

**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): April 30, 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

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 April 30, 2020, Amarin Corporation plc issued a press release announcing its financial results for the three months ended March 31, 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.**

(d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release, dated April 30, 2020</a>
104	<a href="#">Cover Page Interactive Data File (embedded within the Inline XBRL document)</a>

\* \* \*

## 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: April 30, 2020

Amarin Corporation plc

By: /s/ John F. Thero

John F. Thero

President and Chief Executive Officer



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

*Total Revenue Increased 112% to \$155 Million in First Quarter 2020 Compared to Prior Year*

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

DUBLIN, Ireland and BRIDGEWATER, N.J., April 30, 2020 -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the quarter ended March 31, 2020 (Q1 2020) and provided an update on company operations.

Key recent Amarin achievements include:

- **Record revenue**: Net total revenue reached a record high of \$155.0 million in Q1 2020 as compared to \$73.3 in Q1 2019, an increase of approximately 112% primarily reflecting increased VASCEPA® (icosapent ethyl) prescription growth in the United States augmented by \$6.7 million net product revenue from VASCEPA sales outside of the United States.
  - **Commercial expansion**: Increased size of U.S. sales force for VASCEPA in Q1 2020 to approximately 800 sales representatives plus their managers representing a doubling in size compared to most of 2019. All such new hires have now completed training and are interacting with healthcare providers, which interactions, commencing in mid-March, were transitioned to telephonic or other forms consistent with social distancing practices amidst the COVID-19 pandemic.
  - **International progress**: In Canada, Amarin's commercial partner began promotion of VASCEPA in mid Q1 2020. As planned, Amarin's commercial partner for Canada purchased VASCEPA capsules from Amarin to support their launch of VASCEPA. These purchases for Canada represented the majority of Amarin's net product revenue from outside the United States in Q1 2020. In China, Amarin's partner is nearing completion of their clinical trial of VASCEPA, the results of which are expected to be reported later this year based on our partner's assumption of continued limited impact from COVID-19 on study completion. In Europe, the marketing authorization application for VASCEPA with the European Medicines Agency, or EMA, is undergoing review with an approval recommendation anticipated by Amarin near the end of 2020 and associated European Community, or EC, approval expected promptly thereafter, assuming continued limited impact of COVID-19 on the review. As previously disclosed, Amarin is taking a parallel path of evaluating whether it is best for long-term shareholder value to launch VASCEPA directly, in whole or in part, in Europe or to contract with a potential pan-European partner for VASCEPA promotion and sales. Amarin is targeting Q3 2020 for making this decision.
  - **ANDA litigation update**: As previously disclosed, Amarin and the defendants in the patent litigation pertaining to the initial indication for VASCEPA in the United States have agreed to expedite proceedings for the appeal of the district court decision. The parties have requested the U.S. Court of Appeals for the Federal Circuit approve an expedited schedule including requested briefing in Q2 2020 and an expedited hearing. This proposed timing should facilitate a hearing in Q3 2020 (or perhaps early Q4 2020) and position the court to rule thereafter potentially in 2020 or in early 2021. Amarin believes that it has a strong basis for appeal, which will be set out in its opening brief proposed for filing on May 12th.
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“Amarin’s record revenue in Q1 2020 further confirms the value of VASCEPA’s new cardiovascular risk reduction indication and reflects that our commercial launch got off to a good start,” commented John Thero, Amarin’s president and chief executive officer. “We are regularly receiving positive responses from physicians about VASCEPA and witnessing further improvements in already good managed care coverage for VASCEPA supporting the large opportunity for this unique product. With strong science, great employees and wonderful collaborators, we are highly motivated to improve patient care for the millions of people worldwide who might benefit from VASCEPA while aggressively working to overcome challenges caused by COVID-19 restrictions and patent litigation.”

### ***Commercialization Progress for Unique Drug***

In mid-December 2019, the FDA approved VASCEPA as the first and only therapy for lowering persistent cardiovascular risk as studied in the landmark REDUCE-IT® cardiovascular outcomes study. Such approval reflects the results of over a decade of research and development which validated Amarin’s insights regarding the unique effects of the active ingredient in VASCEPA and the interaction of such effects on lipid management and cardiovascular health. This R&D program included three successful Phase 3 studies (MARINE, ANCHOR and REDUCE-IT). Amarin’s success over the development period faced many naysayers as multiple other companies and therapies fail to achieve similar results with other products.

