

# Amarin Corporation

## Amarin Provides Preliminary 2020 Results and 2021 Outlook

January 7, 2021

*Unaudited 2020 Total Net Revenue Estimated to Be Approximately \$610 Million, an Increase of Approximately 42% Compared with 2019*

*Completion of European Regulatory Review and Submission of China Regulatory Application for VASCEPA® (icosapent ethyl) Expected in Late January or February 2021*

DUBLIN, Ireland and BRIDGEWATER, N.J., Jan. 07, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today provided a business update, including preliminary unaudited full-year 2020 revenue results. Amarin plans to discuss these results and expectations with investors in connection with the 39th Annual J.P. Morgan Healthcare Conference at which Amarin is scheduled to present on Tuesday, January 12, 2020, at 2:00 pm Eastern time.

### Preliminary (unaudited) 2020 Financial Results

**Record Revenue Levels:** Full-year 2020 total net revenue, subject to audit, are expected to be approximately \$610 million. Despite the impact of COVID-19, this estimated 2020 net revenue expectation represents an increase of approximately 42% compared with full-year 2019 results. This growth was primarily driven by increased prescription levels of VASCEPA® in the United States.

**Liquid Assets:** Amarin ended 2020 with more than \$550 million in cash and investments, approximately \$150 million in net accounts receivable and approximately \$180 million in inventory.

**No Debt:** At year-end 2020, Amarin had no debt, having fully repaid its prior royalty-like debt instrument in the fourth quarter of 2020, which from 2013 through most of 2020 required approximately 10% of net revenue to be paid against this prior obligation.

### Management Commentary

"Amarin has the people, product and resources to expand globally starting with anticipated 2021 VASCEPA regulatory approval and commercial launch in Europe. Our expected growth in Europe and elsewhere overseas will build on our growth and experience in the United States," commented John F. Thero, president and chief executive officer. "We intend to build on our strong scientific foundation and medical experience. As patients begin to return for medical care beyond the COVID-19 era, we aim to ensure that VASCEPA is increasingly prescribed to help at-risk patients. While 2020 was a challenging year, I am thankful to our employees for the progress they made in countless areas. Their hard work and passion provide a strong foundation from which we will further launch VASCEPA to reduce persistent cardiovascular risk in appropriate patients, or P-CVR, in the United States, Europe and around the world."

### Highlights from 2020 and Outlook

#### U.S. Commercial

Amarin achieved a number of important commercial milestones in 2020, despite the challenges Amarin faced with COVID-19 and the November launch of generic icosapent ethyl in the United States.

U.S. commercial highlights from 2020 include:

- Record levels of VASCEPA revenues, prescriptions, prescribers and patients
- Faster prescription growth for VASCEPA as compared to most other cardiovascular drugs that reported positive outcomes studies in recent years, despite VASCEPA having a lower level of promotional spend than many such drugs
  - VASCEPA growth in 2020 due to COVID-19 was slower than initially expected but compares well with the growth in 2020 of peer drugs
- The P-CVR indication has quickly garnered the largest part of the market as approximately 93% of VASCEPA prescriptions based on the most recent data reported to us by IQVIA were for patients with triglyceride (TG) levels below 500 mg/dL
- Further expanded managed care coverage for VASCEPA during 2020 with additional improvements agreed for 2021
  - Such increases are consistent with third-party analysis, which found VASCEPA to be cost effective, and with medical guidelines or recommendations from six leading U.S. medical societies
- Doubled size of sales force (training for this expanded group was completed in March 2020 just before Amarin's customer-facing team was temporarily prohibited from conducting in-person meetings due to COVID-19)
- Adapted to COVID-19 protocols with various tele-sales, tele-marketing and virtual education initiatives as well as training representatives to safely interact with healthcare professionals where possible

U.S. commercial outlook includes:

- Confidence that millions of at-risk patients remain untreated for P-CVR and could benefit from VASCEPA
- Recognition that many at-risk patients ceased doctor visits for ordinary care in 2020 but are likely to return to their doctors for needed care as COVID-19 risk recedes
  - According to IQVIA, patient visits to medical offices for non-emergency medical care were down approximately 70%

in April 2020 during the height of COVID-19, with visits steadily increasing thereafter. In December 2020, as a result of a spike in COVID-19 cases, patient visits have decreased approximately 50% compared to pre-COVID levels

