

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 5, 2021

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

On August 5, 2021, Amarin Corporation plc (“Amarin”) issued a press release announcing its financial results for the three and six months ended June 30, 2021 and 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 (the “Securities Act”), if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.*

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**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	Description
<a href="#">99.1</a>	<a href="#">Press Release (results of operations), dated April 29, 2021 (furnished herewith)</a>
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 5, 2021

Amarin Corporation plc

By: /s/ Karim Mikhail

Karim Mikhail

President and Chief Executive Officer

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## **Amarin Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update**

*Commercial Launch of VAZKEPA in Europe on Track to Commence in September in Germany*

*Filed Several Market Access Dossiers in Europe with Proposed Pricing of approximately €200 per Month*

*New CEO, Karim Mikhail, to Host Conference Call Today at 7:30 a.m. ET*

DUBLIN, Ireland and BRIDGEWATER, N.J., August 5, 2021 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the second quarter and six months ended June 30, 2021 and provided an update on company operations.

### **Recent Key Amarin Highlights:**

- Second Quarter Revenue: Net total revenue in the second quarter of 2021 was \$154.5 million, an increase of 14% when compared with \$135.3 million in total net revenue during the prior year period. Net product revenue for the three months ended June 30, 2021 was \$153.8 million, an increase of 15% when compared with the net product revenue in the prior year's second quarter. In the U.S., based on data from Symphony Health, Amarin retained approximately 89% of the icosapent ethyl market in the first half of 2021, with approximately eight months of generic presence in the market.
- On Track for European Launch: Amarin plans to launch VAZKEPA in Germany in September and has filed several market access dossiers in Europe with proposed pricing of approximately €200 per month.
- Received Marketing Authorization for VAZKEPA in Great Britain: Amarin received market authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA) for VAZKEPA in Great Britain as a treatment to reduce the risk of cardiovascular (CV) events in high CV risk statin-treated adult patients.
- Executing Global Expansion Strategy: Amarin plans to initiate regulatory approval processes in approximately 20 additional countries in order to reach the top 50 cardiometabolic markets in the world.
- VASCEPA®/VAZKEPA Added to Four Medical Societies' Clinical Treatment Guidelines or Position Statements: VASCEPA is now included in 19 medical societies' clinical treatment guidelines or position statements, including the recent addition of VASCEPA to the "2021 Expert Consensus Decision Pathway on the Management of Patients with Persistent Hypertriglyceridemia for Atherosclerotic Cardiovascular Disease (ASCVD) Risk Reduction" issued by the American College of Cardiology. Click here for more information on the guidelines.
- New Senior Leadership to Support Further Growth: As of August 1, 2021, Karim Mikhail succeeded to the president and chief executive officer position following the planned retirement of his predecessor, John F. Thero. In addition, the company appointed Laurent Abuaf as senior vice president, president of Europe.
- Strong Balance Sheet: Ended second quarter 2021 with \$523.1 million in total cash and investments and no debt.

## Management Commentary

“Amarin enters the second half of 2021 well positioned to deliver on our goals to reignite growth of branded VASCEPA in the U.S., to successfully launch VAZKEPA in Europe and to undertake initiatives to expand its growth in other important geographies,” stated Karim Mikhail, president and chief executive officer of Amarin. “We believe that this additional expansion represents an incremental market potential in excess of \$1 billion that we are confident we can access as there are millions of at-risk patients who could benefit from VASCEPA/VAZKEPA.”

“There continues to be a steady flow of scientific and clinical evidence in support of the cardioprotective benefits of VASCEPA/VAZKEPA presented at key global medical meetings. Later this month, we look forward to the European Society of Cardiology, where VAZKEPA will be featured in a series of oral and poster presentations by key opinion leaders before an audience of leading cardiologists. We are particularly pleased that our product launch in Germany will take place shortly after this important congress.

“Our strategy for reducing the occurrence of the debilitating and deadly effects of cardiovascular disease is sound and we are executing our global plans to efficiently reach physicians, payors, pharmacists and patients. We are transforming our go-to-market model to enhance customer engagement while executing a variety of promotional and educational programs to increase awareness of the cardiovascular risk reduction benefits of our unique therapy. We expect these efforts will build demand for and drive adoption of VASCEPA/VAZKEPA in the U.S. and Europe,” concluded Mr. Mikhail.