The FDA approval of VASCEPA’s new cardiovascular risk indication allowed Amarin to launch VASCEPA in early 2020 with education and promotion to healthcare professionals. Review of educational and promotional messaging for patients has been undergoing separate FDA review. As previously communicated, Amarin intends to create a launch program for patient education and promotion in mid-2020. At the start of 2020, survey data supports that recognition and understanding of the unique effects of VASCEPA was relatively low among healthcare professionals and patients. This is not surprising as over the past decade Amarin spent the majority of its resources on research and development. VASCEPA promotion expanded in 2019. Acceleration of such promotion is a priority for 2020, including launch of VASCEPA’s new indication for cardiovascular risk reduction, the indication Amarin pursued for the past decade with the aim of helping millions of high-risk patients.

Regarding education and promotion of VASCEPA to healthcare professionals, in early 2019 Amarin increased the size of its direct sales force in the United States to approximately 400 sales representatives (plus their managers) representing an approximate doubling of the sales force size from the prior year. By Q3 2019, over 90% of the newly hired sales representatives were contributing positively (i.e., new contributions exceeded their cost). In early 2020, Amarin completed another round of expansion of its direct sales force in the United States. Amarin did so with the expectation that these new additions would contribute and more than cover their costs quickly. At the end of Q1 2020, Amarin had approximately 800 sales representatives (plus their managers). These new sales representatives were trained in waves which commenced in 2019 and accelerated in early 2020. It is too early to fully assess the performance of these newly hired sales representatives, but initial signs are encouraging although these expectations for new sales representative productivity in 2020 compared to 2019 are now tempered due to restrictions on in-person interactions pursuant to COVID-19.

The role of these sales representatives is to help educate healthcare professionals regarding how VASCEPA might be used to help their patients. During Q1 2020, we heard many positive anecdotes from the promotion of VASCEPA for cardiovascular risk reduction. The anecdotes came from prior prescribers and new prescribers of VASCEPA. We witnessed prescription growth among prior prescribers and new prescribers, including prescription growth in areas of the United States where we previously had no sales representation.

The sales growth in Q1 2020 was supported by broad managed care coverage across the United States. This coverage was good at the start of 2020 and improved during the quarter. Such improved managed care coverage reflects: 1) the FDA approval of a broad indication for VASCEPA (which approval did not include any special post-approval commitments reflecting the strength of VASCEPA’s robust and consistent clinical results); 2) ten esteemed medical societies that have already changed their guidelines to recommend icosapent ethyl (VASCEPA ) use or issued favorable statements for using our drug to care for at-risk patients; 3) multiple analyses presented in scientific forums showing that VASCEPA is highly cost effective with such analysis further suggesting that the preventative care solution demonstrated in REDUCE-IT holds the potential in most scenarios to save society money by preventing the high cost of cardiovascular events due to heart

attacks, stroke, revascularization and death; and 4) the effective education of managed care providers and key opinion leaders regarding VASCEPA.

COVID-19 presents unique challenges for the launch of VASCEPA, particularly because many areas of the United States where reports of COVID-19 infection are most pronounced (e.g., metropolitan areas) are areas on which Amarin was relying for sales growth in 2020. During late March 2020, when Amarin suspended in-person sales calls due to COVID-19 social distancing priorities, we witnessed a decline in the rate of new prescriptions for VASCEPA. Our direct sales team has been finding new ways to interact with healthcare professionals and we continue to receive positive feedback from physicians regarding VASCEPA. However, many patients are not coming to physicians' offices for routine visits due to risks of COVID-19 infection and the need for social distancing. While this environment may slow VASCEPA sales growth, we anticipate that most patients who currently take VASCEPA will continue to fill their prescriptions.

