

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

PLAINTIFF, Individually and on  
Behalf of All Others Similarly Situated,

Plaintiff,

v.

AMARIN CORPORATION PLC, JOHN F.  
THERO, and STEVEN KETCHUM,

Defendants.

Civil Action No.

CLASS ACTION

COMPLAINT FOR VIOLATION OF THE  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

**INTRODUCTION AND OVERVIEW**

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of the publicly traded securities of Amarin Corporation plc (“Amarin” or the “Company”) between September 24, 2018 and November 9, 2018 (the “Class Period”), who were damaged thereby.

2. Amarin is a biotechnology company. During the Class Period, Defendants made false and misleading statements about a clinical trial of a drug called Vascepa intended to treat cardiovascular disease. Specifically, Defendants issued a press release stating that the study, called REDUCE-IT, had shown a 25% relative risk reduction for patients taking Vascepa.

3. As a result of these statements, the price of Amarin's securities increased from \$2.99 to \$12.40 the next trading day, an increase of more than 414%. This increase was a result of the artificial inflation caused by Defendants' misleading statements.

4. Subsequently, certain scientists who had participated in the REDUCE-IT trials presented the full results of the study at the Scientific Sessions of the American Heart Association on November 10, 2018 in Chicago, Illinois. Those results showed for the first time that the placebo given to patients in the REDUCE-IT study, mineral oil, may have caused cardiovascular problems in the patients taking it. In other words, instead of Vascepa lowering the rate of cardiovascular problems, the placebo used in REDUCE-IT may have increased them.

5. As a result of this disclosure, the price of Amarin's securities dropped from \$21.05 to \$15.38 in two trading days, a decrease of 27%. This decrease was a result of the artificial inflation caused by Defendants' misleading statements coming out of the price.

#### **JURISDICTION AND VENUE**

6. The claims asserted arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5. Jurisdiction is conferred by Section 27 of the 1934 Act. Venue is proper pursuant to Section 27 of the 1934 Act. Amarin's headquarters are located in this District, false statements were made in this District, and acts giving rise to the violations complained of occurred in this District.

#### **THE PARTIES**

7. Plaintiff purchased Amarin securities during the Class Period as set forth in the attached certification and was damaged thereby.

8. Defendant Amarin is a biotechnology company with its headquarters located in Dublin, Ireland and its U.S. office is located at 1430 Route 206, Bedminster, New Jersey 07921.

Amarin's common stock is traded under the symbol AMRN on the NASDAQ, which is an efficient market.

9. Defendant John F. Thero was, at all relevant times, President and Chief Executive Officer ("CEO") of the Company.

10. Defendant Steven Ketchum, PhD, was, at all relevant times, President of Research and Development and Chief Scientific Officer of the Company.

### **PRE-CLASS PERIOD EVENTS**

11. The REDUCE-IT cardiovascular outcomes study commenced in 2011. It enrolled and followed 8,179 randomized patients, and was conducted based on a special protocol assessment agreement with FDA.

12. REDUCE-IT was the first global cardiovascular outcomes study to prospectively evaluate the effect of Vascepa, or any therapy, in adult patients with both LDL-cholesterol (LDL-C) controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors, including persistent elevated triglycerides (TGs) between 150-499 mg/dL (median baseline 216 mg/dL). In addition, the primary prevention cohort had diabetes mellitus and at least one other cardiovascular risk factor, while the secondary prevention cohort had established cardiovascular disease. The design of the REDUCE-IT cardiovascular outcomes study was published in March 2017 in *Clinical Cardiology*<sup>4</sup> and can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

13. REDUCE-IT tested whether additional cardiovascular risk reduction beyond LDL-C controlled with statin therapy could be achieved in high-risk patients with the putative cardioprotective effects of 4 grams/day of Vascepa.

## **FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD**

14. On September 24, 2018, Amarin issued a press release that stated in relevant part:

BEDMINSTER, N.J. and DUBLIN, Ireland, Sept. 24, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), announced today topline results from the Vascepa® cardiovascular (CV) outcomes trial, REDUCE-IT™, a global study of 8,179 statin-treated adults with elevated CV risk. REDUCE-IT met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ( $p < 0.001$ ), in major adverse CV events (MACE) in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo.

Patients enrolled in REDUCE-IT had LDL-C between 41-100 mg/dL (median baseline LDL-C 75 mg/dL) controlled by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides (TGs) between 150-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other CV risk factor (primary prevention cohort).

Key topline results include:

**Efficacy:** Approximately 25% relative risk reduction, demonstrated to a high degree of statistical significance ( $p < 0.001$ ), in the primary endpoint composite of the first occurrence of MACE, including cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints.

**Safety:** Vascepa was well tolerated with a safety profile consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling. The proportions of patients experiencing adverse events and serious adverse events in REDUCE-IT were similar between the active and placebo treatment groups. Median follow-up time in REDUCE-IT was 4.9 years.

15. As a result of these statements, the price of Amarin's securities increased from \$2.99 on Friday, September 21, to \$12.40 on Monday, September 24, an increase of more than 414%.

