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, 2019

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

England and Wales	**0-21392**	**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))

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, 2019, Amarin Corporation plc, or the Company, issued a press release providing preliminary unaudited fourth quarter and annual 2018 financial guidance, its financial outlook for 2019 and anticipated milestones for 2019. 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

Exhibit No.	Description
99.1	Press Release, dated January 4, 2019

* * *

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, 2019

Amarin Corporation plc

By: /s/ John Thero
John Thero
President and Chief Executive Officer

Amarin Provides Preliminary 2018 Results and 2019 Outlook

U.S. Sales Force Increased to 400 Sales Professionals for 2019 Following Unprecedented Positive Results of Vascepa® Cardiovascular Outcomes Study Presented in November 2018

Unaudited Full-Year 2018 Net Total Revenue Estimated Between $224 and $228 Million, including Fourth Quarter Estimate Between $72 and $76 Million

Anticipate Net Total Revenue in 2019 and Beyond to Grow in Phases with the Greatest Potential Increase After Anticipated Vascepa® Label Expansion in the U.S. and Approval in Additional Countries; Excluding Expected Future Revenue Lift from Anticipated U.S. Label Expansion, 2019 Net Total Revenue Projected to Increase by More than 50% to Approximately $350 Million, Predominantly from U.S. Sales of Vascepa

sNDA Seeking Label Expansion for Vascepa in U.S. Anticipated to be Submitted by the End of Q1 2019; Normal 10-Month Regulatory Review Cycle Currently Assumed

BEDMINSTER, N.J. and DUBLIN, Ireland, Jan. 4, 2019 — Amarin Corporation plc (NASDAQ:AMRN), today provided a business update, including a preliminary estimate of 2018 revenue results and 2019 revenue and spending guidance. Amarin plans to discuss these results and expectations with investors in connection with the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, California, at which Amarin will be presenting.

Preliminary (unaudited) 2018 Financial Results

Record Revenue Levels: Net total revenue for 2018 are estimated to have reached between $224 and $228 million, including estimated net total revenue of $72 to $76 million in Q4 2018. Both the full year and Q4 2018 results represent record revenue levels for Amarin. These results, which are subject to audit, represent increases of approximately $43 to $47 million (approximately 24% to 26%) over full year 2017 results. Both full year and Q4 2018 net total revenue consist predominantly of U.S. sales driven by increased prescriptions for Vascepa® (icosapent ethyl) capsules (less than $1 million in estimated ex-U.S. derived net revenue in 2018). Wholesaler inventory levels of Vascepa were within normal industry ranges at the end of 2018.

Current Assets: Amarin ended 2018 with approximately $249 million in cash, approximately $72 million in net accounts receivable and approximately $56 million in inventory.

No Debt, Except Remaining Balance of Royalty-Bearing Instrument: Amarin ended 2018 with no debt except the remaining balance on its royalty-bearing instrument which is repaid at a rate of

10% of Vascepa revenues; aggregate repayment of less than $90 million remains until this royalty-like obligation is fully extinguished.

2019 Financial and Operational Guidance

In November 2018, results of the REDUCE-IT™ cardiovascular outcomes study of Vascepa were presented and published[1]. These unprecedented placebo-controlled results were headlined by achieving the study's primary endpoint with a 25% reduction in major adverse cardiovascular events and a number needed to treat of 21, as well as achieving multiple prespecified secondary endpoints, including a 20% reduction in cardiovascular-related death. In connection with these results, the company expressed its priorities as follows:

1) Aggressively grow U.S. revenues through promotion and education of healthcare professionals;

2) Pursue label expansion for Vascepa through a supplemental new drug application (sNDA) to the FDA in the U.S. seeking a label which reflects the cardioprotective effects of Vascepa demonstrated in the REDUCE-IT study;

3) Leverage data from the sNDA through third-party relationships to expand Vascepa regulatory approvals and sales internationally; and

4) Operate in a cost-effective, opportunistic manner.