While we continue to experiment with new ways to interact with healthcare professionals during these challenging times, we are also preparing for the time when our sales team can begin to interact directly again with healthcare professionals. We believe that such interactions are important since VASCEPA has a new FDA-approved label and unique potential to help patients of which most healthcare professionals are not yet aware. Also, while VASCEPA has not been shown to reduce COVID-19 infections, patients at risk for cardiovascular disease appear to be at particularly high risk for COVID-19 related complications and we want to give healthcare professionals knowledge about VASCEPA which may be useful in lowering such cardiovascular risk in their patients.

Regarding education of consumers and patients about the cardioprotective effects of VASCEPA, we anticipate incorporating feedback from the FDA to potentially launch a patient-oriented campaign in mid-2020. Due to uncertainties stemming from COVID-19 and ANDA litigation, compared to what Amarin was planning at the start of 2020, Amarin currently intends to limit the extent of our patient-oriented campaign and focus primarily on education of and promotion to healthcare professionals. In particular, we intend to defer most or all of our planned television campaign because it is expensive and most of its value in providing education on the cardiovascular risk reduction effects of VASCEPA are likely not to be near-term. Such campaign will be readied for launch when and if we are successful in the appeal of the ANDA litigation assuming patients have resumed regular visits to their physicians by that time.

### ***Prescription Growth in the U.S.***

Based on monthly compilations of U.S. data provided by a third party, Symphony Health, the estimated number of normalized total VASCEPA prescriptions for the three months ended March 31, 2020 and 2019 was approximately 1,061,000 and 618,000, respectively, reflecting growth of 72%. According to data from another third party, IQVIA, the estimated number of normalized total VASCEPA prescriptions for the three months ended March 31, 2020 and 2019 was approximately 962,000 and 553,000, respectively, reflecting growth of 74%. Normalized total prescriptions represent the estimated total number of VASCEPA prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month's supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors; however, such inventory levels remained within normal industry range.

In Q1 2020, we saw prescription growth lag in January and February compared to trends in Q4 2019. We believe that such lag, similar to prior years, was due to high beginning of the year insurance deductibles as are increasingly prevalent in managed care coverage. Such deductibles are not product specific but do, as previously reported, impact whether patients can afford to fill prescriptions for all drugs at the beginning of the year. Historically this has led to prescriptions of drugs for asymptomatic chronic conditions such as cardiovascular disease not being filled. Throughout March 2020, prescription levels and related shipments of product increased over levels experienced in the first two months of Q1 2020 likely reflecting that some patients had overcome their insurance deductibles and that healthcare professionals were writing more prescriptions for VASCEPA and urging their high-risk patients to fill their VASCEPA prescriptions.

As described more fully in Amarin's Quarterly Report on Form 10-Q, Amarin recognizes product revenue when its customers, consisting mostly of independent commercial distributors in the U.S., take possession of the product which

they order from Amarin and Amarin ships to these customers. Amarin revenue is not recognized when individual patients fill prescriptions.

Shipments to the largest of Amarin's customers, large wholesalers, tend to occur at the beginning of each week. The timing of the weekly calendar for Q1 2020 was such that shipments made to customers on Monday, March 30, 2020 were received by certain customers on March 31, 2020. As a result, for these customers there was effectively an added week of revenue shipments in Q1 2020 that did not exist in Q1 2019 when March 30<sup>th</sup> was on a weekend. While both reported revenue levels and reported prescription levels grew significantly in Q1 2020, this added week of shipments to certain customers, together with shipments of product to Canada (which don't show up in data from Symphony Health or IQVIA) combined with a modest increase in VASCEPA's net selling price (after rebates to managed care and other customary adjustments) in Q1 2020 explain the majority of the greater rate of increase in net product revenue reported for Q1 2020 compared to the rate of increase in prescription levels. Overall, inventory levels reported by wholesalers were within the normal industry range at the end of Q1 2020.

Further, as described previously, both Symphony Health and IQVIA collect and report estimates of prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like VASCEPA during such periods. Data reported by Symphony Health and IQVIA is rarely identical. Their estimates are based on a combination of data received from pharmacies that report such data and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in how pharmacies and other distributors provide data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use and less prevalent and pronounced over longer periods of time such as annually. As such, the resulting conclusions from such sources should be viewed with caution. Amarin cites such third-party information as a courtesy to its investors and because Amarin does not have direct access to prescription information. The prescription levels and changes in prescription levels reported above are based on information made available to Amarin from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions.

