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): May 29, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

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

☐ 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 8.01. Other Events.

On May 29, 2019, Amarin Corporation plc issued a press release titled, "U.S. FDA Grants Priority Review for Vascepa® (icosapent ethyl) Supplemental New Drug Application Seeking Cardiovascular Risk Reduction Indication" (the "Press Release").

A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 29, 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: May 29, 2019

Amarin Corporation plc

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

Exhibit 99.1

U.S. FDA GRANTS PRIORITY REVIEW FOR *VASCEPA*® (ICOSAPENT ETHYL) SUPPLEMENTAL NEW DRUG APPLICATION SEEKING CARDIOVASCULAR RISK REDUCTION INDICATION

- PDUFA date assigned is September 28, 2019, four months sooner than expected
- *Vascepa*, assuming approval, will be first drug indicated to reduce residual cardiovascular risk in patients with statin-managed LDL-C cholesterol, but persistent elevated triglycerides, as studied in the landmark REDUCE-IT™ cardiovascular outcomes study
- Cardiovascular disease is the No. 1 cause of death for U.S. men and women
- Amarin is accelerating plans for commercial expansion, based on Priority Review designation

BEDMINSTER, N.J. and DUBLIN, Ireland, May 29, 2019 – Amarin Corporation plc (NASDAQ:AMRN) announced today that its supplemental new drug application (sNDA) for *Vascepa*® (icosapent ethyl) capsules has been accepted for filing and granted Priority Review designation by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for this sNDA is September 28, 2019. Because of the Priority Review designation, the timing of this PDUFA date is four months earlier than the anticipated standard ten-month review for applications.

Assuming FDA approval, *Vascepa* will be the first drug indicated to reduce residual cardiovascular risk in patients with statin-managed LDL-C cholesterol, but persistent elevated triglycerides, an important indicator of cardiovascular disease. This is a serious health challenge experienced by millions of people.

The FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions when compared to standard applications.

“We expect earlier approval of an expanded indication for *Vascepa* to lead to faster improvements in care for millions of patients with residual cardiovascular risk after statin therapy,” said John F. Thero, president and chief executive officer of Amarin. “These patients will be the focus of our planned expanded REDUCE-IT™ promotional efforts. We are very pleased that the FDA has accepted our application and granted it priority review. We believe the unprecedented REDUCE-IT results position Amarin to lead a transformative change in clinical practice for preventative treatment of cardiovascular

disease, the leading cause of death for both men and women in the United States. Our plans to significantly expand promotion of *Vascepa* following label expansion are being accelerated to reflect the upcoming PDUFA date."

sNDA Based on Landmark REDUCE-IT Trial

The sNDA for *Vascepa* is based on the landmark REDUCE-IT cardiovascular outcomes study, primary results of which were published in *The New England Journal of Medicine* in November 2018.[1] Additional results and analysis of total recurrent events observed were subsequently published in the *Journal of American College of Cardiology* in March 2019.[2] *Vascepa* is currently indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG ≥500 mg/dL) hypertriglyceridemia, an important but much smaller patient population than can be addressed with an approval of this sNDA.

In REDUCE-IT, *Vascepa* achieved the primary endpoint with a 25% relative risk reduction compared to placebo (95% confidence interval [CI], 0.68-0.83; p<0.001) in the first occurrence of a major adverse cardiovascular event (MACE) in the intent-to-treat population. In REDUCE-IT, MACE consisted of a composite of cardiovascular death, nonfatal myocardial infarction (MI or heart attack), nonfatal stroke, coronary revascularization (procedures such as stents and by-pass) and unstable angina requiring hospitalization.

As further evidence of the robustness of the REDUCE-IT results, *Vascepa* achieved the study's key secondary endpoint with a 26% relative risk reduction (HR, 0.74; 95% CI, 0.65-0.83; p<0.001) in 3-point MACE in the intent-to-treat population consisting of a composite of cardiovascular death, nonfatal heart attack and nonfatal stroke. *Vascepa* also achieved seven other secondary endpoints in the pre-specified hierarchical order below the key secondary endpoint, including a 20% relative risk reduction in cardiovascular death compared to placebo (HR, 0.80; 95% CI, 0.66-0.98; p=0.03). REDUCE-IT, a global study of 8,179 statin-treated adults with elevated CV risk, was performed based on a special protocol assessment (SPA) agreement with the FDA.

In REDUCE-IT, adverse events occurring with *Vascepa* use at greater than 5% and greater than placebo were: peripheral edema (6.5% *Vascepa* versus 5.0%), although there was no increase in the rate of heart failure in *Vascepa* patients; constipation (5.4% *Vascepa* versus 3.6%), although mineral oil, as used as placebo, is known to lower constipation; and atrial fibrillation (5.3% V*ascepa* versus 3.9%), although there were reductions in rates of cardiac arrest, sudden death and myocardial infarctions observed in

Vascepa patients. More information on safety data associated with REDUCE-IT is provided below and in the published results.