- Following a resurgence of COVID-19 in recent months, Amarin intends to reduce spending levels for certain forms of promotion (e.g., television advertisements) in early 2021
  - U.S. promotional spending likely to be variable with adjustments upward or downward in response to the changing impact from COVID-19 and generic competition
- As COVID-19 vaccine progress is made, along with other mitigating approaches, Amarin plans to increasingly resume its promotion of VASCEPA for P-CVR while continuing to adapt to market changes
  - Generic competition launched in November 2020 only for the original indication (TG  $\geq$ 500 mg/dL) and is expected to continue to face supply limits, despite stockpiles of generic product likely created prior to launch
  - Variability is expected as patients, pharmacies and payers adjust to the availability, pricing and label of this generic competition
  - Due to the uncertainties regarding COVID-19 and potential generic supply, Amarin will continue to withhold 2021 revenue guidance for VASCEPA in the U.S. until there is greater clarity on the impact of these issues
- Amarin intends to continue to manage its U.S. commercial operations to expand patient care and enhance profits from U.S. operations

### Europe

Europe highlights from 2020 include:

- Reached Day 180 of the European Medicines Agency, or EMA, centralized regulatory review of VASCEPA assuring that the United Kingdom is grandfathered into a facilitated review process despite its withdrawal from the European Union
- An expanded recommendation was issued by the European Society of Cardiology regarding use of icosapent ethyl (U.S. brand name VASCEPA)
- Increased the size of the Amarin team in Europe to approximately 50 experienced professionals to support pre-approval and pre-launch preparations for VASCEPA in select countries
- Commenced interactions with authorities in select countries regarding VASCEPA market access assuming approval, noting that more formal proceedings cannot progress until after the product is approved and the label is established
- Made major advances in expanding company-wide systems to support expected commercial launch of VASCEPA in Europe in 2021

Europe outlook includes:

- Millions of at-risk patients could benefit from VASCEPA in Europe
  - There are more patients on statins in Europe in aggregate compared to the U.S. and the rate of death from cardiovascular disease is higher
- Regulatory approval expected in early 2021
  - CHMP opinion expected in late January or February 2021
  - EMA approval decision expected within 67 days of CHMP decision
- Market access negotiations anticipated on a country-by-country basis promptly after approval
  - Seeking net pricing that equals or exceeds U.S. net pricing with focus on P-CVR indication based on outcomes data in Europe, whereas pricing in the U.S. was based on original TG lowering indication
- Launch timing by country dependent on market access (i.e., insurance coverage)
  - At a minimum, launch expected in Germany in 2021 after initial product awareness campaign
  - Launch in Germany and other countries is anticipated to give priority to specialists (e.g., cardiologists) and to also include substantial digital educational and promotional initiatives
  - Target of approximately 200 employees (or contractors) in the European commercial team by end of 2021

### Rest of World

Rest of world, or ROW, highlights from 2020 include:

- China positive clinical study results reported
- Canada commercial launch of VASCEPA initiated (just prior to slowdown from COVID-19)
- Canada reimbursement levels for VASCEPA established within six months of product regulatory approval to facilitate treating patients with established cardiovascular disease

ROW outlook includes:

- Large at-risk patient opportunities
  - In China 290 million people are reported to have cardiovascular disease, a number which has been increasing

rapidly in recent years, including approximately 52 million reported to have high TG levels, a substantial portion of whom might be able to benefit from VASCEPA

- Plans to submit application for regulatory approval through Amarin's commercial partner in the People's Republic of China
- Anticipate inclusion of VASCEPA in the treatment guidelines in Chinese medical societies
- Pursue opportunities for VASCEPA in untapped countries after approval and market access in Europe is secured, with such approval and market access expected to enhance ROW positioning

#### R&D and Medical Advancement

R&D and medical advancement highlights from 2020 include:

