

AMARIN CORP PLC\UK
Form 8-K
August 07, 2015

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): August 7, 2015

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales (State or other jurisdiction	0-21392 (Commission	Not applicable (I.R.S. Employer
of incorporation)	File Number)	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 August 7, 2015, Amarin Corporation plc (Amarin) announced that the federal district court for the southern district of New York granted Amarin's request for a declaratory judgment in Amarin's lawsuit against the United States Food and Drug Administration (FDA) seeking Amarin's ability to promote to healthcare professionals certain uses of Amarin's lead product, Vascepa® (icosapent ethyl) capsules, that are not covered by current FDA-approved labeling for the drug so long as the promotion is truthful and non-misleading. The court declaration covers promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in Amarin's ANCHOR clinical trial of patients with persistently high triglycerides after statin therapy and use of peer-reviewed scientific publications that present the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease. An appeal of the court's decision can be filed within 60 days.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about any appeal of this decision by FDA. 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 the following: the risk that FDA may appeal the order, and the result of any such appeal, and uncertainties associated generally with litigation, research and development, clinical trials and related regulatory approvals. 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 and 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 Form 8-K, whether as a result of new information, future events or circumstances or otherwise.

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: August 7, 2015

Amarin Corporation plc

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