FDA Advisory Committee Update

In its sNDA filing acceptance communication to Amarin, the FDA did not indicate whether it plans to hold an advisory committee (AdCom) meeting to discuss this application. Amarin previously expressed that it believes an AdCom meeting organized by the FDA in conjunction with its review of the expanded label for *Vascepa* is likely. It is not uncommon for clarification on this topic to be provided by the FDA later in its review process.

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**.

More About REDUCE-IT

REDUCE-IT[1], an 8,179-patient cardiovascular outcomes study, was completed in 2018. REDUCE-IT was the first multinational cardiovascular outcomes study that evaluated the effect of prescription pure EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated triglyceride levels (at least 135 mg/dL). A large portion of the male and female patients enrolled in this outcomes study were diagnosed with type 2 diabetes.

More information on the REDUCE-IT study results can be found at **www.amarincorp.com**.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the No. 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.[3, 4]

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.[5]

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. [6, 7, 8, 9]

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 (≥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* 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**.

Important Safety Information for *Vascepa* based on REDUCE-IT, as previously reported in The New England Journal of Medicine[1] publication of the primary results of the REDUCE-IT study:

- Excluding the major adverse cardiovascular events (MACE) results described above, overall adverse event rates in REDUCE-IT were similar across the statin plus *Vascepa* and the statin plus placebo treatment groups.
- There were no significant differences between treatments in the overall rate of treatment emergent adverse events or serious adverse events leading to withdrawal of study drug.
- There was no serious adverse event (SAE) occurring at a frequency of >2% which occurred at a numerically higher rate in the statin plus *Vascepa* treatment group than in the statin plus placebo treatment group.
- Adverse events (AEs) occurring in 5% or greater of patients and more frequently with *Vascepa* than placebo were:
  - peripheral edema (6.5% *Vascepa* patients versus 5.0% placebo patients), although there was no increase in the rate of heart failure in Vascepa patients
  - constipation (5.4% *Vascepa* patients versus 3.6% placebo patients), although mineral oil, as used as placebo, is known to lower constipation, and
  - atrial fibrillation (5.3% *Vascepa* patients versus 3.9% placebo patients), although there were reductions in rates of cardiac arrest, sudden death and myocardial infarctions observed in *Vascepa* patients
- There were numerically more SAEs related to bleeding in the statin plus *Vascepa* treatment group although overall rates were low with no fatal bleeding observed in either group and no

significant difference in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding events between treatments.

- In summary, *Vascepa* was well tolerated with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling of such products.

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. FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has not reviewed the information herein or determined whether to approve *Vascepa* for use to reduce the risk of MACE. 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.

Important Cautionary Information About These Data

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome. For example, detailed data assessment by regulatory authorities, such as the FDA and Health Canada, will continue and take several months to complete and announce. The final evaluation by regulatory authorities of the totality of efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations: new information or analyses affecting the degree of treatment benefit on studied endpoints; study conduct and data robustness, quality, integrity and consistency; additional safety data considerations and risk/benefit considerations; and consideration of REDUCE-IT results in the context of other clinical studies. Because regulatory reviews are typically fluid and not definitive interactions between sponsor and agency on individual elements of an application and related information, Amarin does not plan to update investors on ongoing communications with regulatory authorities. Amarin plans to announce the final outcome of such regulatory reviews when appropriate.

Recurrent event analyses for the total primary endpoint events and for the total key secondary endpoint in REDUCE-IT as published in the *Journal of the American College of Cardiology* were conducted using a series of statistical models. These analyses were tertiary or exploratory endpoints; most of the models used were prespecified and one was *post hoc*. Each recurrent event statistical model has inherent strengths and weaknesses, with no single model considered definitive or outperforming the other models, and this is an evolving field of science. Nonetheless, results from the total primary and total key secondary endpoint events analyses are consistent across the various recurrent event statistical models and are also consistent with the original primary and secondary endpoint results. Together, the REDUCE-

IT recurrent event analyses and the original primary and key secondary endpoint analyses support the robustness of the clinical benefit of *Vascepa* therapy in reducing cardiovascular risk.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding FDA regulatory review, the applicability and reliability of REDUCE-IT results, expected outcome and timing of review elements and market dynamics for *Vascepa*. 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 gain regulatory approvals, 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 reviews and 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 (**www.amarincorp.com**), the investor relations website (**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 Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med 2019;380:11-22.

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8 Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease—New insights from epidemiology, genetics, and biology. Circ Res. 2016;118:547-563.

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