# 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 4, 2016

### **Amarin Corporation plc**

(Exact name of registrant as specified in its charter)

England and Wales (State or other jurisdiction of incorporation) 0-21392 (Commission File Number) Not applicable (I.R.S. Employer Identification No.)

2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2, Ireland (Address of principal executive offices)

Not applicable (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

ck 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 risions:
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))

### Item 2.02. Results of Operations and Financial Condition.

On August 4, 2016, Amarin Corporation plc issued a press release announcing its financial results for the three and six months ended June 30, 2016 entitled "Amarin Reports Second Quarter 2016 Financial Results and Provides Update on Operations." A copy of this press release is furnished herewith as Exhibit 99.1.

The information in this report furnished pursuant to Item 2.02 and in Exhibit 99.1 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 or in Exhibit 99.1 of this report.

### **Item 8.01 Other Events**

On August 4, 2016, Amarin Corporation plc issued a press release entitled "Amarin and FDA Reaffirm Concurrence on REDUCE-IT Through Special Protocol Assessment Agreement Amendment." A copy of this press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The Company hereby furnishes the following exhibits:

99.1 Press Release, dated August 4, 2016 entitled "Amarin Reports Second Quarter 2016 Financial Results and Provides Update on Operations"

The Company hereby files the following exhibits:

99.2 Press Release, dated August 4, 2016 entitled "Amarin and FDA Reaffirm Concurrence on REDUCE-IT Through Special Protocol Assessment Agreement Amendment"

\* \* \*

### **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 4, 2016 Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer

### **Exhibit Index**

Exhibit No.	<u>Description</u>
99.1*	Press Release, dated August 4, 2016 entitled "Amarin Reports Second Quarter 2016 Financial Results and Provides Update on Operations"
99.2**	Press Release, dated August 4, 2016 entitled "Amarin and FDA Reaffirm Concurrence on REDUCE-IT Through Special Protocol Assessment Agreement Amendment"

- \* Furnished herewith
- \*\* Filed herewith



### Amarin Reports Second Quarter 2016 Financial Results and Provides Update on Operations

Second Quarter Net Product Revenue Up 85% vs. Prior Year Period

Increasing Guidance on Full Year Net Product Revenue to \$112-\$125 Million

Management to Host Conference Call at 7:30 a.m. ET Today

BEDMINSTER, N.J., and DUBLIN, Ireland, August 4, 2016—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 six months ended June 30, 2016, and provided an update on company operations.

Key Amarin achievements since March 31, 2016 include:

- Revenue growth: Recognized \$32.8 million in net product revenue from Vascepa® (icosapent ethyl) sales in Q2 2016 compared to \$17.7 million in Q2 2015, an increase of 85%;
- <u>Prescription growth</u>: Increased normalized prescriptions, based on data from Symphony Health Solutions and IMS Health, by 55% and 58%, respectively, compared to Q2 2015, reflecting the tenth consecutive quarter of greater than 50% growth in normalized prescriptions over the corresponding quarter in the prior year;
- <u>R&D progress</u>: Amended the REDUCE-IT special protocol assessment (SPA) agreement to include a second interim efficacy analysis at approximately 80% of targeted primary events and additional pre-specified secondary and tertiary endpoints while confirming FDA support for the key elements of the SPA agreement that were not amended;
- Research data: Presented data showing Vascepa's reduction of concentrations of potentially atherogenic lipoproteins in patients with Type 2
  diabetes and persistent high triglyceride levels despite statin therapy and further characterizing the efficacy and safety of Vascepa in women;
- <u>Secured regulatory exclusivity</u>: Granted five-year new chemical entity (NCE) marketing exclusivity supplementing the existing patent protection of Vascepa;
- <u>Improved cash flow</u>: Consistent with target of becoming cash flow positive from commercial operations, excluding REDUCE-IT costs, at the start of 2017, net cash used in operating activities in Q2 2016 was lowered to approximately \$9.0 million with spending levels intentionally held relatively flat; and

 Strengthened management team: Appointed Michael W. Kalb, previously chief financial officer and chief accounting officer at Taro Pharmaceutical Industries, as the company's new chief financial officer.

"We continued to identify areas of expanded opportunity in our core commercial business and accelerated growth during the second quarter," stated John F. Thero, president and chief executive officer. "High-frequency calling on targeted physicians together with expanding managed care access and coverage have resulted in higher prescribing rates and overall improved prescription growth. We look forward to continuing to expand market share based on our current indication and First Amendment promotional rights while preparing to potentially significantly expand the population of patients receiving Vascepa due to high triglycerides after statin therapy assuming success of our ongoing cardiovascular outcomes study."

