

AMARIN CORP PLC\UK
Form 8-K
February 21, 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): February 21, 2014

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction

of incorporation)

0-21392
(Commission

File Number)

Not applicable
(I.R.S. Employer

Identification No.)

2 Pembroke House, Upper Pembroke Street 28-32,

Dublin 2, Ireland
(Address of principal executive offices)

Not applicable
(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

FDA Awards Three-Year Marketing Exclusivity for Vascepa® (icosapent ethyl) Capsules

Amarin Corporation plc announced today that the U.S. Food and Drug Administration (FDA) has awarded three years of marketing exclusivity to Vascepa® (icosapent ethyl) capsules in connection with the July 26, 2012 approval of Vascepa pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. Such exclusivity extends through July 25, 2015 and is expected to be supplemented by a 30-month stay under the Hatch-Waxman Amendments that would be triggered after patent infringement litigation initiated by Amarin following valid notice to Amarin of the acceptance of an application to the FDA seeking approval of a generic version of Vascepa. FDA marketing exclusivity is separate from, and in addition to, patent protection, trade secrets and manufacturing barriers to entry which also help protect Vascepa against generic competition. Amarin is reviewing the FDA's reasoning for granting Vascepa three-year, rather than five-year, exclusivity, and evaluating whether to challenge the decision.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about whether Amarin will challenge the FDA exclusivity grant for Vascepa in favor of five-year, NCE exclusivity, about any supplemental stay period under the Hatch-Waxman Amendments and about whether FDA regulatory exclusivity, patents, trade secrets and manufacturing barriers to entry would be sufficient to protect Vascepa against competition. 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 the following: events that could interfere with the issuance of a patent, or once issued, the continued validity or enforceability of a patent; Amarin's ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties; commercializing Vascepa without violating the intellectual property rights of others; and uncertainties associated generally with maintaining trade secrets and manufacturing barriers to entry. 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: February 21, 2014

Amarin Corporation plc

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