AMARIN CORP PLC\UK

FORM 8-K
(Current report filing)

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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): November 1, 2017

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 November 1, 2017, Amarin Corporation plc issued a press release announcing its financial results for the three and nine months ended September 30, 2017 (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.1.

The information in this report furnished pursuant to Item 2.02 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 1, 2017

* * *

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: November 1, 2017

Amarin Corporation plc

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

Amarin Reports Third Quarter 2017 Financial Results and Provides Update on Operations

Record-High Net Product Revenue of $47.1 Million in Third Quarter

Management to Host Conference Call Today at 8:00 a.m. ET

BEDMINSTER, N.J., and DUBLIN, Ireland , November 1 , 2017 -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced financial results for the three and nine months ended September 30, 2017, and provided an update on company operations.

Key Amarin achievements since June 30, 2017 include:

- Product revenue growth : Recognized $47.1 million in U.S. net product revenue from Vascepa® (icosapent ethyl) sales in Q3 2017 compared to $32.4 million in Q3 2016, an increase of 45%.
- U.S. prescription growth : Increased normalized prescriptions for Vascepa by 44% compared to Q3 2016 based on data from both Symphony Health Solutions and QuintilesIMS.
- R&D progress : REDUCE-IT, Amarin's potential landmark long-term cardiovascular outcomes study, progressing towards completion with results expected to be reported in less than a year (before the end of Q3 2018).
- International : Partnered with HLS Therapeutics to commercialize and distribute Vascepa capsules in Canada.
- Management : Appointed Mark W. Salyer to new position of Chief Commercial Officer to build on the company's recent revenue growth and lead future global commercial expansion plans and execution.

"Interest in the results of the REDUCE-IT study continues to grow amongst key opinion leaders and others with knowledge of the study due to multiple factors, including the large unmet need for improved patient care, continued evidence from other studies which suggest support for the hypothesis being evaluated in REDUCE-IT and the proximity of REDUCE-IT results which are less than a year away," stated John F. Thero, president and chief executive officer. "The excitement over the vast potential of the REDUCE-IT study is supplemented by the continued growth we have experienced, and which we anticipate continuing to experience, from our current promotion of Vascepa based on its relatively narrow current label." He added, "We are preparing for anticipated REDUCE-IT success while continuing to focus on positive execution."

Commercial business growth continues

Net product revenue in the third quarter of 2017 achieved record levels. Net cash flow from Amarin's commercial business, which had been modestly positive year-to-date coming into Q3 2017, excluding R&D and finance related cash flow (e.g. cash inflows/outflows from debt-related transaction reported in Q1 2017, interest and royalty), was again positive in Q3 2017. During Q4 2017 and leading into 2018, the company anticipates increasing its sales force size by 10 to 20 sales representatives. While this planned sales force expansion is relatively small it is notable in context that for the past several years Amarin has witnessed Vascepa revenue growth through increased productivity without expanding its sales force. These sales representatives will be methodically added to areas currently uncovered by Amarin sales representatives. However, the company is not planning to extensively expand its sales force for Vascepa until after it sees positive REDUCE-IT results.

Estimated normalized total Vascepa prescriptions, based on data from Symphony Health Solutions and QuintilesIMS, totaled approximately 374,000 and 372,000, respectively, for the three months ended September 30, 2017. These prescription levels represent growth of approximately 44% compared to the respective prior year levels.

REDUCE-IT trial status

The REDUCE-IT cardiovascular outcomes trial, which commenced in 2011, is progressing towards reporting results before the end of Q3 2018. Amarin anticipates the study reaching the onset of 100% of the targeted cumulative total of 1,612 primary major adverse cardiovascular events (MACE) before the end of Q1 2018. Reaching this events target will be followed by final patient visits to

clinical sites, accumulation of final data, including on any primary or other categories of MACE that have been documented and adjudicated, and final efficacy and safety data review by the independent review committees and the REDUCE-IT operational team. After Amarin is unblinded and learns the results of the study, the results will be publicly communicated. Amarin believes that the results of this potential landmark trial, if successful, could lead to improved preventative medical care for tens of millions of patients and could contribute to significantly lower costs for treating these patients.