### ***International Update***

Amarin has expanded VASCEPA commercialization activities outside of the United States through several contractual arrangements in territories including China, the Middle East, North Africa and Canada. Amarin continues to assess other opportunities to develop VASCEPA commercialization outside of the United States through similar arrangements.

Amarin's partner in China is conducting a clinical trial for VASCEPA which should report results later this year. Amarin has been informed by its partner that COVID-19 is not expected to have a significant impact on the clinical trial results in China or on the timing of such results. Assuming clinical trial success, this will position VASCEPA to be first in class in China.

Amarin continues to pursue a parallel process in Europe of evaluating whether to launch VASCEPA by itself in select countries, and partner other countries, or to enter into a pan-European partnership for the launch of VASCEPA. As previously reported, in Q4 2019 our regulatory submission for VASCEPA in Europe was accepted for review by the EMA. While we anticipate some impact on this review due to COVID-19, we do not expect this impact to shift the likely timing of the anticipated EMA recommendation for approval of VASCEPA in Europe from our estimate of near the end of 2020 and associated EC approval expected promptly thereafter. We seek a cardiovascular risk reduction indication in Europe.

In late 2019, Health Canada awarded approval, and in early 2020 granted extended regulatory exclusivity, to Amarin's partner in Canada to market VASCEPA. Sales of VASCEPA have begun in the Canadian market.

### ***Financial Update***

Net product revenue for the three months ended March 31, 2020 and 2019 was approximately \$152.2 million and \$72.7 million, respectively. This \$79.5 million increase in net product revenue was driven primarily by increased volume of sales for VASCEPA in the United States, which includes an additional week of revenue in the first quarter of 2020 of \$10.8 million due to timing of orders placed by customers and related receipt, as well as a modest increase in VASCEPA's net selling price 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 \$6.7 million during the three months ended March 31, 2020 as compared to \$0.3 million during the three months ended March 31, 2019 primarily 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 \$2.8 million and \$0.5 million for the three months ended March 31, 2020 and 2019, respectively, under agreements for the commercialization of VASCEPA outside the U.S.

Cost of goods sold for the three months ended March 31, 2020 and 2019 was \$34.8 million and \$17.1 million, respectively. Amarin's overall gross margin on net product revenue was 77% and 76% for the three months ended March 31, 2020 and 2019, respectively. This increase in gross margin on product sales is driven by gross margin on U.S. product sales of 80%, partially offset by the gross margin on product sales to our partners outside the U.S. as per contractual arrangements. Net product revenue to our partners does not include licensing and royalty revenue.

Selling, general and administrative (SG&A) expenses during the three months ended March 31, 2020 and 2019 were \$133.9 million and \$71.6 million, respectively. This increase is due primarily to increased personnel costs related to the sales force expansion and an increase in promotional activities and direct to consumer promotion following the launch of VASCEPA in early 2020 for the new indication and expanded label approved by FDA.

Research and development expenses during the three months ended March 31, 2020 and 2019 were \$10.3 million and \$7.2 million, 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 our strategic collaboration agreement with Mochida.

Under U.S. GAAP, Amarin reported a net loss of \$20.6 million in the first quarter of 2020, or basic and diluted loss per share of \$0.06. This net loss included \$10.6 million in non-cash stock-based compensation expense. Amarin reported a net loss of \$24.4 million in the first quarter of 2019, or basic and diluted loss per share of \$0.07. This net loss included \$6.9 million in non-cash stock-based compensation expense.

Excluding non-cash gains or losses for stock-based compensation, non-GAAP adjusted net loss was \$10.0 million for the first quarter of 2020, or non-GAAP adjusted basic and diluted loss per share of \$0.03, compared to non-GAAP adjusted net loss of \$17.5 million for the first quarter of 2019, or non-GAAP adjusted basic and diluted loss per share of \$0.05.

