

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): April 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 April 4, 2018, Amarin Corporation plc, or the Company, issued a press release titled “Amarin Updates First Quarter Revenue Guidance, Reiterates Full Year Guidance and Updates on REDUCE-IT Cardiovascular Outcomes Study Progress and Vascepa® Promotion Initiatives” providing an update on its financial results for the first quarter of 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 8.01. Other Events.

On April 4, 2018, the Company issued a press release titled “Amarin’s REDUCE-IT Cardiovascular Outcomes Study Reaches 100% Mark for Estimated Onset of Target Primary Major Adverse Cardiovascular Events.” A copy of the Company’s press release is filed herewith as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release, dated April 4, 2018, titled “Amarin Updates First Quarter Revenue Guidance, Reiterates Full Year Guidance and Updates on REDUCE-IT Cardiovascular Outcomes Study Progress and Vascepa® Promotion Initiatives”</u>
99.2	<u>Press Release, dated April 4, 2018, titled “Amarin’s REDUCE-IT Cardiovascular Outcomes Study Reaches 100% Mark for Estimated Onset of Target Primary Major Adverse Cardiovascular Events”</u>

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: April 4, 2018

Amarin Corporation plc

By: /s/ John Thero

John Thero

President and Chief Executive Officer

Exhibit Index

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99.2	Press Release, dated April 4, 2018, titled “Amarin’s REDUCE-IT Cardiovascular Outcomes Study Reaches 100% Mark for Estimated Onset of Target Primary Major Adverse Cardiovascular Events”



Amarin Updates First Quarter Revenue Guidance, Reiterates Full Year Guidance and Updates on REDUCE-IT Cardiovascular Outcomes Study Progress and Vascepa® Promotion Initiatives

Over 97% of Final Patient Visits in REDUCE-IT Completed or Scheduled for Near-Term Completion

BEDMINSTER, N.J., and DUBLIN, Ireland, April 4, 2018- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced an update to its revenue guidance for the first quarter of 2018, reiteration of full year revenue guidance, further progress towards completing its potential landmark cardiovascular outcomes study, REDUCE-IT, and initiation of previously announced Vascepa® promotion initiatives.

Revenue Guidance

Based on lower than expected orders from Amarin's wholesaler customers attributed to seasonal factors related primarily to patients' beginning of the new year insurance policy deductible amounts, Amarin estimates that net product revenue for its first fiscal quarter, the quarter ended March 31, 2018, is likely to be approximately \$43 million, which represents an estimated increase of 25% to 30% over net product revenue in the same period of the prior year. At the beginning of Q1 2018, the company estimated net product revenue for the quarter would be \$45 to \$48 million. With respect to full year 2018 net product revenue expectations, Amarin continues to believe that it is on track to achieve product revenue of at least \$230 million, with such guidance planned to be updated after REDUCE-IT results.

Historically, first quarter net product revenue from Vascepa® sales are negatively impacted by seasonal factors related to patient insurance deductibles. In 2018, Amarin believes that increased beginning of the year insurance policy deductible amounts at several payor plans made drug coverage more difficult for a significant number of affected patients. The company also believes that wholesaler customers, likely in response to slower than fourth quarter of 2017 Vascepa demand due to these seasonal effects, decreased their levels of Vascepa inventory. Without such decreases in inventory levels at wholesalers, estimated net product revenue for the quarter ended March 31, 2018 would have been approximately \$2 million higher.

New prescriptions (NRx) of Vascepa reached record levels in March 2018 based on data from Symphony Health and IQVIA. The seasonal factors described above appear to most impact prescription refills by patients with prior Vascepa prescriptions. Although it appears to be taking longer on average than last year, Amarin anticipates that most patients have largely worked through their beginning of the year insurance deductibles late in the first quarter and will begin to resume filling prescriptions for Vascepa.

Medical insurance coverage for Vascepa remains strong for most patients with commercial or Medicare Part D insurance coverage. Beginning of year deductibles under payor plans are not drug specific. Based on prescription data from third-party sources, Amarin believes that other branded therapies, particularly those for asymptomatic conditions, also experienced prolonged seasonal impact in the first quarter of 2018.

With respect to Q1 2018, the company noted that total prescription (TRx) growth reported by third-party sources reflect stronger growth than product shipments to wholesalers upon which revenues are recognized. Historically prescription growth reported by such third parties has been consistent with growth in product shipments on an annual basis with some quarterly variability observed in these estimates.

The company intends to provide further updates regarding its operational progress and financial results including in connection with its quarterly report on Form 10-Q anticipated in early May.

REDUCE-IT Final Patient Visits Progressing as Planned

Amarin reported that greater than 97% of patients who are alive and active in the REDUCE-IT study have either completed their final visit or are scheduled to complete their final visit in the coming weeks with work ongoing to schedule the remaining patients for their final study-related visits. This progress is consistent with the company's objective of reporting top-line results from this important study before the end of Q3 2018.

As separately reported today, Amarin estimates that the onset of the 1,612th primary major adverse cardiovascular event (MACE) has occurred in the REDUCE-IT study and anticipates that MACE from the study will be adjudicated through Q2 2018. This timing is also consistent with reporting top-line results before the end of Q3 2018.

