

AMARIN CORP PLC\UK
Form 6-K
November 10, 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)

Edgar Filing: AMARIN CORP PLC\UK - Form 6-K

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 ☒ 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 ☒

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 ☒

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 ☒

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 10, 2010 titled: Amarin Reports Third Quarter 2010 Financial Results and Positively Updates Phase 3 Guidance

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 10, 2010

AMARIN REPORTS THIRD QUARTER 2010 FINANCIAL RESULTS AND POSITIVELY UPDATES PHASE 3 GUIDANCE

-Phase 3 milestones moved ahead into 2010 for report of top line results of

MARINE trial and completion of ANCHOR trial randomization-

Conference call today at 11:00 AM Eastern Time

Dublin, Ireland and Mystic, CT, USA, November 10, 2010 Amarin Corporation plc (NASDAQ: AMRN), a clinical-stage biopharmaceutical company focused on cardiovascular disease, today reported its financial and operational results for the three-month period ended September 30, 2010. In addition, the Company provided an update regarding its MARINE and ANCHOR trials, the two on-going Phase 3 clinical trials of its lead product candidate AMR101 for treating elevated triglyceride levels, including a positive update regarding the timing of key future milestones for these trials. In summary:

MARINE trial top-line results are now expected before the end of 2010

ANCHOR trial patient screening is complete and randomization is now expected to be complete by the end of 2010 with top-line results expected in mid-2011

The above revised guidance is months ahead of previous guidance for both trials

Financial resources remain sufficient to complete both Phase 3 clinical trials and submit the NDA for AMR101. The MARINE and ANCHOR trials are pivotal Phase 3 studies designed to evaluate the efficacy and safety of AMR101 in two separate populations of patients with elevated triglyceride levels. According to current treatment guidelines established by NCEP ATPIII, patients with these levels of triglyceride elevation should be treated with triglyceride lowering therapy.

Q3 Financial Update

Amarin's cash balance as of September 30, 2010 was approximately \$31.4 million. During the three months ended September 30, 2010, net cash outflows were approximately \$6.2 million, including approximately \$5.5 million paid in connection with the Company's two ongoing Phase 3 clinical trials.

The Company's net cash outflows during the quarter were partially offset by approximately \$2.0 million in net proceeds received from the exercise of warrants. These warrant exercises, at exercise prices from \$1.00 to \$1.50 per share, resulted in the issuance of 1.5 million new shares during the quarter ended September 30, 2010.

As of September 30, 2010, the Company had 101.3 million shares outstanding, 38.7 million warrants outstanding at an average exercise price of \$1.77 and 12.3 million stock options outstanding at an average exercise price of \$2.47.

The Company expects that its current financial resources are sufficient to finance its planned operations through the filing of the NDA pending positive clinical results.

Clinical Trial Update

Amarin's two ongoing Phase 3 clinical trials (MARINE and ANCHOR) were initiated near the beginning of 2010 to investigate the efficacy of AMR101 in reducing elevated triglyceride levels in two patient populations. As reported on August 10, 2010, randomization to dosing has been completed in the MARINE trial. Amarin now expects to report top-line results from the MARINE trial before the end of 2010, ahead of previously stated guidance of such report in early 2011.

In addition, at the date of this release, Amarin has screened all of the patients needed to complete the ANCHOR trial and, accordingly, has ceased screening additional patients. Most of the patients screened have been randomized to dosing cohorts of 2 grams, 4 grams or placebo of AMR101. Additional patients have been screened and are currently progressing through the six-to-eight week run-in period prior to randomization. Amarin now anticipates that it will complete randomization of the 650 patients targeted for the ANCHOR trial before the end of 2010, ahead of previously stated guidance of completing randomization in 2011. The company now expects to report top-line results from the ANCHOR trial in mid-2011.

With less than two months remaining before we expect to learn the results of the MARINE trial, it is a very exciting time at Amarin, commented Joseph Zakrzewski, Chairman and Chief Executive Officer. This can be attributed to the tremendous progress made by our Clinical Development and Operations group as well as the outstanding clinical investigators involved in both the ANCHOR and MARINE studies.

