes [REDUCE-IT] study, but that the FDA had not yet determined whether the results of the Outcomes [REDUCE-IT] study would be required for approval of the ANCHOR indication.

4. The January 6, 2011 Prospectus Supplement

40. On January 6, 2011 Amarin issued a Prospectus Supplement on Form 424B5 for an offering of 18.8 million American Depositary Shares ("ADSs") at a price to the public of $7.60 per ADS. The Prospectus Supplement stated, among other things:

> In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the Food and Drug Administration, or FDA, requires that we have a clinical "outcomes study" substantially underway at the time of filing a New Drug Application, or NDA. If we elect to seek this separate indication in our initial NDA filing and commence an outcomes study, we will need to seek additional financing, through a commercial partner or otherwise. The results of an outcomes study are not required for FDA approval of the broader indication, and an outcomes study is not required for the indication being studied in the MARINE trial. [Emphasis added.]

41. The January 6, 2011 Prospectus Supplement was materially false and misleading in that the FDA had only agreed in the SPA that the minimum requirements for filing the NDA did not require the completion of the Outcomes [REDUCE-IT] study, but that the FDA had not yet determined whether the results of the Outcomes [REDUCE-IT] study would be required for approval of the ANCHOR indication.

42. Defendant Zakrzewski signed the Underwriting Agreement on the 2011 offering, which was part of an 8-K filed with the SEC on January 6, 2011. He allowed the false statement to be issued in the Prospectus Supplement.

5. The March 17, 2011 Conference Call

43. On a March 17, 2011 conference call announcing fourth quarter 2010 earnings results, Defendant Zakrzewski, Amarin's then CEO emphasized that "the results of the outcome study are not needed in order to secure approval for the ANCHOR indication, but we do need to have this outcome study well underway."

44. Zakrewski's statement on the March 17, 2011 conference call was materially false and misleading in that the FDA had only agreed in the SPA that the minimum requirements for filing the NDA did not require the completion of the Outcomes [REDUCE-IT] study, but that the FDA had not yet determined whether the results of the Outcomes [REDUCE-IT] study would be required for approval of the ANCHOR indication.

D. Three Tests Considered By the FDA to be Indicators of the Relationship Between Reduction of Trigylcerides and Series Adverse Cardiac Events Proved Unsuccessful

45. The two tests that the FDA identified to Amarin in July 2008 as significant to the FDA's willingness to approve Vascepa without a long-term cardiac effects trial both proved to be failures.

46. The ACCORD study showed the combination of fenofibrate and simvastatin did not reduce the rate of fatal cardiovascular events, nonfatal myocardial infarction, or nonfatal stroke, as compared with simvastatin alone. Those results did not support the routine use of combination therapy with fenofibrate and simvastatin to reduce cardiovascular risk in the majority of high-risk patients with type 2 diabetes. The ACCORD study results were published in April 29, 2010 in the New England of Medicine, "The ACCORD Study Group. Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus."

47. In the AIM-HIGH study, among patients with atherosclerotic cardiovascular disease and LDL cholesterol levels of less than 70 mg per deciliter (1.81 mmol per liter), there was no incremental clinical benefit from the addition of niacin to statin therapy during a 36-month follow-up period, despite significant improvements in HDL cholesterol and triglyceride levels. These results were published on December 15, 2011 in the New England Journal of Medicine, "The AIM-HIGH Investigators. Niacin in patients with low HDL cholesterol levels receiving intensive statin therapy."

48. In addition, HPS2-THRIVE, a study to test the hypothesis that increased levels of HDL, or "good" cholesterol, would reduce the risk of serious adverse cardiovascular events, also provide unsuccessful. On December 20, 2012, Merck & Co., Inc. issued a press release stating that the study "did not significantly further reduce the risk of the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations compared to statin therapy."

E. Defendants Continue to Misrepresent Material Facts Notwithstanding the Failures of the ACCORD, AIM-HIGH, and HPS2-THRIVE Studies

1. The 2012 Form 10-K

49. In its Form 10-K for fiscal 2012, filed with the FDA on February 28, 2013, Amarin stated that:

> In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial), that is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. Based on communications with the FDA, we believe that we are required to be "substantially underway" with a cardiovascular outcomes study at the time of the submission of our sNDA seeking approval of the ANCHOR indication. We believe that we achieved this requirement prior to submitting the sNDA. However, there can be no assurance that the FDA will agree with our assessment or that they will accept our sNDA for the ANCHOR indication. We do not believe the final

> results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication. [Emphasis added.]

50. The Form 10-K also added (at 13) that:

> [I]n order to seek approval for a potentially expanded indication based on the ANCHOR study, we are required to have been substantially enrolled subjects in our REDUCE-IT cardiovascular outcomes study at the time of our NDA submission for the ANCHOR indication. Based upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial. [Emphasis added.]

