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 30, 2017

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))

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

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 7.01 Regulation FD Disclosure.

Item 8.01. Other Events.

Amarin filed a lawsuit to prevent the import and sale into the United States of synthetic omega-3 products that are comprised predominantly of EPA and sold for use in, or as, dietary supplements, contending that, consistent with multiple FDA statements and actions, such products are illegal unapproved new drugs under U.S. law.

On August 30, 2017, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Limited, each wholly-owned subsidiaries of Amarin Corporation plc, filed a lawsuit with the United States International Trade Commission (the ITC) that seeks an investigation by the ITC under Section 337 of the Tariff Act of 1930 (19 U.S.C. §1337). Section 337 of the Tariff Act of 1930 makes unlawful unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. Amarin contends that synthetically produced omega-3 products comprised predominantly of EPA and sold as dietary supplements in the United States are unapproved new drugs under applicable law. As such Amarin contends that the import and sale of such articles in the United States is illegal and amounts to injurious unfair competition with Amarin's FDA-approved drug, Vascepa® (icosapent ethyl) capsules, which contains 1 gram of EPA in ethyl ester form in a 1-gram capsule. Amarin contends, consistent with U.S. law and multiple cited FDA statements and actions, that the public is entitled to the benefit of FDA drug regulations to ensure that synthetic products are appropriately manufactured and safe and effective for their intended uses.

Amarin's Vascepa® capsules are a single-molecule, FDA-approved, prescription product consisting of the ethyl ester form of the omega-3 acid commonly known as EPA. Vascepa® is not fish oil, but is derived from fish through a stringent and complex drug manufacturing process. That drug manufacturing process is highly regulated by the FDA, involves chemical alteration, and is designed to effectively eliminate impurities and isolate and protect the fragile single molecule active ingredient. FDA regulation of drug products like Vascepa® is designed to ensure that patients diagnosed with a disease receive the same drug that demonstrated a favorable efficacy and safety profile in FDA-reviewed human clinical trials.

Amarin has invested more than $200 million on the development, testing and clinical study of Vascepa, including conducting the ongoing REDUCE-IT cardiovascular outcomes study which commenced in 2011. REDUCE-IT is an 8,175-patient clinical trial evaluating whether treatment with Vascepa® will reduce major cardiovascular events in patients who, despite stabilized statin therapy, have elevated triglyceride levels and other cardiovascular risk factors. The results of this important trial could help healthcare professionals save millions of lives and lead to improved medical care for tens of millions of patients. If successful, REDUCE-IT has the potential to significantly change the treatment paradigm for cardiovascular risk reduction, the leading cause of death in the United States. This outcome study commenced following completion by Amarin of two successful Phase 3 clinical studies of Vascepa and years of earlier studies and tests pertaining to safety, efficacy and manufacturing rigor consistent with drug development under FDA regulations.

In the lawsuit, Amarin seeks the issuance of a general exclusion order prohibiting importation into the United States of the purported dietary supplement products and oil. The lawsuit also seeks related cease and desist orders applicable to inventory of such articles of the named respondents already in the United States. Amarin contends that is has the supply capacity to meet through prescriptions replacement demand for the products targeted for exclusion. Vascepa® is a low-cost drug from a consumer perspective. According to Amarin's records, the majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. A consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®.

The lawsuit does not seek action against dietary supplements containing common fish oil (i.e., fish oil in its naturally-occurring chemical composition). A large majority of the omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil and not intended to treat serious medical conditions. Nor does Amarin seek action against synthetically produced omega-3 products that are not predominantly comprised of the omega-3 acid EPA.

The lawsuit is captioned, *In the Matter of Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form,* and was filed with the ITC against manufacturers, importers, and distributors of products containing synthetically produced omega-3 products in ethyl ester or re-esterified triglyceride form that contain more EPA than DHA or any other single component, for use in, or as dietary supplements.

The foregoing information is qualified in its entirety by Amarin's complaint and related documents, copies of the principal litigation documents are available in the FAQ section of the Investor Relations section of Amarin's website at http://www.amarincorp.com/investor-splash.html. Amarin's complaint and related litigation documents are also expected to be available to the public within a few days and throughout the litigation through EDIS, the ITC's online docketing 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.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements, including statements about Amarin's plans for pursuing the lawsuit and the merits of Amarin's legal arguments. 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 the ITC will not initiate the investigation requested and consider Amarin's contentions on their merits; and uncertainties associated generally with litigation, legal arguments and regulatory interpretations. 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 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 30, 2017

Amarin Corporation plc

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