Amarin is intentionally blinded to the results of the study and will remain blinded to such results until after the study is completed and the database is locked.

Expanded Vascepa® Promotion and Disease Awareness Initiatives on Track

Amarin recently commenced its previously described pilot awareness initiative including an updated website at www.vascepa.com and limited airings of a television commercial based on the current indication for Vascepa. The company was pleased by the participation of professional societies and patient advocacy groups for the recent first annual National Triglycerides Day on March 28th. Patients are encouraged to learn more about their risks for cardiovascular disease, including learning more about their triglyceride levels and to consult with their healthcare professionals.

"We look forward to continuing to educate healthcare professionals regarding Vascepa based on its current label and supporting data while advancing REDUCE-IT to provide broadly sought outcomes

data,” stated John F. Thero, president and chief executive officer. “Recent studies by other companies highlight that significant cardiovascular risk remains beyond well-controlled cholesterol management. I have great confidence in the unique clinical attributes of Vascepa to potentially mitigate a substantial portion of this residual cardiovascular risk.”

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. 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 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, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. 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.

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.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of \$500 billion.^{1, 2}

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease.^{3, 4, 5, 6}

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding net product revenue from sales of Vascepa for the first quarter of 2018, for the year ended December 31, 2018 and inclusive quarterly periods; expectations related to seasonal trends thought to affect sales of Vascepa and their anticipated impact on Vascepa sales in future periods; expectations for continued final patient visits, estimated event rates, results and related announcement timing associated with Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the successful completion of the REDUCE-IT study; and expectations regarding the ability to promote Vascepa and to educate healthcare professionals regarding the efficacy and safety of Vascepa. 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 the sale of pharmaceutical products, research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations 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 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 annual report on Form 10-K. 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.

References

¹ American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.

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Amarin's REDUCE-IT Cardiovascular Outcomes Study Reaches 100% Mark for Estimated Onset of Target Primary Major Adverse Cardiovascular Events

On Track to Report REDUCE-IT Results Before the End of Q3 2018

BEDMINSTER, N.J., and DUBLIN, Ireland, April 4, 2018- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced today that its REDUCE-IT cardiovascular outcomes study of Vascepa® (icosapent ethyl) is estimated to have reached the onset of the targeted 1,612 primary major adverse cardiovascular events (MACE) specified in the study design. The REDUCE-IT cardiovascular outcomes study began with patient dosing at the end of 2011. The onset of the targeted number of cardiovascular events in REDUCE-IT is an important milestone toward completion of this potentially landmark study.

The estimated onset of the targeted number of cardiovascular events in REDUCE-IT is based on documented events having exceeded 90% of target as reported in January 2018, subsequently reported MACE in the adjudication process, and projected events based on standard industry methodology. The MACE onset projection was made by independent statisticians and reviewed by Amarin and the independent steering committee for the trial. Each group is blinded to the study results. Amarin anticipates that MACE from the study will be adjudicated through Q2 2018, consistent with the company's objective of reporting top-line results from this important study before the end of Q3 2018.

As previously reported, completion of the REDUCE-IT study does not require reaching exactly 1,612 MACE. The actual number of events is likely to differ from this study design target. The powering assumptions for the study were based on 1,612 MACE with 90% power to detect a 15% relative risk reduction. A final cumulative MACE tally from inception date of the study which is slightly above or below 1,612 MACE is not anticipated to have a significant impact on the overall powering of the study results.

Amarin maintains its guidance to report top-line results from the study before the end of Q3 2018.

"We are excited to be nearing conclusion of this potentially landmark cardiovascular outcomes study," commented Dr. Steven Ketchum, president of R&D and chief scientific officer of Amarin. "We appreciate the continued dedication of patients participating in this important study and the continued commitment and hard work at the clinical sites and by the many professionals involved in study conduct and completion. We will work diligently to rapidly roll-up and report the results of the study in the hope that such results can lead to better informed preventative care of patients at high cardiovascular risk."

Amarin is intentionally blinded to the results of the study and will remain blinded to such results until after the study is completed and the database is locked. Final patient visits will be followed by adjudication of newly reported cardiovascular events in the study, completing data entry for the greater than 33,000 patient years of study in REDUCE-IT, and typical database quality control measures, known as cleaning. This will be followed by the database lock and final efficacy and safety analyses, including analysis of the trial's primary endpoint of first MACE events in the study, and the analyses of more than thirty pre-defined secondary and tertiary endpoints. Publication of the study design can be found at <https://doi.org/10.1002/clc.22692>. The lead author of this paper, published in Clinical Cardiology, is Deepak L. Bhatt, M.D., M.P.H., executive director of the Interventional Cardiovascular Programs at Brigham and Women's Hospital, professor of medicine, Harvard Medical School in Boston, Mass.

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

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Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding anticipated MACE onset in the REDUCE-IT study, the timing of clinical trial event adjudication, clinical trial results and related announcement timing associated with Amarin's REDUCE-IT cardiovascular outcomes study; and expectations related to the successful completion of REDUCE-IT. 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

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