AMARIN CORP PLC\UK
Form 8-K
September 26, 2011

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): September 26, 2011

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.)**

First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge,

Dublin 4, 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 8.01. Other Events.

On September 26, 2011, Amarin Corporation plc (the Company) announced that on September 26, 2011 it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of AMR101 for treatment of patients with very high triglycerides. The submission is based on the entire data set from the Company s AMR101 development program, including safety and efficacy data from the Phase 3 MARINE and ANCHOR studies. The FDA has 60 days after receipt of the NDA to preliminarily review and determine if the application is sufficiently complete to permit a substantive review and meets the threshold for filing.

Elevated triglycerides are clinically stratified into three groups: very high triglycerides (>500 mg/dL), high triglycerides (>200 and <500 mg/dL) and borderline high triglycerides (>150 and <200 mg/dL). The Company estimates that approximately 4 million adults in the United States have very high triglycerides, the target indication of the NDA.

This Current Report on Form 8-K contains forward-looking statements, including statements about the regulatory submission and acceptance of the Company s NDA and the market opportunity of 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: the risk that the NDA will not be accepted by FDA for deficiencies in the application or other reasons; the risk that SPAs are not a guarantee that FDA will accept an NDA or approve a product candidate upon submission; 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 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 Current Report on Form 8-K, whether as a result of new information, future events or circumstances or otherwise.

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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: September 26, 2011

Amarin Corporation plc

By: /s/ John Thero
John Thero
President