AMARIN CORP PLC\UK
Form 8-K
October 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): October 9, 2012

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.

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

The U.S. Food and Drug Administration (FDA) typically 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 (icosapent ethyl) capsules was approved by the FDA in July 2012.

As previously disclosed, in each of mid-August and mid-September, the FDA communicated to Amarin Corporation plc (Amarin) that it had not yet made a determination with respect to Amarin s pending request for five-year, new chemical entity (NCE) exclusivity for Vascepa, and the cumulative supplements to the Orange Book published shortly thereafter, respectively, 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 October 9, 2012, the FDA has not yet made a determination with respect to regulatory exclusivity for Vascepa. In mid-October, the FDA is expected to publish the September 2012 cumulative supplement to the Orange Book. Based on communication with the FDA on October 9, 2012, Amarin does not anticipate that the September cumulative Orange Book Supplement will include an entry with respect to the regulatory exclusivity status of Vascepa.

As previously disclosed, since prior to FDA approval of the Vascepa New Drug Application, Amarin has had an active dialogue with the FDA related to its regulatory exclusivity request for Vascepa. In recent months, Amarin has repeatedly followed up with the FDA seeking a determination. While Amarin continues to believe its arguments in support of an NCE determination for Vascepa are strong, the FDA may not agree with Amarin s arguments. Based on Amarin s dialogue with the FDA, Amarin does not know what determination the FDA will make on the pending Vascepa exclusivity request or when the FDA will make such determination. Accordingly, Amarin can make no assurance that Vascepa will be granted NCE exclusivity, or that the FDA will make a determination in a timely manner. If Vascepa is not awarded five-year marketing exclusivity, Amarin expects it will be awarded three-year marketing exclusivity.

As previously disclosed, Amarin continues to anticipate commercial launch of Vascepa in the first quarter of 2013, and continues to consider three potential paths for the marketing and sale of the product: an acquisition of Amarin, a strategic collaboration, or self-commercialization, the latter of which could include third-party support. As previously disclosed, Amarin is now focused on continued commercial preparations for Vascepa which includes, but is not limited to, finalizing the introduction of Vascepa to managed care plans to gain formulary access, building up inventory levels, hiring key personnel and coordinating other pre-launch marketing activities.

This Current Report on Form 8-K contains forward-looking statements, including statements concerning FDA s consideration of regulatory exclusivity for Vascepa, the timing of any such determination, the timing of a commercial launch of Vascepa and the potential commercialization paths for Vascepa. 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 herein include the following: the risk that FDA may not grant new chemical entity status to Vascepa; the risk that FDA may not reach an exclusivity determination on the timetable that investors might expect; uncertainties associated generally with the launch of new pharmaceutical products and the commercialization path for Vascepa, such as Amarin s ability to negotiate and execute a successful acquisition of Amarin or a strategic collaboration with a third party for the commercialization of Vascepa, or launch the product on its own and other risks associated with preparations associated with a commercial launch. A more complete 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 the Risk Factors section in 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. Amarin also undertakes no obligation to provide updates on launch preparations or whether or not FDA will update the exclusivity status of Vascepa in future editions of its monthly cumulative Orange Book supplement.

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: October 10, 2012

Amarin Corporation plc

By: /s/ John Thero
John Thero
President