



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

April 29, 2021

*Commercial Launch of VAZKEPA in Europe on Track to Commence in Q3 2021 Following Recent Market Authorization with VASCEPA® Growth in the United States Positioned to Increase as the Impact of COVID-19 Recedes*

*Expenses Managed in Q1 2021 to Minimize Operating Loss Despite Revenue Impact of COVID-19 and Other Factors*

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

DUBLIN, Ireland and BRIDGEWATER, N.J., April 29, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the quarter ended March 31, 2021 and provided an update on company operations.

### Recent Key Amarin Highlights:

- **Q1 net total revenue:** Net total revenue in the first quarter of 2021 was \$142.2 million, consisting of \$140.8 million in net product revenue from the United States, \$0.5 million in net product revenue from outside the United States and \$0.8 million in licensing and royalty revenue. Net product revenue from the United States declined \$4.7 million, or 3% in the first quarter of 2021 compared to the first quarter of 2020. Results in the first quarter of 2021 were significantly impacted by COVID-19 and by severe winter storms and power outages in various areas of the country such as Texas. In addition, while generic supply has been limited with generic icosapent ethyl (IPE) accounting for 9% of icosapent ethyl normalized prescriptions in the first quarter of 2021, as reported by Symphony Health, the generic introduction created disruption to VASCEPA growth. Moreover, as reported in conjunction with first quarter 2020 results, net product revenue in the first quarter of 2020 included \$10.8 million from a shipment timing anomaly which effectively provided an added week of revenue shipments. This anomaly did not reoccur in the first quarter of 2021.
- **Q1 bottom line improvement:** Operating expenses were reduced by \$29.0 million in the first three months of 2021 compared to the prior year, primarily as a result of lower sales and marketing expenditures incurred as the company worked to efficiently manage expenses in light of COVID-19 related limitations impacting physicians, patients and the level of our promotions. These savings resulted in a reported net loss of \$1.6 million (\$0.00 per share) in the first quarter of 2021 compared to a net loss of \$20.6 million (\$0.06 per share) in the first quarter of 2020. On a pro forma non-GAAP basis, excluding reported non-cash expenses, net operating results were profitable in the first quarter of 2021.
- **Received European marketing authorization for VAZKEPA and commenced pre-launch commercial initiatives in Europe:** Received market authorization from the European Commission (EC) for icosapent ethyl (brand name VAZKEPA in Europe) to reduce the risk of cardiovascular events in high-risk, statin-treated adult patients who have elevated triglycerides ( $\geq 150$  mg/dL) and either established cardiovascular disease or diabetes and at least one additional cardiovascular risk factor. Commenced pre-launch disease and brand awareness campaigns in preparation for the planned commercial launch of VAZKEPA in Germany, anticipated to commence before the end of the third quarter of 2021. Similar to the United States, cardiovascular disease is the number one cause of death in Europe and, subject to upcoming market access negotiations, millions of at-risk patients could potentially benefit from this marketing authorization.
- **Received Great Britain marketing authorization for VAZKEPA from the Medicines and Healthcare Products Regulatory Agency (MHRA):** Received market authorization from MHRA for icosapent ethyl (brand name VAZKEPA in Great Britain) as a treatment to reduce the risk of cardiovascular events in high cardiovascular risk statin-treated adult patients who have elevated triglycerides ( $\geq 150$  mg/dL) and either established cardiovascular disease or diabetes and at least one additional cardiovascular risk factor. The Great Britain Marketing Authorization for VAZKEPA applies to England, Scotland and Wales. Under the Brexit Northern Ireland agreement, the European centralized marketing authorization for the European Union covers Northern Ireland.
- **Mainland China and Hong Kong approval expected near the end of 2021:** As submitted by the company's partner, Edding, in Mainland China the Chinese National Medical Products Administration (NMPA) has accepted for review icosapent ethyl. On a separate track, in Hong Kong, the Hong Kong Department of Health is evaluating icosapent ethyl. In addition, medical guidelines of the Chinese Society of Cardiology (CSC) were updated to recommend use of icosapent ethyl in China.
- **Icosapent ethyl use now included in clinical treatment guidelines or position statements from 15 medical societies:** Among these, most directly relevant to Amarin's commercialization plans in Europe and China, are medical treatment guidelines from both the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) as well as a

recommendation from the Chinese Society of Cardiology (CSC).

