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): August 8, 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.)**

77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, 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 (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 8.01. Other Events.

On August 8, 2019, Amarin Corporation plc ("Amarin") issued a press release titled "Amarin Announces FDA Notification of Advisory Committee Meeting Planned to be Held in November 2019 in Connection With Vascepa® REDUCE-IT™ sNDA". 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 August 8, 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: August 9, 2019

Amarin Corporation plc

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

Amarin Corporation

Amarin Announces FDA Notification of Advisory Committee Meeting Planned to be Held in November 2019 in Connection With Vascepa® REDUCE-IT™ sNDA

August 8, 2019

PDUFA Date Extension to End of December 2019 Expected

Management to Host Conference Call Today at 7:00 p.m. ET

BEDMINSTER, N.J. and DUBLIN, Ireland, Aug. 08, 2019 (GLOBE NEWSWIRE) — Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, announced today that it received notice today from the U.S. Food and Drug Administration (FDA) that the FDA plans to hold an advisory committee meeting (AdCom), tentatively scheduled for November 14, 2019, in connection with its review of the pending supplemental new drug application (sNDA) for expansion of *Vascepa*® (icosapent ethyl) labeling based on the REDUCE-IT™ cardiovascular outcomes study. Before this communication, the FDA had been silent as to whether it would convene an AdCom in connection with its review of the REDUCE-IT sNDA. The FDA expressed, based on the timing of its recent decision to convene an AdCom, that November 14th is the earliest date on which it could hold an AdCom due to scheduling constraints for such a meeting.

Accordingly, Amarin does not expect the FDA to take action on the sNDA by the previously announced September 28, 2019 Prescription Drug User Fee Act (PDUFA) goal date. Amarin did not receive notice from the FDA of a PDUFA date extension. In light of the tentative AdCom date, Amarin anticipates that the PDUFA date will be extended, assuming a typical three-month extension, to a date in late December 2019. If so, this anticipated revised PDUFA date timing would offset three of the four months that were expected to be gained from FDA's earlier determination to conduct a priority review of the REDUCE-IT sNDA. Prior to such determination, Amarin had expected a PDUFA goal date in January 2020, based on a standard 10-month review. Amarin plans to update the investment community after appropriately definitive information is available related to a new PDUFA date.

The FDA informed Amarin in its August 8th notice that the agency is in the process of developing the agenda for the AdCom meeting. Topics to be raised by the FDA for discussion at an AdCom meeting are typically announced publicly by the agency in connection with its publication of its briefing book. Under the FDA's standard process, the FDA briefing book is scheduled to be published 48 hours prior to the start of the AdCom meeting. Because *Vascepa*, assuming anticipated FDA approval of the pending sNDA, would be the first drug approved based on the large patient population studied in REDUCE-IT, Amarin anticipates that discussion of REDUCE-IT results at the AdCom will be broad. At this time, Amarin expects topics to be reviewed at an AdCom meeting for the sNDA regarding *Vascepa* to be consistent with those discussed at similar meetings held by the FDA such as, but not limited to, topics covered as part of the publication of REDUCE-IT primary results in *The New England Journal of Medicine*1 and additional results published in the *Journal of American College of Cardiology*2, including review of the study conduct, populations studied, efficacy and safety. Because regulatory reviews are typically fluid and not definitive interactions between the sponsor and agency on individual elements of an application and related information, Amarin does not plan to update investors further on ongoing communications with regulatory authorities except with respect to potential updates regarding any change to the expected timing of the AdCom or the PDUFA date.

"We look forward to the planned advisory committee meeting as an opportunity to highlight the landmark REDUCE-IT data and the important role we expect *Vascepa* should play in the treatment of cardiovascular disease in appropriate patients," stated John Thero, president and chief executive officer of Amarin. "We plan to continue to work collaboratively with the FDA on the pending REDUCE-IT sNDA while we prepare for a robust launch of REDUCE-IT data assuming approval of *Vascepa* before the end of 2019 for a cardiovascular risk reduction indication based on REDUCE-IT."

Amarin intends to continue to move forward with its plans to double the size of its sales force to support the launch of *Vascepa*. Amarin plans to use the anticipated three-month delay in the PDUFA clock to better prepare for the assumed launch of *Vascepa* including more time to hire and train new sales representatives. To the extent that new sales managers and representatives are hired prior to the expanded label for *Vascepa*, Amarin intends to have them join the company's existing sales team in promoting *Vascepa* based on its current indication and existing promotional messaging.

Event Details:

The conference call can be heard live on the investor relations section of the company's website at www.amarincorp.com, or via telephone by dialing 877-407-8033 within the United States or 201-689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 53214. A replay of the call will also be available through the company's website shortly after the call.

To Ask Questions:

During the teleconference, following prepared remarks, management will respond to questions from investors and analysts, subject to time limitations. Participants in the live teleconference will be provided an opportunity to ask questions. Investors may also e-mail their questions to investor.relations@amarincorp.com. e-mail questions will be accepted until Thursday, August 8, 2019 at 6:30 p.m. ET.

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 REDUCE-IT™

REDUCE-IT[1] was an 8,179-patient multinational cardiovascular outcomes study completed in 2018. REDUCE-IT 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 #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.[6-9]

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 orserious 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 (³500 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 AdCom process and 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 statements about anticipated FDA review of the REDUCE-IT sNDA and the timing of such review, and Amarin's plans for commercial expansion related thereto. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 data interpretations or other information from third parties, the regulatory review process, regulatory authorities and in connection with an AdCom could be made public that are negative or may delay approval or limit *Vascepa*'s marketability; the risk that special protocol assessment (SPA) agreements with the FDA are not a guarantee that FDA will approve a product candidate; the risk associated with the FDA's rescinding the REDUCE-IT SPA agreement; the risk related to FDA advisory committee meetings; and the risk that the FDA may not complete its review of the REDUCE-IT sNDA within the timing expected. 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.

2 Bhatt DL, Steg PG, Miller M, et al. Effects of Icosapent Ethyl on Total Ischemic Events: From REDUCE-IT. J Am Coll Cardiol 2019;73(22):2791-2802.

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

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6 Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. Am J Cardiol. 2016;118:138-145.

7 Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. J Am Heart Assoc. 2018;7(15):e008740.

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

9 Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. Lancet. 2014;384:626–635.

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