AMARIN CORP PLC\UK
Form 8-K
October 29, 2013

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): October 29, 2013

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales	**000-21392**	**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

Consistent with the discussion at the October 16, 2013, Endocrinologic and Metabolic Drugs Advisory Committee (the Advisory Committee) meeting at which the Advisory Committee voted to recommend against approval of the proposed label expansion for Vascepa® (icosapent ethyl) capsules under the pending supplemental New Drug Application (the sNDA) that seeks to expand Vascepa labeling to include the proposed ANCHOR indication, on October 29, 2013, Amarin Corporation plc (Amarin) received written notification from the U.S. Food and Drug Administration (the FDA) that the FDA has rescinded the ANCHOR study special protocol assessment agreement because the FDA has determined that a substantial scientific issue essential to determining the effectiveness of Vascepa in the studied population was identified after testing began. Specifically, consistent with discussion at the Advisory Committee meeting, the FDA cited results from the ACCORD-Lipid and AIM-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). Thus, the FDA stated that it no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL.

Amarin is working with the FDA to schedule a Type A meeting to discuss with the FDA, as permitted by applicable FDA guidance.

The Prescription Drug User Fee Act goal date for Amarin s pending sNDA for Vascepa in the ANCHOR indication is December 20, 2013. The FDA could complete its review of the sNDA prior to this date and there can be no assurance that the FDA will complete its review of the sNDA by this date. No omega-3 based drug is currently approved for the indication being sought by this sNDA.

Vascepa was previously approved by the FDA in 2012 for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (³500 mg/dL) hypertriglyceridemia (the MARINE indication). The FDA approved Vascepa MARINE indication is not a matter under review in, or affected by, the outcome of FDA review of the pending sNDA that seeks approval to expand Vascepa labeling to include the ANCHOR indication.

Forward-looking statement

This Current Report on Form 8-K contains forward-looking statements, including statements about the expected timing and outcome of the FDA s review of Amarin s pending sNDA and Amarin s plan to meet with the FDA to discuss the pending ANCHOR application. 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 administrative decisions and the bases for such decisions, research and development, clinical trials and related regulatory reviews and approvals. 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.

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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: October 29, 2013

Amarin Corporation plc

By: /s/ John Thero
John Thero
President