AMARIN CORP PLC\UK
Form 6-K
November 29, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16

under the Securities Exchange Act of 1934

For the month of November, 2010.

Commission File Number 0-21392

AMARIN CORPORATION PLC

(Translation of registrant s name into English)

First Floor, Block 3, The Oval, Shelbourne Road, Ballsbridge, Dublin 4, Ireland

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F x Form 40-F ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ¨ No x

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ¨ No x

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant s home country), or under the rules of the home country exchange on which the registrant s securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant s security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ¨ No x

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____ .

This report on Form 6-K is hereby incorporated by reference into the registration statements of Amarin Corporation plc and in the prospectus contained therein, and this report on Form 6-K shall be deemed a part of each such registration statement from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished by Amarin Corporation plc under the Securities Act of 1933 or the Securities Exchange Act of 1934.

AMARIN CORPORATION PLC

Exhibit	**Description**
99.1	Press release dated November 29, 2010

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, thereunto duly authorized.

AMARIN CORPORATION PLC

By: /s/ John Thero
John Thero
President

Date: November 29, 2010

Exhibit 99.1

Amarin s AMR101 Meets Pivotal Phase 3 Study Endpoints with Highly Statistically Significant Reductions in Triglycerides at 4 Gram and 2 Gram Doses in MARINE Trial with No Statistically Significant Increase in LDL-C and Safety Profile Similar to Placebo

Largest controlled therapeutics trial in patients with very high triglycerides
Trial conducted in accordance with Special Protocol Assessment with FDA
NDA submission moved forward to 2011
Conference call and Webcast scheduled for 8:30 a.m. EST (1:30 p.m. GMT) today

MYSTIC, Conn., and DUBLIN, Nov. 29, 2010 Amarin Corporation plc (Nasdaq: AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, today reported positive, statistically significant top-line results from the MARINE study, its first Phase 3 clinical trial of lead drug candidate AMR101. The MARINE study, investigating AMR101 as a treatment for very high triglycerides (≥500 mg/dL), met its primary efficacy endpoints as defined in the clinical trial protocol and demonstrated a positive safety profile. The Company believes that AMR101 has the potential to be the best-in-class product for this indication and that the MARINE study results may support additional patentable claims that could further protect the Company s rights to this product through 2030.

The study s primary endpoint, the percent change in triglyceride (TG) levels from baseline to week 12, was met for both the 4 gram and 2 gram dose groups. The MARINE study was required to meet a stringent level of statistical significance of 1% ($p < 0.01$), as agreed in the Company s SPA (Special Protocol Assessment) with the FDA. Twenty-five percent of patients were on background statin therapy. The patient group treated with 4 grams of AMR101 showed a significant median TG decrease of 33 % ($P < 0.0001$) compared to placebo, and the patient group treated with 2 grams of AMR101 showed a significant median TG decrease of 20 % ($P = 0.0051$) compared to placebo. The median baseline triglyceride levels were 703 mg/dL, 680 mg/dL and 657 mg/dL for the patient groups treated with placebo, 4 grams of AMR101 and 2 grams of AMR101, respectively.

In a pre-specified secondary analysis in the subgroup of patients with baseline TG > 750 mg/dL, representing 39% of all patients, the effect of AMR101 in reducing TG levels was even more pronounced. In this group, the median decrease in TG levels from placebo was 45% for 4 grams and 33% for 2 grams, both statistically significant ($P= 0.0001$ for 4 grams and $P= 0.0016$ for 2 grams, respectively). The median baseline TG levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4 gram and 2 gram groups, respectively. In addition, the subgroup of patients on background statin therapy had much greater median reductions in TG, which were also statistically significant, than those not on statin therapy.

Importantly, AMR101 did not result in an increase in median LDL-C compared to placebo at either dose (-2.3% for the 4 gram group and +5.2% for the 2 gram group [p=NS]). This is the first and only

triglyceride-lowering therapy studied in this population with very high triglyceride levels to show a lack of elevation in LDL-C. Furthermore, there was a statistically significant decrease in median non-HDL-C (total cholesterol less good cholesterol) compared to placebo with both of the AMR101 treated groups (-18% for the 4 gram group [p < 0.001] and -8% for the 2 gram group [p < 0.05]).

There were also statistically significant reductions in several important lipid markers, including Apo B, Lp-PLA2 (Lipoprotein-phospholipase A2), VLDL-C and Total Cholesterol. These results are particularly encouraging given that no other TG-lowering therapy studies have shown such results. For these achieved endpoints, p-values were <0.01 for most and <0.05 for all. Apo B (Apolipoprotein B) is a sensitive index of residual cardiovascular risk and is generally considered to be a better predictor than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis. Furthermore, AMR101 appeared to be very well tolerated with a safety profile that appears to be both comparable to placebo and more favorable compared to other triglyceride lowering therapies. There were no treatment-related serious adverse events in the MARINE study. The Company will present more details of these results at an upcoming scientific meeting.