As of March 31, 2020, Amarin reported aggregate cash and investments of \$623.7 million, consisting of cash and cash equivalents of \$329.0 million and liquid short-term investments and long-term investments of \$213.2 and \$81.5 million, respectively. Net cash flow from operations was positive in Q1 2020 of approximately \$4.1 million despite increases, as expected, in net accounts receivable, all of which were then current, reflecting revenue growth and inventory in preparation for anticipated future growth. As of March 31, 2020, Amarin reported \$158.3 million in net accounts receivable (\$189.6 million in gross accounts receivable before allowances and reserves), and \$92.1 million in inventory. While, as previously expressed, until uncertainties regarding the effects and duration of COVID-19 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 although results are anticipated to vary significantly on a quarterly basis including some potential negative net cash flow periods as Amarin works to launch VASCEPA based on its new cardiovascular risk reduction indication and adjust for various scenarios regarding the impacts of COVID-19 and potential launch of generic versions of VASCEPA in the United States.



As of March 31, 2020, Amarin had approximately 361.7 million American Depositary Shares (ADSs) and ordinary shares outstanding, 28.9 million common share equivalents of Series A Convertible Preferred Shares outstanding and approximately 17.2 million equivalent shares underlying stock options at a weighted-average exercise price of \$ 7.92, as well as 7.0 million equivalent shares underlying restricted or deferred stock units.

In light of logistics and financial difficulties created on some companies by COVID-19, Amarin recently completed a review of its supply chain to ensure continued supply and of its largest customers to ensure creditworthiness. We are pleased with the findings of this review. Regarding supply, the steps that we have taken to geographically diversify our supply chain together with steps we took to bolster inventory levels gives us confidence that we have adequate VASCEPA supply to meet anticipated demand for the foreseeable future. Regarding customers, we have little concern about our large wholesaler customers being able to continue to pay Amarin as and when amounts are due. As is done in the ordinary course, Amarin intends to periodically conduct such reviews and address new concerns, if any, as they arise.

### ***Patent Litigation***

As previously reported, the trial for the ANDA patent litigation against defendants Dr. Reddy's Laboratories, Hikma Pharmaceuticals USA Inc. and certain of their respective affiliates, or the Defendants, took place in January 2020. On March 30, 2020, the Court issued its ruling in favor of the Defendants. Amarin is appealing the decision and may pursue additional remedies, including seeking a preliminary injunction against a generic product launch. If the generic version of VASCEPA proposed by either Defendant is approved by the FDA and the sponsor has qualified supply available and elects to launch at risk during the appeal process, such a launch would be at risk of damages such as lost profits to us should we prevail on appeal.

We intend to vigorously pursue appeal of the district court decision and plan robust increased product education and promotion if we win the appeal and plan various strategies for seeking to profit if the appeal is unsuccessful.

The results of this litigation do not apply to Canada, China, Europe or other international jurisdictions that don't rely on determinations in United States courts. Furthermore, the label being sought for VASCEPA in many of these geographies are not for the triglyceride reduction indication at issue in this patent litigation in the United States. In addition, certain of the regulatory authorities in these geographies (e.g., Europe) provide added regulatory exclusivity that augments patent protection.

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

Amarin will host a conference call April 30, 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](http://www.amarincorp.com), or via telephone by dialing 877-407-8133 within the United States, 201-689-8040 from outside the United States, or by using the call back feature at <https://bit.ly/2Knoe4L>. 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: 34453. 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 loss was derived by taking GAAP net 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, the European Union and the Middle East. For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

## **About Cardiovascular Risk**

The number of deaths in the United States attributed to cardiovascular disease continues to rise. <sup>1, 2</sup> 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 similar, accounting for 1 of every 19 U.S. deaths (approximately 1 every 40 seconds). <sup>3</sup>

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% – but that still leaves a 65-75% risk remaining. <sup>4</sup> People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins. <sup>5, 6, 7</sup>

## **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 ( $\geq 500$  mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over eight million times and 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 ( $\geq 150$  mg/dL) and