### Increases in New and Recurring Prescriptions Drive Steady Commercial Growth

During the second quarter, Amarin continued to see substantial prescription growth and steady increases in prescription omega-3 and non-statin market share, particularly among detailed physicians. Increased switching of patients to Vascepa from earlier generation triglyceride lowering therapy (i.e., generic omega-3 ethyl ester mixtures and fenofibrate products) is increasingly contributing to overall new prescription growth. Vascepa growth continues to be driven by focused message delivery, compelling supportive data and improved managed care coverage.

Normalized total Vascepa prescriptions, based on data from Symphony Health Solutions and IMS Health, totaled approximately 230,000 and 248,000, respectively, for the three months ended June 30, 2016. These prescription levels represent growth of approximately 55% and 58%, respectively, from prior year levels, and approximately 14% and 16%, respectively, compared to Q1 2016. This increase in prescriptions reflects the sales and marketing activities of both Amarin and our Vascepa co-promotion partner, Kowa Pharmaceuticals America, Inc.

Growth in both new and recurring Vascepa prescriptions resulted in increased shipment volumes to wholesalers during the quarter. While prescription growth was the foundation for reported revenue growth in Q2 2016, the growth in revenue reported in Q2 2016 compared to Q2 2015 also included the effect of increased inventory levels at wholesalers and to a smaller extent higher net product pricing.

Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors. In Q1 2016, overall wholesaler inventory levels decreased from year-end 2015 calculated based on estimated days of Vascepa sales on hand. In Q2 2016, the trend was reversed and overall wholesaler inventory levels increased. Consequently, we estimate that the net overall increase in wholesaler inventory levels contributed approximately \$1.5 million to \$1.8 million to net product revenues for the six months ended June 30, 2016. During the same six-month period last year, we estimate that the impact of fluctuations in wholesaler inventory levels was more modest with lower net wholesaler inventory levels decreasing revenue by less than \$1.0 million.

On a quarterly basis, we estimate that the net overall increase in Q2 2016 wholesaler inventory levels from Q1 2016 added approximately \$2.9 million to \$3.2 million to our reported revenues for the second quarter of 2016. The increase in inventory levels at wholesalers during Q2 2016 follows an estimated \$1.2 million to \$1.5 million decline in Q1 2016 revenues due to reduced wholesaler inventory levels during the first three months of 2016. The foregoing estimates are based on inventory data provided to us by certain wholesalers and prescription data provided by Symphony Health Solutions and IMS Health.

### Additional Endpoints and Second Interim Efficacy Analysis Strengthen REDUCE-IT Trial

The REDUCE-IT cardiovascular outcomes trial continues on schedule towards anticipated completion in 2017 and publication of results in 2018. The results of this important trial, if successful, could lead to improved medical care for tens of millions of patients. As the trial progresses toward completion, Amarin has explored ways to mitigate regulatory risk, broaden the potential findings and accelerate the availability of final data. To this end, the company recently amended the study protocol to add more pre-specified secondary and tertiary efficacy endpoints and a second protocol-specified interim efficacy analysis. The SPA amendment does not change the primary endpoint or the overall size of the REDUCE-IT study, as confirmed with the FDA in the SPA agreement as amended. The SPA amendment does not change the company's prior guidance on timing.

In an effort to more broadly characterize the potential benefits of Vascepa, particularly among key patient subgroups, the study now includes more than 30 pre-specified secondary and tertiary endpoints designed to capture multiple potential drug effects in various subpopulations. The added endpoints could result in improved patient care for specific groups within the diverse population studied in REDUCE-IT and are expected to support a variety of new publications furthering our goal to support informed medical decisions.

The first interim efficacy and safety analysis by the independent data monitoring committee (DMC) at approximately 60% of targeted primary events is expected to occur in September or October 2016. Preparations for the second planned interim efficacy analysis will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, Amarin anticipates that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy and safety analysis by the DMC expected around mid-2017. As is typical of interim analyses, the statistical threshold for defining overwhelming efficacy on the primary endpoint that would call for stopping the study early in connection with such analysis is considerably higher than the threshold for defining statistical significance after the expected completion of the study. Accordingly, Amarin continues to expect that the DMC's 60% and 80% interim analyses will each result in a recommendation to continue the REDUCE-IT study as planned.