51. Amarin's Form 10-K was materially false and misleading in that the FDA had only agreed in the SPA that the minimum requirements for filing the NDA did not require the completion of the Outcomes [REDUCE-IT] study, but that the FDA had not yet determined whether the results of the Outcomes [REDUCE-IT] study would be required for approval of the ANCHOR indication. The FDA was increasingly likely to require the completion of the REDUCE-IT study prior to the approval of the ANCHOR indication in light of the failure of the ACCORD, AIM-HIGH, and HPS2-THRIVE studies to achieve reduced levels of severe cardiovascual activity. Therefore, the "feedback from the FDA" did not support the stated belief that "the results of the REDUCE-IT outcomes study" were not "required for FDA approval of Vascepa for the ANCHOR indication."

52. Defendant Zakrzewski knew of the falsity of the statements in the 2012 Form 10-K. He signed the Form 10-K allowing the false statements to be contained therein.

2. The July 10, 2013 Prospectus

53. Amarin filed a Prospectus under Rule 424(b)(5) with the SEC on July 10, 2013 for an offering of 21.7 million ADS at a price to the public of $5.60 per ADS. Among other

things, the Prospectus stated:

> We are also developing Vascepa for the treatment of patients with high triglyceride levels (TG >200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels. This indication is referred to as mixed dyslipidemia or the ANCHOR indication. In February 2013, we submitted a supplemental New Drug Application, or NDA, to the FDA seeking approval of Vascepa for the ANCHOR indication. In April 2013, the FDA notified us that it accepted the sNDA for review. The acceptance of the sNDA indicates that the application is sufficiently complete to permit a substantive review by the FDA.
>
> On June 18, 2013, the FDA informed us that it plans to convene an advisory committee in October 2013 to review our NDA seeking approval for the marketing and sale of Vascepa for the treatment of patients with high triglyceride levels (TG >200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels. The application is subject to a standard review and has been assigned a Prescription Drug User Fee Act, or PDUFA, date of December 20, 2013. The PDUFA date is the target date for the FDA to complete its review of the sNDA. However, there can be no assurance that the FDA will complete its review of the sNDA by this date.
>
> * * *
>
> In December 2011 we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA – Intervention Trial), which is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events population on statin therapy. We do not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication, although there can be no assurance that this will be the case.

54. Amarin's July 10, 2013 Prospectus was materially false and misleading in that the FDA had only agreed in the SPA that the minimum requirements for filing the NDA did not require the completion of the Outcomes [REDUCE-IT] study, but that the FDA had not yet determined whether the results of the Outcomes [REDUCE-IT] study would be required for approval of the ANCHOR indication. The FDA was increasingly likely to require the

completion of the REDUCE-IT study prior to the approval of the ANCHOR indication in light of the failure of the ACCORD, AIM-HIGH, and HPS2-THRIVE studies to achieve reduced levels of severe cardiovascual activity.

55. Defendant Zakrzewski knew of the falsity of these statements and allowed them to be disseminated. He signed the Underwriting Agreement on the 2013 offering, which was part of an 8-K filed with the SEC on July 10, 2013.

F. Defendants Misrepresent the Significance of the AIM-HIGH and ACCORD Studies Notwithstanding Their Knowledge that the FDA Considered Those Studies Significant to the Prospects for Approval of the ANCHOR Indication

56. Notwithstanding their knowledge that the FDA considered the AIM-HIGH and ACCORD test studies significant, Defendants publicly stated that those test results were not significant to the prospects of approval of the ANCHOR study.

57. In the August 8, 2013 second quarter earnings call, Steven B. Ketchum, AMRN's head of R&D said:

> Some investors have argued that because the AIM-HIGH study with niacin failed, that the FDA will change its view on Vascepa. As a reminder, niacin is an HDL-raising drug, not a triglyceride lowering drug, and niacin remains approved and on the market. Some also argue the fenofibrate failed the outcome studies and that this will have a bearing on getting the FDA to reassess its requirement for Vascepa. Fenofibrates were not directly studied in a patient population with alleviated triglycerides in an outcome setting. In fact, in the ACCORD study of fenofibrates, the subgroup of patients who had alleviated baseline triglycerides showed improved outcomes. This has not been widely publicized because this was not the pre-specified primary endpoint of the study and the study was not powered for this purpose, but it is supportive of the value of lowering triglyceride levels in patients with high triglycerides.