- Management succession plans: John Thero, Amarin's president and chief executive officer announced plans to retire effective August 1, 2021 with a planned transitional support period thereafter. Karim Mikhail, Amarin's senior vice president and head of commercial for Europe, has been appointed as his successor. Joseph Kennedy, Amarin's executive vice president, general counsel, another of the small number of senior management members at Amarin who have been with the company since before VASCEPA was originally approved in 2012, also announced his plans to retire from Amarin, as disclosed separately. A search has commenced to hire a new general counsel with Mr. Kennedy also intending to support his transition, including continued support of certain legal matters.
- Strong balance sheet: Ended first quarter 2021 with \$538.7 million in total cash and investments and no debt.

#### **Management Commentary**

"Results in the first quarter of 2021 reflect a mixture of positive accomplishments and continued headwinds, particularly from COVID-19, the effects of which continued to be more persistent than was hoped," stated John Thero, president and chief executive officer of Amarin. "A clear highlight of the quarter was the broad label for VASKEPA which is now authorized for marketing in Europe. The opportunity for VASKEPA in Europe is large and our team in Europe is making tremendous progress."

Mr. Thero added, "In the United States, while we ended the first quarter of 2021 with some early signs of potential recovery from the effects of COVID-19, such as increased rates of patients new to the brand and more prescribers of VASCEPA, such signs are based on limited data, inconsistent, and vary by geography. Awareness and understanding of VASCEPA remain low and many at-risk patients are using alternative products that have failed to demonstrate benefit in cardiovascular outcomes studies. As we witness greater evidence that the effects of COVID-19 are receding, we plan to increase what we believe to be our most cost-effective marketing initiatives to continue the launch of this important product for the cardiovascular risk reduction indication that we pulled-back due to COVID-19. We believe that millions of at-risk patients in the United States could benefit from VASCEPA if they become better informed regarding the risks of cardiovascular disease and the proven efficacy and safety profile of VASCEPA."

"We have an immense opportunity to reduce occurrences of the often debilitating and deadly effects of cardiovascular disease and the economic and societal burdens associated with it globally," stated Karim Mikhail, who will be succeeding to the roles of president and chief executive officer of Amarin upon Mr. Thero's retirement. "We believe that we have multi-billion dollar opportunities in the United States, Europe and potentially in the rest of the world. Regarding Europe, we are pleased with the label for VASKEPA authorized for marketing and sale in the European Union. We have commenced product awareness initiatives, particularly in Germany where at a recent cardiology meeting our product was broadly discussed and well received. While key opinion leaders in Germany are aware of VASKEPA, between now and our anticipated product launch in Germany we will work to increase product awareness more broadly with our greatest priority on pursuing approved product pricing and related market access across Europe. We anticipate that any successes in Europe will aid our plans to expand use of this important product globally."

Mr. Mikhail added, "I am thankful for the support that I am getting from John and everyone at Amarin in preparation for our planned transition on August 1<sup>st</sup>. With the effectiveness of our product, and the talent and experience of our teams globally, I am confident we will achieve every milestone on our roadmap to success."

#### **U.S. Prescription Growth**

Normalized prescriptions for VASCEPA (prescription of 120 grams of VASCEPA representing a one-month supply) in the United States was relatively flat based on Symphony Health data and increased by approximately 4% based on IQVIA data, during the first quarter 2021 compared to the same period in 2020. Estimated normalized VASCEPA prescriptions, based on data from Symphony Health and IQVIA, totaled approximately 1,064,000 and 989,000 in the first quarter of 2021, respectively, compared with 1,061,000 and 955,000 in the first quarter of 2020, respectively. The icosapent ethyl market in aggregate, consisting of branded and generic product, increased for the three months ended March 31, 2021 by approximately 11% as compared to the three months ended March 31, 2020, based on data from Symphony Health. Unlike product shipments, upon which revenue is recognized, prescription data tends not to be lumped primarily into one day each week and therefore the anomaly which effectively resulted in an added shipment week for VASCEPA in the first three months of 2020, but not in the first three months of 2021, is not believed to have impacted reported prescription levels.