Preliminary feedback from physicians, payers and other healthcare professionals regarding REDUCE-IT results have been broadly positive. *The New England Journal of Medicine* on December 26, 2018 designated the REDUCE-IT study as a top story of 2018 in the *NEJM Journal Watch Cardiology* section. Similarly, the American College of Cardiology included REDUCE-IT results in its top 10 list for 2018.

While such initial feedback is encouraging, the REDUCE-IT results remain new and unknown in detail to most healthcare professionals and payers. Also unknown in detail by most healthcare professionals and payers are the failures of prior-generation therapies to demonstrate cardiovascular benefit and the important differentiation of Vascepa from these other products. While the potential need for Vascepa is estimated to be millions of patients, and while Vascepa is the first therapy for its targeted population to demonstrate positive results in a robust, globally-conducted cardiovascular outcomes study, Vascepa is creating a new paradigm in preventative cardiovascular care. Significant advancement in preventative cardiovascular care has been infrequent. Statin therapy, the standard of care for treating cholesterol related cardiovascular risk, was introduced approximately three decades ago and grew tremendously over many years. There is no historical revenue analog for a cardiovascular drug that is directly comparable to the current market dynamic in which Vascepa operates with its status as an increasingly recognized preferred add-on to statin therapy in select patients and its favorable efficacy, safety and cost profile. However, usage rates of new drugs for chronic needs have shown more pronounced growth following label expansion than following positive outcomes study results. This is likely due in part to expanded consumer promotion and greater payer acceptance following label expansion; recent examples include Repatha® and Jardiance®, neither of which are competitors to Vascepa, nor is Vascepa seeking to replace statin therapy. Rather, Vascepa is seeking to address cardiovascular risk not fully addressed by other available therapies.

2019 Revenue Guidance: While we are optimistic that Vascepa will reach billions of dollars in revenues, history of other therapies for chronic conditions suggests that growth occurs over many years. Forecasting Vascepa revenues at this early stage is difficult as feedback from physicians and payers remains preliminary and the timing of an expanded U.S. label for Vascepa is not yet known. Fortunately, managed care coverage for Vascepa is already generally good. While such coverage may improve further following label expansion, we do not expect Vascepa coverage by most payers to change dramatically in 2019 compared to current coverage. Amarin begins 2019 anticipating that its 2019 net total revenue will increase by more than 50% over 2018 results to approximately $350 million, mostly from sales of Vascepa in the U.S.

Vascepa Label Expansion: Amarin anticipates submitting a sNDA in the U.S. seeking an expanded indication for Vascepa before the end of Q1 2019. Assuming a standard 10-month review by the FDA, an expanded label for Vascepa is not currently expected to impact 2019 Vascepa revenue levels. After the sNDA is submitted, Amarin will seek clarification as to whether priority review by the FDA is possible for this important submission. The dataset from Vascepa, representing greater than 35,000 patient years of study, is large. Additionally, the list of prespecified endpoints which the company intends to evaluate in support of the sNDA is extensive. As a result, submission of the sNDA is not anticipated until late in Q1 2019.

Inventory Purchases: Because the rate of Vascepa revenue growth is difficult to predict, including potentially significantly varied timing regarding FDA review of the sNDA, Amarin intends to purchase inventory during 2019 at a rate which could support at least twice the 2019 net total revenue guidance described above. Such purchases do not change Amarin's revenue guidance. Rather, they prepare Amarin for a situation in which actual revenue turns out to be significantly higher than the guidance described above. One of the important features of Vascepa is the product's stability achieved through the expert manufacturing of its fragile single-active ingredient. This stability achievement presents limited financial risk of over-purchasing Vascepa inventory as the product has demonstrated stability supporting approved commercial expiry dating through four years. The incremental cost of this inventory build is anticipated to be between $50 and $75 million in 2019.

