# **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, 2020

# 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.)

77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, 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

	the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing ing provisions:	g obligation o	of the registrant under any of the							
	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 C	FR 240.14d-2	2(b))							
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CI	FR 240.13e-4	(c))							
Securit	ies 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							
Rule 1	e by check mark whether the registrant is an emerging growth company as defined in Rule 405 2b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).  Emerging growth company	of the Secur	ities Act of 1933 (17 CFR §230.405)							
	Emerging growth company									
	nerging growth company, indicate by check mark if the registrant has elected not to use the extended financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. $\Box$		ion period for complying with any ne							

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

On August 4, 2020, Amarin Corporation plc issued a press release announcing its financial results for the three and six months ended June 30, 2020 (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.
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(d) Exhibits

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Exhibit No.	Description
99.1	Press Release, dated August 4, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
	* * *

# 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, 2020 Amarin Corporation plc

By: <u>/s/ John</u> F. Thero

John F. Thero President and Chief Executive Officer



### Amarin Reports Second Quarter 2020 Financial Results and Provides Update on Operations

Total Revenue Increased 34% in Second Quarter 2020 Compared to Second Quarter 2019 Despite COVID-19 Headwinds

Multiple Upcoming Milestones Regarding VASCEPA® Opportunity in United States and Internationally

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

DUBLIN, Ireland and BRIDGEWATER, N.J., August 4, 2020 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the three and six months ended June 30, 2020, and provided an update on company operations.

Key Amarin achievements since its last quarterly report include:

- <u>Maintaining favorable revenue progress amid COVID-19 challenges:</u> Reported \$135.3 million in net total revenue in Q2 2020, an increase of 34% over Q2 2019, resulting in H1 2020 net total revenue of \$290.3 million, an increase of 67% over H1 2019.
- <u>Progressing VASCEPA®</u> development in Europe towards expected approval in early 2021: Continued to support review of VASCEPA by the European Medicines Agency in anticipation of expected approval of VASCEPA for commercial sale in Europe in early 2021 while advancing commercial plans for VASCEPA reimbursement and related commercial launch in Europe.
- <u>Decision made on commercialization in Europe</u>: As announced separately today, Amarin plans to maximize the blockbuster potential of VASCEPA in Europe through its own dedicated European commercial organization. Amarin's plan retains for shareholders substantially all of the economic upside to participate in the multi-billion-dollar cardiovascular risk reduction market in Europe while preserving strategic optionality and enabling later partnering of VASCEPA in smaller countries in Europe. To help execute on this European strategy Amarin appointed industry veteran, Mr. Karim Mikhail, as senior vice president, commercial head Europe. As detailed in today's separate press release, Mr. Mikhail has extensive cardiovascular and international experience and a track-record of success to rely on in building multi-billion-dollar brands.
- Results of VASCEPA clinical trial in China nearing reporting: VASCEPA clinical trial results on-track to be reported by Amarin's partner in China before end of 2020.
- <u>Patent appeal progressing</u>: Substantive briefing completed with two supporting amicus briefs submitted and September 2, 2020 hearing date scheduled in Amarin's appeal to the U.S. Court of Appeals for the Federal Circuit of the March 30, 2020 adverse district court decision on patents covering the first FDA-approved indication for VASCEPA.

• <u>Strong cash and investments balance</u>: As of June 30, 2020, Amarin reported total cash and investments of \$611.3 million with its only debt remaining to be paid being a maximum of \$23.0 million on its royalty-like instrument.

"The second quarter of 2020 was a challenging but productive quarter for Amarin. Despite headwinds brought on by the adverse patent judgment and the onset of COVID-19 related societal restrictions at the end of the first quarter, the Amarin team continues to be productive with an increasingly positive outlook. We recently resumed a substantial level of in-person interactions with healthcare professionals in various geographies to build on the January launch of VASCEPA for its new and differentiated cardiovascular risk reduction indication. Amarin's employees are working diligently to succeed driven by our mission to bring the promise of VASCEPA to millions of cardiovascular disease patients in need in the United States and internationally," stated John F. Thero, president and chief executive officer, Amarin.