SEC Filing Status

Amarin Corporation plc is currently a foreign private issuer for U.S. Securities and Exchange Commission (SEC) reporting purposes. In accordance with SEC rules applicable to foreign private issuers, Amarin currently reports its financial results in accordance with International Financial Reporting Standards. Effective January 1, 2011, Amarin will no longer be a foreign private issuer and for SEC purposes will report its financial results in accordance with generally accepted accounting principles in the United States (US GAAP).

Conference Call and Webcast Information

Amarin will host a conference call today, November 10, 2010 at 11:00 am Eastern Time (4:00 pm UTC/GMT). To participate in the call, please dial (877) 407-0778 within the U.S or (201) 689-8565 from outside the U.S. Replay will be made available for a period of two weeks following the conference calls. To hear a replay of the call dial 1-877-660-6853 (inside U.S.) 1-201-612-7415 (outside U.S.). For both dial in numbers please use account number 286 and conference id 359371. The conference call can also be heard live via the investor relations section of the Company's website at www.amarincorp.com.

A replay of the call will be available via the Company's website.

About AMR101 Phase 3 Clinical Trials

The MARINE 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 fasting triglyceride levels greater than or equal to 500 mg/dL. Patients in this trial are characterized as having very high triglyceride levels as per NCEP ATPIII guidelines. Patient randomization in this trial has been completed at 229 patients. The single primary endpoint in the trial is the percentage change in triglyceride level from baseline after 12 weeks of treatment. Following completion of the 12-week double-blind treatment period, patients will be eligible to enter a 40-week, open-label, extension period. Results from the extension period are not required for regulatory approval. The Principal Investigator of the MARINE Study is Harold Bays, M.D., Medical Director Louisville Metabolic and Atherosclerosis Research Center, Kentucky.

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 between 200 mg/dL and 500 mg/dL who are 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 randomize approximately 650 patients into the study. The primary endpoint in the trial is the percentage change in triglyceride level from baseline after 12 weeks of

treatment. This study will also evaluate whether AMR101 is devoid of the LDL-C elevating effects commonly seen in patients with mixed dyslipidemia on statin therapy who take concomitant prescription omega-3 therapies. The Principal Investigator of the ANCHOR study is Christie M. Ballantyne, M.D., Methodist DeBakey Heart and Vascular Center, Houston, Texas. No prescription omega-3 based drug, such as AMR101, is currently approved in the U.S. for treating high triglyceride levels in statin-treated patients who have mixed dyslipidemia.

In both the MARINE and ANCHOR trials, all patients undergo a six-to-eight week washout period of lipid altering drugs, as well as diet and lifestyle stabilization, prior to randomization into the 12-week double-blind treatment period. Both the MARINE and ANCHOR trials received Special Protocol Assessment (SPA) agreements in 2009 from the U.S. Food and Drug Administration (FDA). Because the trials address separate and important patient populations the results from one trial may not be indicative of the results of the other trial.

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 two Phase 3 clinical trials, one for the treatment of patients with very high triglyceride levels and the other for the treatment of patients with high triglycerides with mixed dyslipidemia. Both of these Phase 3 trials are 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.

Contacts:

Investor Contact Information:

John F. Thero

President

In U.S.: +1 (860) 572-4979

investor.relations@amarincorp.com

Lee M. Stern

The Trout Group

In U.S.: +1 (646) 378-2922

lstern@troutgroup.com

Media Contact Information:

David Schull or Martina Schwarzkopf, Ph.D.

In U.S.: +1 (212) 845-4271 or +1 (212) 845-4292 (office)

+1 (347) 591-8785 (mobile)

david.schull@russopartnersllc.com

martina.schwarzkopf@russopartnersllc.com

Mark Swallow or David Dible

Citigate Dewe Rogerson

In U.K.: +44 (0)207 638 9571

mark.swallow@citigatedr.co.uk

Disclosure Notice

This press release contains forward-looking statements, including statements about the timing of clinical trial randomization, the timing of announcement of results from these trials, the timing of filing an NDA for AMR101 and the potential indications and market opportunity for AMR101 if approved by the U.S. Food and Drug Administration. 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 enrolment and randomization rates may not be predictive of future results; uncertainties relating to the timing of data collection and analysis for the ANCHOR and MARINE trials; 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.

###