Commenting on the results of the study, Harold Bays, M.D., Medical Director, Louisville Metabolic and Atherosclerosis Research Center, and Principal Investigator of the study, said, The MARINE trial included a study population of patients with very high TG levels (i.e. > 500 mg/dl). In this study, AMR101 reduced TG levels to within the range observed with common approved triglyceride-lowering drugs. Clinicians are aware, and some may have concerns, that common TG-lowering agents may raise LDL-C by 40 50% in patients with very high TG levels. In the MARINE trial, AMR101 did not significantly increase LDL-C levels. Another surprise to me was the degree of TG-lowering efficacy in the statin-treated group, which exceeded the TG lowering in the non-statin treated group. It was also reassuring that the safety and tolerability of AMR101 was similar to placebo. Adding these favorable findings to the significant reductions in total cholesterol, non-HDL-C, Apo B, and Lp-PLA2 levels, this suggests that AMR101 may prove to represent an effective, and safe alternative treatment option to improve cardiovascular risk factors in patients with very high triglycerides. In summary, the results of the MARINE trial suggest that AMR101 may prove to represent a first in class EPA TG-lowering agent that not only represents a new chemical entity, but a potential novel therapy with favorable lipid efficacy effects that differ from common TG-lowering agents, such as fibrates and previously approved prescription omega-3 drugs. We very much look forward to presenting the full dataset at a scientific meeting.

Joseph S. Zakrzewski, Executive Chairman and Chief Executive Officer of Amarin, added, The MARINE study was conducted in a population representative of millions of people with very high triglyceride levels, including more than 3.8 million in the U.S. alone. We believe that these results and the overall profile of AMR101 position the drug candidate to be best in class in this market. Furthermore, the MARINE study results are encouraging, especially the positive outcomes with respect to LDL-C and other lipids, as we await the results of the ongoing ANCHOR study. This separate Phase 3 study is designed to investigate AMR101 in patients with high triglycerides (≥200 and <500mg/dL) with mixed dyslipidemia treated with statins, a patient population for which no drug in this class is currently approved. While the market for a drug labeled for treatment of triglycerides of ≥500 mg/dL is already proven to be a billion dollar market, there are ten times the number of patients with triglycerides of ≥200 and <500 mg/dL.

Based on the timing and nature of these results, Amarin intends in 2011 to submit a New Drug Application (NDA) seeking approval to market and sell AMR101 in the U.S. Previous Company guidance projected 2012 for the NDA submission. The Company further added that, based on the

positive results of the MARINE trial, Amarin has advanced additional patent claims to add to its growing portfolio of U.S. and international intellectual property claims related to AMR101.

Conference Call & Webcast Information

The conference call may be accessed by dialing 877-407-0778 for U.S. callers and 201-689-8565 for callers from outside the U.S. The conference call will be Webcast live under the investor relations section of Amarin s Web site at http://www.amarincorp.com and will be archived there for 30 days following the call. Please connect to Amarin s Web site several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary.

About AMR101

AMR101 is ethyl icosapentate (ethyl-EPA). Significant scientific and clinical evidence supports the efficacy of ethyl-EPA in reducing triglyceride levels. In addition to the MARINE trial, Amarin has completed patient screening in a second Phase 3 clinical trial to investigate the efficacy of AMR101 in reducing elevated triglyceride levels in a patient population with high triglycerides (≥200 and <500mg/dL) who also have mixed dyslipidemia (the ANCHOR trial). Top-line results for the ANCHOR trial are expected in mid-2011.

About AMR101 Phase 3 Clinical Trials

The MARINE trial, a multi-center, placebo-controlled, randomized, double-blind, study enrolled 229 patients with fasting triglyceride levels greater than or equal to 500 mg/dL. Patients in this trial were characterized as having very high triglyceride levels according to the National Cholesterol Education Program Adult Treatment Panel III treatment guidelines. The MARINE trial is the largest controlled therapeutic study ever conducted in patients with very high triglyceride levels (≥500mg/dL). The Company believes that AMR101 is positioned to be best-in-class in this patient population.

The ANCHOR trial is a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in patients with high triglyceride levels from 200 mg/dL to less than 500 mg/dL who are also on statin therapy. Patients in this trial are characterized as having high triglyceride levels with mixed dyslipidemia (two or more lipid disorders). The trial aims to recruit approximately 650 patients into clinical sites in the U.S. The primary endpoint in the trial is the percent change in triglyceride level from baseline to week 12. A secondary endpoint in the ANCHOR trial is to show that the addition of AMR101 to statin therapy does not increase LDL-C compared to placebo in this population. The Company believes that AMR101 is positioned to be first-in-class to address this patient population.

In both the MARINE and ANCHOR trials, prior to randomization into the 12-week double-blind treatment period, all patients underwent a six-to-eight week washout period of lipid altering drugs, as well as diet and lifestyle stabilization. Both the MARINE and ANCHOR trials received Special Protocol Assessment (SPA) agreements in 2009 from the U.S. Food and Drug Administration (FDA).

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 (ethyl icosapentate), which is presently being investigated in a second Phase 3 clinical trial for the treatment of patients on statin therapy with high triglycerides (≥200 and <500mg/dL) with mixed dyslipidemia. The MARINE trial was, and the ANCHOR trial currently is, 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. For more information please visit www.amarincorp.com.

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Disclosure Notice

This press release contains forward-looking statements, including statements about the timing and success of clinical trial results and NDA submission, the potential label of any approved drug, intellectual property protection, competitive market positioning and the commercial opportunity for AMR101, including the number of patients that could potentially benefit from 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; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that historical clinical trial enrolment and randomization rates may not be predictive of future results; uncertainties relating to the timing of data collection and analysis for the ANCHOR trial; 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 20-F. 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.

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