Amarin will remain blinded to the interim and ongoing results of the REDUCE-IT study as well as to any interim p-values and other statistical information until after the study is ready to be stopped, either at an interim analysis or at the final analysis.

### Financial Update

Net product revenue for the three months ended June 30, 2016 and 2015 was \$32.8 million and \$17.7 million, respectively. Net product revenue for the six months ended June 30, 2016 and 2015 was \$58.1 million and \$33.3 million, respectively. These increases in net product revenue were primarily attributable to increases both in new and recurring prescriptions of Vascepa driven by increased sales productivity and a significant increase in the level of inventories held by independent wholesalers, our customers, as of June 30, 2016.

Based on year-to-date results and anticipated trends, Amarin is increasing its guidance estimate for total 2016 net product revenue to \$112 million to \$125 million. Amarin expects continued total prescription (TRx) growth to drive increased full-year 2016 revenue despite the potential impact of periodic fluctuations in wholesaler inventory levels. Amarin continues to expect that, based on its projected revenue growth, the company is positioned to enter 2017 cash flow positive from commercial operations, excluding REDUCE-IT and other R&D expenses not required to sustain current commercial operations.

In addition, Amarin recognized licensing revenue of \$0.5 million in the six months ended June 30, 2016 related to agreements for the commercialization of Vascepa outside the United States. Based upon current estimates, Amarin anticipates approximately \$1.1 million in licensing revenue to be recognized in aggregate during 2016 from existing agreements, including the \$0.5 million recognized in the first six months of 2016.

Cost of goods sold for the three months ended June 30, 2016 and 2015 was \$8.9 million and \$6.4 million, respectively. Cost of goods sold for the six months ended June 30, 2016 and 2015 was \$15.8 million and \$12.0 million, respectively. Gross margin on product sales improved to 73% in the three and six months ended June 30, 2016 as compared to 64% in the three and six months ended June 30, 2015. The improvement in gross margin on product sales was primarily driven by lower active pharmaceutical ingredient cost.

Selling, general and administrative (SG&A) expenses in the six months ended June 30, 2016 and 2015 were \$54.1 million and \$50.8 million, respectively. The increase in SG&A expenses primarily reflects a \$4.9 million increase in co-promotion fees payable to Kowa Pharmaceuticals America, Inc., resulting from a year-over-year increase in gross margin on product sales in 2016 coupled with an increase from 15% to 19% of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc.; and an increase in non-cash stock-based compensation expense, partially offset by a decrease in legal fees. Focused on continued increases in sales productivity, the company currently anticipates its SG&A costs in 2016 as a whole will be substantially consistent with that in 2015, with the exception of non-cash costs and anticipated increases in the co-promotion fees earned by Kowa Pharmaceuticals America, Inc. associated with anticipated increases in net product revenues.

Research and development expenses in the six months ended June 30, 2016 and 2015 were \$26.3 million and \$24.6 million, respectively. This increase in expense was primarily driven by the timing of REDUCE-IT expenses. Research and development costs in 2016, excluding non-cash costs, are expected to be similar in aggregate to 2015, including annual REDUCE-IT costs of approximately \$30 million to \$40 million until study completion with quarterly variability due to the timing of study-related costs.

Under GAAP, Amarin reported a net loss applicable to common shareholders of \$13.4 million in the second quarter of 2016, or basic and diluted loss per share of \$0.07. This net loss included \$3.4 million in non-cash stock-based compensation expense and a \$5.8 million non-cash gain on the change in fair value of derivatives. Amarin reported a net loss applicable to common shareholders of \$62.9 million in the second quarter of 2015, or basic and diluted loss per share of \$0.35. This net loss included \$3.2 million in non-cash stock-based compensation expense, a \$0.6 million non-cash loss on the change in fair value of derivatives, and a \$31.3 million charge for a non-cash deemed dividend for accounting purposes.

Under GAAP, Amarin reported a net loss applicable to common shareholders of \$43.1 million in the six months ended June 30, 2016, or basic and diluted loss per share of \$0.23. This net loss included \$7.0 million in non-cash stock-based compensation expense and a \$4.6 million non-cash gain on the change in

fair value of derivatives. For the six months ended June 30, 2015, Amarin reported a net loss applicable to common shareholders of \$94.8 million, or basic and diluted loss per share of \$0.53. This net loss included \$6.3 million in non-cash stock-based compensation expense, a \$0.1 million non-cash loss on the change in fair value of derivatives, and \$32.2 million in charges for non-cash deemed dividends for accounting purposes.