Quarterly Variability and Other Considerations: As of the end of 2018, Amarin had promoted REDUCE-IT published results, subject to various off-label related disclosures and disclaimers, to approximately 25,000 of its targeted 50,000 physicians. However, most of these 25,000 physicians have thus far met with Amarin sales reps only once since the results were published in *The New England Journal of Medicine* in November (see investor relations section of Amarin's website for link to this publication and discussion of frequently asked investor questions regarding REDUCE-IT results). As Amarin discussed when Vascepa was initially launched for its currently approved niche indication as a treatment for adult patients with very high triglyceride levels (TG $\geq$500 mg/dL), data from promotion of other products by other companies suggests that target audiences often need to see data multiple times (e.g. 5 – 7 times) before usage patterns are significantly changed. Accordingly, while we believe that a small portion of the increase in Q4 2018 revenues reflects REDUCE-IT results, we anticipate that most of the upside from these unprecedented clinical trial results will be realized in the future. It is encouraging and important to note that cardiologists who, while fewer in number, appear to be embracing REDUCE-IT results rapidly. As a result, beginning in January we increased the number of cardiologists to be targeted by our sales representatives.

Amarin has increased its sales force to 400 sales representatives, up from 150 for most of 2018. More than 90% of these sales representatives are now well trained and will be meeting with healthcare professionals this week. The remainder, fewer than 40 sales representatives, are scheduled to complete their training and begin Vascepa promotion within two weeks. This rapid hiring and training of these new sales representatives, which more than doubles Amarin's sales force, completed over a period of approximately three months is an example of Amarin's execution-oriented approach. By the end of March 2019, we anticipate that nearly all our 50,000 physician targets will be called upon at least once regarding REDUCE-IT results with most of these targets called upon two to three times.

Patients who are good candidates for Vascepa tend to visit their physicians once, sometimes twice, a year. As a result, similar to the experience of other therapies for treating chronic conditions, we do not anticipate prescription rates for Vascepa to spike upwardly immediately. Also, for context, note that we do not anticipate broadly expanding consumer promotion of Vascepa until the label for Vascepa is expanded. At that time, we will also evaluate whether 400 sales representatives are sufficient to support the multi-billion dollar potential of this important new cardiovascular therapy.

While Amarin anticipates that net total revenue will increase in each quarter of 2019 compared to the corresponding quarter of 2018, at this time the company is not providing quantified revenue guidance by quarter. The company anticipates continued industry-wide seasonality regarding prescription growth with, for example, Q1 impacted by headwinds caused by annual beginning of the year deductibles under insurance plans for some patients. This dynamic has historically caused some patients to ration the number of prescriptions they fill until they satisfy their deductibles and can better afford all of their prescriptions. This beginning of the year challenge is not specific to Vascepa but has historically most significantly impacted therapies such as Vascepa which address chronic, asymptomatic medical conditions. In addition, while 400 sales representatives giving Vascepa top promotion priority is anticipated to grow revenues, Amarin, as previously described, did not renew its agreement with its prior co-promotion partner beyond the December 31, 2018 expiration date of the co-promotion agreement. That partner was primarily promoting Vascepa in a second position by its sales representatives. All Amarin sales representatives will be promoting Vascepa in the first and only position. A short adjustment period is expected between the impact of ceasing the sales calls under that co-promotion agreement and Amarin's new sales representatives becoming fully productive.

Spending: Currently, Amarin anticipates operating expenses for 2019 to increase $25 to $50 million over 2018 levels. Included in these amounts are increased costs associated with Vascepa promotion partially offset by elimination of expenses associated with the company's prior co-promotion partner, expense which is estimated to have exceeded $40 million in 2018, and modestly lower R&D expenses as the REDUCE-IT trial is complete. R&D expenses, while lower than 2018, are anticipated to remain relatively high to support the sNDA submission, to support multiple potential additional publications of REDUCE-IT results, to support partners with respect to international submissions for Vascepa and to evaluate future product opportunities on Amarin's own and in collaboration with its development partner, Mochida. Total R&D expenses for 2019 are anticipated to be approximately $40 million and likely highest in the first half of 2019. These expense estimates assume that Vascepa label expansion is approved following an anticipated 10-month FDA review

cycle. In the event that the label is expanded earlier than expected or product revenue grows faster than expected, selling, general & administrative (SG&A) expenses may be higher than reflected in this operating expense guidance.