## U.S. Prescription Growth

Normalized prescriptions for VASCEPA (prescription of 120 grams of VASCEPA representing a one-month supply) in the United States were flat according to data from Symphony Health and increased by approximately 2% during the second quarter 2021 compared to the same period in 2020 based on data from IQVIA. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 1,086,000 and 1,015,000 in the second quarter of 2021, respectively, compared with 1,089,000 and 998,000 in the second quarter of 2020, respectively. The icosapent ethyl market in aggregate, consisting of branded and generic product, increased for the three months ended June 30, 2021 by approximately 13% as compared to the three months ended June 30, 2020, based on data from Symphony Health. Revenue recognition, which is based on control of the product transferring to customers, and levels of prescriptions as estimated by third parties, often do not directly correlate, particularly over relatively short periods of time such as a fiscal quarter.

Amarin remains confident that the patient need for VASCEPA in the United States remains high and that, as the negative impact of COVID-19 on patient visits and lab tests recedes, VASCEPA growth will be positioned to accelerate as more patients seek routine doctor visits and lab tests and as our promotional activities become less restricted.

Two generic versions of VASCEPA have launched in the United States, both of which are indicated only as an adjunct to diet for lowering triglyceride levels in adult patients with severe hypertriglyceridemia (TG  $\geq$ 500 mg/dL), which represents a limited patient population. Amarin has filed a lawsuit to defend its cardiovascular risk reduction patent rights against what it believes to be unlawful infringement by a company sponsoring a generic product and a healthcare insurance company that the Company believes has likewise infringed on its rights. Based on data from Symphony Health, VASCEPA captured approximately 88% of the total icosapent ethyl normalized prescriptions for the three months ended June 30, 2021.

## Europe

After receiving marketing authorization for VAZKEPA in Europe by the European Commission and in Great Britain by the MHRA, Amarin has filed market access dossiers in four out of ten planned first wave European country submissions. The dossiers were filed in the United Kingdom, France, Italy and Denmark. The German dossier is ready for submission just prior to the launch date in September 2021. These dossiers are an important component for successful product launch as they support pricing and reimbursement, a key determining factor in market penetration. The submitted filings include data demonstrating the uniqueness of VAZKEPA from a scientific perspective, various country-specific demographic data sets to define the eligible patient population based on the drug's approved label, and proposed pricing of approximately €200 per month. Amarin is seeking pricing it believes is well justified based on the demonstrated clinical effectiveness of VAZKEPA and the high economic burden of heart attacks, strokes and other cardiovascular events, which VAZKEPA can help avoid.

### **Global Market Expansion**

Amarin's goal is to unlock the potential of VASCEPA by bringing the cardioprotective benefits of VASCEPA/VAZKEPA to patients worldwide. The Company plans to access 20 additional countries to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA. In these territories which include Australia, New Zealand, key Latin American markets, and select Asian markets, Amarin will initiate regulatory filing processes in the coming months and year. With approvals in the U.S. and Europe and backed by the global REDUCE-IT study outcomes, Amarin has the clinical data to support these filings and expects regulatory submissions and approval decision times to range from six to eighteen months depending on the region. This expansion has the potential to add a significant number of patients who can benefit from VASCEPA, which Amarin believes represents a market opportunity in excess of \$1 billion.

In early 2021, in Mainland China, the Chinese National Medical Products Administration (NMPA) accepted for review the New Drug Application (NDA) for VASCEPA. In addition, the medical guidelines of the Chinese Society of Cardiology were updated to recommend use of icosapent ethyl in China as a treatment consideration to further lower ASCVD in the appropriate patient population. Edding, Amarin's marketing partner in China, expects to receive a decision on the NDA in Mainland China and separately, in Hong Kong, near the end of 2021. Following approval, Edding will undertake the process to ensure that this unique therapy is reimbursed in the major provinces of Mainland China as the first and only drug for its important potential indication for use based on VASCEPA's demonstrated clinical results.

### **New Leadership to Support Further Growth**

Amarin significantly enhanced its senior leadership team with the promotion of Mr. Mikhail to president and chief executive officer on August 1, 2021. Mr. Mikhail has a successful track-record of leading significant growth of cardiovascular and other franchises with Merck for 22 years, where he served in leadership roles in seven countries across three continents and where he led Merck's multibillion-dollar lipid franchise among other senior management positions.

In addition, the Company announced the appointment of Laurent Abuaf as the new senior vice president and president of Europe to fill the opening left by Mr. Mikhail's promotion to president and chief executive officer. He will join Amarin and assume the role on August 23, 2021. Mr. Abuaf joins Amarin with nearly 20 years of global pharmaceutical commercialization experience, primarily with AstraZeneca, where he most recently served as President, United Kingdom. He brings a wealth of European marketing management experience across small, medium and large markets. Mr. Abuaf has significant cardiometabolic launch experience having contributed to the successful launch of Crestor® and Farxiga®. He also has significant entrepreneurial and strategic project management experience, having led and managed commercial activities in multiple countries in Asia. Prior to his career in pharmaceuticals, Mr. Abuaf spent nearly five years with Boston Consulting Group.