Excluding non-cash gains or losses for stock-based compensation, change in fair value of derivatives, and the non-cash deemed dividend, non-GAAP adjusted net loss was \$15.8 million for the second quarter of 2016, or non-GAAP adjusted basic and diluted loss per share of \$0.09, compared to non-GAAP adjusted net loss of \$27.7 million for the second quarter of 2015, or non-GAAP adjusted basic and diluted loss per share of \$0.15.

Excluding non-cash gains or losses for stock-based compensation, warrant compensation, change in fair value of derivatives, and the non-cash deemed dividends, non-GAAP adjusted net loss was \$40.7 million for the six months ended June 30, 2016, or non-GAAP adjusted basic and diluted loss per share of \$0.22, compared to non-GAAP adjusted net loss of \$56.3 million for the six months ended June 30, 2015, or non-GAAP adjusted basic and diluted loss per share of \$0.32.

Amarin reported cash and cash equivalents of \$72.5 million at June 30, 2016. Net cash used in operating activities in the quarter ended June 30, 2016 of \$9.0 million decreased compared to \$25.6 million in the corresponding quarter of 2015 as a result of increased collections due to higher revenues, which resulted in decreased net loss. As of June 30, 2016, the company had \$17.6 million in net accounts receivable (\$21.5 million in gross accounts receivable before allowances and reserves) and \$20.3 million in inventory.

As of June 30, 2016, Amarin had approximately 184.6 million American Depository Shares (ADSs) and ordinary shares outstanding, 32.8 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 20.6 million equivalent shares underlying stock options at a weighted-average exercise price of \$3.42, as well as 10.4 million equivalent shares underlying restricted or deferred stock units.

### Conference call and webcast information

Amarin will host a conference call at 7:30 a.m. ET today, August 4, 2016. 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 877-660-6853 (inside the United States) or 201-612-7415 (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 conference ID 13641286.

### Use of non-GAAP adjusted financial information

Included in this press release and the conference call referenced above are non-GAAP adjusted financial information as defined by U.S. Securities and Exchange Commission Regulation G. The GAAP financial measure most directly comparable to each non-GAAP adjusted financial measure used or discussed, and a reconciliation of the differences between each non-GAAP adjusted financial measure and the comparable GAAP financial measure, is included in this press release after the condensed consolidated financial statements.

Non-GAAP adjusted net loss was derived by taking GAAP net loss and adjusting it for non-cash gains or losses for stock-based compensation, warrant compensation, change in fair value of derivatives, and non-cash deemed dividends. Management uses these non-GAAP adjusted financial measures for internal reporting and forecasting purposes, when publicly providing its business outlook, to evaluate the company's performance and to evaluate and compensate the company's executives. The company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP adjusted financial measures provide investors with a better understanding of the company's historical results from its core business operations.

While management believes that these non-GAAP adjusted financial measures provide useful supplemental information to investors regarding the underlying performance of the company's business operations, investors are reminded to consider these non-GAAP measures in addition to, and not as a substitute for, financial performance measures prepared in accordance with GAAP. Non-GAAP measures have limitations in that they do not reflect all of the amounts associated with the company's results of operations as determined in accordance with GAAP. In addition, it should be noted that these non-GAAP financial measures may be different from non-GAAP measures used by other companies, and management may utilize other measures to illustrate performance in the future.

### **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. 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 1 gram 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 (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**

- 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 (3500 mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. 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 statements about the future commercialization of Vascepa; expectations regarding TRx trends and wholesaler inventory levels; expectations regarding Vascepa sales, revenue, costs and other financial metrics; expectations related to Amarin's anticipated financial position and outlook in 2016 and the years that follow such as the company's potential to enter 2017 as cash flow positive from commercial operations; expectations for event rates, interim data reviews, results and related announcements with respect to Amarin's REDUCE-IT cardiovascular outcomes study; expectations related to the interim and final outcome of the REDUCE-IT study and the anticipated successful completion of the REDUCE-IT study; and statements regarding the potential efficacy, safety 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, these risks and uncertainties include the following: Amarin's ability to effectively commercialize Vascepa will depend in part on its ability to continue to effectively finance its business (including the REDUCE-IT study), is based on management's current expectations concerning TRx trends and wholesaler inventory levels, which tend to fluctuate based on seasonal factors, prescription trends and other factors and accordingly may be lower in subsequent periods, 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 historical REDUCE-IT clinical trial event rates may not be predictive of future results and related cost may increase beyond expectations; the risk that future litigation, court decisions and interpretation 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 and applications may not result in issued patents. 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.

