AMARIN CORP PLC\UK
Form 8-K
April 28, 2015

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): April 27, 2015

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,		**Not applicable**

Upper Pembroke Street 28-32,

Dublin 2, Ireland
(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 7.01 Regulation FD Disclosure.

Item 8.01. Other Events.

Anticipated ANCHOR Complete Response Letter Received; Amarin Reaffirms Commitment to Business Plan

Amarin Corporation plc announced today receipt of the anticipated Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Vascepa® (icosapent ethyl) capsules ANCHOR trial supplemental New Drug Application (sNDA). Vascepa remains FDA approved for use as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Current Vascepa labeling remains unchanged. The ANCHOR sNDA sought to expand approved Vascepa labeling to include use as an adjunct to diet to reduce TG levels in adult patients on statin therapy with mixed dyslipidemia (one or more lipid disorder) and triglyceride levels from 200 to 499 mg/dL, the ANCHOR population.

As previously guided by Amarin, the CRL has been expected in recent months following Amarin s determination to not further appeal the October 2013, FDA ANCHOR Special Protocol Assessment (SPA) agreement rescission after the reconsideration and denial of the rescission appeal at three levels of increasing authority within the FDA. The originally assigned Prescription Drug User Fee Act, or PDUFA, goal date for the completion of the ANCHOR sNDA was December 20, 2013.

In the CRL, FDA acknowledged that Vascepa yielded a treatment difference showing reduced TG levels compared to placebo in patients treated in the ANCHOR study. The clinical rationale for reducing serum TGs with Vascepa and modifying other lipid/lipoprotein parameters shown in ANCHOR among statin-treated patients with TGs 200-499 mg/dL is to reduce cardiovascular risk. FDA concluded that, for regulatory approval purposes, there are insufficient data at this time to support a drug-induced change in serum TGs as a surrogate for reducing cardiovascular risk in the ANCHOR population. FDA did not determine that the drug-induced effects of Vascepa, which go beyond TG-lowering, would not actually reduce cardiovascular risk in this population. Amarin had proposed to FDA multiple alternative indications, data presentations, disclaimers and other regulatory pathways to approval under the sNDA, but FDA determined not to approve label expansion reflecting the ANCHOR clinical trial efficacy data at this time. Safety data from the ANCHOR study remains in the currently approved label for Vascepa.

REDUCE-IT Cardiovascular Outcomes Study to Continue, as Urged by FDA

In prior dialogue with Amarin, FDA urged Amarin to complete the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial) cardiovascular outcomes study. Consistent with this position, FDA stated to Amarin in the CRL that FDA anticipates that the final results from the REDUCE-IT trial could be submitted to satisfy the FDA s uncertainty regarding the benefits of drug-induced changes in lipid/lipoprotein parameters on cardiovascular risk in the ANCHOR population. The CRL has no effect on the SPA agreement for the REDUCE-IT study or the anticipated timing for results from the REDUCE-IT study.

REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled, parallel-group study designed to evaluate the effectiveness of 4 grams daily of Vascepa on top of statin therapy in reducing the prevalence of first major cardiovascular events in a high-risk patient population. REDUCE-IT is designed to lead to a first-in-class approval of Vascepa for a multi-billion dollar market opportunity in reducing cardiovascular events in a high-risk patient population. The study is ongoing with approximately 93% of the targeted 8,000 patients enrolled. In accordance with the SPA agreement for the REDUCE-IT study, an interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We expect this interim review by the study s independent data monitoring committee (DMC) to occur during 2016 based on our understanding of the current event rates in the study and expected future event rates. Based on projected event rates, we also estimate the REDUCE-IT study can be completed in or about 2017 with final results then expected to be

available and published in 2018.

About Vascepa® (icosapent ethyl) Capsules

Vascepa® (icosapent ethyl) capsules, known in scientific literature as AMR101, is a highly pure-EPA omega-3 prescription product in a 1 gram capsule.

Indications and Usage

Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (³500 mg/dL) hypertriglyceridemia.

The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components and should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

The most common reported adverse reaction (incidence >2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction >3% and greater than placebo.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa is under various stages of development for potential use in indications that have not been approved by the FDA. Nothing in this Form 8-K should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

Forward-looking statement

This Form 8-K contains forward-looking statements, including statements about the potential efficacy, safety and therapeutic benefits of Amarin s product candidates; the potential for the REDUCE-IT study design to lead to a first-in-class approval of Vascepa for a multi-billion dollar market opportunity in reducing cardiovascular events in a high-risk patient population; the expected timing of the interim review of REDUCE-IT s efficacy and safety results based on cardiovascular event rates in the study; and the expected timing of the completion of the REDUCE-IT study and the publication of its results. 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, that changes in studied lipid biomarkers may not have clinically meaningful effect or support regulatory approvals and that the market size for and potential acceptance of Vascepa by the REDUCE-IT patient population may be less than we estimate. Other factors that could cause results to differ materially include factors 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 Annual Report on Form 10-K. 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 press release, whether as a result of new information, future events or circumstances or otherwise.

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.

Amarin Corporation plc

Date: April 28, 2015

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