

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

**Date of Report (Date of Earliest Event Reported): November 3, 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 November 3, 2021, Amarin Corporation plc (“Amarin”) issued a press release announcing its financial results for the three and nine months ended September 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 November 3, 2021 (furnished herewith)</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 3, 2021

Amarin Corporation plc

By: /s/ Karim Mikhail

Karim Mikhail

President and Chief Executive Officer

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## Amarin Reports Third Quarter 2021 Financial Results and Provides Business Update

*Launched VAZKEPA in Germany with Multiple European Country Launches Expected in 2022*

*Introduced New Go-to-Market Strategy in U.S. to Enhance Awareness and Drive Demand for VASCEPA®*

*Plans for Regulatory Filings and Approvals of VASCEPA in Several Additional Countries in 2022*

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

DUBLIN, Ireland and BRIDGEWATER, N.J., November 3, 2021 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the third quarter and nine months ended September 30, 2021 and provided an update on Company operations.

### Recent Key Amarin Highlights:

- Topline Financial Results: Total net revenue for the three and nine months ended September 30, 2021 were \$142.0 million and \$438.7 million, respectively, compared to \$156.5 million and \$446.8 million in the corresponding periods of 2020, respectively, indicating decreases of 9% and 2%, respectively. Net product revenue for the three and nine months ended September 30, 2021 were \$141.4 million and \$436.6 million, respectively, compared to \$155.2 million and \$441.1 million in the corresponding periods of 2020, respectively, indicating decreases of 9% and 1%, respectively. In the U.S., based on data from Symphony Health, Amarin retained approximately 83% and 87% of the icosapent ethyl market in the three and nine months ended September 30, 2021, respectively, with approximately one year of generic presence in the market.
  - Launched VAZKEPA (icosapent ethyl) in Europe: Amarin launched VAZKEPA in Germany as a treatment to reduce the risk of cardiovascular events in statin-treated adult patients at high cardiovascular risk who have elevated triglycerides ( $\geq 150$  mg/dL [ $\geq 1.7$  mmol/L]) and either established cardiovascular disease or diabetes and at least one additional cardiovascular risk factor.<sup>1</sup> Amarin is deploying a distinct digitally native omnichannel approach to marketing VAZKEPA in Europe, which is supported by an approximately 150-person commercial field force in Germany and further Medical and Commercial teams in all major markets. In addition, the Company today announced the successful submission of market access dossiers for reimbursement in ten major countries in Europe.
  - Introduced new Go-to-Market Strategy for VASCEPA® (icosapent ethyl) in U.S.: The new Go-to-Market strategy is designed to accelerate growth of VASCEPA in the U.S., with plans focused on expanding healthcare professional reach and engagement through a new digital omnichannel platform, driving further enhancements in managed care access and optimizing VASCEPA prescriptions for cardiovascular (CV) risk reduction.
  - Executing International Expansion Strategy: Amarin announced plans to initiate regulatory filing and review processes and obtain approvals in several additional countries in 2022 as part of its global growth strategy to reach the top 50 cardiometabolic markets in the world.
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- [VASCEPA/VAZKEPA Added to Two Additional Medical Societies' Clinical Treatment Guidelines or Position Statements:](#) VASCEPA/VAZKEPA is now included in more than 20 medical societies' clinical treatment guidelines or position statements. Click [here](#) for more information on the guidelines.
- [New Senior Executive Further Strengthens Leadership Team:](#) As of August 19, 2021, Jason Marks was appointed senior vice president, chief legal officer & corporate secretary, succeeding Joseph Kennedy who retired as general counsel, effective August 2021.
- [Strong Balance Sheet:](#) Ended third quarter 2021 with \$517.9 million in total cash and investments and no debt.

## **Management Commentary**

“During the third quarter we made important strides toward our goal to bring the CV risk reduction benefits of VASCEPA/VAZKEPA to at-risk patients around the world,” stated Karim Mikhail, president and chief executive officer of Amarin. “We are delighted with the launch of VAZKEPA in Germany in mid-September and to report that we have submitted market access dossiers for VAZKEPA in ten major countries in Europe ahead of our year end timeline. These filings form the foundation for pricing negotiations and, ultimately, for the launch of VAZKEPA in multiple other European countries throughout 2022.