### **Important Information Regarding Prescription Data and Product Revenue**

The historical prescription data provided in this press release is based on data published by third parties. References to normalized prescriptions equate to 120 capsules or one month's supply. Although Amarin believes these data are prepared on a period to period basis in a manner that is generally consistent and that such results are indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. These data may overstate or understate actual prescriptions. Based on other data available to Amarin and the history of such third-party prescription estimates in similar stages of launch of other pharmaceutical products, Amarin believes that the trends provided by this information can be useful to gauge current prescription levels. There is a limited amount of information available to determine the actual number of total prescriptions for prescription products like Vascepa. Amarin believes that investors should view these data with caution, as data for this single and limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales may affect future prescription trends of Vascepa on a monthly and quarterly basis, for example, as could changes in prescriber sentiment and other factors. Amarin believes investors should consider its results during this quarter together with its results over several future quarters, or longer, and in light of seasonal fluctuations before making an assessment about potential future performance. The commercialization and co-promotion of a new pharmaceutical product are complex undertakings, and Amarin's ability to effectively and profitably commercialize Vascepa will depend in part on its ability to continue to generate market demand for Vascepa through education, marketing and sales activities, its ability to achieve market acceptance of Vascepa, its ability to generate product revenue and its ability to receive adequate levels of reimbursement from third-party payers and its ability to benefit from continued contributions of its Vascepa co-promotion partner, Kowa Pharmaceuticals America, Inc. See "Risk Factors—Risks Related to the Commercialization and Development of Vascepa" included in Part II, Item 1A. Risk Factors in Amarin's most recent Quarterly Report on Form 10-Q.

### **Availability of Other Information about Amarin**

Investors and others should note that we communicate with our investors and the public using our company website (www.amarincorp.com), our investor relations website (http://www.amarincorp.com/investor-splash.html), 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 we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

### **Amarin contact information:**

Investor Relations:

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

	<u>June 30, 2016</u>	December n thousands)	December 31, 2015	
ASSETS	(i	i tilousalius)		
Current Assets:				
Cash and cash equivalents	\$ 72,491	\$	106,961	
Restricted cash	600		600	
Accounts receivable, net	17,639		13,826	
Inventory	20,306		18,985	
Prepaid and other current assets	5,476		3,152	
Total current assets	116,512		143,524	
Property, plant and equipment, net	137		243	
Deferred tax assets	21,718		19,872	
Other long-term assets	174		174	
Intangible asset, net	9,095		9,417	
TOTAL ASSETS	\$ 147,636	\$	173,230	
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current Liabilities:				
Accounts payable	\$ 14,811	\$	10,832	
Accrued expenses and other current liabilities	31,052		24,226	
Current portion of long-term debt	30,816		14,742	
Deferred revenue, current	1,172		923	
Total current liabilities	77,851		50,723	
Long-Term Liabilities:				
Exchangeable senior notes, net of discount	125,644		136,734	
Long-term debt	90,150		91,512	
Long-term debt derivative liabilities	3,610		8,170	
Deferred revenue, long-term	14,529		13,308	
Other long-term liabilities	268		335	
Total liabilities	312,052		300,782	
Stockholders' Deficit:				
Preferred stock	24,364		24,364	
Common stock	151,183		149,978	
Additional paid-in capital	822,013	1	816,171	
Treasury stock	(1,197)		(411)	
Accumulated deficit	(1,160,779)	(1,	117,654)	
Total stockholders' deficit	(164,416)	(	127,552)	
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 147,636	\$	173,230	