## Financial Update

Net total revenue for the three and six months ended June 30, 2021 were \$154.5 million and \$296.7 million, respectively, compared to \$135.3 million and \$290.3 million in the corresponding periods of 2020, respectively, indicating increases of 14% and 2%, respectively. Net product revenue for the three and six months ended June 30, 2021 were \$153.8 million and \$295.2 million, respectively, compared to \$133.7 million and \$285.9 million in the corresponding periods of 2020, respectively, indicating increases of 15% and 3%, respectively. The increase in net product revenue and net total revenue was driven primarily by increased volume of VASCEPA sales to customers in the United States.

In addition, net total revenue includes licensing and royalty revenue of approximately \$1.5 million and \$4.4 million in the six months ended June 30, 2021 and 2020, 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, 2021 was \$32.2 million and \$60.5 million, respectively, compared to \$28.8 million and \$63.6 million in the corresponding periods of 2020, respectively. Amarin's overall gross margin on net product revenue for the three and six months ended June 30, 2021 and was 79% and 80%, respectively, compared to 78% for both the three and six months ended June 30, 2020.

Selling, general and administrative (SG&A) expense for the three and six months ended June 30, 2021 were \$107.2 million and \$213.0 million, respectively, compared to \$92.4 million and \$226.3 million, respectively, in the corresponding periods of 2020, representing an increase of 16% for the same three month period and a decrease of 6% for the same six month period. The increase for the same three month period in 2021 and 2020, was due primarily to personnel costs related to preparation for expansion into the European market as well as increased promotional activity in connection with the resumption of marketing and direct-to-consumer promotions. The decrease for the same six month period in 2021 and 2020, was due primarily to a decrease in promotional activity as a result of the COVID-19 pandemic, which included reduced marketing and direct-to-consumer promotions, travel, and a slower hiring process to replace open positions due to ordinary turnover.

Research and development (R&D) expense for the three and six months ended June 30, 2021 were \$6.4 million and \$15.7 million, respectively, compared to \$10.0 million and \$20.2 million, respectively, in the corresponding periods of 2020, representing decreases of 36% and 22%, respectively. These decreases were primarily driven by the completion of certain analyses performed beyond the REDUCE-IT cardiovascular outcomes trial and the reversal of expense for certain performance-based awards that were no longer deemed probable.

Under U.S. GAAP, Amarin reported net income of \$7.8 million in the three months ended June 30, 2021, or basic and diluted earnings per share of \$0.02. This net income included \$2.5 million in non-cash stock-based compensation expense. Amarin reported net income of \$4.4 million in the second quarter of 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. The company expects financial results regarding net income or net loss to be variable through the balance of 2021.

Under U.S. GAAP, Amarin reported net income of \$6.2 million in the six months ended June 30, 2021, or basic and diluted earnings per share of \$0.02. This net income included \$16.4 million in non-cash stock-based compensation expense. For the six months ended June 30, 2020, Amarin reported a net loss of \$16.1 million, or basic and diluted loss per share of \$0.04. This net loss included \$22.7 million in non-cash stock-based compensation expense.



Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$10.3 million for the second quarter of 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.03, compared to non-GAAP adjusted net income of \$16.5 million for the second quarter of 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.04.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net income was \$22.6 million for the six months ended June 30, 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.06, compared to non-GAAP adjusted net income of \$6.6 million for the six months ended June 30, 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.02.

As of June 30, 2021, Amarin reported aggregate cash and investments of \$523.1 million, consisting of cash and cash equivalents of \$327.0 million and liquid short-term and long-term investments of \$181.9 million and \$14.2 million, respectively. The Company believes its current resources are sufficient to fund projected operations including ongoing promotion of VASCEPA in the U.S. and a successful commercial launch of VAZKEPA in Europe.

As of June 30, 2021, Amarin had approximately 395.2 million American Depositary Shares (ADSs) and ordinary shares outstanding approximately 19.7 million equivalent shares underlying stock options at a weighted-average exercise price of \$7.54 and 10.4 million equivalent shares underlying restricted or deferred stock units.