- established cardiovascular disease or
  - 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 [1]	174 (4.3)	1.0	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)
[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 VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://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 in China, Europe and elsewhere; the timing and outcome of the clinical trial in China; the timing and outcome of the decision on whether to launch VASCEPA directly or with a partner on good terms in Europe; the timing and outcome of Amarin's appeal of the patent litigation district court decision; the timing and status 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; 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 foregoing. 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 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 ( [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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**CONSOLIDATED BALANCE SHEET DATA**  
**(U.S. GAAP)**  
**Unaudited**

	March 31, 2020	December 31, 2019
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 329,045	\$ 644,588
Restricted cash	3,910	3,907
Short-term investments	213,190	—
Accounts receivable, net	158,288	116,430
Inventory	92,121	76,769
Prepaid and other current assets	20,760	13,311
Total current assets	817,314	855,005
Property, plant and equipment, net	2,466	2,361
Long-term investments	81,519	—
Operating lease right-of-use asset	8,397	8,511
Other long-term assets	1,074	1,074
Intangible asset, net	14,898	15,258
TOTAL ASSETS	\$ 925,668	\$ 882,209
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 98,330	\$ 49,950
Accrued expenses and other current liabilities	170,731	139,826
Debt from royalty-bearing instrument	36,978	50,130
Deferred revenue, current	4,288	2,342
Total current liabilities	310,327	242,248
Long-Term Liabilities:		
Deferred revenue, long-term	17,519	18,504
Long-term operating lease liability	9,381	9,443
Other long-term liabilities	2,665	3,751
Total liabilities	339,892	273,946
Stockholders' Equity:		
Preferred stock	21,850	21,850
Common stock	270,716	269,173
Additional paid-in capital	1,774,671	1,764,317
Treasury stock	(49,731)	(35,900)
Accumulated deficit	(1,431,730)	(1,411,177)
Total stockholders' equity	585,776	608,263
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY		
	\$ 925,668	\$ 882,209

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

	<b>Three months ended March 31,</b> <b>(in thousands, except per share amounts)</b>	
	<b>2020</b>	<b>2019</b>
Product revenue, net	\$ 152,204	\$ 72,731
Licensing and royalty revenue	2,789	547
Total revenue, net	154,993	73,278
Less: Cost of goods sold	34,807	17,140
Gross margin	120,186	56,138
Operating expenses:		
Selling, general and administrative (1)	133,937	71,633
Research and development (1)	10,278	7,242
Total operating expenses	144,215	78,875
Operating loss	(24,029)	(22,737)
Interest income (expense), net	1,208	(1,697)
Other (expense) income, net	(91)	3
Loss from operations before taxes	(22,912)	(24,431)
Income tax benefit	2,359	—
Net loss	\$ (20,553)	\$ (24,431)
Loss per share:		
Basic	\$ (0.06)	\$ (0.07)
Diluted	\$ (0.06)	\$ (0.07)
Weighted average shares:		
Basic	361,136	328,712
Diluted	361,136	328,712

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$124,919 and \$66,027 for the three months ended March 31, 2020 and 2019, respectively, and research and development expenses were \$8,705 and \$5,964, respectively, for the same periods.

**RECONCILIATION OF NON-GAAP NET LOSS**  
**Unaudited**

	Three months ended March 31, (in thousands, except per share amounts)			
	2020		2019	
Net loss for EPS <sup>1</sup> - GAAP	\$	(20,553)	\$	(24,431)
		10,591		6,884
Adjusted net loss for EPS <sup>1</sup> - non-GAAP	\$	(9,962)	\$	(17,547)
<sup>1</sup> basic and diluted				
Loss per share:				
Basic and diluted - non-GAAP	\$	(0.03)	\$	(0.05)
Weighted average shares:				
Basic and diluted		361,136		328,712

## References

- <sup>1</sup> American Heart Association. Heart Disease and Stroke Statistics – 2019 Update: A Report from the American Heart Association. Published January 31, 2019.
- <sup>2</sup> American Heart Association / American Stroke Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.
- <sup>3</sup> American Heart Association: Heart Disease and Stroke Statistics -- 2019 At-a-Glance.
- <sup>4</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>5</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. Am J Cardiol. 2016;118:138-145.
- <sup>6</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>7</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. Circ Res. 2016;118:547-563.