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

	Three months ended June 30, (in thousands, except per share amounts)					Six months ended June 30, (in thousands, except per share amounts)				
		2016	_	2015			2016	2015		
Product revenue, net	\$	32,815	\$		17,707	\$	58,122	\$	33,265	
Licensing revenue		296	_				532	_	375	
Total revenue, net		33,111			17,707		58,654		33,640	
Less: Cost of goods sold		8,861			6,381		15,757		12,008	
Gross margin		24,250			11,326		42,897		21,632	
Operating expenses:										
Selling, general and administrative (1)		26,066		7	26,054		54,086		50,795	
Research and development (1)		12,578			12,009		26,308		24,623	
Total operating expenses		38,644	_		38,063		80,394	_	75,418	
Operating loss		(14,394)		(2	26,737)		(37,497)		(53,786)	
Gain (loss) on change in fair value of derivative										
liabilities (2)		5,810			(600)		4,560		(136)	
Interest expense, net		(5,616)			(4,807)		(11,202)		(9,692)	
Other (expense) income, net		(182)			95		(303)		(33)	
Loss from operations before taxes		(14,382)		()	32,049)		(44,442)		(63,647)	
Benefit from income taxes		1,028	_		537		1,317	_	1,009	
Net loss		(13,354)		()	31,512)	· <u> </u>	(43,125)		(62,638)	
Preferred stock purchase option		_			_		_		(868)	
Preferred stock beneficial conversion feature		_		()	31,341)		_		(31,341)	
Net loss applicable to common shareholders	\$	(13,354)	\$	((	62,853)	\$	(43,125)	\$	(94,847)	
Loss per share:						· <u> </u>			_	
Basic	\$	(0.07)	\$		(0.35)	\$	(0.23)	\$	(0.53)	
Diluted	\$	(0.07)	\$		(0.35)	\$	(0.23)	\$	(0.53)	
Weighted average shares:										
Basic		184,471		18	80,464		184,262		178,036	
Diluted		184,471		18	80,464		184,262		178,036	

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$23,173 and \$23,680 for the three months ended June 30, 2016 and 2015, respectively, and research and development expenses were \$12,106 and \$11,167, respectively, for the same periods. Excluding non-cash stock-based compensation as well as co-promotion fees paid to our U.S. co-promotion partner, selling, general and administrative expenses were \$18,622 and \$21,981 for the three months ended June 30, 2016 and 2015, respectively.

(2) Non-cash gains and losses result from changes in the fair value of a warrant derivative liability, long-term debt derivative liabilities, and a preferred stock purchase option derivative liability.

### RECONCILIATION OF NON-GAAP NET LOSS Unaudited

	Three months ended June 30, (in thousands, except per share amounts)					Six months ended June 30, (in thousands, except per share amounts)				
		2016	ot per snare	2015	2016		2015			
Net loss for EPS1 — GAAP		(13,354)	\$	(62,853)	\$	(43,125)	\$	(94,847)		
Stock-based compensation expense		3,365		3,216		6,962		6,258		
Warrant compensation income		_		_		_		(9)		
(Gain) loss on change in fair value of derivatives		(5,810)		600		(4,560)		136		
Preferred stock purchase option		_		_		_		868		
Preferred stock beneficial conversion feature				31,341				31,341		
Adjusted net loss for EPS <sup>1</sup> — non GAAP		(15,799)	\$	(27,696)	\$	(40,723)	\$	(56,253)		
<sup>1</sup> basic and diluted										
Loss per share:										
Basic and diluted — non GAAP	\$	(0.09)	\$	(0.15)	\$	(0.22)	\$	(0.32)		
Weighted average shares:										
Basic and diluted		184,471		180,464		184,262		178,036		



### Amarin and FDA Reaffirm Concurrence on REDUCE-IT Through Special Protocol Assessment Agreement Amendment

Primary Endpoint and Overall Study Timing and Size Unchanged

Statistical Analysis Plan Finalized

Second Interim Efficacy Analysis and Additional Pre-Specified Endpoints Added

**BEDMINSTER, NJ and DUBLIN, IRELAND** – August 4, 2016 – Amarin Corporation plc (NASDAQ: AMRN) today announced that the U.S. Food and Drug Administration (FDA) agreed to an amendment of the company's special protocol assessment (SPA) agreement for the REDUCE-IT cardiovascular outcomes study reaffirming concurrence on critical components of the revised study protocol and analysis plans and incorporating recommendations from the trial's independent oversight committees.

Key new elements reflected in the company's amendment include:

- Finalized details of the statistical analysis plan covering both final and interim efficacy analyses;
- Added a second pre-specified interim efficacy analysis at approximately 80% of the 1,612 primary cardiovascular events targeted for completion of the study; and
- Expanded to over 30 the number of pre-specified secondary and tertiary endpoints in an effort to more fully capture the broad potential clinical effects of Vascepa® (icosapent ethyl) and the diversity of the patient population being studied.