The resurgence of COVID-19 experienced in late 2020 continued throughout the first quarter of 2021, particularly in certain parts of the United States where VASCEPA usages have historically been most robust. Based on prescription data reported by Symphony Health, in the first quarter of 2021 there was a slowing in prescription growth for major categories of lipid lowering drugs and the 11% growth of icosapent ethyl prescriptions was second only to PCSK9s for which prescriptions reportedly grew, based on data from Symphony Health, albeit against a much smaller denominator for prescription volume.

In the United States, public reports from IQVIA showed patient visits, on average, during the three months ended March 31, 2021 were down to approximately 78% of the first quarter 2020 pre-COVID levels, which tempered the ability to grow new VASCEPA prescriptions. As a likely consequence of fewer doctors' visits, fewer lab tests and prioritization of COVID-19 safety, there have been reports during the COVID-19 era of increased heart attacks and other urgent cardiovascular events which might have been avoided through preventative cardiovascular risk management. Amarin remains confident that the patient need for VASCEPA in the United States remains high and that, as the impact of COVID-19 on patient visits and lab tests recede, VASCEPA growth will be positioned to accelerate as more patients seek routine doctor visits and lab tests and as our promotional activities become less restricted.

As previously disclosed, in November 2020, a generic version of VASCEPA was launched in the United States, which is indicated only as an adjunct to diet for lowering triglyceride levels in adult patients with severe hypertriglyceridemia (TG  $\geq$ 500 mg/dL). The population related to this indication is limited. We have filed a lawsuit to defend our cardiovascular risk reduction patent rights against what we believe is unlawful infringement by the company sponsoring the generic product and a healthcare insurance company that we believe is likewise representative. The generic version of VASCEPA captured approximately 9% of the total icosapent ethyl normalized prescriptions for the three months ended March 31, 2021, based on data

from Symphony Health. In addition, based on available information we believe that a significant number of icosapent ethyl prescriptions have gone unfilled in the three months ended March 31, 2021, due to general market disruption of order fulfillment processes caused by the launch of the generic product. Thus far, growth of the generic product has been limited by lack of qualified supply capacity. While other generic versions of VASCEPA have regulatory approval to launch in the United States, they have not yet done so. The extent to which generics companies are making investments in supply capacity expansion is unclear. Support for manufacturing capacity expansion and efficiency improvements have been centerpieces of our development efforts for the past decade and continue to be key to enable supply to meet our commercialization plans in the United States, Europe and globally.

Since the generic product launched in November 2020, various managed care companies improved their insurance coverage of branded VASCEPA. In addition, many insurance companies and patients have reported that branded VASCEPA is less expensive to them than the generic version and the wholesale acquisition cost of branded VASCEPA continues to be lower than that of other branded drugs which have positive outcomes study results. In these and other ways, this is an atypical generic launch in the United States. Amarin believes the untapped market opportunity in the cardiovascular risk reduction indication is large and that more patients will be helped by VASCEPA with continued investment in market education regarding its benefits. Amarin's goal is to grow the market faster than generic competition can take share, this opportunity is expected to be more readily achieved as impacts of COVID-19 recede. Amarin intends to continue to vigorously defend its intellectual property rights.

## **Global Market Expansion**

### Europe

After receiving marketing authorization for VASKEPA in Europe by the EC in late March 2021, Amarin commenced training sales representatives in Germany to advance pre-launch disease and brand awareness initiatives in preparation for the planned commercial launch of VASKEPA in Germany before the end of the third quarter 2021. In the coming weeks, Amarin expects to have approximately 150 sales representatives deployed for pre-launch product and disease state awareness programs in Germany. Similar outreach in other countries is being planned with timing linked to negotiation of product pricing on a country-by-country basis as is the norm for drug launches in Europe.

In seeking market access, Amarin expects to file dossiers in 10 European countries in the coming months, including the largest countries of Europe. After this first wave of dossiers is advanced, additional dossier filings are planned. These dossiers include data demonstrating the uniqueness of VASKEPA from a scientific perspective, various country-specific demographic data sets to define the eligible patient population based on the label, and proposed pricing. Amarin is seeking pricing it believes is well justified based on the demonstrated clinical effectiveness of VASKEPA and the high economic burden of heart attacks, strokes and other cardiovascular events, which VASKEPA can help avoid along with the associated pain and suffering for at-risk patients and their families caused by such events.