REDUCE-IT is the first prospectively conducted, multi-national, double-blinded study to evaluate the effects of treating patients who despite well-controlled LDL-cholesterol have high triglycerides and other risk factors associated with cardiovascular disease. This 8,175-patient study, which commenced in late 2011, has accumulated over 30,000 years of study of treated patients. Amarin seeks to determine whether the potentially broad clinical effects of an intentionally high daily dose (4 grams per day) of Vascepa translate into fewer cardiovascular events for at-risk patients. If successful in demonstrating positive cardiovascular outcomes results, Amarin believes that Vascepa is well-positioned to be prescribed for treatment of at-risk patients due to the efficacy, tolerability, ease of administration and affordable price of Vascepa.

Financial update

Net product revenue for the three months ended September 30, 2017 and 2016 was $47.1 million and $32.4 million, respectively. Net product revenue for the nine months ended September 30, 2017 and 2016 was $126.3 million and $90.6 million, respectively. Increased revenue is mainly attributed to increased Vascepa prescriptions.

Licensing revenue associated with agreements for the commercialization of Vascepa outside the United States during the nine months ended September 30, 2017 and 2016 was $0.9 million and $0.8 million, respectively.

Gross margin on product sales improved to 75% in the three and nine months ended September 30, 2017, as compared to 74% and 73%, in the three and nine months ended September 30, 2016, respectively. This improvement was primarily driven by lower unit cost API purchases.

Selling, general and administrative expense for the nine months ended September 30, 2017 and 2016 was $98.9 million and $80.1 million, respectively. This increase is due primarily to increased promotion activities, including costs to support anticipated expansion following successful REDUCE-IT results, increased legal costs and increased co-promotion fees resulting from increased sales.

Research and development expense for the nine months ended September 30, 2017 and 2016 was $35.2 million and $39.8 million, respectively. This decrease is primarily due to timing of REDUCE-IT and related costs.

Under GAAP, Amarin reported a net loss of $10.8 million in the three months ended September 30, 2017, or basic and diluted loss per share of $0.04. This net loss included $3.5 million in non-cash stock-based compensation expense. For the three months ended September 30, 2016, Amarin reported a net loss of $15.8 million, or basic and diluted loss per share of $0.08. This net loss included $3.4 million in non-cash stock-based compensation expense and a $3.6 million non-cash gain on the change in fair value of derivatives.

Under GAAP, Amarin reported a net loss of $45.4 million in the nine months ended September 30, 2017, or basic and diluted loss per share of $0.17. This net loss included $10.5 million in non-cash stock-based compensation expense. For the nine months ended September 30, 2016, Amarin reported a net loss of $58.9 million, or basic and diluted loss per share of $0.31. This net loss included $10.4 million in non-cash stock-based compensation expense and an $8.2 million non-cash gain on the change in fair value of derivatives.

Amarin reported cash and cash equivalents of $79.1 million at September 30, 2017. Net cash flow from operations, excluding debt restructuring, interest and royalties, and R&D costs, in the three and nine months ended September 30, 2017 was modestly positive. On this basis, the company anticipates that net cash flow for 2017 will be positive. For the nine months ended September 30, 2017, cash outflows relating to research and development were approximately $31.7 million and cash paid for interest and royalties, in aggregate, was approximately $12.5 million.

As of September 30, 2017, the company had $34.6 million in net accounts receivable ($49.1 million in gross accounts receivable before allowances and reserves), which are current and $28.6 million in inventory. As of September 30, 2017, the company had accounts payable and accrued expenses of $67.4 million which increased from $43.8 million at December 31, 2016 primarily due to the timing of rebate and certain supplier payments.

As of September 30, 2017, Amarin had approximately 270.9 million American Depository Shares (ADSs) and ordinary shares outstanding, 32.8 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 23.6

million equivalent shares underlying stock options at a weighted-average exercise price of $3.26, as well as 11.9 million equivalent shares underlying restricted or deferred stock units.

