

AMARIN CORP PLC\UK
Form 8-K
September 10, 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): September 4, 2012

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

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(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
(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

No determination on regulatory exclusivity related to Vascepa (icosapent ethyl) Capsules expected in August Orange Book Supplement

Typically, the U.S. Food and Drug Administration (FDA) publishes a determination on the exclusivity of recently approved products in a cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, mid-month in the month following the drug's approval. Vascepa was approved by the FDA in July 2012.

As previously disclosed, on August 16, 2012, the FDA communicated to Amarin Corporation plc (Amarin) that it had not yet made a determination with respect to the regulatory exclusivity of Vascepa and the July 2012 cumulative supplement to the Orange Book published on August 17, 2012 did not include an entry with respect to the regulatory exclusivity of Vascepa.

Based on information available to Amarin as of the filing of this report, including communication with the FDA on September 7, 2012, the FDA has not made a determination with respect to regulatory exclusivity for Vascepa. On or about September 14, 2012, the FDA is expected to publish the August 2012 cumulative supplement to the Orange Book. Based on communication with the FDA on September 7, 2012, Amarin does not anticipate that the August Orange Book Supplement will include an entry with respect to the regulatory exclusivity status of 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 timing and content of the August 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.

Item 8.01. Other Events.

Patent Application Notices of Allowance related to Vascepa capsules

On September 4, 2012, Amarin announced that the United States Patent and Trademark Office (USPTO) published notification of a Notice of Allowance for U.S. Patent Application Serial Number 13/282,145.

On September 5, 2012, Amarin announced that the USPTO published notification of Notices of Allowance for U.S. Patent Application Serial Numbers 12/702,889 and 13/349,153.

On September 6, 2012, Amarin announced that the USPTO published notification of a Notice of Allowance for U.S. Patent Application Serial Number 13/284,408.

On September 10, 2012, Amarin announced that the USPTO published notification of a Notice of Allowance for U.S. Patent Application Serial Number 13/349,150.

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: September 10, 2012

Amarin Corporation plc

By: /s/ John Thero
John Thero
President