AMARIN CORP PLC\UK
Form 8-K
July 08, 2013

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): July 8, 2013

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales	**000-21392**	**Not applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2, 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

Commercialization Update

Amarin Corporation plc, or the Company, is providing the following information regarding its business.

Vascepa® (icosapent ethyl) became commercially available in the United States by prescription in January 2013 when the Company commenced sales and shipments to its network of U.S.-based wholesalers. On January 28, 2013, the Company commenced its full commercial launch of Vascepa in the United States. In preparation for its commercial launch, the Company hired and trained a direct sales force of approximately 275 sales representatives. The Company also employs various marketing and medical affairs personnel to support its commercialization of Vascepa.

In June 2013, the Company completed its fifth full calendar month of marketing and selling Vascepa. As of the date hereof, based on monthly compilations of data provided by a third party, the estimated number of normalized total Vascepa prescriptions (TRx) for the first four calendar months were as follows: 3,224 (Feb); 7,260 (Mar); 12,314 (Apr); and 16,076 (May). As of the date hereof, based on weekly compilations of data from a third party source for the four weeks ended June 28th, the estimated number of normalized total Vascepa prescriptions (TRx) for June is 18,367 (partial data available). Data provided for June excludes the last two calendar days of June; weekly compilations generally tend to understate the number of prescriptions in the monthly compilations. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month s supply). The data reported above is based on information made available to the Company from a third party resource and may be subject to adjustment and may overstate or understate actual prescriptions.

As of June 30, 2013, over 7,300 clinicians have written prescriptions for Vascepa.

Although the Company believes these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. In addition, as described in the Company s most recent quarterly report on Form 10-Q, because of its limited selling history, during the quarter ended March 31, 2013, the Company only recognized revenue on product that it could substantiate being resold by retailers, such as pharmacies, for purposes of fulfilling prescriptions. Those prescription data may differ from the prescription data provided above or otherwise reported by third parties.

Because of its limited selling history, the Company does not believe that it can provide a reasonably accurate forecast of Vascepa prescriptions or revenues. The Company provides no guidance regarding anticipated levels of Vascepa prescriptions or revenues and no such guidance should be inferred from the operating metrics described above. The Company believes that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with

the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could change in prescriber sentiment and other factors. The Company believes investors should consider the Company s results over several quarters, or longer, before making an assessment about potential future performance.

The commercial launch of a new pharmaceutical product is a complex undertaking, and the Company s ability to effectively and profitably launch Vascepa will depend in part on its ability to generate market demand for Vascepa through education, marketing and sales activities, its ability to achieve market acceptance of Vascepa, its ability to generate product revenue and its ability to receive adequate levels of reimbursement from third-party payers. See *Risk Factors Risks Related to the Commercialization and Development of Vascepa* in the Company s most recent quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission.

By filing this information, the Company makes no admission as to the materiality of any information in this Current Report on Form 8-K. The information contained in this Current Report on Form 8-K is intended to be considered in the context of the Company s filings with the Securities and Exchange Commission and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

This Current Report on Form 8-K contains forward-looking statements, including statements about the commercial launch of Vascepa, including the number of total prescriptions to date and current sales trends. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in its previous filings with the U.S. Securities and Exchange Commission, the Company s ability to effectively commercialize Vascepa will depend in part on its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, and to obtain and maintain patent protection and regulatory exclusivity. A list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin s filings with the U.S. Securities and Exchange Commission, including 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.

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: July 8, 2013

Amarin Corporation plc

By: /s/ John Thero
John Thero
President