## **Prescription Growth**

Normalized prescriptions for VASCEPA (prescription of 120 grams of VASCEPA representing a one-month supply) increased by approximately 44% and 47% in Q2 2020 compared to Q2 2019 based on data from Symphony Health and IQVIA, respectively. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 1,090,000 and 1,007,000 in the second quarter of 2020. Year to date, estimated normalized prescriptions for VASCEPA increased by approximately 57% and 59%, compared to the first half of 2019 based on data from Symphony Health and IQVIA, respectively. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 2,151,000 and 1,969,000 in the first half of 2020, respectively. As is typically true, prescription and net revenue growth values are rarely the same in any quarter. In Q2 2020, the estimates of prescriptions made by these third parties reflected slightly stronger growth than Amarin experienced in shipments of product to customers upon which revenues are recognized. Such differences are likely due to the estimated nature of these prescription growth numbers and the timing of purchases by customers. In Q1 2020, the inverse was true with the rate of growth in net revenue exceeding the third-party estimates of prescription growth.

VASCEPA revenue and prescription growth in Q2 2020 were adversely impacted by actions taken to slow the spread of COVID-19 infections. Due to various state and local shelter in place and other travel restrictions, reports from IQVIA indicated that patient visits to medical offices in April were down approximately 70% compared to pre-COVID-19 levels. Similarly, IQVIA reported a significant drop in the number of routine lab tests, including blood tests, being conducted. Physicians typically require office visits, including physical examinations and blood tests, prior to prescribing new medications such as VASCEPA. Further impacting VASCEPA growth in Q2 2020, for safety reasons Amarin reduced face-to-face interactions between Amarin sales personnel and healthcare professionals. While Amarin's field team utilized various means to virtually interact with healthcare professionals in Q2 2020, such interactions were less frequent and potentially less impactful than in-person communications, in particular as VASCEPA is being newly introduced to many healthcare professionals.

Per IQVIA data, patient visits to physicians increased in June compared to the lows of April indicating encouraging signs of recovery. However, per data from IQVIA for the week ending July 3, 2020, patient visits to physicians remained approximately 35% below pre-COVID-19 levels<sup>1</sup>. Similarly, the number of lab tests in June also remained well below pre-COVID-19 levels. This data is independent of VASCEPA and reflects continued patient cautiousness in the COVID-19 era.

In June, Amarin initiated a phased redeployment of sales representatives in a manner consistent with federal, Centers for Disease Control and Prevention, and state and local regulations. Amarin's redeployment expanded in July although not all healthcare professionals will currently allow sales representatives into their offices, particularly in some of the densely populated areas including New York City and Los Angeles where VASCEPA is best known, and historically most highly prescribed. Amarin intends to remain flexible and responsible in its promotion of VASCEPA while seeking effective ways to ensure that prescribers and at-risk patients are increasingly aware of the demonstrated positive efficacy and safety of VASCEPA.

#### **Increasing Promotion in the United States**

As society begins to emerge from COVID-19 restrictions, albeit partially and inconsistently, Amarin views the need for VASCEPA to be greater than ever. Cardiovascular disease is among the most significant underlying conditions that could lead to less favorable outcomes in patients infected by COVID-19. Therefore, patients' need for preventative cardiovascular care is greater than ever. Amarin is confident that its branded commercial launch activities, medical education, and other efforts will help patients and healthcare providers understand the value of VASCEPA for cardiovascular protection in appropriate patients.

Amarin's launch of VASCEPA for its new cardiovascular risk reduction indication remains in its infancy. Based on a recent survey of approximately 300 randomly sampled cardiologists, endocrinologists and primary care physicians, unaided awareness of VASCEPA for cardiovascular risk was just 32%. And among 302 statin-treated patients with triglycerides above 150 mg/dL and other relevant factors, unaided awareness was less than 1%.

To augment Amarin's ongoing activities to educate healthcare professionals and in parallel with our sales team getting back into the field, in mid-July Amarin began to launch its first ever direct-to-consumer campaign for VASCEPA focused on the use of VASCEPA for cardiovascular risk reduction in indicated patients. The campaign focuses on persistent cardiovascular risk and the benefit of VASCEPA to reduce risk of a heart attack or stroke by 25% when added to a statin. The campaign, which informs healthcare professionals as well as consumers, encourages patients to ask their providers about VASCEPA. As healthcare professionals and patients learn more about VASCEPA, Amarin anticipates expanded VASCEPA prescriptions and revenue. However, the timing and magnitude of such increases remain difficult to predict due to the challenges of quantifying the pace of COVID-19 recovery and the unprecedented nature and limited history of VASCEPA's approved indication.

