AMARIN CORP PLC\UK
Form 8-K
March 31, 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): March 31, 2014

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 1.01. Entry into a Material Definitive Agreement

On March 31, 2014, Amarin Pharmaceuticals Ireland Limited (APIL) and Amarin Pharma, Inc. (API , and together with APIL, Amarin), each a wholly-owned subsidiary of Amarin Corporation plc (the Company), entered into a Co-Promotion Agreement (the Agreement) with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa® (icosapent ethyl) capsules in the United States. Under the terms of the Agreement, Amarin granted to Kowa Pharmaceuticals America the right to be the sole co-promoter, together with API, of Vascepa in the United States during the term. The initial term of the Agreement extends through 2018.

During the term, Kowa Pharmaceuticals America and Amarin have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the Agreement. The performance requirements include a negotiated minimum number of details to be delivered by each party in the first and second position, and the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America sales representatives. Kowa Pharmaceuticals America has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs resulting from the Agreement associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. Amarin remains responsible for marketing efforts related to Vascepa, and providing to Kowa Pharmaceuticals America all promotional materials and samples, subject to such cost sharing arrangement. Additionally, Amarin has agreed to use commercially reasonable efforts to maintain a minimum amount of inventory of Vascepa for use in the United States. Amarin s commitments under the Agreement are within its commercialization plans prior to the Agreement.

Kowa Pharmaceuticals America has agreed to limitations on its ability to undertake specified commercialization-related activities on certain products that may be competitive with Vascepa in the United States during the term and for specified periods thereafter. There are no restrictions on Kowa Pharmaceuticals America s ability to commercialize LIVALO® (pitavastatin), but Kowa Pharmaceuticals America has agreed to certain guidelines related to the promotion of its product LIPOFEN® (fenofibrate capsules, USP) that substantially limit current promotional efforts.

Amarin and Kowa Pharmaceuticals America agreed to form a joint steering committee to oversee the day-to-day promotion, detailing and compliance activities of the parties associated with the Agreement. Kowa Pharmaceuticals America will have the opportunity through the joint steering committee to confer with or make recommendations to Amarin regarding such activities. However, Amarin has final decision-making authority and responsibility for all sales, marketing and promotional activities related to Vascepa. Amarin retains the exclusive right to make, sell and offer Vascepa for sale and is responsible for matters relating to the regulatory status of Vascepa and to pharmacovigilance. The Agreement also contains indemnification, record keeping, audit rights, reporting obligations, and representations and warranties that are customary for an arrangement of this type.

Amarin will continue to recognize all revenue from sales of Vascepa under the Agreement. In exchange for Kowa Pharmaceuticals America s co-promotional services, Kowa Pharmaceuticals America is entitled to a quarterly co-promotion fee based on a percentage of Vascepa gross margins that increases during the Agreement s term, from the high single digits in 2014 to the low twenty percent levels in 2018. The co-promotion fee also varies based on sales levels and whether the U.S. Food and Drug Administration (FDA) has approved an ANCHOR indication labeling expansion for Vascepa or has permitted the use of data generated to support obtaining FDA approval of the ANCHOR indication in the promotion of Vascepa, in which case the co-promotion fee would be decreased if specified requirements are met. In certain circumstances, upon the earlier of the expiration or termination of the Agreement in accordance with its terms, Kowa Pharmaceuticals America may be eligible for a co-promotion tail fee equal to declining fractions of the co-promote fee in effect prior to such expiration or termination for periods ranging from one to three years following such expiration or termination. For example, in the event of a change of control of

Amarin, Amarin may terminate the Agreement, which would result in the payment of a residual tail fee to Kowa Pharmaceuticals America calculated as provided above.

After the initial term, provided that gross sales for Vascepa in the United States in 2018 exceed a negotiated dollar threshold as set forth in the Agreement, the Agreement may be extended by mutual agreement of Amarin and Kowa Pharmaceuticals America for an additional two years. Each party may terminate the Agreement before the expiration of the initial term upon the uncured material breach of the other party, upon the bankruptcy or insolvency of the other party, after a force majeure that persists for 90 days, and upon certain criminal proceedings against the other party or certain of its constituents. In addition, each party may terminate the Agreement upon a change of control of either party, upon the failure of the other party to meet certain minimum detail requirements, or in the event that gross sales of Vascepa in the United States do not exceed minimum thresholds, which thresholds increase each year during the term of the Agreement. Amarin may terminate the Agreement upon Kowa Pharmaceuticals America s promotion of any other product that, despite its approved label, is being used to reduce triglyceride levels in 50% or more of its prescribed applications. Other termination provisions apply. Certain restrictions on Kowa Pharmaceuticals America s promotion of specified competitive products to Vascepa apply after termination of the Agreement.

The foregoing description of the terms of the Agreement is qualified in its entirety by reference to the available text of the Agreement, a redacted copy of which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the three months ending March 31, 2014.

Item 8.01. Other Events

On March 31, 2014, the Company issued a press release entitled Amarin and Kowa Pharmaceuticals America Announce U.S. Co-Promotion Agreement for Vascepa® (icosapent ethyl) Capsules .

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The contents of the press release are deemed to be filed for purposes of the Securities Exchange Act of 1934, as amended.

* * *

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated March 31, 2014

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: March 31, 2014

Amarin Corporation plc

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated March 31, 2014