AMARIN CORP PLC\UK
Form 8-K
March 14, 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 10, 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 8.01 Other Events

On March 10, and 12, 2014, Amarin Corporation plc (Amarin), through its subsidiary Amarin Pharmaceuticals Ireland Limited, received paragraph IV certifications from Apotex Inc. and Roxane Laboratories, Inc., respectively, advising Amarin that such companies have filed abbreviated new drug applications (each, an ANDA) with the U.S. Food and Drug Administration (FDA) for generic versions of Vascepa® (icosapent ethyl) capsules.

The pharmaceutical composition and current FDA approved use of Vascepa are covered by the following patents, each of which is listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book:

Patent number	Patent Coverage Type	Expiration Date
8188146	Pharmaceutical composition	Jan 27, 2020
8293727	Method of use	Feb 9, 2030
8293728	Method of use	Feb 9, 2030
8298554	Pharmaceutical composition	Apr 29, 2030
8314086	Method of use	Feb 9, 2030
8318715	Method of use	Feb 9, 2030
8357677	Method of use	Feb 9, 2030
8367652	Method of use	Feb 9, 2030
8377920	Method of use	Feb 9, 2030
8399446	Method of use	Feb 9, 2030
8415335	Method of use	Feb 9, 2030
8426399	Method of use	Feb 9, 2030
8431560	Method of use	Feb 9, 2030
8440650	Method of use	Feb 9, 2030
8445003	Method of use	Apr 29, 2030
8445013	Method of use	Apr 29, 2030
8501225	Method of use	Apr 29, 2030
8518929	Method of use	Apr 29, 2030
8524698	Method of use	Apr 29, 2030
8546372	Method of use	Apr 29, 2030
8551521	Method of use	Apr 29, 2030
8563608	Method of use	Apr 29, 2030
8617593	Method of use	Apr 29, 2030
8617594	Method of use	Apr 29, 2030
8623406	Method of use	Apr 29, 2030

The paragraph IV certifications allege to varying degrees that the above-listed patents are invalid, unenforceable and/or will not be infringed by the respective parties manufacture, use or sale of the proposed generic products for which the ANDAs were submitted.

Under the Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, after receipt of a valid paragraph IV notice, Amarin may, and plans to, bring patent infringement suits in federal district court against such generic companies seeking approval for their respective products within 45 days from the date of receipt of each respective notice. If such a suit is commenced within this 45 day period, Amarin is entitled under the Hatch Waxman Amendments to receive a 30 month stay on FDA s ability to give final approval to any of the proposed products that reference Vascepa. The stay may be shortened or lengthened if either party fails to cooperate in the litigation and it

may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of a generic applicant before the expiration of the 30 month period, the stay will be immediately lifted and the FDA s determination on the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

Amarin intends to vigorously enforce its intellectual property rights. Paragraph IV litigation typically results in the consolidation of pending cases into one case. Because, as previously disclosed, the FDA recently granted Vascepa three year marketing exclusivity, because this effectively opened the regulatory window for ANDA filings, and because companies which contemplate ANDA filings may prefer to commence the 30 month stay now rather than waiting, Amarin expects that it may receive additional paragraph IV certifications in the near future. Amarin plans to update investors on any such additional certifications and Amarin s planned patent

litigation against such ANDA filers in its quarterly and annual reports, including its Form 10-Q for the quarter ended March 31, 2014. For example, as disclosed in Amarin s Form 10-K filed with the Securities and Exchange Commission on February 27, 2014, in February 2014, prior to the FDA s three-year exclusivity determination for Vascepa, Amarin received a purported paragraph IV notice from another generic drug company, Par Pharmaceuticals, Inc., or Par, with respect to an ANDA to Vascepa. The FDA confirmed with Amarin after it received the purported notice and before Vascepa was granted three-year exclusivity under the Hatch Waxman Amendments that the FDA had not accepted the Par ANDA at that time. The FDA has repeatedly taken the position that paragraph IV notices delivered to pioneer companies such as Amarin prior to the acceptance for review by the FDA of a submitted ANDA are not effective under the Hatch-Waxman Amendments. Because Amarin, consistent with FDA s position, does not believe the purported paragraph IV notice from Par is an effective notice under the Hatch-Waxman Amendments, Amarin does not plan to initiate patent litigation against Par unless and until Amarin receives a valid paragraph IV notice from Par.

As previously disclosed, on February 27, 2014, Amarin filed a lawsuit against the FDA that challenges FDA s denial of Amarin s request for five-year exclusivity for Vascepa based on Amarin s reading of the relevant statute and Amarin s view that FDA s denial of five-year exclusivity to Vascepa was inconsistent with its past actions. Our complaint requests that the court vacate FDA s decision to deny Amarin five-year statutory exclusivity, declare that Vascepa is entitled to the benefits of such five-year statutory exclusivity, bar the FDA from accepting any ANDA or similar application for which Vascepa is the reference-listed drug until after the statutory exclusivity period expires, and if necessary, set aside FDA s premature acceptance of any such application, such as the applications described above.

The information contained herein is intended to be considered in the context of more complete information included in Amarin s filings with the SEC and other public announcements that Amarin has made and may make from time to time by press release or otherwise. Amarin undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For more information on the risks associated with Amarin s efforts to secure and maintain intellectual property protection for Vascepa, please see the Risk Factors section of Amarin s Form 10-K filed with the Securities and Exchange Commission on February 27, 2014.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about additional paragraph IV certifications Amarin may receive in the future from ANDA filers, the effectiveness and procedural posture of the purported PAR paragraph IV notice, Amarin s intention to file patent infringement suits against generic companies from which it receives valid paragraph IV notices and to otherwise vigorously enforce its intellectual property rights, Amarin s lawsuit against the FDA challenging FDA s denial of Amarin s request for five-year exclusivity for Vascepa, Amarin s expectations regarding the timing and outcome of any of the foregoing litigation and the expected timing of any updates to investors regarding any of the foregoing matters. 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: Amarin s ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend its patents; the possible introduction of generic competition of Vascepa; the scope, validity and duration of patent protection to provide exclusivity for Vascepa; and Amarin s ability to raise sufficient capital to fund its operations, including any patent infringement litigation. 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, filed with the Securities and Exchange Commission on February 27, 2014. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

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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 14, 2014

Amarin Corporation plc

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