

AMARIN CORP PLC\UK
Form 8-K
January 25, 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): January 22, 2016

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction

of incorporation)

0-21392
(Commission

File Number)

Not applicable
(I.R.S. Employer

Identification No.)

**2 Pembroke House, Upper Pembroke Street 28-32,
Dublin 2, Ireland**

(Address of principal executive offices)

Not applicable

(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 7.01 Regulation FD Disclosure.

Item 8.01. Other Events.

On January 22, 2016, the U.S. District Court for the District of New Jersey granted Amarin's motion to dismiss all patent infringement litigation related to the acceptance by FDA of abbreviated new drug applications, or the ANDAs, to Vascepa® (icosapent ethyl) capsules in the first half of 2014. With this dismissal, there is no pending patent litigation related to Vascepa. Separately, as previously disclosed and described below, the FDA no longer considers the ANDAs accepted.

This dismissal of the patent infringement litigation follows the May 2015, U.S. District Court for the District of Columbia order granting Amarin's motion for summary judgment that set aside FDA's denial of five-year, NCE exclusivity in connection with FDA approval of Vascepa on July 26, 2012. That order vacated FDA's denial of Amarin's claim for such exclusivity and remanded to FDA for proceedings consistent with the decision. A new exclusivity determination by FDA has not been made. In June 2015, following communication with the parties, the FDA changed the status of the ANDAs at FDA to submitted, but no longer accepted. In July 2015, Amarin moved to dismiss the ANDA patent litigation on the basis that the statutory grounds for patent infringement (accepted ANDAs) no longer existed. The New Jersey court adopted this reasoning in its ruling granting Amarin's motion to dismiss. An appeal of the court's decision can be filed within 30 days.

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: January 25, 2016

Amarin Corporation plc

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