Amarin Corporation

Amarin Provides Update to Preliminary 2019 Results and Further Details on 2020 Outlook

January 7, 2020

Unaudited Full-Year 2019 Net Total Revenue Estimated At or Slightly Above Upper-End of Prior Guidance of $410 to $425 Million

U.S. Sales Force Expansion On-Track for Doubling to 800 Sales Professionals in Early 2020

Full-Year 2020 Net Total Revenue Guidance Reiterated at $650 to $700 Million, Predominately from U.S. Sales of VASCEPA®

DUBLIN, Ireland and BRIDGEWATER, N.J., Jan. 07, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), today provided a business update, including an update of preliminary 2019 results and additional 2020 financial guidance. Amarin plans to discuss these results and expectations with investors in connection with the 38th Annual J.P. Morgan Healthcare Conference in San Francisco, California, at which Amarin is scheduled to present on Wednesday, January 15, 2020, at 10:30 a.m. Pacific Time (PT) / 1:30 p.m. Eastern Time (ET).

Preliminary (unaudited) 2019 Financial Results

Record Revenue Levels: 2019 net total revenue, subject to audit, are expected to be at or potentially slightly above the upper-end of the company's previously expressed guidance of $410 to $425 million, this upper end representing an increase of ~85% over 2018 results. Net total revenue consists predominantly of U.S. sales driven by increased prescriptions for VASCEPA® (icosapent ethyl) capsules. Wholesaler inventory levels of VASCEPA were within normal industry ranges at the end of 2019.

Current Assets: Amarin ended 2019 with approximately $645 million in cash, approximately $117 million in net accounts receivable and approximately $76 million in inventory.

No Debt, Except Remaining Balance of Royalty-Bearing Instrument: Amarin ended 2019 with no debt except the remaining balance on its royalty-bearing instrument which is repaid at a rate of 10% of VASCEPA revenue until this royalty-like obligation is fulfilled; aggregate repayment of less than $55 million remained as of December 31, 2019.

2020 Financial and Operational Guidance

On December 13, 2019, Amarin announced the approval of VASCEPA as the first and only drug with an FDA-approved indication for reducing cardiovascular risk in patients with persistent high cardiovascular risk despite statin therapy as studied in the REDUCE-IT® cardiovascular outcomes study. With this new indication, Amarin aims to help millions of patients through aggressively launching VASCEPA in the United States while exploring additional international opportunities.

Amarin is increasing its United States sales force to 800 sales representatives, up from 400 in most of 2019. Health professional targets will be expanded from approximately 50,000 to a planned 75,000 physicians along with planned increased frequency in the number of calls to these targets. The hiring of the expanded sales team is well underway as more than two-thirds of the new sales representatives are hired and in the process of being trained. The remaining sales professionals are targeted to be hired in January or early February 2020. While trained sales representatives are already in the field with the new label for VASCEPA, the company's national sales launch meeting is scheduled for next week, after which the sales team will be more fully trained and more prepared for field promotion.

In addition, Amarin is training select physicians to present VASCEPA to their peers and sponsoring various medical education programs that cover VASCEPA starting this month.

While Amarin anticipates revenue growth to be stimulated by such activities, it is common for patients who are candidates for VASCEPA to visit their physicians only once, sometimes twice, annually. As a result, similar to the experience of other therapies for treating chronic conditions, we do not anticipate prescription rates for VASCEPA to spike upwardly immediately. In addition, historically, the first calendar quarter of each year has started relatively slowly due to a number of recurring seasonal factors that have also affected similarly situated prescription therapies.

Branded direct-to-consumer (DTC) promotion of VASCEPA for cardiovascular risk reduction is subject to separate FDA approval which Amarin anticipates receiving by mid-2020 (submission was not possible until after the new label for VASCEPA was approved). Based on results shown for other products, such DTC promotion when launched is anticipated to further accelerate VASCEPA revenue growth. Until such branded DTC promotion is permitted, the company anticipates various programs to increase awareness and remind physicians and consumers that previously approved therapies are insufficient to address persistent cardiovascular risk for many patients.

2020 Revenue Guidance: Amarin anticipates total net revenue in 2020 will be in a range of $650 to $700 million, mostly from sales of VASCEPA in the United States. The guidance remains unchanged from the total net revenue guidance issued by the company on December 13, 2019.

Beyond 2020, Amarin reiterates that it believes that VASCEPA total net revenue will grow to reach multiple billions of dollars. The history of other therapies for chronic conditions suggests that growth builds over multiple years. At this time, the company is not providing guidance regarding annual revenue levels beyond 2020.

