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): May 6, 2020

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.)**

77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	**AMRN**	**NASDAQ Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

As previously disclosed in 2016, Apotex Inc. ("Apotex") sent to Amarin Corporation plc ("Amarin"), through its subsidiaries, Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc., a paragraph IV certification notice in September 2016 (the "2016 Notice") advising Amarin that Apotex has filed an abbreviated new drug application (an "ANDA") with the U.S. Food and Drug Administration ("FDA") that sought regulatory approval for a generic version of VASCEPA® (icosapent ethyl) 1 gram capsules. To date, no approval of the Apotex ANDA has been obtained based on a review of FDA's website. The 2016 Notice reflected that Apotex made a paragraph IV certification as to some, but not all, of the patents then listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for VASCEPA. Because in the 2016 Notice Apotex did not make a paragraph IV certification as to any patents then asserted in Amarin's patent litigation against other generic filers, Apotex was not sued by Amarin for patent infringement and Apotex could not then market a generic version of VASCEPA until after FDA approval of the Apotex ANDA and before the last to expire of the patents for which Apotex did not make a paragraph IV certification, which is in 2030.

On May 6, 2020, Amarin received a new notice from Apotex with new paragraph IV certifications (the "2020 Notice"). The 2020 Notice reflects that Apotex has amended its ANDA and has made new paragraph IV certifications with regard to patents listed in the Orange Book for the VASCEPA indication, originally approved by the FDA in July 2012, for the reduction in triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. As previously disclosed, Amarin is currently appealing the United States District Court for the District of Nevada's March 30, 2020 ruling in favor of generic companies in Amarin's patent litigation against two filers of ANDAs for VASCEPA (the "Nevada Litigation") to the United States Court of Appeals for the Federal Circuit. The 2020 Notice alleges to varying degrees that the certified patents, including those subject to the Nevada Litigation and related appeal, are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the proposed generic product for which the Apotex ANDA was submitted. In light of the Nevada Litigation and related appeal, Amarin is currently considering the most effective path to respond to the 2020 Notice and plans to update investors at an appropriate time after such decision is acted upon. Because Apotex is not a party to the Nevada Litigation or related appeal, it is not directly subject thereto. Generally, options include litigation and settlement.

Under the Food Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch Waxman Amendments"), after receipt of a valid paragraph IV notice, Amarin could bring a patent infringement suit 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 the proposed generic product, in this case, from the date of the lawsuit. 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 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 has not received notice of a paragraph IV certification from Apotex for patents listed just for the cardiovascular risk reduction indication, which indication was based on results from the REDUCE-IT® cardiovascular outcomes study. Under the Hatch-Waxman Amendments, Apotex cannot obtain approval of labeling with the cardiovascular risk reduction indication without certifying to the patents listed for that indication and providing notice to Amarin. Thus, it is Amarin's expectation that Apotex is not also seeking approval for labeling including that cardiovascular risk reduction indication. Thus, Amarin does not plan to sue Apotex based on infringement of the REDUCE-IT-related patents at this time.

Amarin could receive additional paragraph IV certifications in the future. Amarin plans to update investors on any such additional certifications and Amarin's planned patent litigation against such ANDA filers in its current or periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC").

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about potential litigation and other actions in connection with a notice and paragraph IV certification, Amarin's understanding of the content of the notice and related regulatory implications as well as statements that Amarin may receive other similar notices in the future from ANDA filers and Amarin's options in connection therewith, Amarin's expectations regarding matters related to the notice and litigation and the expected timing of any updates to investors regarding 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 Annual Report on Form 10-K for the year ended December 31, 2019 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and any other subsequently filed reports, including any Current Reports on Form 8-K. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

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, on its corporate website (www.amarincorp.com) 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, website disclosures 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 for the quarter ended March 31, 2020 and any other subsequently filed reports, including any Current Reports on Form 8-K.

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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: May 8, 2020

Amarin Corporation plc

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