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

Amarin will host a conference call August 5, 2021, 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](http://www.amarincorp.com), or via telephone by dialing 888-506-0062 within the United States, 973-528-0011 from outside the United States, and referencing conference ID 401474. 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: 42077. 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 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 is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation to our focus on clinical trials, and now our commercial expansion, we are evolving and growing rapidly. Amarin primarily has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, and Zug in Switzerland as well as commercial partners and suppliers around the world. We are committed to rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

## **About Cardiovascular Risk**

Cardiovascular disease is the number one cause of death in the world. In the United States alone, cardiovascular disease results in 859,000 deaths per year.<sup>2</sup> And the number of deaths in the United States attributed to cardiovascular disease continues to rise. In addition, in the United States there are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds). Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. In aggregate, in the United States alone, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, 1 every 13 seconds.

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*.<sup>7</sup> The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.<sup>8</sup> The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.<sup>9</sup> These and other publications can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

## About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. 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 ( $\geq 500$  mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, Lebanon and the United Arab Emirates. In Europe, in March 2021 marketing authorization was granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VASKEPA.

### Indications and Limitation of Use (in the United States)

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 ( $\geq 150$  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 ( $\geq 500$  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  $\geq 3\%$  and  $\geq 1\%$  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  $\geq 1\%$  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**

	VASCEPA		Placebo		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)
<b>Primary composite endpoint</b>					
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)
<b>Key secondary composite endpoint</b>					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
<b>Other secondary endpoints</b>					
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)
Cardiovascular death <sup>[1]</sup>	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina <sup>[2]</sup>	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)
[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality.					
[2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.					

**FULL U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).**

**Forward-Looking Statements**

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including beliefs about the world-wide market potential for VASCEPA; 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 disappointing outcome of patent litigation and the launch of generic competition on these metrics; beliefs that Amarin is well positioned to deliver on its goals to grow VASCEPA in the U.S. and beyond; beliefs about patient needs for VASCEPA; effects of the COVID-19 pandemic on Amarin's operations and on the healthcare industry more broadly, which effects

continue to be fluid; beliefs that Amarin's strategy for reducing the effects of cardiovascular disease is sound and that Amarin is efficiently reaching physicians, payors, pharmacists and patients; plans for Amarin's go-to-market model; the timing and outcome of regulatory reviews, recommendations and approvals and related reimbursement decisions and commercial launches in Europe, the China region and elsewhere; plans for Amarin's expected launch of VASCEPA directly in major markets in Europe, directly and indirectly; beliefs about the cardioprotective and other benefits of VASCEPA; beliefs about the strength of data in market access dossiers and other reports; expectations for the timing, effectiveness and outcome of promotional activities, including patient-oriented campaigns, conference and posted presentations and education of healthcare professionals; commercial and international expansion, prescription growth and revenue growth and future revenue levels, including the contributions of sales representatives and the new leadership team; beliefs that Amarin's current resources are sufficient to fund projected operations; ongoing patent litigation efforts; 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 and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business, VASCEPA approval in geographies outside the U.S., efforts of third parties, Amarin's ability to create and increase 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, maintain and defend its patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the possibility that VASCEPA may not receive regulatory approval in the China region or other geographies on the expected timelines or at all, the risk that additional generic versions of VASCEPA will enter the market and that generic versions of VASCEPA will achieve greater market share and more commercial supply than anticipated, particularly in light of the recent and disappointing outcome of Amarin's litigation against two generic drug companies and subsequent requests for appeal; the risk that the scope and duration of the COVID-19 pandemic will continue to impact access to and sales of VASCEPA; the risk that Amarin has overestimated the market potential for VASCEPA in the U.S., Europe and other geographies; risks associated with Amarin's expanded enterprise; 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 Amarin's quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed on or about the date hereof. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward looking statements, 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 ([www.amarincorp.com](http://www.amarincorp.com)), the investor relations website ([investor.amarincorp.com](http://investor.amarincorp.com)), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is

posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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Crestor® and Farxiga® are registered trademarks of AstraZeneca group of companies.

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

	June 30, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 327,016	\$ 186,964
Restricted cash	3,917	3,915
Short-term investments	181,910	313,969
Accounts receivable, net	182,259	154,574
Inventory	272,455	188,864
Prepaid and other current assets	28,426	30,947
Total current assets	995,983	879,233
Property, plant and equipment, net	1,713	2,016
Long-term investments	14,158	62,469
Operating lease right-of-use asset	7,861	8,054
Other long-term assets	456	432
Intangible asset, net	24,820	13,817
TOTAL ASSETS	\$ 1,044,991	\$ 966,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	141,251	105,876
Accrued expenses and other current liabilities	226,545	198,641
Current deferred revenue	2,643	2,926
Total current liabilities	370,439	307,443
Long-Term Liabilities:		
Long-term deferred revenue	14,825	15,706
Long-term operating lease liability	8,875	9,153
Other long-term liabilities	5,528	6,214
Total liabilities	399,667	338,516
Stockholders' Equity:		
Common stock	292,782	290,115
Additional paid-in capital	1,834,548	1,817,649
Treasury stock	(59,011 )	(51,082 )
Accumulated deficit	(1,422,995 )	(1,429,177 )
Total stockholders' equity	645,324	627,505
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 1,044,991	\$ 966,021

