AMARIN CORP PLC\UK
Form 8-K
November 22, 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): November 21, 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

Status update on special protocol assessment (SPA) rescission appeal.

Vascepa is currently approved for the MARINE indication. The PDUFA date for FDA s action on Amarin s sNDA for the ANCHOR indication is December 20, 2013. The FDA, at its discretion, could act sooner than this date. The ANCHOR study supporting the sNDA was conducted under a Special Protocol Assessment (SPA) agreement with the FDA. On October 29, 2013, the FDA rescinded that SPA agreement and on November 7, 2013 Amarin appealed the rescission within FDA.

On November 21, 2013, Amarin received notification from the dispute resolution group of the Office of New Drugs at the FDA that it has not accepted for review, on procedural grounds, Amarin s appeal. Amarin and the FDA have communicated on the above matters, but Amarin has not been successful to date in convincing the FDA to accept its appeal for review at a level above the review division within FDA or in convincing the FDA that the appeal of the SPA rescission is a matter sufficiently distinct from the ANCHOR sNDA to warrant separate consideration under the formal FDA appeal process. Amarin plans to continue to interact with the review division of the FDA regarding the sNDA and the SPA. Amarin believes its appeal is procedurally correct and that whether the ANCHOR SPA agreement was lawfully rescinded is a distinct legal issue (from our pending ANCHOR sNDA) that is appealable under applicable regulations and guidelines. Amarin was also notified by the FDA that Amarin s request for a meeting at a high level within FDA regarding the appeal was not granted and that Amarin would first need to address the matter at the division level within FDA.

Amarin plans to continue to pursue the appeal of the ANCHOR SPA rescission and approval of the ANCHOR sNDA with FDA and to update investors as appropriate. 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 FDA s rescission of the SPA agreement for the ANCHOR study, FDA s review of Amarin s pending sNDA for the ANCHOR indication, and Amarin s current intention to engage with 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: November 21, 2013

Amarin Corporation plc

By: /s/ John Thero
John Thero
President