AMARIN CORP PLC\UK
Form 6-K
September 14, 2005

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
OF THE SECURITIES EXCHANGE ACT OF 1934

September 13, 2005

Commission File Number 0-21392

AMARIN CORPORATION PLC
(Translation of registrant's name into English)

7 Curzon Street
London W1J 5HG
England
(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 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]

Attachment:

Material Events

(a) Amarin Corporation receives special protocol assessment from FDA for Phase III clinical trials for Miraxion.

This report on Form 6-K is hereby incorporated by reference in (a) the registration statement on Form F-3 (Registration No. 333-104748) of Amarin Corporation plc and in the prospectus contained therein, (b) the registration statement on Form F-3 (Registration No. 333-13200) of Amarin Corporation plc and in the prospectus contained therein, (c) the registration statement on Form F-3 (Registration No. 333-12642) of Amarin Corporation plc and in the prospectus contained therein, (d) the registration statement on Form F-3 (Registration No. 333-121431) of Amarin Corporation plc and in the prospectus contained therein and (e) the registration statement on Form F-3 (Registration No. 333-121760) 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be deemed a part of each such registration statement from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished by Amarin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.

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/ Jonathan S. Lamb
Name: Jonathan S. Lamb
Title: General Counsel & Company Secretary

Date: September 13, 2005

EXHIBIT INDEX

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AMARIN RECEIVES SPECIAL PROTOCOL ASSESSMENT FROM FDA FOR TWO PIVOTAL PHASE III CLINICAL TRIALS FOR MIRAXION IN HUNTINGTON'S DISEASE

LONDON, United Kingdom, 12th September, 2005 -- Amarin Corporation plc (NASDAQ: AMRN) today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) procedure for the design of two pivotal Phase III clinical trials of Miraxion(TM) (ultra-pure ethyl-EPA) in Huntington's disease. The Special Protocol Assessment (SPA) is a process under which the FDA provides evaluation and guidance on clinical trial protocols for Phase III trials.

Rick Stewart, Chief Executive Officer of Amarin, commented; "Reaching agreement with the FDA on the trial designs is a positive development for Amarin. This is a major milestone for the company and we look forward to immediate enrollment in the U.S. trial."

The U.S. and European trials will be multi-centre, randomized, double blind, placebo-controlled studies of Miraxion at 43 sites in the U.S. and up to 28 sites in Europe. The trials are expected to involve a total of up to 540 Huntington's disease patients with approximately 300 in the U.S. Phase III trial and approximately 240 in the European Phase III trial over a 6 month period. Patients in the U.S. trial will participate in a further 6-month extension

period.

The Huntington Study Group (H.S.G.), based at the University of Rochester, will conduct the U.S. clinical trial on behalf of Amarin. The H.S.G. is a non-profit group of physicians and other health care providers from medical centers in the U.S., Canada, Europe and Australia, experienced in the care of Huntington's disease patients and dedicated to clinical research of Huntington's disease. The European clinical trial will be conducted in collaboration with EURO-HD and ICON, a leading contract research organization (CRO). EURO-HD is a non-profit group of physicians and other healthcare professionals dedicated to the research and care of Huntington's disease patients.

The primary endpoint of the trials will be to determine whether Miraxion taken 2 grams per day (1gram twice daily) results in clinically and statistically significant changes in the Total Motor Score-4 subscale of the Unified Huntington's Disease Rating Scale (UHDRS).

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About Amarin Corporation
Amarin Corporation plc is a neuroscience company focused on the development and commercialization of novel drugs for the treatment of central nervous system disorders. Miraxion, Amarin's lead development compound, is in phase III development for Huntington's disease and in phase II development for depressive disorders.

For press releases and other corporate information, visit our website at http://www.amarincorp.com.

DISCLOSURE NOTICE: The information contained in this document is as of 12th September, 2005. Amarin assumes no obligation to update any forward-looking statements contained in this document as a result of new information or future events or developments.

This document contains forward-looking statements about Amarin's financial condition, results of operations, business prospects and products in research that involve substantial risks and uncertainties. You can identify these statements by the fact that they use words such as "will", "anticipate", "estimate", "project", "intend", "plan", "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or events. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: the success of Amarin's research and development activities; decisions by regulatory authorities regarding whether and when to approve Amarin's drug applications, as well as their decisions regarding labelling and other matters that could affect the commercial potential of Amarin's products; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the success with which developed products may be commercialized; competitive developments affective Amarin's products under

development; the effect of possible domestic and foreign legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including under Medicaid and Medicare in the United States, and involuntary approval of prescription medicines for over-the-counter use; Amarin's ability to protect its patents and other intellectual property; claims and concerns that may arise regarding the safety or efficacy of Amarin's product candidates; governmental laws and regulations affecting Amarin's operations, including those affecting taxation; Amarin's ability to maintain sufficient cash and other liquid resources to meet its operating requirements; general changes in U.K. and U.S. generally accepted accounting principles; growth in costs and expenses; and the impact of acquisitions, divestitures and other unusual items, including Amarin's ability to integrate its acquisition of Amarin Neuroscience Limited. A further list and description of these risks, uncertainties and other matters can be found in Amarin's Annual Report on Form 20-F for the fiscal year ended December 31, 2004, and in its Reports of Foreign Issuer on Form 6-K filed with the SEC.