## **International Update**

In Europe, EMA review of Amarin's application remains active. Based on the pace of the review, Amarin anticipates the timing of completion of EMA's review to support early 2021 European Community approval of VASCEPA for marketing and sale in Europe. Amarin is rapidly preparing for the commercial launch of VASCEPA in Europe with an emphasis on pursuing reasonable reimbursement for VASCEPA on a country-by-country basis. Amarin is confident that it has the resources to be successful in launching VASCEPA in Europe without having to share a significant portion of the economics from such launch with a commercial partner, except perhaps in certain of the smaller countries of Europe. Notably, the physician targets to be educated about VASCEPA in Europe tend to be more concentrated than in the United States as high-risk patients in Europe are more likely to be treated by a specialist. Therefore, targeting European physicians for education should be a more efficient process than in the United States where primary care physicians continue to manage most statin-treated patients. While Amarin has been preparing for an extended period of time for certain aspects of commercializing VASCEPA in Europe, Amarin recently began to expand its commercialization team for Europe including hiring an experienced head of commercialization for Europe with a core group of other key hires anticipated to be added before the end of 2020.

In Canada, Amarin's partner appears to have had early success in getting VASCEPA recommended for reimbursement for a significant patient population, patients with established cardiovascular disease consistent with VASCEPA's approved label, and aims to pursue further expansion of such reimbursement to other at-risk patient groups over time. VASCEPA was launched in Canada in February 2020. Receiving a positive reimbursement recommendation this quickly is a credit to Amarin's partner and to the demonstrated clinical effectiveness of VASCEPA.

In China, results of the study of VASCEPA in treating patients with severe hypertriglyceridemia (TG  $\geq$ 500 mg/dL) is anticipated to be reported by Amarin's partner before the end of 2020. Based on the results of this study, Amarin and its partner in China will evaluate how to best proceed toward regulatory approval of VASCEPA in China.

#### ANDA Update

Substantive legal briefs have been filed with the U.S. Court of Appeals for the Federal Circuit in Amarin's appeal of the previously announced district court's decision in favor of two filers of abbreviated new drug applications, or ANDAs, for Amarin's VASCEPA capsules in the United States based on the MARINE indication. The oral hearing date for this appeal is September 2, 2020. More information regarding this appeal can be found in this <u>FAQ</u> on the Amarin website.

Amarin believes strongly that the lower court judgment was seriously flawed and that it has strong arguments on appeal that could result in a victory for Amarin. If generic companies ultimately succeed at this effort, Amarin anticipates that for an extended period of time a significant portion of the icosapent ethyl market may remain branded due to potential supply volume constraints for high quality, generic versions of VASCEPA. At this time, Amarin is increasing promotion of VASCEPA with the expectation that Amarin will benefit from such promotion under these conditions with or without the launch of generic VASCEPA.

#### Financial Update

Net total revenue for the three and six months ended June 30, 2020 were \$135.3 million and \$290.3 million, respectively, compared to \$100.8 million and \$174.1 million in the corresponding periods of 2019, respectively, indicating increases of 34% and 67%, respectively. Net product revenue for the three and six months ended June 30, 2020 were \$133.7 million and \$285.9 million, respectively, compared to \$100.4 million and \$173.1 million in the corresponding periods of 2019, respectively, indicating increases of 33% and 65%, respectively. The increase in net product revenue was driven primarily by increased volume of VASCEPA sales to customers in the United States, as well as a modest increase in VASCEPA's net selling price in the United States reflecting various factors including managed care coverage improvements. In addition, the increase was also driven by VASCEPA sales outside of the United States of approximately \$1.8 million and \$8.5 million during the three and six months ended June 30, 2020 as compared to nil and \$0.3 million during the three and six months ended June 30, 2019, primarily as a result of an initial order in the first half of 2020 to ensure adequate product supply for Amarin's commercial partner's launch of VASCEPA in Canada (recognized upon shipment by Amarin to that partner).

In addition, Amarin recognized licensing and royalty revenue of approximately \$4.4 million and \$1.0 million in the six months ended June 30, 2020 and 2019, respectively, under agreements for the commercialization of VASCEPA outside the United States.

Cost of goods sold for the three and six months ended June 30, 2020 was \$28.8 million and \$63.6 million, respectively, compared to \$22.8 million and \$39.9 million in the corresponding periods of 2019, respectively.

Amarin's overall gross margin on net product revenue for the three and six months ended June 30, 2020 and 2019 was 78% and 77%, respectively. This increase in gross margin on net product sales is driven by gross margin on U.S. product sales of 79% and 80% for the three and six months ended June 30, 2020, partially offset by the gross margin on product sales to Amarin's partners outside the United States as per contractual arrangements. Net product revenue to Amarin's partners does not include licensing and royalty revenue.