Inventory Purchases: Because the rate of VASCEPA revenue growth is difficult to predict, in 2020 Amarin intends to spend approximately $250 million on inventory purchases, which is approximately twice the amount spent for inventory purchases in 2019. Such planned purchases do not change Amarin's revenue guidance. Rather, the company believes they prepare Amarin, together with existing inventory, for a situation in which actual revenue turns out to be significantly higher than the revenue guidance described above. One of the important features of VASCEPA is the product's stability achieved through the expert manufacturing of its fragile single-active ingredient. This stability achievement presents limited financial risk of

over-purchasing VASCEPA inventory as the product has demonstrated stability supporting approved commercial expiry dating through four years.

Spending and Net Cash Flow: Currently, Amarin anticipates operating expenses in 2020 to increase approximately $200 to $250 million over 2019 levels. Included in these amounts are previously described increased costs associated with the company's planned expansion of its sales team and REDUCE-IT promotional activities, including direct-to-consumer advertising. In the event that net product revenue grows faster than expected, selling, general and administrative (SG&A) expenses may be higher than reflected in this operating expense guidance.

Amarin, after being cash flow positive in the second and third quarters of 2019, had net cash outflow of approximately $28 million in the fourth quarter of 2019 reflecting the expansion of the company's sales force and other costs associated with the new FDA-approved label for VASCEPA and the U.S. launch of this new label. Amarin anticipates starting 2020 with net cash outflows as it completes its sales force expansion and as these sales representatives become productive and other forms of expanded promotion take hold. On a steady-state basis, including the expanded sales force size, but excluding incremental purchases to build inventory and incremental spending for launch-level DTC, Amarin estimates that it needs approximately $150 million in quarterly net revenue to collect adequate cash to achieve cashflow breakeven. During the ramp-up phase, including the estimated higher cash outflow levels for inventory build and DTC launch of a new indication, Amarin estimates that approximately $200 million in quarterly net revenue is required to generate required cash collections to achieve cashflow breakeven. Above these breakeven levels, additional cash inflows should be net positive. Amarin reiterates that it believes that its current cash resources are adequate to reach positive net cash flow based on VASCEPA following its launch for its new FDA-approved cardiovascular risk reduction indication and reiterated that such spending levels are likely to vary quarterly. Amarin will consider added promotion as well as further sales force expansion if the pace of revenue growth exceeds expectations and if such added promotion can be reasonably predicted to pay for itself on a reasonably prompt basis.

International: Internationally, Amarin currently has three partners for commercialization of VASCEPA in select geographies and intends to consider potential additional partners to commercialize VASCEPA in other parts of the world. Amarin's partner HLS received approval of VASCEPA from Health Canada on December 31, 2019. In the Middle East, Amarin's partner Biologix, received approval for VASCEPA in two countries, Lebanon and the United Arab Emirates, with additional approvals in the region requested. In the Greater China region, Amarin's partner, Eddingpharm, continues to run the biomarker focused clinical study of VASCEPA. The pace of patient enrollment in this trial has been increasing, positioning that study for potential completion in 2020, with the intention of making VASCEPA the first approved prescription drug of its type in Mainland China and other markets in that region. With respect to commercialization partners for VASCEPA in other geographies, Amarin intends to continue to be receptive to inquiries from qualified companies.

Comment from Amarin's President and CEO

"Early feedback from physicians and medical societies has been positive regarding the new indication for VASCEPA," commented John F. Thero, president and chief executive officer. "Publications from both the AHA and ACC listed icosapent ethyl in their top cardiovascular news lists for 2019, a particularly major accomplishment as icosapent ethyl was on these lists for 2018 as well. With extraordinary employees, broad support from leading physicians, good payor coverage, a large patient need, and the only approved indication to address this need, Amarin commences 2020 with confidence and focus. Our aim is to make VASCEPA a new standard of care for the benefit of millions of patients."

Amarin will provide further details regarding its 2019 results and plans to provide further outlook for 2020 in connection with the company's annual report on Form 10-K when filed near the end of February 2020.

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, Lebanon and the United Arab Emirates, and is expected to be available in Canada through an anticipated February 2020 commercial launch. 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.

About Cardiovascular Disease

Cardiovascular disease is an enormous and growing medical issue worldwide.[1,2] In the United States alone, a heart attack, stroke, death or other major cardiovascular event is experienced every 14 seconds.[2,3]

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk of experiencing a cardiovascular event. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent cardiovascular risk, especially those patients with high triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35% – but that still leaves 65-75% of risk remaining.[4] People with high triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.[5,6,7]

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 (≥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 (≥ 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 (≥ 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 ≥3% and ≥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 ≥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 for bleeding should be monitored.

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)**
Primary composite endpoint					
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)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
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.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding prescription growth and revenue growth from sales of VASCEPA; expectations that REDUCE-IT results could lead to a new treatment paradigm in the patient population studied; expectations regarding managed care coverage for VASCEPA; expectations regarding levels of operating spending and levels of inventory purchases and plans for commercial and international expansion. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In addition, 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 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 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 not be determined to be infringed or upheld 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.

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), the investor relations website (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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