

AMARIN CORP PLC\UK
Form 8-K
June 01, 2016

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): May 31, 2016

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction

of incorporation)

2 Pembroke House, Upper Pembroke Street 28-32,

0-21392
(Commission

File Number)

Not applicable
(I.R.S. Employer

Identification No.)

Not applicable

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 8.01 Other Events

On May 31, 2016, the U.S. Food and Drug Administration (FDA) advised Amarin Corporation plc (Amarin) that it has determined that Vascepa[®] (icosapent ethyl) capsules are eligible for five-year, new chemical entity (NCE) marketing exclusivity pursuant to the Hatch-Waxman Amendments to the U.S. Federal Food, Drug, and Cosmetic Act. This determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. Under the statute, NCE exclusivity for Vascepa runs from its date of FDA approval on July 26, 2012 and extends until July 26, 2017. The statutory 30-month stay triggered by patent litigation following generic application submissions permitted on July 26, 2016 would expire on January 26, 2020, seven and one-half years from FDA approval.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about FDA's determination that Vascepa[®] (icosapent ethyl) capsules are eligible for five-year NCE exclusivity, the benefits of NCE exclusivity under the statutory scheme as it applies to Vascepa under that determination and the expiration of the statutory 30-month stay period. 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: the risk that third parties may seek to appeal or otherwise challenge FDA's determination, and the result of any such appeals, the risk that events that could interfere with the continued validity or enforceability of Amarin's patents, risks associated with Amarin's ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties, risks associated with commercializing Vascepa without violating the intellectual property rights of others and uncertainties associated generally with litigation, research and development, clinical trials and related regulatory approvals and commercialization of approved drugs. 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 and 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. Amarin undertakes no obligation to update or revise the information contained in this Form 8-K, 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.

Date: June 1, 2016

Amarin Corporation plc

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