### China

In January 2021, VASCEPA was accepted for introduction into the Hainan Boao Lecheng International Medical Tourism Pilot Zone program. Most recently, in Mainland China, the Chinese National Medical Products Administration (NMPA) accepted for review the New Drug Application for VASCEPA. In addition, the medical guidelines of the CSC were updated to recommend use of icosapent ethyl in China. Edding currently anticipates receiving a decision in Mainland China and separately, Hong Kong, near the end of 2021, followed by steps to ensure that this unique therapy is reimbursed in the major provinces of Mainland China as the first and only drug for its important potential indication for use based on VASCEPA's demonstrated clinical results.

## **Financial Update**

Net total revenue for the three months ended March 31, 2021 and 2020 were \$142.2 million and \$155.0 million, respectively. The \$12.8 million decrease in net total revenue consisted of a \$6.2 million decrease in net product revenue from outside the United States (results in the first quarter of 2020, as previously reported, including an initial stocking order for Canada), a \$4.6 million decrease in net product sales in the United States, and a \$2.0 million decline in license and royalty revenue associated with the timing of commercial partners achieving various pre-defined milestones. Net product revenue from the United States for the three months ended March 31, 2021 and 2020 were \$140.8 million and \$145.5 million, respectively, a decrease of 3%. This decrease was driven primarily by the effects of 1) COVID-19; 2) severe weather and related power outages; 3) generic competition; and 4) effectively one fewer week of shipments in the first quarter of 2021 as compared to the first quarter of 2020, which (as reported in 2020) added \$10.8 million to net product revenue in the first quarter of 2020. This anomaly, as expected, was not repeated in 2021. Net product revenue in the first quarter of 2021 was likely also impacted by our decision to reduce our level of promotional activities. This expense savings we deemed appropriate due to limited physician access and fewer patients visits to doctors as a result COVID-19, as well as regional weather issues which closed offices for numerous healthcare professionals. Partially offsetting the effects of reduced promotional activities were improvements in insurance coverage at various payers which improved overall throughout 2020 with some continued improvements in 2021.

Cost of goods sold for the three months ended March 31, 2021 and 2020 was \$28.3 million and \$34.8 million, respectively. Amarin's overall gross margin on net product revenue for the three months ended March 31, 2021 and 2020 was 80% and 77%, respectively, in part reflecting the mix of net product revenue between sales in the United States and sales to our commercial partners (gross margins are generally lower for sales to commercial partners the resell the product and are responsible for promotional costs in their agreed territories).

Selling, general and administrative (SG&A) expenses for the three months ended March 31, 2021 and 2020 was \$105.8 million and \$133.9 million, respectively, representing a decrease of 21%. This decrease was primarily due to a decrease in marketing and direct-to-consumer promotions in 2021, as our partial response to limitations imposed by COVID-19 and our focus on improving the profitability of our operations in the United States. Additionally, due to COVID-19, the company intentionally slowed the hiring of replacements for open positions in the United States resulting from ordinary turnover, partially offset by increased personnel costs related to preparing for the launch of VASKEPA in Europe. The decrease in SG&A expenses also reflects lower legal fees associated with the timing of prior ANDA patent litigation in the United States.

Research and development expenses for the three months ended March 31, 2021 and 2020 were \$9.4 million and \$10.3 million, respectively. This decrease primarily reflects completion of certain analyses performed beyond the REDUCE-IT cardiovascular outcomes trial primary results. Included in such expenses for the three months ended March 31, 2021 were certain costs to support ongoing studies of VASCEPA regarding its potential to help prevent or mitigate the clinical effects of COVID-19. The results of such ongoing studies are blinded to Amarin.

Under U.S. GAAP, Amarin reported a net loss of \$1.6 million in the first quarter of 2021, or basic and diluted loss per share of \$0.00. This net loss

included \$13.9 million in non-cash stock-based compensation expense. 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.

