

AMARIN CORP PLC\UK

FORM 8-K (Current report filing)

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**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): January 5, 2017

Amarin Corporation plc
(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction
of incorporation)

0-21392
(Commission
File Number)

Not applicable
(I.R.S. Employer
Identification No.)

**2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2,
Ireland**
(Address of principal executive offices)

Not applicable
(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))
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Item 2.02. Results of Operations and Financial Condition.

On January 5, 2017, Amarin Corporation plc, or the Company, issued a press release providing preliminary unaudited fourth quarter and annual 2016 financial guidance and its financial outlook for 2017. A copy of the Company's press release is furnished herewith as Exhibit 99.1.

The information set forth under Item 2.02 and in Exhibit 99.1 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 5, 2017

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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: January 5, 2017

Amarin Corporation plc

By: /s/ John Thero

John Thero

President and Chief Executive Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 5, 2017



Amarin Provides Preliminary 2016 Results and 2017 Outlook

Unaudited Full-Year 2016 Net Product Revenue Estimated to Modestly Exceed Upper End of \$112 to \$125 Million Previously Guided Range

Anticipate Full-Year 2017 Net Product Revenues Between \$155 Million and \$165 Million; Commercial Operations Positioned to be Cash Flow Positive for 2017

BEDMINSTER, N.J., and DUBLIN, Ireland, January 5, 2017 — Amarin Corporation plc (NASDAQ: AMRN), today provided a business update, including an update on 2016 revenue guidance and 2017 revenue forecast. Amarin plans to discuss these results and expectations with investors in conjunction with the 35th Annual J.P. Morgan Healthcare Conference in San Francisco, California.

2016 Operational Progress

Product Revenue: Continued growth in both new and recurring Vascepa prescriptions in Q4 2016 resulted in increased market share and directly supported record revenue levels for Q4 and full-year 2016. The company estimates full-year 2016 product revenues, on a GAAP basis subject to audit, modestly exceeded \$125 million, representing growth of more than 50% over reported 2015 net product revenue of \$81 million. As reported in the past, inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescribing trends and other factors. During 2016, predominantly in Q2, wholesaler inventory levels increased based on estimated days of inventory on hand. In addition, regional stocking of Vascepa expanded at certain retail pharmacies, likely due to higher volume sales of Vascepa. Amarin estimates that these changes in channel inventory increased net product revenues by approximately \$3 to \$6 million during 2016 and that without these increases full-year 2016 net product revenues would have been in the upper end of the company's previously provided guidance of \$112 to \$125 million. Estimated prescriptions of Vascepa, based on data from Symphony Health Solutions, increased more than 50% in 2016 over 2015 with Vascepa market share for both total prescriptions (TRx) and new prescriptions (NRx) exceeding 20% of the prescription omega-3 market.

REDUCE-IT: Five years of the six-year estimated duration for this 8,175 patient cardiovascular outcomes study are now complete. Cardiovascular risk, despite LDL-cholesterol management via statin therapy, remains high. REDUCE-IT is the first multi-national prospective cardiovascular outcomes study ever conducted to evaluate the effect of treating patients who despite statin use have elevated triglyceride levels with a therapy that significantly lowers triglycerides. REDUCE-IT is also the first cardiovascular outcomes study to test a high, 4-gram per day dose of a pure-EPA omega-3 product. REDUCE-IT results, assuming success, are intended to support significantly expanded promotion and use of Vascepa to treat at-risk patients to lower the rates of major adverse cardiovascular events. Tens of millions of people in the United States alone have elevated triglycerides.

REDUCE-IT is a cardiovascular events driven study designed to provide 90% power to detect a 15% relative risk reduction between the patient arm treated with Vascepa added to well-controlled statin therapy compared to the patient arm treated with placebo added to well-controlled statin therapy. The study is designed to be completed upon reaching 1,612 primary cardiovascular events which Amarin estimates will occur near the end of 2017 with results expected to be reported and published in 2018. The study is being conducted under a special protocol assessment (SPA) agreement with the FDA which was amended and re-affirmed with the FDA in 2016 along with finalization of the study's statistical plan. A pre-specified interim efficacy and safety analysis is scheduled to be conducted by the independent data monitoring committee (DMC) at approximately 80% of the total 1,612 primary cardiovascular events targeted for completion of the study. Amarin anticipates that onset of 80% of the target events will be reached in the first half of 2017 and that the interim analysis will be conducted before the end of Q3 2017. Consistent with the trial design, Amarin continues to believe that the REDUCE-IT study is most likely to continue to completion of 100% of the target events as the requirements for early stoppage for overwhelming efficacy are high.

Balance Sheet: Amarin ended 2016 with approximately \$98 million in cash and approximately \$20 million in net accounts receivable. The company also has \$15.1 million of outstanding exchangeable debt which, as previously disclosed, may be put to the company on January 19, 2017. The company is positioned to be cash flow positive for 2017 from commercial operations excluding costs for REDUCE-IT, interest and royalties.