The amendment does not change the primary endpoint or the overall size of the REDUCE-IT study or the company's prior guidance on timing. Prospective study of additional endpoints could lead to improved patient care for specific groups within the diverse population studied in REDUCE-IT. The addition of a second interim efficacy analysis at approximately 80% completion is expected to facilitate the compilation of the final locked dataset at study end and potentially shorten the time needed to complete final analysis and final result reporting.

"This amendment reflects timely modification and fine tuning of an already robust clinical trial design and helps ensure that expectations are clear between all parties directly involved regarding the formalities of data presentation and analysis at trial completion and interim looks," commented Steven Ketchum, Ph.D., chief scientific officer of Amarin. "Residual cardiovascular risk is high in the patient population being studied in REDUCE-IT. Because of this important unmet clinical need, the opportunity it presents and the years invested in this study, our goal is to promptly report and broadly publish the multiple findings anticipated from the study. We remain confident that REDUCE-IT is positioned for success."

### **Statistical Analysis Plan Finalized**

The primary endpoint of REDUCE-IT is the time from randomization to the first occurrence of a composite of adjudicated cardiovascular events (including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina). Consistent

with the protocol, patients in REDUCE-IT have been randomized in a 1:1 ratio to either the Vascepa plus statin treatment arm of the study or to the placebo plus statin treatment arm of the study. The time to the first occurrence of the composite endpoint will be compared between arms.

REDUCE-IT is designed to provide 90% power to detect a 15% relative risk reduction between arms at study end. The final analysis for the comparison of the time to onset of the first primary cardiovascular event between the treatment and control groups will be considered significant if the two-sided p-value is less than 0.0422.

The planned interim analyses by the DMC are based on a group sequential design with classic O'Brien-Fleming boundaries generated using the typical Lan-DeMets alpha-spending function. The use of the spending function allows for possible deviations from the target event numbers at the times of the respective interim analyses. As is standard with similar statistical assessments and permitted by study protocol, should either the first or second planned interim efficacy analysis include slightly more or slightly fewer adjudicated events, the target p-value stopping boundaries will be adjusted accordingly. The statistical analysis plan for REDUCE-IT does not include futility analysis at either interim analysis.

Amarin will remain blinded to the interim and ongoing results of the REDUCE-IT study as well as to any interim p-values or other statistical information until after the study is stopped and the database is locked, either at the final analysis or, in the event of a determination by the independent DMC of overwhelming efficacy, at an interim analysis. Guidelines for the independent DMC to recommend stopping the study at an interim analysis for overwhelming efficacy require that the study achieve the applicable pre-specified statistical significance threshold for the primary endpoint for that interim analysis, and generate robust efficacy evidence on selected subgroup analyses for the primary endpoint and certain pre-specified secondary outcome measures, to support an overall favorable benefit/risk profile. Given the high thresholds of overwhelming efficacy required prior to a DMC recommending an early stop to a cardiovascular outcomes trial like REDUCE-IT, Amarin continues to expect that the DMC's 60% and 80% interim analyses will each result in a recommendation to continue the REDUCE-IT study as planned.

### First Efficacy Analysis Anticipated Within 90 Days

As previously announced, late in the first quarter of 2016, the onset of approximately 60% of the target aggregate number of primary cardiovascular events triggered formal preparation for a protocol-specified interim efficacy and safety analysis by the DMC. The study has undergone multiple prior safety reviews by the DMC with each such review resulting in a DMC recommendation that REDUCE-IT continue as planned. The upcoming interim analysis in the September-October timeframe will include the first review of unblinded efficacy data by the DMC.

To be considered statistically significant at this interim look, based on the assumption that exactly 60% of target events are adjudicated and available for assessment by the DMC, the primary efficacy analysis must show that the two-sided p-value for relative risk reduction on the primary endpoint is less than 0.0076 in favor of the Vascepa plus statin treatment arm.

### **Second Efficacy Analysis Added**

Preparations for the second planned interim efficacy analysis will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, Amarin anticipates that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy and safety analysis by the DMC expected around mid-2017.

Assuming that exactly 80% of the target primary events have been adjudicated and included in the second interim efficacy analysis by the DMC, the primary efficacy analysis must show that the two-sided p-value for relative risk reduction on the primary endpoint is less than 0.0220 in favor of the Vascepa plus statin treatment arm.

### Final Efficacy Analysis Anticipated in 2018

The final analysis will be conducted from a locked database after notification that 1,612 primary cardiovascular events have been formally adjudicated. Amarin currently expects that the final event will occur in the second half of 2017, with top-line data announcement anticipated in 2018.