International: Internationally, Amarin currently has three partners for commercialization of Vascepa in select geographies and intends to consider potential additional partners to commercialize Vascepa in other parts of the world. In the Middle East, Amarin's partner Biologix, in 2018, received approval for Vascepa in two countries, Lebanon and the United Arab Emirates, with additional approvals in the region requested. In Greater China, Amarin's partner Eddingpharm began enrolling patients in a clinical study for Vascepa, with the intention of making Vascepa the first approved prescription drug of its type in Mainland China and other markets in that region. In Canada, Amarin and its newest partner HLS Therapeutics are hopeful that REDUCE-IT results will support efforts to gain regulatory approval to commercialize Vascepa although, similar to the pathway in the U.S., the REDUCE-IT data package is still being prepared and regulatory submission in Canada cannot be made until after that data package is ready for submission in the U.S. With respect to commercialization partners for Vascepa in other geographies, Amarin intends to continue to be receptive to inquiries from qualified companies. However, in the near-term, Amarin's priority is the U.S. sNDA submission and label expansion approval.

Comment from Amarin's President and CEO

"We enter 2019 with great confidence that Vascepa will lead to improved cardiovascular care for millions of at-risk patients," commented John F. Thero, president and chief executive officer. He continued, "2018 was a landmark year for Amarin as an unprecedented positive outcomes result from the use of Vascepa was demonstrated in the REDUCE-IT study and, prior to presenting REDUCE-IT results, we achieved record product revenues from Vascepa. With the support of our investors, we are well financed and positioned to increase Vascepa promotion. Amarin's dedicated team of employees and collaborators give me confidence that we will successfully pursue Vascepa label expansion while further accelerating Vascepa revenue growth in the U.S. and advancing Vascepa internationally."

Amarin will provide further details regarding its 2018 results and plans to provide further outlook for 2019 in connection with the company's annual report on Form 10-K when issued near the end of February 2019.

About Amarin

Amarin Corporation plc. is a rapidly growing, innovative pharmaceutical company focused on developing therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in polyunsaturated fatty acids and lipid science. Vascepa® (icosapent ethyl) is Amarin's first FDA-approved drug and is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin's commercial partners are pursuing additional regulatory approvals for Vascepa in Canada, China and the Middle East. For more information about Amarin, visit www.amarincorp.com.

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.[2, 3]

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.[4]

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. [5, 6, 7, 8]

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 from degradation. 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.

Indication and Usage Based on Current FDA-Approved Label (not including REDUCE-IT results)

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (³500 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 Based on Current FDA-Approved Label (not including REDUCE-IT results) (Includes Data from Two 12-Week Studies (n=622) (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL)

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- 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.

- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.

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 (³500 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 expectations regarding planned regulatory filings and the nature of FDA's review and related timing thereof; expectations regarding regulatory approvals outside the United States; expectations that REDUCE-IT results could lead to a new treatment paradigm in the patient population studied; expectations concerning the extent and timing of any increase in usage rates following the announcement of the REDUCE-IT results; expectations regarding sales force expansion and medical education and marketing initiatives expected in 2019 and beyond; expectations concerning revenue and prescriptions growth, operating and R&D expenses, inventory purchases and other financial metrics; expectations concerning quarterly variability and general market trends; and expectations regarding international and insurance coverage expansion. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, 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 sales may not meet expectations and related cost may increase beyond expectations; 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.

References

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