Excluding non-cash stock-based compensation expense, non-GAAP adjusted net income was \$12.3 million for the three months ended March 31, 2021, or non-GAAP adjusted basic and diluted earnings per share of \$0.03, compared to non-GAAP adjusted net loss of \$10.0 million for the three months ended March 31, 2020, or non-GAAP adjusted basic and diluted loss per share of \$0.03.

As of March 31, 2021, Amarin reported aggregate cash and investments of \$538.7 million, consisting of cash and cash equivalents of \$291.0 million and liquid short-term and long-term investments of \$223.7 million and \$24.0 million, respectively. As of March 31, 2021, Amarin reported \$151.3 million in net accounts receivable (\$220.2 million in gross accounts receivable before allowances and reserves) and \$230.9 million in inventory. Amarin reiterates that, based on the current plans, we believe that our existing resources are sufficient to fund VAZKEPA's launch in Europe and to support our ongoing US promotion.

As of March 31, 2021, Amarin had approximately 394.8 million ADSs and ordinary shares outstanding and approximately 19.4 million equivalent shares underlying stock options at a weighted-average exercise price of \$7.68, as well as 10.3 million equivalent shares underlying restricted or deferred stock units.

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

Amarin will host a conference call April 29, 2021, at 7:30 a.m. ET to discuss this information. The conference call can be heard live on the investor relations section of the company's website at [www.amarincorp.com](http://www.amarincorp.com), or via telephone by dialing 888-506-0062 within the United States, 973-528-0011 from outside the United States, and referencing conference ID 942273. A replay of the call will be made available for a period of four weeks following the conference call. To hear a replay of the call, dial 877-481-4010, PIN: 40926. 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) income and adjusting it for non-cash stock-based compensation expense. Management uses these non-GAAP adjusted financial measures for internal reporting and forecasting purposes, when publicly providing its business outlook, to evaluate the company's performance and to evaluate and compensate the company's executives. The company has provided these non-GAAP financial measures in addition to GAAP financial results because it believes that these non-GAAP adjusted financial measures provide investors with a better understanding of the company's historical results from its core business operations.

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

#### **About Amarin**

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation to our focus on clinical trials, and now our commercial expansion, we are evolving and growing rapidly. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, and Zug in Switzerland as well as commercial partners and suppliers around the world. We are committed to rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

#### **About Cardiovascular Risk**

Cardiovascular disease is the number one cause of death in the world. In the United States alone, cardiovascular disease results in 859,000 deaths per year.<sup>1</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>2</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>3,4,5</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>6</sup> The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.<sup>7</sup> The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.<sup>8</sup> These and other publications can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

#### About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, Lebanon and the United Arab Emirates. In Europe, in March 2021 marketing authorization was granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VASKEPA.

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

VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and
  - 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 <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 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 and expectations that VASCEPA growth is positioned to increase as the impact of COVID-19 recedes, the timing and outcome of patent litigation and the impact of the launch and future launches of generic competition on these metrics; plans and expected timing to launch VASKEPA in Europe and the timing and outcome of other regulatory reviews, recommendations and approvals and related reimbursement decisions and commercial launches in the China region, Europe and elsewhere; beliefs about the opportunity for VASKEPA in Europe and that the team is making tremendous progress; expectations for the executive succession; the timing and outcome of promotion activities, including patient-oriented campaigns and education of healthcare professionals and plans to resume marketing initiatives and increase product awareness; beliefs about the market opportunity for VASCEPA in the U.S. and worldwide, including that millions of at-risk patients in the U.S. could benefit from VASCEPA; the expectation that any successes in Europe will aide plans to expand globally; statements regarding prescription growth and revenue growth and future revenue levels, including the contributions of sales representatives; the sufficiency of current capital resources to achieve sustained positive cash flows; beliefs about the generic market, including the availability of commercial supply to generic companies and Amarin, the population addressable by the generic version of VASCEPA and pricing dynamics; plans to grow the market faster than generic competition can take share; expectations related to exclusivity in various jurisdictions; beliefs about the ongoing patent litigation efforts, including the lawsuit we filed to defend our patent rights and plans to vigorously defend our intellectual property rights; plans for our global market expansion, including the sales teams, dossier filings, pricing negotiations and other launch initiatives, and our belief that our existing resources are sufficient to fund VASKEPA's launch in Europe and to support our U.S. promotion; 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 and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business, 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 and that, even if VASCEPA does receive regulatory approval, we might not be successful or timely in launching and commercializing the product in a particular geography, including Europe, particularly since we have no experience commercializing a product internationally; 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; the risk that we have overestimated U.S. and worldwide market opportunities and our ability to successfully access them; 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 our annual report on Form 10-K for the year ended December 31, 2020, filed on February 25, 2021 and Amarin's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed on 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 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.amarinincorp.com](http://www.amarinincorp.com)), the investor relations website ([investor.amarinincorp.com](http://investor.amarinincorp.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.

