

AMARIN CORP PLC\UK
Form 8-K
August 17, 2012

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): August 17, 2012

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.)

Edgar Filing: AMARIN CORP PLC\UK - Form 8-K

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 7.01. Regulation FD Disclosure

On August 17, 2012, the U.S. Food and Drug Administration (FDA) is expected to publish the July 2012 cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book (the July Orange Book Supplement), in which, among other things, FDA will list new product approvals, issued patents related to such products and associated regulatory exclusivity grants made pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. Vascepa (icosapent ethyl) Capsules is expected to be included in the July Orange Book Supplement along with U.S. Patent No. 8,188,146 (a pharmaceutical composition patent known as the EPA with no DHA in a capsule patent). No entry is expected to be made with respect to the regulatory exclusivity status of Vascepa in the July Orange Book Supplement. Based on information available to Amarin Corporation plc (Amarin) as of the filing of this report on August 17, 2012, including communication with FDA on August 16, 2012, FDA has not yet made a determination with respect to regulatory exclusivity for Vascepa.

This Current Report on Form 8-K contains forward-looking statements, including statements concerning FDA's consideration of regulatory exclusivity with respect to Vascepa, the timing of any such determination and expected publication of the July Orange Book Supplement. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. A list and description of risks, uncertainties and other matters related to 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. Amarin undertakes no obligation to update or revise the information contained in this Current Report on 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: August 17, 2012

Amarin Corporation plc

By: /s/ John Thero
John Thero
President