Selling, general and administrative (SG&A) expense for the three and six months ended June 30, 2020 were \$92.4 million and \$226.3 million, respectively, compared to \$73.4 million and \$145.0 million, respectively, in the corresponding periods of 2019, representing increases of 26% and 56%. This increase is due primarily to personnel costs related to the sales force expansion. This increase was offset during the three months ended June 30, 2020 compared to the corresponding period in 2019 by a decrease in consumer-focused promotion. Such consumer-focused promotion was augmented in July 2020 when Amarin launched its first television advertisement of VASCEPA focused on cardiovascular risk reduction based on the product's new label. While there was a decrease in promotional activities in the second quarter of 2020, in early 2020 there was an increase in promotional activities to support the launch of VASCEPA for its new cardiovascular risk reduction indication resulting in an increase in year-to-date costs for such promotional activities compared to the same prior year period. Primarily driven by the increase in educational and marketing initiatives described above, Amarin anticipates SG&A expense to be approximately \$10 million to \$20 million higher in the second half of 2020 compared to the first half of 2020.

Research and development (R&D) expense for the three and six months ended June 30, 2020 were \$10.0 million and \$20.2 million, respectively, compared to \$7.1 million and \$14.4 million, respectively, in the corresponding periods of 2019, representing increases of 40% and 41%, respectively. The increase in expense was primarily driven by costs beyond the conduct of the REDUCE-IT® study to further analyze samples collected from REDUCE-IT patients as well as costs associated with the achievement of certain milestones under Amarin's strategic collaboration agreement with Mochida and costs to support various publications and pilot studies.

Under U.S. GAAP, Amarin reported net income of \$4.4 million in the three months ended June 30, 2020, or basic and diluted earnings per share of \$0.01. This net income included \$12.1 million in non-cash stock-based compensation expense. Amarin reported a net loss of \$1.8 million in the second quarter of 2019, or basic and diluted loss per share of \$0.01. This net loss included \$7.9 million in non-cash stock-based compensation expense.

Under U.S. GAAP, Amarin reported a net loss of \$16.1 million in the six months ended June 30, 2020, or basic and diluted loss per share of \$0.04. This net loss included \$22.7 million in non-cash stock-based compensation expense. For the six months ended June 30, 2019, Amarin reported a net loss of \$26.3 million, or basic and diluted loss per share of \$0.08. This net loss included \$14.8 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$16.5 million for the second quarter of 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.04, compared to non-GAAP adjusted net income of \$6.1 million for the second quarter of 2019, or non-GAAP adjusted basic and diluted earnings per share of \$0.02.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$6.6 million for the six months ended June 30, 2020, or non-GAAP adjusted basic and diluted earnings per share of

\$0.02, compared to non-GAAP adjusted net loss of \$11.5 million for the six months ended June 30, 2019, or non-GAAP adjusted basic and diluted loss per share of \$0.03.

As of June 30, 2020, Amarin reported aggregate cash and investments of \$611.3 million, consisting of cash and cash equivalents of \$214.0 million and liquid short-term investments and long-term investments of \$336.3 and \$61.0 million, respectively. As of June 30, 2020, Amarin reported \$125.0 million in net accounts receivable (\$173.2 million in gross accounts receivable before allowances and reserves) and \$124.8 million in inventory. As previously expressed, until uncertainties regarding the effects and duration of the COVID-19 pandemic and patent litigation are better understood, Amarin is not providing an estimate of expected 2020 revenue results. Based on its current plans and expectations, Amarin believes that its current capital resources are sufficient to achieve sustained positive cash flows from VASCEPA, including commercial launch of VASCEPA in Europe. Results are anticipated to vary significantly on a quarterly basis including some likely negative net cash flow periods. Factors that are expected to contribute to this variability include Amarin's efforts to continue with a robust launch of VASCEPA in its new cardiovascular risk reduction indication, further developments from the influence of the COVID-19 pandemic on Amarin's business and society, the potential launch of generic versions of VASCEPA in the United States and Amarin's efforts toward the further development and launch of VASCEPA in Europe.

As of June 30, 2020, Amarin had approximately 385.8 million American Depository Shares (ADSs) and ordinary shares outstanding, 5.2 million common share equivalents of Series A Convertible Preferred Shares outstanding, approximately 17.2 million equivalent shares underlying stock options at a weighted-average exercise price of \$7.87, and 7.6 million equivalent shares underlying restricted or deferred stock units.