G. The True Facts Are Revealed in the FDA's Briefing Book and At the Advisory Committee's Meeting

58. The true facts were first revealed on October 11, 2013, when the FDA published its Briefing Document for the October 16, 2013 Advisory Committee Meeting. That Briefing Document both summarized the FDA's significant doubt expressed to Amarin in July 2008 that reduction of TGs alone evidenced an improved risk of cardiac issues (quoted supra at ¶ 28) and stated that based on published test results first available to Amarin in 2010 that there was little indication that a reduction in TGs alone would improve the incidence of cardiac events:

> Several cardiovascular outcome trials of non-statin lipid-modulating therapy, such as those referenced by the Division in 2008, have since completed. ACCORD-Lipid, AIM-HIGH, and HPS2-THRIVE, which were designed to target residual cardiovascular risk by improving lipid parameters other than LDL-C (e.g., HDL-C and/or TG) in patients optimally treated with statin therapy, failed to demonstrate unequivocally additional cardiovascular benefit from non-statin lipid-modulating drugs. Several hypotheses could be put forward regarding the failures of these large, carefully designed trials to demonstrate benefit on their primary endpoints, but the evidence to date certainly challenges the hypothesis that adding lipid-modulating therapies to patients optimally treated with statins will reduce residual cardiovascular risk. [Emphasis added.]

59. Amarin's stock price fell $1.38 per share on October 11, 2013 (from $6.37 to $5.09) as a result of the revelations of true facts in the FDA's Briefing Document. Trading volume was an extraordinarily high 37.9 million shares.

60. On October 16, 2013, the NASD halted trading in Amarin common stock while the Advisory Committee considered Amarin's new drug application based on the ANCHOR study. Those deliberations were conducted in a public forum. The FDA presenter emphasized at the Advisory Committee Meeting that Amarin was advised by the FDA in July 2008, with respect to the application for approval of the ANCHOR indication based only on the ANCHOR

study, that "ongoing cardiovascular outcomes trials – e.g., ACCORD-Lipid and AIM-High – would provide *important* information on the incremental benefit of adding a second lipid-altering drug to statin therapy." Emphasis added.

61. The Advisory Committee, after hearing testimony and deliberating on Amarin's application, voted 9-2 to reject the NDA for ANCHOR, adopting the FDA's position that the ANCHOR study itself was not indicative of the efficacy of the drug to reduce severe cardiovascular events, and that the FDA should wait for completion of the REDUCE-IT study before approving Vascepa for the ANCHOR indication.

62. Upon the resumption of trading on October 17, 2013, Amarin common stock declined by an additional $3.16 per share (from $5.17 per share to $2.01 per share), on extraordinary trading volume of 105.7 million shares.

63. On October 29, 2013, Amarin filed a Form 8-K with the FDA. The Form 8-K informed investors that the FDA had "rescinded the ANCHOR study special protocol assessment agreement." According to the Form 8-K, "the FDA cited results from the ACCORD-Lipid and IM-HIGH outcome trials, as well as the publicly presented results from the HPS2-THRIVE outcome trial, which the FDA stated in its October 29, 2013 notice to Amarin, fail to support the hypothesis that a triglyceride-lowering drug significantly reduces the risk for cardiovascular events among statin-treated patients with mixed dyslipidemia and residually high serum triglyceride levels (200-499 mg/dL)."

64. The grounds for suspension of the SPA are precisely the same grounds that Amarin was apprised of by the FDA at the pre-NDA meeting in July 2008 (quoted *supra* at Paragraph 28), that would require the completion of the REDUCE-IT outcomes, study prior to approval of the ANCHOR indication, as follows:

> the Division noted [in July 2008] that there was a lack of prospective, controlled clinical trial data demonstrating that pharmaceutical reduction of non-HDL-C (or TG) with a second drug, in patients with elevated TG Levels at LDL goal on statin therapy, significantly reduces residual cardiovascular risk. The Division referenced trials ongoing at the time (e.g., AIM-HIGH, ACCORD-Lipid) that, while not able to assess the effect of specifically lowering non-HDL-C (or TG) on clinical outcomes, would be expected to provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy.

H. Scienter

65. By virtue of Amarin's meetings with the FDA, Defendants had actual knowledge that the FDA was substantially unlikely to approve Vascepa for the ANCHOR indication in the absence of completion of the REDUCE-IT study, and further, that the FDA would look to the AIM-HIGH and ACCORD-Lipid studies as indicative of whether the reduction in TGs (without an outcomes study) had been scientifically proven to diminish the incidence of severe cardiovascular events.

66. Moreover, Defendants were financially motivated to misrepresent the truth and artificially inflate the market price of Amarin stock. During the Class Period, Amarin conducted two secondary offerings – on January 6, 2011 – 18.8 million ADS at $7.60 per ADS, and on July 10, 2013 – 21.7 million ADS at $5.60 per ADS.