“We are very pleased with the progress Amarin made in 2016 with revenue growth, execution on REDUCE-IT, expense management, increased productivity, lowered product cost and improved gross margins, strengthening of our management team, securing new chemical entity designation, publication of scientific findings, expanded managed care coverage, international expansion and numerous other advances that individually and collectively position Amarin for continued growth and positive execution,” commented John F. Thero, president and chief executive officer. “We expect 2017 to be an exciting year for Amarin as we build upon this progress and prepare for results of the REDUCE-IT study.”

2017 Objectives and Financial Outlook

Amarin's core strategy remains unchanged. Our primary objectives are to:

- 1) Continue to aggressively grow revenues;
- 2) Complete the REDUCE-IT study on a timely basis while maximizing the likelihood of success; and
- 3) Operate in a cost effective, opportunistic manner.

The company begins 2017 expecting to achieve the following results:

U.S. Product Revenues : Estimated to reach between \$155 and \$165 million with quarterly variability continuing based on seasonal factors.

International Expansion : Clarification expected from China FDA regarding the clinical and regulatory path for Vascepa approval in China. First country approval for marketing Vascepa in the Middle East expected before the end of 2017.

REDUCE-IT : As per above, onset of 80% of primary cardiovascular events to occur in the first half of 2017, the pre-specified 80% interim look to be conducted by the DMC before the end of Q3 2017 and targeted final primary cardiovascular event (the 1,612th patient with a primary cardiovascular event) to be reached near the end of 2017 with trial results presented and published in 2018. A publication on the clinical design of REDUCE-IT is anticipated in or before mid-2017. Amarin will remain blinded to results of the REDUCE-IT study until after the study is stopped and the database is locked at either the second interim analysis or at the final analysis.

Spending : Excluding commercial spending for anticipated expansion post successful REDUCE-IT results, sales, general and administrative expenses, excluding non-cash costs, to increase by less than 10% in 2017 compared with 2016 with the exceptions of increased co-promotion fees anticipated to be paid to Kowa associated primarily with anticipated increased revenue growth. Amarin anticipates that R&D expenses in 2017, excluding non-cash costs, will remain relatively consistent with 2016 levels with the majority of such spending devoted to the ongoing REDUCE-IT trial.

Commercial Preparations for Expansion Post-REDUCE-IT : Our intention is to significantly expand promotion of Vascepa upon positive results from REDUCE-IT. However, currently we do not intend to significantly expand the size of our sales force until after the REDUCE-IT results are available. Rather, as has been successful in the past two years, we intend to continue to work to improve the productivity of our existing sales team while planning and evaluating how to best expand Vascepa promotion assuming positive REDUCE-IT results. We anticipate that research and other activities to support such preparations will cost \$3 to \$5 million in 2017. In addition, we anticipate increasing purchases of supply for Vascepa in 2017 both to support anticipated revenue growth in 2017 and to prepare for REDUCE-IT success.

Cash Flow : Assuming projected revenue growth and spending assumptions per above, we expect Amarin to be cash flow positive from commercial operations for 2017, excluding REDUCE-IT, interest and royalties.

Amarin plans to provide further details regarding its 2016 results and 2017 outlook in connection with the company's annual report on Form 10-K in late February 2017.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of either 1 gram or 0.5 grams of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101.

FDA-approved Indication and Usage

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence $> 2\%$ and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction $> 3\%$ and greater than placebo.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the FDA as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa[®] (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, omega-3 fatty acid product available by prescription. For more information about Vascepa, visit www.vascepa.com. For more information about Amarin, visit www.amarincorp.com.

Forward-looking statements

This press release contains forward-looking statements, including statements about the future commercialization of Vascepa; expectations regarding Vascepa sales and resulting revenue amounts and company expenses for the fourth quarter of 2016 and for the years ended December 31, 2016 and 2017; expectations related to Amarin's 2017 financial outlook and potentially ending 2017 as cash flow positive from commercial operations; including expectations for continued event rates, interim data review and results announcements in Amarin's REDUCE-IT cardiovascular outcomes study; expectations regarding the continued effect and scope of the court-expanded ability to promote Vascepa and to educate healthcare professionals regarding the efficacy and safety of Vascepa; expectations related to the interim and final outcome of the REDUCE-IT study and the successful completion of the REDUCE-IT study; statements regarding quarterly changes and seasonal effects on Vascepa sales; and statements regarding the potential efficacy, safety and therapeutic benefits of Vascepa, regulatory reviews and approvals of Vascepa internationally and related commercial potential. 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, Amarin's ability to effectively commercialize Vascepa will depend in part on its ability to continue to effectively finance its business (including the REDUCE-IT study), efforts of third parties, 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, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that historical REDUCE-IT clinical trial enrollment and randomization rates may not be predictive of future results and related cost may increase beyond expectations; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for intended uses; the risk associated with pending litigation; and the risk that patents may not be upheld in patent litigation and applications may not result in issued patents. A further 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. Amarin 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.

Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (www.amarincorp.com), our investor relations website (<http://www.amarincorp.com/investor-splash.html>), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls

and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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