If the study is continued until the planned end, subsequent to the two interim efficacy analyses by the DMC, the final analysis for the comparison of the time to onset of first primary cardiovascular event between the treatment and control groups will be considered significant if the two-sided p-value is less than 0.0422. This final p-value reflects accepted statistical methodology for adjustment of multiple analyses.

### **Secondary and Tertiary Endpoints Expanded**

Recognizing the potential to observe broad beneficial impact from treatment with Vascepa in REDUCE-IT, the study's statistical analysis plan now includes more than 30 pre-specified secondary and tertiary endpoints designed to capture multiple potential drug effects in multiple additional sub-populations. Such pre-specified endpoints are designed to better assess the potential therapeutic benefits of Vascepa across multiple patient subpopulations and support a variety of related new publications. We anticipate these publications could help us improve patient care by supporting informed medical decisions in the treatment of cardiovascular disease.

"The data generated by this trial, if successful, could define how residual cardiovascular risk is treated in the studied patient population," added Dr. Ketchum. "As a result, the comprehensive value of REDUCE-IT data could come not just from a statistically significant reduction in risk for the overall patient population, which is paramount, but also from the potential for consistent and robust REDUCE-IT data across multiple secondary outcome measures and patient subgroups. We seek efficacy and safety results that are unequivocal, robust, and consistent to provide the strongest foundation from which to seek expanded labeling for Vascepa."

### **About Special Protocol Assessment Agreements**

An SPA agreement documents FDA's agreement that the design and planned analysis of a study can adequately address objectives in support of a regulatory submission. The FDA agreed that, based on the information submitted to the agency, the critical elements of the revised REDUCE-IT protocol and analysis plans would support a regulatory submission based on the study's primary endpoint. Secondary and/or tertiary endpoints, their clinical significance, or whether any such endpoints would yield results appropriate for labeling are considered review issues and are not intended to be a binding component of the REDUCE-IT SPA agreement. An SPA agreement is not a guarantee of approval. An SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy is identified after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. The FDA reserves the right of final determinations for approval based on its review of the entire data presented in a marketing application.

### **About REDUCE-IT**

REDUCE-IT is a global Phase 3, randomized, multicenter, double-blind, placebo-controlled study designed to evaluate whether treatment with Vascepa reduces cardiovascular events in patients who have persistently elevated triglyceride levels despite stabilized statin therapy. The primary endpoint of the study is the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint.

Additional information on the REDUCE-IT trial and Amarin's other clinical studies of Vascepa can be found at www.clinicaltrials.gov.

### About VASCEPA® (icosapent ethyl) capsules

VASCEPA® (icosapent ethyl) capsules are a single-molecule prescription product consisting of 1 gram 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 ( $\geq 500 \text{ mg/dL}$ ) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. 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.

### **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 the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, omega-3 fatty acid product available by prescription. For more information about Vascepa, visit <a href="https://www.vascepa.com">www.vascepa.com</a>. For more information about Amarin, visit <a href="https://www.amarincorp.com">www.vascepa.com</a>.

### **Forward-looking statements**

This press release contains forward-looking statements, including statements about the potential efficacy and therapeutic benefits of Vascepa, including implications about the potential clinical importance of the potential findings from REDUCE-IT; statements regarding the REDUCE-IT study's potential success and its effects on patient care, including as relating to the more than 30 pre-specified secondary and tertiary endpoints focused on additional effects and patient sub-populations; the expected timing of the planned 60% and 80% interim data analyses by the DMC and related effects on the analysis and reporting of final data from the REDUCE-IT study; expectations regarding the DMC's recommendations to continue the REDUCE-IT study as planned following the 60% and 80% interim data analyses; expectations regarding the timing of the final cardiovascular event in the REDUCE-IT study and the release of top-line data; and the potential for an expansion of the approved Vascepa label based on the possible results of the REDUCE-IT study. 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 uncertainties associated generally with research on biomarkers thought to be relevant in the treatment of cardiovascular disease, as well as research and development and clinical trial risk generally, including the risk that study results may not be predictive of future results and that studied parameters may not have clinically meaningful effect. 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

### Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (<a href="www.amarincorp.com">www.amarincorp.com</a>), our investor relations website (<a href="http://www.amarincorp.com/investor-splash.html">http://www.amarincorp.com/investor-splash.html</a>), 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 we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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