

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 4, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On January 4, 2018, Amarin Corporation plc, or the Company, issued a press release providing preliminary unaudited fourth quarter and annual 2017 financial guidance, its financial outlook for 2018 and anticipated milestones for 2018. 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 4, 2018

* * *

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 4, 2018

Amarin Corporation plc

By: /s/ John Thero

John Thero

President and Chief Executive Officer



Amarin Provides Preliminary 2017 Results and Provides 2018 Outlook

Unaudited Full-Year 2017 Net Product Revenue Estimated Between \$177 and \$180 Million, Exceeding Upper End of Previously Provided Guidance, with Fourth Quarter Estimate Between \$51 and \$54 Million

Anticipate 2018 Net Product Revenue Growth of Approximately \$50 Million or \$230 Million for Full-Year 2018 Net Product Revenue with Guidance to Be Updated After REDUCE-IT Results, Expected Before End of Q3 2018

BEDMINSTER, N.J. and DUBLIN, Ireland, Jan. 4, 2018 (GLOBE NEWSWIRE) — Amarin Corporation plc (NASDAQ:AMRN), today provided a business update, including an update on 2017 revenue guidance, 2018 revenue forecast and potential 2018 milestones. Amarin plans to discuss these results and expectations with investors in connection with the 36th Annual J.P. Morgan Healthcare Conference in San Francisco, California, at which Amarin will be presenting.

Preliminary (unaudited) 2017 Financial Results

Record Revenue Levels: Net product revenue for 2017 are estimated to have reached between \$177 million and \$180 million, including estimated net revenues of \$51 million to \$54 million in Q4 2017. Both the full year and Q4 2017 results represent record revenue levels for Amarin. These results, which are subject to audit, are estimated to have exceeded the upper end of the company's previously reported guidance for 2017 net product revenue and represent an increase of approximately \$48 million to \$51 million (approximately 37% to 40%) over full year 2016 results. Both full year and Q4 2017 net revenue growth were driven by increased prescriptions for Vascepa[®] (icosapent ethyl) capsules. Wholesaler inventory levels of Vascepa were within normal industry ranges at the end of 2017.

Balance Sheet: Amarin ended 2017 with approximately \$73.6 million in cash, approximately \$44 million in net accounts receivable and approximately \$29 million in inventory. During 2017, the company's net cash outflows, excluding the \$13.7 million net proceeds of exchangeable debt transactions disclosed in Q1 2017, were approximately \$38.4 million, comprised of net cash outflow in Q1, Q2, Q3 and Q4 of approximately \$15.9, \$10.6, \$6.4 and \$5.5 million, respectively. The company believes that it was effective in 2017 in controlling its cash expenditures to achieve greater contribution from the growing revenues of its commercial operations. The company achieved its stated objective of being net cash flow positive in 2017 after excluding, on a non-GAAP basis, the net proceeds of the Q1 2017 exchangeable debt transactions and excluding greater than \$40 million of payments for R&D (primarily REDUCE-IT related) and approximately \$17 million of payments for financing-type costs (e.g., interest and royalties).

The company's accounts receivable were all current as of year-end and the company has not factored or otherwise borrowed against accounts receivable, inventory or other assets. Due in part to recent U.S. tax reform, Amarin anticipates further increasing its valuation allowance against deferred tax assets in Q4 2017, which will result in a non-cash charge for income taxes of as much as \$11.1 million. The deferred tax assets relate to the company's U.S. subsidiary. The valuation allowance does not change the amount the company pays in income taxes and does not have any impact on the company's tax loss carryforwards, primarily in Ireland, which are estimated at over \$570 million at the end of 2017. At the end of 2017, the company's debt consisted of \$30 million face value of exchangeable debt, which cannot be put to the company before 2022, and the continuing 10% royalty-like obligation on Vascepa net revenue.

Gross Margin: In addition to the company's increased revenues and improved cash flow, in 2017 Amarin also increased its gross margin on product sales to approximately 75% while taking steps to ensure that it has capacity to support a broad-range of potential revenue scenarios following REDUCE-IT results, including capacity to provide supply to support the potential of over \$1 billion in product revenues in 2019. These steps to expand supply capacity are intended to provide the company with flexibility to support business growth. At this time, the company is not providing guidance regarding projected Vascepa net revenue levels after REDUCE-IT results and does not plan to provide such guidance until after the results of this important study are known.