16. On October 3, 2018, Defendant Thero spoke to investors at the Cantor Global Healthcare Conference in New York City. During that presentation, Thero described the results of the REDUCE-IT trial, stating in relevant part, "Our target had been 15% relative risk reduction,

we achieved 25% relative risk reduction. And we did that with the p value which was statistically significant p less than 0.001.”

17. On November 1, 2018, Defendants held a conference call with investors during which Defendant Thero stated in relevant part:

A recap of the-top [*sic*] line results we reported for REDUCE-IT study is as follows. Primary endpoint achieved with approximate 25% relative risk reduction in the composite of first occurrence of major adverse cardiovascular events known as MACE. The 25% is on top of LDL cholesterol controlled by statin therapy and REDUCE-IT patients.

LDL cholesterol controlled by statin therapy is generally understood the [*sic*] lower cardiovascular risk by 25% to 35%. Our REDUCE-IT results add approximately 25% cardiovascular risk reduction on top of controlled LDL-C. The top-line risk reduction of approximately 25% was achieved to a high degree of statistical significance P less than 0.001.

18. Defendants’ statements set forth above did not disclose that the placebo given to patients in the control arm of REDUCE-IT may have increased the incidence of cardiovascular events in those patients, thus making Vascepa appear more effective than it actually was.

### **THE TRUTH EMERGES**

19. On November 10, 2018, scientists that conducted the REDUCE-IT trial presented the full results of that study at the Scientific Sessions of the American Heart Association in Chicago, Illinois. In that presentation, the scientists disclosed for the first time “bad” LDL cholesterol levels rose three percent in the Vascepa patients and ten percent in the placebo patients. Other markers of blood fat were also higher in the placebo patients.

20. These data raised concerns that the mineral oil placebos might be interfering with the background regimen of cholesterol-lowering statins that all the patients in the study were taking. The 10 percent increase in LDL cholesterol might have led to more adverse cardiovascular events among placebo patients.

21. As a result of these disclosures, the price of Amarin's securities dropped from \$21.05 to \$15.38 in two trading days, a decrease of 27%.

### **LOSS CAUSATION/ECONOMIC LOSS**

22. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market. This artificially inflated the price of Amarin's securities and operated as a fraud or deceit on the Class. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Amarin's securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of Amarin securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

### **NO SAFE HARBOR**

23. Amarin's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

24. The Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Amarin who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

**APPLICABILITY OF PRESUMPTION OF  
RELIANCE: FRAUD ON THE MARKET**

25. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Plaintiff and other members of the Class purchased Amarin securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

26. At all relevant times, the market for Amarin securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Amarin filed periodic public reports with the SEC; and

(b) Amarin regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

**CLASS ACTION ALLEGATIONS**

27. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased the publicly traded securities of Amarin

during the Class Period (the “Class”). Excluded from the Class are Defendants, directors and officers of Amarin and their families and affiliates.

28. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Amarin had more than 293 million shares outstanding, owned by thousands of persons.

29. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether Defendants violated the 1934 Act;
- (b) Whether Defendants omitted and/or misrepresented material facts;
- (c) Whether Defendants’ statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether Defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the prices of Amarin securities were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

30. Plaintiff’s claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants’ wrongful conduct.

31. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in securities class actions. Plaintiff has no interests which conflict with those of the Class.

32. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

33. Plaintiff incorporates the paragraphs above by reference.

34. During the Class Period, Defendants disseminated or approved the false or misleading statements specified above. Defendants knew or recklessly disregarded that these statements were false or misleading. The statements contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

35. Defendants violated Section 10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted material facts necessary in order to make the statements, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Amarin securities during the Class Period.

36. Defendants' statements set forth above were materially false and misleading because they did not disclose that the placebo given to patients in the control arm of REDUCE-IT

may have increased the incidence of cardiovascular events in those patients, thus making Vascepa appear more effective than it actually was.

37. Defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the false or misleading nature of the statements they made or acted in reckless disregard of the false or misleading nature of the statements. In so doing, Defendants participated in a scheme to defraud, and committed acts and participated in a course of business that operated as a fraud or deceit on purchasers of Amarin securities during the Class Period.

38. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Amarin securities. Plaintiff and the Class would not have purchased Amarin securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by Defendants' false or misleading statements.

39. As a result of these disclosures, the price of Amarin's securities dropped from \$21.05 to \$15.38 in two trading days, a decrease of 27%. This decrease in the price of Amarin's securities was a result of the artificial inflation caused by Defendants' misleading statements coming out of the price.

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

## **COUNT II**

### **For Violation of Section 20(a) of the 1934 Act Against All Defendants**

41. Plaintiff incorporates the paragraphs above by reference.

42. Defendants Thero and Ketchum acted as controlling persons of Amarin within the meaning of Section 20 of the 1934 Act. By virtue of their positions and their power to control public statements about Amarin, Defendants Thero and Ketchum had the power and ability to

control the actions of Amarin and its employees. Amarin controlled Defendants Thero and Ketchum and its other officers and employees. By reason of such conduct, Defendants are liable pursuant to Section 20(a) of the 1934 Act.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding Plaintiff and the members of the Class damages and interest;
- C. Awarding Plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.