

AMARIN CORP PLC\UK

FORM 8-K

(Current report filing)

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**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 10, 2011

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.)

**First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge,
Dublin 4, 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))
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Item 8.01. Other Events.

On August 10, 2011, Amarin Corporation plc issued a press release announcing that it had reached agreement with the U.S. Food and Drug Administration on a Special Protocol Assessment for the design of the REDUCE-IT (“Reduction of Cardiovascular Events with EPA - Intervention Trial”) cardiovascular outcomes study of AMR101. The full text this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 10, 2011

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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 10, 2011

Amarin Corporation plc

By: /s/ John Thero

John Thero

President

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 10, 2011



Amarin Announces Agreement from FDA on Special Protocol Assessment for AMR101 Outcomes Study
-Study Positions AMR101 to Potentially Address Patient Populations of More Than 70 Million in the U.S. Alone-

MYSTIC, Conn. and DUBLIN, August 10, 2011 – Amarin Corporation plc (Nasdaq: AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) agreement for the design of the previously described cardiovascular outcomes study of AMR 101 formally titled REDUCE-IT (Reduction of Cardiovascular Events with EPA - Intervention Trial). Amarin previously announced that it achieved the primary endpoints of two Phase 3 studies of AMR101, both of which were conducted under separate SPAs.

In REDUCE-IT, Amarin will evaluate the effectiveness of AMR101 in reducing the first major cardiovascular events in an at-risk patient population. The control arm of the study will be patients on optimized statin therapy. The active arm of the study will be patients on optimized statin therapy plus AMR101. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. Amarin will be responsible for the study which will be conducted internationally. The Company will use an experienced clinical research organization (CRO) to help manage the study and is in the late stages of contract negotiations with a leading CRO for that purpose.

Consistent with prior comments, Amarin estimates that the study will require approximately 8,000 patients and take approximately 6 years for completion. The Company anticipates that if, as intended, it commences Outcomes study activities in 2011 that it will be positional to achieve approximately 50% enrollment before the end of 2012.

Once REDUCE-IT is substantially underway, the Company believes that it will have met all of the requirements to request approval of AMR101 for treating the mixed dyslipidemia patient population studied in the ANCHOR trial. AMR101 is positioned to be the first drug in its class approved for treatment of this indication. Upon completing REDUCE-IT, and assuming a successful result, Amarin anticipates being able to pursue an indication for the prevention of cardiovascular events ; this population is estimated to be greater than twice the size of the combined indications studied in the MARINE and ANCHOR trials. The Company also anticipates that, similar to ANCHOR, a significant number of the patients in REDUCE-IT will have diabetes.

“We are delighted to have finalized the protocol for REDUCE-IT and to have the FDA agree to this via a Special Protocol Assessment, our third SPA for AMR101, which is remarkable,” stated Joseph Zakrzewski, Amarin’s Executive Chairman and CEO. “Based on the strong safety profile of AMR101, our positive Phase 3 results for AMR101 and success in Japan with an outcomes study of highly pure EPA, we believe that REDUCE-IT is positioned for success.” Mr. Zakrzewski added, “The design of REDUCE-IT reflects the

diligent evaluation of numerous other outcome studies by our clinical team, advisors and other interested parties all of whom are commended and thanked for their contributions to the very direct and efficient design of this study.”

About AMR101

AMR101 is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA), that Amarin is developing as a potentially best-in-class prescription medicine for the treatment of patients with very high triglyceride levels (>500 mg/dL) and as a potentially first-in-class therapy for patients with high triglyceride levels (>200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels (which we refer to as mixed dyslipidemia). Significant scientific and clinical evidence support the efficacy and safety of ethyl-EPA in reducing triglyceride levels.

About Amarin

Amarin Corporation plc is a clinical-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. The Company’s lead product candidate is AMR101 (icosapent ethyl). Amarin reported positive, statistically significant top-line results for both of its two pivotal Phase 3 clinical trials, the MARINE trial (investigation of AMR101 as a treatment for patients with very high triglycerides [≥ 500 mg/dL]), as reported on November 29, 2010, and the ANCHOR trial (investigation of AMR101 for the treatment of patients on statin therapy with high triglycerides [≥ 200 and <500mg/dL] with mixed dyslipidemia), as reported on April 18, 2011. Both the MARINE and ANCHOR trials were conducted under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA). Amarin also has next-generation lipid candidates under evaluation for preclinical development.

About Special Protocol Assessment (SPA) Agreements

An SPA agreement is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the REDUCE-IT trial adequately address the objectives necessary to support a regulatory submission. An SPA is generally binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing begins. However, there can be no assurance that this will be the case. If the FDA does not consider the SPA to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

Disclosure Notice

This press release contains forward-looking statements, including statements about the efficacy and safety of the Company’s product candidates, likelihood of success of clinical trial, the timing of initiating, enrolling and completing a planned cardiovascular outcomes study and the status of negotiations with contract research organizations in connection with such study, and the potential market positioning and market potential for AMR101. 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 are the following: anticipated operating losses and the likely need for additional capital to fund future operations and the planned cardiovascular outcomes study; uncertainties associated generally with

research and development, clinical trials and related regulatory approvals; risks associated with qualifying new contract manufacturers prior to commercial launch; the risk that SPAs are not a guarantee that FDA will accept an NDA or approve a product candidate upon submission; the risk that historical clinical trial enrolment and randomization rates may not be predictive of future results; risks associated with our intellectual property including the risk that our recently filed patent applications may not issue; dependence on third-party manufacturers, suppliers and collaborators; significant competition; loss of key personnel; and uncertainties associated with market acceptance and adequacy of reimbursement, technological change and government regulation. A further list and description of these risks, uncertainties and other matters 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 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. The Company undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise. The Company's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials. Nothing in this press release should be construed as marketing the use of such product candidates.

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