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

	<b>Three months ended June 30,</b>		<b>Six months ended June 30,</b>	
	<b>(in thousands, except per share amounts)</b>		<b>(in thousands, except per share amounts)</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Product revenue, net	\$ 153,773	\$ 133,724	\$ 295,156	\$ 285,928
Licensing and royalty revenue	715	1,593	1,502	4,382
Total revenue, net	154,488	135,317	296,658	290,310
Less: Cost of goods sold	32,155	28,797	60,481	63,604
Gross margin	122,333	106,520	236,177	226,706
Operating expenses:				
Selling, general and administrative (1)	107,203	92,395	213,001	226,332
Research and development (1)	6,357	9,969	15,734	20,247
Total operating expenses	113,560	102,364	228,735	246,579
Operating income (loss)	8,773	4,156	7,442	(19,873)
Interest income, net	285	151	756	1,359
Other (expense) income, net	(191)	108	(333)	17
Income (loss) from operations before taxes	8,867	4,415	7,865	(18,497)
Income tax (provision) benefit	(1,059)	-	(1,683)	2,359
Net income (loss)	<u>\$ 7,808</u>	<u>\$ 4,415</u>	<u>\$ 6,182</u>	<u>\$ (16,138)</u>
Earnings (loss) per share:				
Basic	\$ 0.02	\$ 0.01	\$ 0.02	\$ (0.04)
Diluted	\$ 0.02	\$ 0.01	\$ 0.02	\$ (0.04)
Weighted average shares:				
Basic	395,899	384,663	395,272	373,300
Diluted	401,767	399,664	402,778	373,300

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$104,550 and \$82,035 for the three months ended June 30, 2021 and 2020, respectively, and research and development expenses were \$6,531 and \$8,198, respectively, for the same periods.



# RECONCILIATION OF NON-GAAP NET INCOME (LOSS)

## Unaudited

	Three months ended June 30, (in thousands, except per share amounts)		Six months ended June 30, (in thousands, except per share amounts)	
	2021	2020	2021	2020
Net income (loss) for EPS <sup>1</sup> - GAAP	7,808	4,415	6,182	(16,138)
Non-cash stock-based compensation expense	2,479	12,131	16,403	22,722
Adjusted net income for EPS <sup>1</sup> - non-GAAP	\$ 10,287	\$ 16,546	\$ 22,585	\$ 6,584
<sup>1</sup> basic and diluted				
Earnings per share:				
Basic - non-GAAP	\$ 0.03	\$ 0.04	\$ 0.06	\$ 0.02
Diluted - non-GAAP	\$ 0.03	\$ 0.04	\$ 0.06	\$ 0.02
Weighted average shares:				
Basic	395,899	384,663	395,272	373,300
Diluted	401,767	399,664	402,778	402,033

<sup>1</sup> Cardiovascular Branch of Chinese Medical Association, Cardiac Prevention and Rehabilitation Professional Committee of Chinese Rehabilitation Medicine Association, Chinese Gerontology and Elderly Cardiology Committee of the National Medical Association, et al. Guidelines for Primary Prevention of Cardiovascular Diseases in China. Chinese Journal of Cardiovascular Diseases. 2020;48(12):1000-1038.

<sup>2</sup> American Heart Association. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association. Circulation. 2020;141:e139–e596.

<sup>3</sup> Ganda OP, Bhatt DL, Mason RP, et al. Unmet need for adjunctive dyslipidemia therapy in hypertriglyceridemia management. J Am Coll Cardiol. 2018;72(3):330-343.

<sup>4</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. Am J Cardiol. 2016;118:138-145.

<sup>5</sup> Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. J Am Heart Assoc. 2018;7(15):e008740.

<sup>6</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. Circ Res. 2016;118:547-563.

<sup>7</sup> Bhatt DL, Steg PG, Brinton E, et al., on behalf of the REDUCE-IT Investigators. Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl—Intervention Trial. Clin Cardiol. 2017;40:138-148.

<sup>8</sup> Bhatt DL, Steg PG, Miller M, et al., on behalf of the REDUCE-IT Investigators. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med. 2019;380:11-22.

<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.