#### **Conference Call and Webcast Information**

Amarin will host a conference call August 4, 2020, at 7:30 a.m. ET to discuss this information. 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 877-869-3847 within the United States, 201-689-8261 from outside the United States, or by using the call back feature at <a href="https://bit.ly/3j5aEDx">https://bit.ly/3j5aEDx</a>. 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: 35819. A replay of the call will also be available through the company's website shortly after the call.

#### **Use of Non-GAAP Adjusted Financial Information**

Included in this press release 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 income (loss) was derived by taking GAAP net income (loss) and adjusting it for non-cash stock-based compensation expense. 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 rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, VASCEPA (icosapent ethyl), is available by prescription in the United States, Canada, Lebanon and the United Arab Emirates. Amarin, together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in China, Europe and the Middle East. For more information about Amarin, visit <a href="https://www.amarincorp.com">www.amarincorp.com</a>.

#### **About Cardiovascular Risk**

The number of deaths in the United States attributed to cardiovascular disease continues to rise. There are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds), in the United States. Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. Cardiovascular disease results in 859,000 deaths per year in the United States. In aggregate, this is more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, one every 13 seconds in the United States alone.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent risk of cardiovascular events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>3</sup> Significant cardiovascular risk remains after statin therapy. People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.<sup>4,5,6</sup>

#### **About REDUCE-IT**

REDUCE-IT was a global cardiovascular outcomes study designed to evaluate the effect of VASCEPA in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other cardiovascular risk factor (primary prevention cohort).

REDUCE-IT, conducted over seven years and completed in 2018, followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States. REDUCE-IT was conducted

based on a special protocol assessment agreement with FDA. The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology*. The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.8 The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.9 These and other publications can be found in the R&D section on the company's website at <a href="https://www.amarincorp.com">www.amarincorp.com</a>.

## About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the FDA comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA-approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over eight million times. VASCEPA is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019.

#### **Indications and Limitation of Use**

#### VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - O established cardiovascular disease or
  - O diabetes mellitus and two or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

#### **Important Safety Information**

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of
  its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an

allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.

- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
- Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA, as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASO	CEPA	Placaba		VASCEPA vs Placebo
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
Primary composite endpoint	1				
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint	•				
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)

	VA	ASCEPA	P	lacebo	VASCEPA vs Placebo	
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)	
Cardiovascular death [1]	eath [1] 174 (4.3)		213 (5.2)	1.2	0.80 (0.66, 0.98)	
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)	
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)	

<sup>[1]</sup> Includes adjudicated cardiovascular deaths and deaths of undetermined causality.

#### FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

#### **Forward-Looking Statements**

This press release contains forward-looking statements, including expectations regarding financial metrics and performance such as prescription growth, revenue growth, operating expenses, inventory purchases, and managed care coverage for VASCEPA, including the impact of the COVID-19 pandemic, the outcome of patent litigation and the launch of generic competition on these metrics; the timing and outcome of regulatory reviews, recommendations and approvals and related reimbursement decisions in China, Europe and elsewhere; the timing and outcome of the clinical trial in China; the timing and outcome of Amarin's decision to launch VASCEPA directly in major markets in Europe and with a partner potentially in some markets in Europe; the timing and outcome of Amarin's appeal of the patent litigation district court decision; the timing and outcome of promotion activities, including patient-oriented campaigns and education of healthcare professionals; commercial and international expansion, prescription growth and revenue growth and future revenue levels, including the contributions of recently hired sales representatives; the sufficiency of current capital resources to achieve sustained positive cash flows; ability of commercial supply to generic companies and Amarin; creditworthiness of its largest customers; expectations related to exclusivity in various jurisdictions and ongoing patent litigation appeal and associated business plans in various scenarios; and the impact of the COVID-19 pandemic on all of the forgoing. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Amarin's ability to effectively commercialize VASCEPA will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for VASCEPA through education, marketing and sales activities, to achieve broad 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 secure and maintain patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein

<sup>[2]</sup> Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

include the following: uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may be determined to not be infringed or not be valid in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

#### **Availability of Other Information About Amarin**

Investors and others should note that Amarin communicates with its investors and the public using the company website (<a href="www.amarincorp.com">www.amarincorp.com</a>), the investor relations website (<a href="investor.amarincorp.com">investor.amarincorp.com</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 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.