- EVAPORATE exploratory study results, as previously reported, reported 17% reduction in plaque volume in patients with coronary atherosclerosis treated with VASCEPA
- Numerous other studies presented in support of the potential unique mechanism of action of VASCEPA
  - In aggregate, Amarin supported over 40 scientific publications and presentations in 2020
- CardioLink-19 exploratory study results, as previously reported, evaluated a higher initial dose of VASCEPA and suggested VASCEPA could potentially have utility as a therapeutic option for mitigating COVID-19 effects in an out-patient setting
  - This pilot study was rapidly commenced and completed with results that exceeded expectations
  - Additional COVID-19 investigational studies of VASCEPA were also commenced in 2020
- Witnessed an increase to twelve (12) the number of medical societies globally that now include icosapent ethyl in their guidelines or have otherwise recommended its use

R&D and medical outlook includes:

- Supporting approval of VASCEPA in Europe and regulatory review processes initiated by Amarin's commercial partner in the People's Republic of China
- Supporting cost-effectiveness studies and market access for VASCEPA wherever it is approved
- Support completion of COVID-19 investigational studies and, based on the results, decide on appropriate next steps
- Continue to study and differentiate the unique clinical and biological effects of VASCEPA
- In concert with Amarin's business development and other efforts, prioritize and execute on potential opportunities to expand indications for VASCEPA or develop new products

#### Financial Resources

Amarin reiterates that it believes its current cash resources are adequate to support the European launch and its planned operations and priorities in the United States and globally. Such guidance included anticipated resources likely needed to further expand its VASCEPA supply capacity in anticipation of launches of VASCEPA in Europe, China and other countries as well as the opportunity to continue to grow prescription levels in the United States after COVID-19 recedes, continuing the launch of VASCEPA for P-CVR as commenced in 2020.

Currently, Amarin anticipates 2021 operating expenses of approximately \$550 million to \$600 million which represents an increase of approximately 10% to 20%, compared with 2020 levels. Included in these anticipated expenses are increased costs associated with Amarin's commercial launch preparations and initial launch in Europe as well as continued U.S. promotional activities, including increased face to face interactions between Amarin's sales professionals and health care providers and direct-to-consumer advertising in the U.S. after the impact of COVID-19 becomes less pronounced and at-risk patients begin returning to their doctors for non-urgent medical care. With continued investment in consumer and in-person marketing, Amarin expects VASCEPA revenue growth in the U.S. As described above, these spending levels may vary from quarter to quarter. Further these operating expense levels assume substantial societal recovery in 2021 from COVID-19 and the continued limited availability of supply to the generic companies. Amarin will re-evaluate its planned spend in 2021 if any of these assumptions change.

#### More Information to Follow

Amarin expects to provide further details regarding its 2020 results and perspective regarding its future outlook in the company's annual report on Form 10-K.

#### **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<sup>®</sup> (icosapent ethyl), is available by prescription in the United States, Canada, Lebanon and the United Arab Emirates. VASCEPA is not yet approved and available in any other countries. Amarin, on its own or together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in China, Europe and the Middle East. For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).

#### **About Cardiovascular Risk**

Cardiovascular disease is an enormous and growing public burden globally. In the United States alone there are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds), in the United States. Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. Cardiovascular disease results in 859,000 deaths per year in the United States.<sup>1</sup> In aggregate, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, one every 13 seconds in the United States alone.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent risk of cardiovascular

events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>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 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. VASCEPA is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019.

#### Indications and Limitation of Use

VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  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](http://www.vascepa.com) CAN BE FOUND AT [WWW.VASCEPA.COM](http://www.vascepa.com).

### Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding revenue and prescription growth, the impacts of COVID-19, including its future trajectory and effects on non-urgent medical care, the impacts of generic competition, including expected levels of generic supply, changes to U.S. commercial operations, including to spending and promotional levels, plans for commercial and international expansion, including the timing and outcome of regulatory approvals, market access negotiations and commercial launch, R&D and medical outlook, including the timing and results of future studies, market access efforts and indication expansion opportunities, the adequacy of its current cash resources and its 2021 operating expenses. 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 with the COVID-19 pandemic and generic competition; factors outside of our control may prevent VASCEPA from achieving market acceptance and commercial success; the commercial value of VASCEPA outside the United States may be smaller than we anticipate; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; and sales may not meet expectations and related costs may increase beyond expectations. 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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