“Importantly, we introduced a new Go-to-Market strategy in the U.S. that is designed to significantly expand reach and engagement with our target audiences through multiple digital omnichannels in order to increase awareness of and drive demand for VASCEPA in its CV risk reduction indication. In tandem, we are optimizing VASCEPA prescriptions in this indication by addressing factual errors by certain stakeholders in the prescribing ecosystem to reduce generic substitution for non-indicated uses. We have secured significant, positive managed care access for VASCEPA, but we continue working to enhance that access by further removing barriers and reducing patient out-of-pocket costs for VASCEPA prescriptions.

“Our global growth strategy in the near-term remains steadfast: expand the markets for VASCEPA/VAZKEPA in Europe and around the world and grow the U.S. market for VASCEPA through our new Go-to-Market initiatives. We are well positioned to deliver on our commitment to reduce the occurrence of the debilitating and deadly effects of cardiovascular disease by bringing the CV risk reduction benefits of VASCEPA/VAZKEPA to patients globally, while building value for our stakeholders,” concluded Mr. Mikhail.

## **Europe**

In September 2021, Amarin launched VAZKEPA in Germany with a scientific conference that was led by eleven internationally renowned cardiovascular specialists and was attended by more than 200 healthcare professionals from Germany, with a live stream to many more physicians across the continent. The commercial team has made great strides introducing the cardioprotective benefits of VAZKEPA to the German market with 60 events hosted to date and more than 50 events approved and ready to execute before year-end. As Germany is the largest economy in Europe, and there are more than 300,000 deaths due to cardiovascular disease (CVD) in Germany every year<sup>ii</sup>, it represents both a significant market need and opportunity.

Amarin has filed market access dossiers for reimbursement in ten European countries, including Germany, the United Kingdom, France, Italy, Spain, Denmark, Sweden, Finland, Norway and the Netherlands. Amarin expects to file several additional dossiers in various other European countries throughout 2022. The submitted filings include health economic 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 or U.S. \$240 per month. Amarin is seeking pricing it believes is well justified based on the demonstrated clinical

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effectiveness of VAZKEPA and the high economic burden of heart attacks, strokes and other adverse cardiovascular events, the risk of which VASKEPA is proven to reduce.

### **U.S. Icosapent Ethyl Market**

The icosapent ethyl market in aggregate, consisting of branded and generic product, increased for the three months ended September 30, 2021 by approximately 11% as compared to the same period in 2020, based on data from Symphony Health. Based on data from Symphony Health, VASCEPA captured approximately 83% of the total icosapent ethyl normalized prescriptions for the three months ended September 30, 2021.

Two generic versions of VASCEPA have launched in the U.S., 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 Amarin believes has likewise infringed on its rights.

The COVID – 19 Delta Variant caused a resurgence of positive COVID cases, which peaked in the third quarter of 2021. According to IQVIA, this resulted in a decrease in patient office visits of approximately 6% and lab tests of approximately 7% as compared with the same period of 2020. We expect that continued recovery from COVID-19 will further contribute to future market growth.

### **International Market Expansion**

Amarin is gaining traction in its goal to unlock the potential of VASCEPA/VAZKEPA internationally. The Company plans to file three waves of regulatory submissions for approval of VASCEPA/VAZKEPA in 20 additional countries in order to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA/VAZKEPA. Amarin today announced plans to initiate the first wave of regulatory filings in several countries in 2022, including Australia, New Zealand and Israel. With approvals in the U.S. and Europe, and backed by the results from the global REDUCE-IT® long-term CV outcomes study, Amarin has significant clinical data to support these filings. In total, this expansion across an additional 20 markets 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.<sup>1</sup>

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 atherosclerotic cardiovascular disease 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 use based on VASCEPA's demonstrated clinical results.

In August 2021, Amarin's partner in Canada, HLS Therapeutics (HLS), announced a promotional agreement with Pfizer, which addresses the expansion of VASCEPA promotion to the primary care physician (PCP) audience in Canada. HLS will retain responsibility over VASCEPA's commercialization and will continue to record all revenue related to VASCEPA sales in Canada.

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## Financial Update

Total net revenue for the three and nine months ended September 30, 2021 were \$142.0 million and \$438.7 million, respectively, compared to \$156.5 million and \$446.8 million in the corresponding periods of 2020, respectively, indicating decreases of 9% and 2%, respectively. Net product revenue for the three and nine months ended September 30, 2021 were \$141.4 million and \$436.6 million, respectively, compared to \$155.2 million and \$441.1 million in the corresponding periods of 2020, respectively, indicating decreases of 9% and 1%, respectively. The decrease in net product revenue and total net revenue for the three months ended September 30, 2021 was driven primarily by decreased volume of VASCEPA sales to customers in the U.S.

