

AMARIN CORP PLC\UK
Form 8-K
March 09, 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): March 8, 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 8.01. Other Events.

On March 8, 2016, Amarin Corporation plc (Amarin) announced settlement terms to resolve the Amarin First Amendment litigation (*Amarin Pharma, Inc. et al. v. FDA et al.*, No. 15-3588 (S.D.N.Y. May 7, 2015)). The Court approved the terms on the same date and the case is now closed. The key settlement terms include:

The U.S. Food and Drug Administration (FDA) and the U.S. government have agreed to be bound by the court's earlier conclusions from the August 7, 2015 declaration issued in the litigation that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that Amarin proposed to make to healthcare professionals are truthful and non-misleading.

Amarin bears the responsibility of assuring that its communications to doctors regarding off-label use of Vascepa remain truthful and non-misleading.

The settlement terms are to be interpreted consistently with the August 7, 2015 opinion and order and are not to be construed to limit Amarin's constitutional rights to free speech concerning Vascepa.

FDA has agreed to provide Amarin with an optional preclearance provision through 2020 for new off-label claims.

The parties have agreed to a dispute resolution provision designed to avoid future litigation on matters arising under the settlement order.

The court would retain jurisdiction over the matter to ensure compliance with and resolve any future dispute arising from the settlement order.

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 9, 2016

Amarin Corporation plc

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