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

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
	<b>(in thousands)</b>	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 290,994	\$ 186,964
Restricted cash	3,917	3,915
Short-term investments	223,742	313,969
Accounts receivable, net	151,275	154,574
Inventory	230,892	188,864
Prepaid and other current assets	29,696	30,947
Total current assets	<u>930,516</u>	<u>879,233</u>
Property, plant and equipment, net	1,862	2,016
Long-term investments	24,004	62,469
Operating lease right-of-use asset	7,958	8,054
Other long-term assets	456	432
Intangible asset, net	25,456	13,817
<b>TOTAL ASSETS</b>	<u><u>\$ 990,252</u></u>	<u><u>\$ 966,021</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	94,262	105,876
Accrued expenses and other current liabilities	228,734	198,641
Current deferred revenue	2,773	2,926
Total current liabilities	<u>325,769</u>	<u>307,443</u>
Long-Term Liabilities:		
Long-term deferred revenue	15,197	15,706
Long-term operating lease liability	9,015	9,153
Other long-term liabilities	5,660	6,214
Total liabilities	<u>355,641</u>	<u>338,516</u>
Stockholders' Equity:		
Common stock	292,360	290,115
Additional paid-in capital	1,831,388	1,817,649
Treasury stock	(58,334)	(51,082)
Accumulated deficit	(1,430,803)	(1,429,177)
<b>Total stockholders' equity</b>	<u>634,611</u>	<u>627,505</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u><u>\$ 990,252</u></u>	<u><u>\$ 966,021</u></u>

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

**Three months ended March 31,**



	(in thousands, except per share amounts)	
	2021	2020
Product revenue, net	\$ 141,383	\$ 152,204
Licensing and royalty revenue	787	2,789
Total revenue, net	142,170	154,993
Less: Cost of goods sold	28,326	34,807
Gross margin	113,844	120,186
Operating expenses:		
Selling, general and administrative (1)	105,798	133,937
Research and development (1)	9,377	10,278
Total operating expenses	115,175	144,215
Operating loss	(1,331)	(24,029)
Interest income, net	471	1,208
Other expense, net	(142)	(91)
Loss from operations before taxes	(1,002)	(22,912)
Income tax (provision) benefit	(624)	2,359
Net loss	\$ (1,626)	\$ (20,553)
Loss per share:		
Basic	\$ (0.00)	\$ (0.06)
Diluted	\$ (0.00)	\$ (0.06)
Weighted average shares:		
Basic	394,638	361,136
Diluted	394,638	361,136

(1) Excluding non-cash stock-based compensation, selling, general and administrative expenses were \$94,801 and \$124,919 for the three months ended March 31, 2021 and 2020, respectively, and research and development expenses were \$6,449 and \$8,705, respectively, for the same periods.

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

	Three months ended March 31, (in thousands, except per share amounts)	
	2021	2020
Net loss for EPS1 - GAAP	(1,626)	(20,553)
Non-cash stock-based compensation expense	13,925	10,591
Adjusted net income (loss) for EPS1 - non-GAAP	\$ 12,299	\$ (9,962)
1basic and diluted		
Earnings (loss) per share:		
Basic - non-GAAP	\$ 0.03	\$ (0.03)
Diluted - non-GAAP	\$ 0.03	\$ (0.03)
Weighted average shares:		
Basic	394,638	361,136
Diluted	403,650	373,238

<sup>1</sup> American Heart Association. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association. Circulation. 2020;141:e139–e596.

<sup>2</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>3</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. Am J Cardiol. 2016;118:138-145.

<sup>4</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>5</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. Circ Res. 2016;118:547-563.

<sup>6</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>7</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>8</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.