67. Defendant Zakrzewski was also financially motivated to commit the fraud and artificially inflate the market price of Amarin stock. From February 22, 2011 through October 1, 2012, Zakrzewski sold 1,070,000 shares of Amarin common stock for a total amount of $11,102,697 – or an average of $10.38 per share.

68. Defendants were also motivated to commit the fraud as, during the Class Period, Amarin was actively seeking partners to assist in financing the REDUCE-IT study in exchange

for purchasing an interest in revenue to be derived by Vascepa. Defendants were motivated to not tell the truth concerning their discussions with the FDA to maintain an inflated stock price and negotiate the best possible deal with a third party.

COUNT 1

Against Defendants for Violation of Sections 10(b) of The Exchange Act and Rule 10b-5 Thereunder

69. Plaintiff incorporates each of the foregoing paragraphs as if fully set forth herein.

70. Defendants participated in a course of conduct involving misrepresentation and concealment of adverse material information about the business of Amarin as specified herein.

71. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of fraudulent conduct as alleged herein in an effort to assure investors of Amarin's progress, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statement made about Amarin and its business, in light of the circumstances under which they were made, not misleading. This conduct operated as a fraud and deceit upon the purchasers of Amarin securities during the Class Period.

72. Had Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or had they been aware of Defendants' material misstatements, they would not have purchased Amarin's securities at artificially inflated prices.

73. Plaintiff and the Class were injured because the risks that materialized were risks of which they were unaware as a result of Defendants' misrepresentations, omissions and other fraudulent conduct alleged herein. The decline in the price of Amarin's securities was caused by the public dissemination of the true facts, which were previously concealed or hidden. Absent

Defendants' wrongful conduct, plaintiffs and the Class would not have been injured.

74. The price of Amarin securities declined materially upon public disclosure of the true facts which had been misrepresented or concealed, as alleged in this complaint. Plaintiff and other members of the Class have suffered substantial damages as a result of the wrongs alleged herein.

75. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT 2

Against Defendant Zakrzewski Pursuant to Section 20(a) of the Exchange Act

76. Plaintiff incorporates by reference and realleges each of the foregoing allegations.

77. Defendant Zakrzewski is liable as a direct participant in the wrongs complained of herein. Zakrzewski is able to and did control, directly or indirectly, the content of the aforesaid public statements and financial statements disseminated by Amarin. With knowledge of the falsity of the statements contained therein and in the reckless disregard of the true status of the FDA analysis of Vascepa, Zakrzewski caused the complained of misstatements and omissions of material fact as alleged herein, and knowingly or recklessly failed in his duty to update or correct misleading statements issued by him or on his behalf.

78. Since joining Amarin, Defendant Zakrzewski had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and disclose such facts, even though such facts were available to him.

79. In particular, Defendant Zakrzewski had direct involvement in the day-to-day operations of the Company and therefore had the power to control or influence the particular

statements giving rise to the securities violations as alleged herein, and exercised the same.

80. As set forth above in Count I, Amarin violated Section 10(b) and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint. By virtue of his position as Chairman and Chief Executive Officer of Amarin, Zakrzewski is liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the Exchange Act.

81. As a result of the deceptive practices and false and misleading statements and omissions, the market price of Amarin's common stock was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the representations described above and the deceptive and manipulative devices employed by Defendants, Plaintiff and the other members of the Class, in reliance on either the integrity of the market and/or directly on the statements and reports of Defendants, purchased Amarin's common stock at artificially inflated prices.

82. Had Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or had they been aware of the truth behind Defendants' material misstatements, they would not have purchased Amarin's securities at artificially inflated prices.

83. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

84. By virtue of the foregoing, Defendant Zakrzewski has violated Section 20(a) of the Exchange Act.

85. Plaintiff and the other members of the Class have been damaged by the violations

as described in this Count and seek recovery for the damages caused thereby.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for judgment as follows:

1. Declaring this action to be a proper class action maintainable pursuant to Rule 23(b)(3) of the Fed.R.Civ.P. and declaring Plaintiff to be a proper Class representative;

2. Awarding Plaintiff and the other members of the Class damages suffered as a result of the wrongs complained of herein, together with appropriate interest;

3. Awarding Plaintiff and the other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

4. Awarding Plaintiff and the other members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury for all claims so triable.

Dated: November 1, 2013

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP

By: *s/ Jeffrey W. Herrmann*
Jeffrey W. Herrmann
Peter S. Pearlman
Park 80 Plaza West-One
Saddle Brook, New Jersey 07663
(201) 845-9600

-and-

Lester L. Levy
Robert C. Finkel
Natalie M. Mackiel
WOLF POPPER LLP
845 Third Avenue, 12th Floor
New York, New York 10022
(212) 759-4600

Counsel for Plaintiff and the Class