

AMARIN CORP PLC\UK
Form 8-K
September 23, 2016

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 22, 2016

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction

of incorporation)

2 Pembroke House, Upper Pembroke Street 28-32,

0-21392
(Commission

File Number)

Not applicable
(I.R.S. Employer

Identification No.)

Not applicable

Dublin 2, Ireland

(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

As expected and consistent with typical timelines under the five-year, new chemical entity, exclusivity regulatory structure, on September 22 and 23, 2016, Amarin Corporation plc (Amarin), through its subsidiary Amarin Pharmaceuticals Ireland Limited, received paragraph IV certifications from Roxane Laboratories, Inc. and Dr. Reddy's 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) that seek regulatory approval 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, the Hatch-Waxman Amendments provide for a

30-month stay on FDA's ability to grant final approval to any of the proposed generic products that reference Vascepa. Such 30-month stay would expire on January 26, 2020, seven-and-a-half years from FDA approval of Vascepa on July 26, 2012. 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 before the end of the 30-month stay. If the litigation is resolved in favor of a generic applicant before the expiration of the 30-month period, the stay would be lifted and 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, July 26, 2016 marked the four year anniversary of FDA's approval of Vascepa and the opening of the regulatory window for ANDA filings, 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 planned quarterly report on Form 10-Q for the quarter ended September 30, 2016.

The information contained herein is intended to be considered in the context of more complete information included in Amarin's filings with the Securities and Exchange Commission (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 quarterly report on Form 10-Q filed with the SEC on August 4, 2016.

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, Amarin's intention to file patent infringement suits against generic companies from which it has received and may receive valid paragraph IV notices and to otherwise vigorously enforce its intellectual property rights, Amarin's expectations regarding the timing and outcome of the planned 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 regulatory exclusivity and intellectual property rights, and to defend its patents; the possible introduction of generic competition of Vascepa; and the scope, validity and duration of patent protection to provide exclusivity for Vascepa. 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 SEC, including its most recent Quarterly Report on Form 10-Q, filed on August 4, 2016. 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: September 23, 2016

Amarin Corporation plc

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