AMARIN CORP PLC\UK
Form 8-K
September 16, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 12, 2014

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales	**0-21392**	**Not applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2 Pembroke House, Upper Pembroke Street 28-32,
Dublin 2,

Ireland	**Not applicable**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: +353 1 6699 020

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

Amarin Reaffirms Commitment to Completing REDUCE-IT Cardiovascular Outcomes Study

On September 16, 2014, Amarin Corporation plc (Amarin) announced its plans to continue the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA - Intervention Trial) cardiovascular outcomes study. The REDUCE-IT study, a prospective cardiovascular outcomes study of patients who, despite stable statin therapy, have elevated triglyceride levels, is being conducted with Vascepa® (icosapent ethyl) capsules, a highly-pure EPA omega-3 prescription product. This multinational, prospective, randomized, double-blind, placebo-controlled study is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Vascepa is currently approved as an adjunct to diet to reduce triglyceride levels in adult patients with severely high (≥500 mg/dL) triglyceride levels, based on results from the Phase 3 MARINE clinical trial. Vascepa also demonstrated favorable effects on triglycerides and a spectrum of other lipid, lipoprotein and inflammatory biomarkers in the Phase 3 ANCHOR clinical trial, which included patients with cardiovascular risk profiles under study in the REDUCE-IT trial. But, because an outcomes trial of Vascepa has not been completed, the effect of Vascepa on cardiovascular risk has not been determined. Amarin has always been scientifically committed to the REDUCE-IT cardiovascular outcomes study, but previously expressed that it was considering not completing the study as planned due to difficulties obtaining an expanded indication for the drug from the U.S. Food and Drug Administration (FDA).

The REDUCE-IT study, since its commencement at the end of 2011, has enrolled over 7000 patients into this event-driven trial. Amarin currently estimates that full patient enrollment in this study will be completed in 2015. The pre-specified interim analysis by the independent data monitoring committee at 60% of the targeted events is anticipated in 2016, with 100% of the targeted events currently anticipated to occur by the end of 2017 with results expected to be available in 2018. The independent data monitoring committee periodically reviews the ongoing safety results of the study.

Appeal of FDA s Rescission of ANCHOR Special Protocol Assessment (SPA) Agreement is Denied

On September 12, 2014, Amarin announced that the Office of New Drugs within FDA has denied Amarin s appeal of FDA s rescission of the ANCHOR clinical trial Special Protocol Assessment (SPA) agreement. The underlying supplemental new drug application associated with this clinical trial and previously filed to expand the indicated use of Vascepa to adult patients with high triglycerides (≥200 mg/dL and <500 mg/dL) who are also on statin therapy is still pending with FDA.

To approve an indication based on triglyceride lowering in statin-treated patients with triglyceride levels below 500 mg/dL, FDA stated in the October 2013 Vascepa advisory committee meeting that it needs to be confident that the triglyceride lowering effects will result in cardiovascular risk reduction. As previously disclosed, failed results of cardiovascular outcomes studies of other drugs, fenofibrates in the ACCORD-Lipid study and nicotinic acid in the AIM-HIGH and HPS2-THRIVE studies, reduced FDA s confidence in the use of triglycerides as a surrogate for regulatory approval of a drug focused on cardiovascular risk reduction. In its most recent appeal denial, FDA acknowledged that Vascepa demonstrated a reduction in triglycerides over placebo in the ANCHOR study and urged Amarin to complete the REDUCE-IT cardiovascular outcomes study. However, FDA concluded that in its view the totality of scientific data and information, including its reevaluation and improved understanding of the relevant scientific knowledge since the ANCHOR trial began, does not support use of decreases in triglycerides as a validated surrogate for cardiovascular risk reduction in the proposed patient population.

Forward-looking statement

This Current Report on Form 8-K contains forward-looking statements, including statements about the regulatory review, potential efficacy, safety and therapeutic benefits of Amarin s product candidates, Amarin s statements regarding clinical

trial results, including statements about the clinical importance of certain biomarkers and potential mechanisms of action and the impact and potential impact of Vascepa on such biomarkers, cardiovascular risk reduction after statin therapy and the endpoints defined in the REDUCE-IT study. Forward-looking statements also include statements about Amarin s plans to continue the REDUCE-IT study, anticipated enrollment, event occurrence and data availability. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, including the risk that historical and comparable clinical trial results may not be predictive of future REDUCE-IT study results, that regulatory reviews may impact the current design of the REDUCE-IT study and cause a change in strategic direction with respect to continuation of the study, and that changes in studied lipid biomarkers may not have clinically meaningful effect or support regulatory approvals. Other factors that could cause results to differ materially include factors that contribute to Amarin s operational cash flow, such as revenue levels from Vascepa sales, costs related to the sale of the drug and company operations, and Amarin s ability to protect Vascepa from generic and other competition through patent protection and other means. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin s filings with the U.S. Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this Current Report on Form 8-K, whether as a result of new information, future events or circumstances or otherwise.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 16, 2014

Amarin Corporation plc

By: /s/ John Thero
John Thero
President and Chief Executive Officer