More than 150,000 patients currently benefit from Vascepa prescriptions.

2018 Financial and Operational Guidance

Amarin's core strategy entering 2018 remains unchanged. Its primary objectives are as follows:

- 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's outlook for 2018 is divided between the timeframes before and after anticipated results of the REDUCE-IT cardiovascular outcomes study. REDUCE-IT, which has been the centerpiece of the company's strategy, is expected to be completed in 2018 with top-line results reported before the end of Q3 2018. The degree of cardiovascular relative risk reduction achieved in this study will impact future levels of Vascepa promotion and revenues. Assuming that statistically significant relative risk reduction of at least 15% is achieved and, as expected, there is no major negative safety issue, the company intends to expand its U.S.-based sales force promptly after the outcomes study results. As previously

disclosed, Amarin is planning to grow from its current level of approximately 150 sales representatives calling on targeted physicians in limited geographies, to more than 400 sales representatives with considerably broader reach and increased frequency of sales calls. Amarin plans to support this sales force growth with increased promotional outreach to consumers and other expanded promotion of Vascepa.

The financial guidance described below reflects expectations prior to the impact of REDUCE-IT results. The company intends to update guidance after such outcomes study results are known. The company begins 2018 expecting to achieve the following results:

U.S. Product Revenue : Without adjustment for the impact of REDUCE-IT results, the company estimates full year 2018 net product revenue from Vascepa will grow approximately \$50 million to approximately \$230 million. Amarin estimates in each quarter of 2018 net product revenue should grow approximately 30% or more as compared to the same quarter in 2017. This guidance for 2018 will be updated after REDUCE-IT results. The company anticipates quarterly variability to continue with respect to net product revenue. For example, seasonal factors associated with large beginning of the year insurance deductibles for patients under certain of their medical insurance plans has historically slowed prescription rates in the first quarter of each year. Amarin estimates that its net product revenue in Q1 2018 will be between \$45 and \$48 million, representing significant growth over the same period in the prior year. Further, consistent with prior year results, Amarin anticipates that Q2 2018 results will rebound with net product revenue anticipated in Q2 2018 of \$55 million or more.

R&D Spending : The REDUCE-IT study, which commenced in December 2011, is expected to be completed in 2018 with top-line results made public before the end of Q3 2018 and, if all goes as expected, publication and presentation of the results at a medical congress before the end of 2018. REDUCE-IT R&D costs generally have been between \$10 and \$15 million per quarter with variability from quarter to quarter. This level of spending and quarterly variability of spending are likely to continue until the study is completed and published. Savings anticipated to be realized after patients in the study complete their final study visits are anticipated to be offset by costs of preparing for publication and other activities intended to support robust reporting and presentation of results from this first ever study of the large population of patients being evaluated in REDUCE-IT. While the company is evaluating various potential product development projects to emphasize after REDUCE-IT, the primary thrust of the company's development efforts in 2018 will be related to completing the REDUCE-IT study and then publishing and presenting its results.

SG&A Spending: As previously disclosed, after learning the results of the REDUCE-IT study, assuming the results are positive, the company intends to significantly expand the size of its U.S.-based sales force and to otherwise significantly expand commercial promotion of Vascepa in the U.S., including direct to consumer promotion. Prior to REDUCE-IT results, the company, consistent with its growth over the past four years, will work to continue to increase sales productivity from its existing field team. During the period prior to REDUCE-IT results, the company intends to continue to expand medical education and market awareness initiatives. In addition, Amarin intends to pilot test new promotional initiatives for potential broader application following REDUCE-IT results.

Balance Sheet : As previously disclosed, based on its current cash balance and anticipated net cash flows, Amarin believes that it has adequate cash to get to REDUCE-IT results and additional capital may be warranted to expand promotion of Vascepa based on anticipated successful results of the REDUCE-IT study. During the period of 2018 which is prior to REDUCE-IT results, the company expects to be net cash flow positive, excluding interest, royalties and payments for REDUCE-IT R&D and other costs incurred (mostly medical affairs and supply-related expenditures) in preparation for positive REDUCE-IT results. However, these results will continue to vary from quarter to quarter, including, as seen in prior years, the impact of certain annual payments in Q1 which will likely result in Q1 2018 net cash outflows exceeding Q4 2017 results. The company anticipates that accounts receivable will grow in proportion to net revenue growth and remain current. The company anticipates that inventory balances will grow in proportion to anticipated revenue growth, plus up to approximately \$10 million for incremental inventory build prior to REDUCE-IT results. The company periodically reviews proposals for borrowing against accounts receivable and inventory balances but has not made any commitment to such potential arrangements.