In addition, total net revenue includes licensing and royalty revenue of approximately \$0.6 million and \$2.1 million in the three and nine months ended September 30, 2021, which compares with licensing and royalty revenue of approximately \$1.3 million and \$5.7 million in the three and nine months ended September 30, 2020, respectively, under agreements for the commercialization of VASCEPA outside the U.S.

Cost of goods sold for the three and nine months ended September 30, 2021 was \$30.2 million and \$90.7 million, respectively, compared to \$33.1 million and \$96.7 million in the corresponding periods of 2020, respectively. Amarin's overall gross margin on net product revenue for both the three and nine months ended September 30, 2021 was 79%, compared to 79% and 78% for the three and nine months ended September 30, 2020, respectively.

Selling, general and administrative (SG&A) expense for the three and nine months ended September 30, 2021 were \$103.0 million and \$316.0 million, respectively, compared to \$120.2 million and \$346.5 million, respectively, in the corresponding periods of 2020, representing a decrease of 14% and 9% for the same three and nine month periods one year ago. The decreases were due primarily to reduced promotional initiatives when compared to the same periods in the prior year.

Research and development (R&D) expense for the three and nine months ended September 30, 2021 were \$7.8 million and \$23.6 million, respectively, compared to \$10.2 million and \$30.5 million, respectively, in the corresponding periods of 2020, representing decreases of 23%, respectively. These decreases were primarily driven by the completion of certain activities related to 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 a net loss of \$13.2 million in the three months ended September 30, 2021, or basic and diluted loss per share of \$0.03, which included \$10.4 million in non-cash stock-based compensation expense and \$14.1 million in restructuring expense. In comparison, Amarin reported a net loss of \$6.8 million in the three months ended September 30, 2020, or basic and diluted loss per share of \$0.02, which included \$11.6 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 and into 2022.

Under U.S. GAAP, Amarin reported a net loss of \$7.0 million in the nine months ended September 30, 2021, or basic and diluted loss per share of \$0.02, which included \$26.8 million in non-cash stock-based compensation expense and \$14.1 million in restructuring expense. For the nine months ended September 30, 2020, Amarin reported a net loss of \$22.9 million, or basic and diluted loss per share of \$0.06, which included \$34.3 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation and restructuring expense, non-GAAP adjusted net income was \$11.4 million for the third quarter of 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.03, compared to non-GAAP adjusted net income of \$4.8 million for the third quarter of 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.01.

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Excluding non-cash gains or losses for stock-based compensation and restructuring expense, non-GAAP adjusted net income was \$34.0 million for the nine months ended September 30, 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.09 and \$0.08, respectively, compared to non-GAAP adjusted net income of \$11.4 million for the nine months ended September 30, 2020, or non-GAAP adjusted basic and diluted earnings per share of \$0.03.

As of September 30, 2021, Amarin reported aggregate cash and investments of \$517.9 million, consisting of cash and cash equivalents of \$222.9 million and liquid short-term and long-term investments of \$256.3 million and \$38.8 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 September 30, 2021, Amarin had approximately 395.6 million American Depository Shares (ADSs) and ordinary shares outstanding approximately 19.1 million equivalent shares underlying stock options at a weighted-average exercise price of \$7.38 and 10.3 million equivalent shares underlying restricted or deferred stock units.

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

Amarin will host a conference call today, November 3, 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 877-545-0523 within the United States, 973-528-0016 from outside the United States, and referencing conference ID 527493. 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: 43234. 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 loss and adjusting it for non-cash stock-based compensation expense and restructuring 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.

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## 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 has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, Zug in Switzerland, and other countries in Europe 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>iii</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>iv</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>v,vi,vii</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>viii</sup> The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.<sup>ix</sup> The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.<sup>x</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

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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:

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**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)
<sup>[1]</sup> Includes adjudicated cardiovascular deaths and deaths of undetermined causality.					
<sup>[2]</sup> 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 September 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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AMARIN, REDUCE-IT, VASCEPA and VAZKEPA are trademarks of Amarin Pharmaceuticals Ireland Limited. VAZKEPA is a registered trademark in Europe and other countries and regions and is pending registration in the United States.