Conference call and webcast information

Amarin will host a conference call at 8:00 a.m. ET today, November 1, 2017. The call will be webcast live with slides and accessible through 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 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use PIN: 20579.

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. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, omega-3 fatty acid product available by prescription. 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. 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 is known in scientific literature as AMR101.

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.

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 (≥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.

Forward-looking statements

This press release contains forward-looking statements, including expectations regarding revenue growth, spending levels and cash flow as well as REDUCE-IT related expectations for continued event rates, results and related timing and announcements; expectations related to the final outcomes of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential and therapeutic benefits of Vascepa. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and 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 increased 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 historical REDUCE-IT event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that regulatory reviews may alter current expectations related thereto; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be upheld in patent litigation. 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 (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.

CONSOLIDATED BALANCE SHEET DATA
(U.S. GAAP)
(Unaudited)

	September 30, 2017	December 31, 2016
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 79,086	$ 98,251
Restricted cash	600	600
Accounts receivable, net	34,610	19,985
Inventory	28,550	20,507
Prepaid and other current assets	4,185	6,983
Total current assets	147,031	146,326
Property, plant and equipment, net	39	78
Deferred tax assets	11,082	11,082
Other long-term assets	174	741
Intangible asset, net	8,287	8,772
TOTAL ASSETS	$ 166,613	$ 166,999
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 15,805	$ 6,062
Accrued expenses and other current liabilities	51,627	37,720
Current portion of exchangeable senior notes, net of discount	219	15,351
Current portion of long-term debt from royalty-bearing instrument	20,197	15,944
Deferred revenue, current	2,222	1,172
Total current liabilities	90,070	76,249
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,938	—
Long-term debt from royalty-bearing instrument	75,559	85,155
Deferred revenue, long-term	16,997	13,943
Other long-term liabilities	1,158	710
Total liabilities	212,722	176,057
Stockholders' Deficit:		
Preferred Stock	24,364	24,364
Common stock	208,642	207,166
Additional paid-in capital	974,343	964,914
Treasury stock	(4,054)	(1,498)
Accumulated deficit	(1,249,404)	(1,204,004)
Total stockholders' deficit	(46,109)	(9,058)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 166,613	$ 166,999

CONSOLIDATED STATEMENTS OF OPERATIONS DATA
(U.S. GAAP)
Unaudited

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2017	2016	2017	2016
Product revenue, net	$ 47,051	$ 32,441	$ 126,343	$ 90,563
Licensing revenue	309	293	895	825
Total revenue, net	47,360	32,734	127,238	91,388
Less: Cost of goods sold	11,921	8,451	31,520	24,208
Gross margin	35,439	24,283	95,718	67,180
Operating expenses:				
Selling, general and administrative (1)	33,194	26,061	98,910	80,147
Research and development (1)	10,694	13,490	35,211	39,798
Total operating expenses	43,888	39,551	134,121	119,945
Operating loss	(8,449)	(15,268)	(38,403)	(52,765)
Gain on change in fair value of derivative liabilities (2)	—	3,610	—	8,170
Interest expense, net	(2,401)	(5,051)	(7,097)	(16,253)
Other income (expense), net	25	(78)	100	(381)
Loss from operations before taxes	(10,825)	(16,787)	(45,400)	(61,229)
Benefit from income taxes	—	1,015	—	2,332
Net loss	$ (10,825)	$ (15,772)	$ (45,400)	$ (58,897)
Loss per share:				
Basic	$ (0.04)	$ (0.08)	$ (0.17)	$ (0.31)
Diluted	$ (0.04)	$ (0.08)	$ (0.17)	$ (0.31)
Weighted average shares:				
Basic	270,803	209,149	270,566	192,618
Diluted	270,803	209,149	270,566	192,618

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were $30,223 and $23,215 for the three months ended September 30, 2017 and 2016, respectively, and research and development expenses were $10,170 and $12,922, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to the company's U.S. co-promotion partner, selling, general and administrative expenses were $24,295 and $18,657 for the three months ended September 30, 2017 and 2016, respectively.

(2) Non-cash gains and losses result from changes in the fair value of long-term debt derivative liabilities.

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