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

	<u>Jur</u>	1e 30, 2020		mber 31, 2019
		(in tho	usands)	
ASSETS				
Current Assets:	ф	24.4.00	ф	044 <b>5</b> 00
Cash and cash equivalents	\$	214,007	\$	644,588
Restricted cash		3,913		3,907
Short-term investments		336,273		
Accounts receivable, net		124,985		116,430
Inventory		124,844		76,769
Prepaid and other current assets		23,589		13,311
Total current assets		827,611		855,005
Property, plant and equipment, net		2,316		2,361
Long-term investments		61,039		_
Operating lease right-of-use asset		8,291		8,511
Other long-term assets		1,074		1,074
Intangible asset, net		14,538		15,258
TOTAL ASSETS	\$	914,869	\$	882,209
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	86,757	\$	49,950
Accrued expenses and other current liabilities		168,549		139,826
Debt from royalty-bearing instrument		22,455		50,130
Deferred revenue, current		5,706		2,342
Total current liabilities		283,467		242,248
Long-Term Liabilities:				
Deferred revenue, long-term		14,507		18,504
Long-term operating lease liability		9,311		9,443
Other long-term liabilities		4,821		3,751
Total liabilities		312,106		273,946
Stockholders' Equity:				
Preferred stock		7,166		21,850
Common stock		285,672		269,173
Additional paid-in capital		1,787,492		1,764,317
Treasury stock		(50,252)		(35,900
Accumulated deficit		(1,427,315)		(1,411,177
Total stockholders' equity		602,763		608,263
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	914,869	\$	882,209

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

	(in th	Three months ended June 30, (in thousands, except per share amounts)			Six months ended June 30, (in thousands, except per share amounts)			
		2020	2019 20		2020		2019	
Product revenue, net	\$	133,724	\$	100,366	\$	285,928	\$	173,097
Licensing and royalty revenue		1,593		426		4,382		973
Total revenue, net		135,317		100,792		290,310		174,070
Less: Cost of goods sold		28,797		22,770		63,604		39,910
Gross margin		106,520		78,022		226,706		134,160
Operating expenses:								
Selling, general and administrative (1)		92,395		73,406		226,332		145,039
Research and development (1)		9,969		7,130		20,247		14,372
Total operating expenses		102,364		80,536		246,579		159,411
Operating income (loss)		4,156		(2,514)		(19,873)		(25,251)
Interest income (expense), net		151		789		1,359		(908)
Other income (expense), net		108		(95)		17		(92)
Income (loss) from operations before taxes	-	4,415		(1,820)		(18,497)		(26,251)
Income tax benefit		_		_		2,359		_
Net income (loss)	\$	4,415	\$	(1,820)	\$	(16,138)	\$	(26,251)
Earnings (loss) per share:								
Basic	\$	0.01	\$	(0.01)	\$	(0.04)	\$	(80.0)
Diluted	\$	0.01	\$	(0.01)	\$	(0.04)	\$	(80.0)
Weighted average shares:								
Basic		384,663		330,863		373,300		329,793
Diluted		399,664		330,863		373,300		329,793

<sup>(1)</sup> Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$82,035 and \$66,564 for the three months ended June 30, 2020 and 2019, respectively, and research and development expenses were \$8,198 and \$6,089, respectively, for the same periods.

# RECONCILIATION OF NON-GAAP NET INCOME (LOSS) Unaudited

Six months ended June 30

Three months ended June 30

	(in thousands, except per share amounts)				Six mondis ended June 30,			
					(in thousands	share amounts)		
	2020		2019		2020		2019	
Net income (loss) for EPS <sup>1</sup> - GAAP	\$	4,415	\$	(1,820)	\$	(16,138)	\$	(26,251)
Non-cash stock-based compensation expense		12,131		7,883		22,722		14,766
Adjusted net income (loss) for EPS1 - non-GAAP	\$	16,546	\$	6,063	\$	6,584	\$	(11,485)
<sup>1</sup> basic and diluted								
Earnings (loss) per share:								
Basic - non-GAAP	\$	0.04	\$	0.02	\$	0.02	\$	(0.03)
Diluted - non-GAAP		0.04		0.02		0.02		(0.03)
Weighted average shares:								
Basic		384,663		330,863		373,300		329,793
Diluted		399,664		373,238		402,033		329,793

#### References

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- <sup>9</sup> Bhatt DL, Steg PG, Miller M, et al., on behalf of the REDUCE-IT Investigators. Reduction in first and total ischemic events with icosapent ethyl across baseline triglyceride tertiles. *J Am Coll Cardiol*. 2019;74:1159-1161.