AMARIN CORP PLC\UK
Form 8-K
May 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): May 7, 2015

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.)**

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 7.01 Regulation FD Disclosure.

Item 8.01. Other Events.

Amarin and independent physicians, in support of improved patient care, seek a judicial declaration to allow Amarin to communicate to healthcare professionals the ANCHOR clinical study results and the state of research on the potential effect of Vascepa® (icosapent ethyl) capsules on the risk of cardiovascular disease.

On May 7, 2015, Amarin Pharma, Inc., a wholly-owned subsidiary of Amarin Corporation plc, and four independent physicians, in support of improved patient care, filed a lawsuit to permit Amarin to share truthful and non-misleading information with healthcare professionals in the United States that would be considered off-label by the Food and Drug Administration (FDA). The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.*, was filed in the United States District Court for the Southern District of New York. It seeks a judicial declaration that FDA regulations limiting off-label promotion of such truthful and non-misleading information are unconstitutional under the First Amendment (freedom of speech) or Fifth Amendment (restriction against vague laws) as applied in this case to Amarin s proposed promotion of Vascepa. The physicians in the suit regularly treat patients at risk of cardiovascular disease and, as the complaint contends, have First Amendment rights to receive truthful and non-misleading information from Amarin. The suit is based on the principle that better informed physicians make better treatment decisions for their patients.

The lawsuit seeks a court declaration that Amarin may communicate to healthcare professionals (not the general public) the following information with respect to Vascepa:

- efficacy data from Amarin s ANCHOR clinical trial of Vascepa in patients with high triglyceride levels despite statin therapy, which met all primary and secondary endpoints and was conducted under a special protocol assessment agreement with FDA (safety data is already reflected in approved Vascepa labeling);

- the qualified health claim that the FDA has permitted for over a decade for omega-3 dietary supplement products: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease; and

- peer-reviewed scientific publications relevant to the potential effect of EPA on the reduction of the risk of coronary heart disease.

The use covered by the ANCHOR study is consistent with multiple national and international medical treatment guidelines and position statements and relevant to millions of patients on statin therapy still at risk of cardiovascular disease. In the complaint, Amarin has proposed disclaimers be used to ensure the truthful information communicated is not misleading, including that the effect of Vascepa on cardiovascular risk has not been determined and that FDA has not approved Vascepa to reduce the risk of coronary heart disease or for the use studied in the ANCHOR trial.

The plaintiffs contend that broader communication of truthful information about Vascepa will improve patient care by making physicians better informed with current scientific data before deciding how to treat patients consistent with multiple national and international medical treatment guidelines. Currently, FDA regulations restricting off-label promotion limit this type of truthful and non-misleading communication, preventing most physicians from making fully-informed treatment decisions.

The lawsuit does not:

seek to compel the FDA to approve an expanded indication for Vascepa based on the ANCHOR trial results;

require the court to evaluate whether FDA s scientific conclusions about Vascepa are right or wrong;

seek to strike down off-label promotion laws and regulations as facially unconstitutional; or

challenge the government s ability to prohibit pharmaceutical companies, including Amarin, from disseminating false or misleading information about their products.

About prohibitions on communication of off-label drug information

Once a drug is approved by FDA for a specific use in a specific patient population, physicians may exercise their medical judgment to prescribe the drug for any use in any patient population. It is estimated that approximately 20% of all prescriptions in the United States are used by physicians for such off-label indications. FDA has taken the position, however, that federal law prohibits pharmaceutical companies from proactively promoting data to the medical community regarding off-label uses even when such information is accurate, not misleading and reflective of accepted medical treatment.

FDA has acknowledged the importance of the off-label use of many pharmaceutical products. In fact, federal, state and private health plans routinely pay for many off-label drug uses, including off-label uses of Vascepa. FDA permits limited communications on off-label uses, such as in response to unsolicited requests for information, under FDA s publication reprint guidances and in connection with scientific exchanges. These restrictions significantly limit the flow of information about available drug therapies.

General information

Amarin and the individual physician plaintiffs are represented in the lawsuit by Floyd Abrams, Joel Kurtzberg and Michael Weiss, partners at Cahill Gordon & Reindel LLP.

The foregoing information is qualified in its entirety by the subject complaint, a copy of which is available in the FAQ section of the Investor Relations section of Amarin s website at http://www.amarincorp.com/investor-splash.html and through Public Access to Court Electronic Records (PACER), an electronic public access service that allows users to obtain case and docket information online from federal courts. Investors are encouraged to follow the progress of this lawsuit through the PACER system. Amarin is not responsible for misinformation provided by the PACER system.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules, known in scientific literature as AMR101, is a highly pure-EPA omega-3 prescription product in a 1 gram capsule.

Indications and Usage

Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (³500 mg/dL) hypertriglyceridemia.

The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components and should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

The most common reported adverse reaction (incidence >2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction >3% and greater than placebo.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the FDA as an adjunct to diet to reduce triglyceride levels in adult patients with severe (³500 mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Nothing in this Current Report on Form 8-K should be construed as marketing the use of Vascepa in any indication that has not been approved by the FDA.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about Amarin s objectives in filing the lawsuit, the merits of Amarin s legal arguments, whether or not the demonstrated clinical effects of Vascepa will result in cardiovascular risk reduction benefit in the REDUCE-IT trial. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. There can be no guarantee that Amarin will be successful in this lawsuit. Even if Amarin is successful, the litigation process could involve appeals and take a significant amount of time to reach conclusion. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the risk that Amarin s interpretation of the applicable legal standards may not be determinative or adjudicated in Amarin s favor; the risk that a court will not consider the lawsuit on its merits; 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 upcoming 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: May 7, 2015

Amarin Corporation plc

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