2018 Anticipated Milestones

REDUCE-IT : This potential landmark cardiovascular outcomes study has accumulated more than 30,000 patient years of study. Estimated timing for its completion is as follows:

First patient last visit:	March 2018
Report of top-line results:	Before end of Q3 2018
Publication/presentation at medical congress:	Before end of Q4 2018

Closing the REDUCE-IT study is a monumental process, as the REDUCE-IT study is being conducted at over 400 clinical sites in 11 countries. It is estimated that approximately 1,612 of the 8,175 patients in this placebo-controlled study will have experienced a primary major adverse cardiovascular event during the term of this study with patients averaging between four and five years of study. Amarin continues to be blinded to the results of the study and will remain blinded to the results of the study until the study is completed and the database is locked. Amarin believes that this study will lead to a new era in cardiovascular care with a pragmatic, cost-effective therapy that is well tolerated and can benefit potentially tens of millions of at-risk patients.

In 2017, Amarin supported publication or presentation of 25 scientific papers and posters. For example, data was presented at the American Heart Association’s annual scientific sessions in November 2017 from two recent real-world-evidence (RWE) studies which each showed that patients with well-controlled LDL-cholesterol are at significantly higher risk of cardiovascular events with correspondingly higher costs of medical care if they have high triglyceride levels. Amarin anticipates continuing to support numerous scientific papers and posters in 2018, both before and after REDUCE-IT results.

International Expansion: Internationally, Amarin’s partner in the Middle East, Biologix, is working towards a series of country-by-country approvals allowing for promotion of Vascepa with the potential for the first such approval to be received in early 2018. While Amarin does not expect to report significant revenues from international sources in 2018, it is pleased to be nearing these important milestones. In parallel, Amarin’s partner for Vascepa in Greater China, Eddingpharm, continues to pursue clinical study of Vascepa with the intention of making Vascepa the first approved prescription drug of its type in Mainland China and other markets in that region. Amarin is also actively working with its newest partner, HLS Therapeutics, towards seeking regulatory approval to commercialize Vascepa in Canada.

Comment from Amarin’s President and CEO

“2017 was another year of tremendous accomplishment for Amarin as we achieved record product revenues, advanced our landmark outcomes study towards completion and otherwise made broad operational progress to support anticipated growth in 2018 and beyond,” commented John F. Thero, president and chief executive officer. Mr. Thero continued, “We enter 2018 with a strong, experienced and dedicated team of Amarin employees and collaborators and a terrific product in Vascepa. We also enter 2018 with expectations that our outcomes study will be successful and confidence that with such success we will be well positioned to improve preventative cardiovascular care for at-risk patients while accelerating Amarin’s growth. It should be an exciting and positive year.”

Amarin plans to provide further details regarding its 2017 results and 2018 outlook in connection with the company’s annual report on Form 10-K when issued near the end of February 2018.

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 an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin’s first FDA approved product, is a highly-pure, 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.

About REDUCE-IT

Amarin’s clinical development program for Vascepa includes a trial known as the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011. REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or

any triglyceride lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150-499 mg/dL). A large portion of the male and female patients enrolled in this outcomes study are anticipated to also be diagnosed with type 2 diabetes. As reported previously, Amarin expects to announce top-line results of this important study before the end of Q3 2018.

Additional information on clinical studies of Vascepa can be found at www.clinicaltrials.gov.

About VASCEPA® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting 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. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

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 United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. 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.

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 2017 and for the years ended December 31, 2017 and 2018 and inclusive quarterly periods; expectations related to Amarin's 2018 financial outlook; expectations for continued event rates, results and related announcement timing associated with Amarin's REDUCE-IT cardiovascular outcomes study; expectations regarding the ability to promote Vascepa and to educate healthcare professionals regarding the efficacy and safety of Vascepa; expectations related to 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, 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 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 that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. 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 Amarin communicates with its investors and the public using the company website (<http://www.amarincorp.com/>), the investor relations website (<http://investor.amarincorp.com/>), 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 Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a

regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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