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(in thousands)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 222,875	\$ 186,964
Restricted cash	3,917	3,915
Short-term investments	256,267	313,969
Accounts receivable, net	149,361	154,574
Inventory	309,268	188,864
Prepaid and other current assets	21,345	30,947
<b>Total current assets</b>	<u>963,033</u>	<u>879,233</u>
Property, plant and equipment, net	1,569	2,016
Long-term investments	38,802	62,469
Operating lease right-of-use asset	7,762	8,054
Other long-term assets	456	432
Intangible asset, net	24,183	13,817
<b>TOTAL ASSETS</b>	<u>\$ 1,035,805</u>	<u>\$ 966,021</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 72,415	\$ 105,876
Accrued expenses and other current liabilities	289,684	198,641
Current deferred revenue	2,646	2,926
<b>Total current liabilities</b>	<u>364,745</u>	<u>307,443</u>
Long-Term Liabilities:		
Long-term deferred revenue	14,486	15,706
Long-term operating lease liability	8,729	9,153
Other long-term liabilities	5,350	6,214
<b>Total liabilities</b>	<u>393,310</u>	<u>338,516</u>
Stockholders' Equity:		
Common stock	293,140	290,115
Additional paid-in capital	1,845,103	1,817,649
Treasury stock	(59,602)	(51,082)
Accumulated deficit	(1,436,146)	(1,429,177)
<b>Total stockholders' equity</b>	<u>642,495</u>	<u>627,505</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 1,035,805</u>	<u>\$ 966,021</u>

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 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	\$ 141,442	\$ 155,190	\$ 436,598	\$ 441,118
Licensing and royalty revenue	596	1,309	2,098	5,691
Total revenue, net	142,038	156,499	438,696	446,809
Less: Cost of goods sold	30,211	33,071	90,692	96,676
Gross margin	111,827	123,428	348,004	350,133
Operating expenses:				
Selling, general and administrative (1)	102,965	120,164	315,966	346,496
Research and development (1)	7,820	10,204	23,554	30,450
Restructuring	14,115	—	14,115	—
Total operating expenses	124,900	130,368	353,635	376,946
Operating loss	(13,073)	(6,940)	(5,631)	(26,813)
Interest income, net	163	549	919	1,908
Other (expense) income, net	(57)	33	(390)	50
Loss from operations before taxes	(12,967)	(6,358)	(5,102)	(24,855)
Income tax (provision) benefit	(184)	(430)	(1,867)	1,929
Net loss	\$ (13,151)	\$ (6,788)	\$ (6,969)	\$ (22,926)
Loss per share:				
Basic	\$ (0.03)	\$ (0.02)	\$ (0.02)	\$ (0.06)
Diluted	\$ (0.03)	\$ (0.02)	\$ (0.02)	\$ (0.06)
Weighted average shares:				
Basic	396,618	389,699	395,681	378,770
Diluted	396,618	389,699	395,681	378,770

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$93,723 and \$110,241 for the three months ended September 30, 2021 and 2020, respectively, and research and development expenses were \$6,630 and \$8,544, respectively, for the same periods.



**RECONCILIATION OF NON-GAAP NET INCOME**

**Unaudited**

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2021	2020	2021	2020
	Net loss for EPS <sup>1</sup> - GAAP	(13,151)	(6,788)	(6,969)
Non-cash stock-based compensation expense	10,432	11,583	26,836	34,306
Restructuring expense	14,115	—	14,115	—
Adjusted net income for EPS <sup>1</sup> - non-GAAP	\$ 11,396	\$ 4,795	\$ 33,982	\$ 11,380
<sup>1</sup> basic and diluted				
Earnings per share:				
Basic - non-GAAP	\$ 0.03	\$ 0.01	\$ 0.09	\$ 0.03
Diluted - non-GAAP	\$ 0.03	\$ 0.01	\$ 0.08	\$ 0.03
Weighted average shares:				
Basic	396,618	389,699	395,681	378,770
Diluted	402,657	399,400	402,787	401,454

<sup>i</sup> Summary of Product Characteristics Vazkepa – April 2021 [https://ec.europa.eu/health/documents/community-register/2021/20210326150935/anx\\_150935\\_en.pdf](https://ec.europa.eu/health/documents/community-register/2021/20210326150935/anx_150935_en.pdf). Accessed August 2021

<sup>ii</sup> Destatis: Federal Statistical Office: Causes of death - the number of deaths fell by 1.6% in 2019. (last accessed on January 6, 2021)

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

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

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

<sup>viii</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>ix</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>x</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.

<sup>1</sup> The company is pursuing expansion into these various additional markets and the status of regulatory and/or patent approval will vary between market to market.

