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): July 17, 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.

The Company hereby supplements Item 1A. of the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and Item 1A. of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 with the following supplemental risk factors:

If FDA decides to hold an advisory committee meeting in connection with our sNDA for the REDUCE-IT indication, data interpretations or other information from FDA or the committee could be made public that are negative or may delay approval or limit Vascepa's marketability.

The FDA is not required to inform sponsor companies that it does not intend to hold an AdCom. As of the date of this Current Report on Form 8-K, the FDA has not informed Amarin whether it plans to hold an AdCom meeting to discuss our sNDA seeking an expanded indication for Vascepa in the United States based on the results of the REDUCE-IT study, nor has the FDA informed us of the subject matter intended to be the focus of a potential AdCom meeting if one were to be scheduled. While such notification now would be considered by some to be relatively late notice, it remains possible that the FDA will elect to organize such a meeting in conjunction with its review of the expanded label for Vascepa. In the event that the FDA informs us that it plans to hold an AdCom meeting in connection with our sNDA, the FDA will publish on its website shortly before the AdCom meeting a briefing book that includes questions for committee consideration and the agency's evaluation of data and issues relevant to FDA's review of the sNDA. The briefing book may identify concerns the agency has with our sNDA that differ from public expectations. Even if the AdCom ultimately disagrees with agency concerns, the publication of concerns from FDA and the degree to which the public views agency concerns as material to, for example, the prospects and scope of approval of the sNDA, may negatively affect us. The FDA is not bound by the recommendations of an advisory committee, which is typically composed of clinicians, statisticians and other experts, but it generally follows such recommendations. In addition, the AdCom may recommend against approval of our application or may recommend that the FDA require, as a condition of approval or as a post-approval commitment, additional preclinical studies or clinical trials. This may delay and increase the cost of the review and approval process. Although not typically the case, the FDA can also, at its option, delay the target date for completion of our sNDA to allow for additional time for an advisory committee meeting or to, for example, provide more time to assess new or existing information in connection with the sNDA review. Any delay in obtaining, or an inability to obtain, expanded marketing approval could prevent us from commercializing Vascepa in the REDUCE-IT indication, generating revenue at current or increasing rates of growth, and achieving profitability, any of which could materially harm our business and cause our stock price to decline.

Our internal computer systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our research and development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Any such incident could cause interruptions in our operations or a material disruption of our programs. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or products candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and our research and development program could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. For instance, in June 2019, a report published by security researchers claimed that a database, which we are informed did not include social security numbers or credit card information, belonging to one of our vendors containing information about individuals who use or have expressed interest in Vascepa was accessible to unauthorized users. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks and to repair reputational costs. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We may incur significant costs or divert significant internal resources as a result of any regulatory actions or private litigation. Any of the foregoing consequences may adversely affect our business and financial condition.

Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

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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: July 17, 2019

AMARIN CORPORATION PLC

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