AMARIN CORP PLC\UK
Form 8-K
December 20, 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): December 19, 2013

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 Receives FDA Notification that Action on ANCHOR sNDA Review Will Be Delayed

Amarin Corporation plc announced today that the U.S. Food and Drug Administration (FDA) notified the company last night that the FDA does not expect to take action on Amarin s supplemental new drug application (sNDA) for the proposed ANCHOR indication labeling expansion for Vascepa® (icosapent ethyl) capsules on the December 20, 2013 Prescription Drug User Fee Act (PDUFA) goal date because Amarin s request to re-instate the ANCHOR Special Protocol Assessment (SPA) agreement remains under consideration with the FDA. No new PDUFA date was established.

The FDA also communicated to Amarin that it now views Amarin s appeal of the ANCHOR SPA agreement rescission and the ANCHOR sNDA as separate administrative decisions worthy of separate consideration. FDA plans to complete its review of Amarin s request to re-instate the ANCHOR SPA agreement and plans to convey its decision to Amarin no later than January 15, 2014. The FDA provided no additional information on when it expects to complete its review of the ANCHOR sNDA.

There can be no assurance that Amarin will be successful in its appeal of the SPA agreement rescission or, more importantly, the approval of the ANCHOR indication sNDA.

Forward-looking statement

This Current Report on Form 8-K contains forward-looking statements, including statements about the status, timing and outcome of Amarin s appeal of the FDA s rescission of the SPA agreement for the ANCHOR study, the FDA s review of Amarin s appeal and pending sNDA for the ANCHOR indication, and Amarin s current intention to engage with the FDA on these matters. 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: December 20, 2013

Amarin Corporation plc

By: /s/ John Thero
John Thero
President