Amarin Reports First Quarter 2023 Financial Results and Provides Business Update

May 3, 2023

-- Stable Revenue and Cash Position Due to Performance of U.S. Business and Savings from Operational Initiatives --

-- Early Progress in Launch of VAZKEPA® (icosapent ethyl) in England & Wales; Pricing & Reimbursement Discussions in Key European Markets Ongoing --

-- International Strategy Progressing with CSL Seqirus Partnership for Australia & New Zealand --

-- Leadership Team and New Board of Directors Focused on Shareholder Value Creation --

-- Company to Host Conference Call Today at 8:00 a.m. EDT --

DUBLIN, Ireland and BRIDGEWATER, N.J., May 03, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), today announced financial results for the quarter ended March 31, 2023 and provided an update on the Company's operations.

"I am truly honored to lead Amarin during this time of transition," said Aaron Berg, Amarin's Interim President and CEO. Mr. Berg continued, "Amarin's first quarter performance was marked by solid revenue generation in the U.S. and a stable cash position. However, we are not where we need to be in Europe. While we will continue to work to optimally manage the U.S. business, I am focused with the team on ways to accelerate patient access and revenue in Europe. Amarin's objectives remain to bring the benefits of VASCEPA®/VAZKEPA® to patients around the globe and to maximize value for shareholders."

United States

U.S. product net revenue was $82.3 million in the first quarter of 2023, compared to $88.0 million in the fourth quarter of 2022, a decrease of seven percent. The Company maintains approximately 57% market share of the IPE molecule despite generic competition as the U.S. commercial organization continues an efficient support of branded VASCEPA.

Amarin continues to actively monitor key performance indicators in the U.S. market to thoughtfully support its strategy.

Europe

Amarin has early launches underway of VAZKEPA in the U.K. (England & Wales), Sweden and Finland. To date in the U.K., Amarin is working to secure VAZKEPA patient access through local formulary negotiations, and we expect those negotiations will continue to progress throughout 2023.

In addition to these launch activities, the team in Europe further advances the various Health Technology Assessment (HTA) processes and pricing & reimbursement discussions in all markets where Amarin has submitted market access dossiers.

International

The company is in the process of filing regulatory submissions for approval in 20 additional countries to ensure that patients in these markets can benefit from VASCEPA/VAZKEPA. In the first quarter of 2023, Amarin secured regulatory approval for VAZKEPA in New Zealand and Israel.

In addition, Amarin continues to make progress in international markets with our partners and recently announced a new partnership. In February 2023, Amarin and CSL Seqirus announced that the two companies entered into an exclusive license and distribution agreement under which Amarin will license exclusive rights to VAZKEPA to CSL Seqirus to secure pricing and reimbursement and commercialize VAZKEPA across Australia and New Zealand.

Financial Update

"We continue to make progress on our financial initiatives and our pursuit of operational excellence, beyond our initial $100 million cost savings target," said Tom Reilly, Amarin's CFO. "We have been working to renegotiate our supply agreements including the most recent settlement this quarter. With these efforts, we reduced operating expense guidance for 2023," said Mr. Reilly.

Total net revenue for the three months ended March 31, 2023, was $86.0 million, compared to $94.6 million in the corresponding period of 2022, a decrease of 9%. Net product revenue for the three months ended March 31, 2023, was $84.7 million, compared to $94.0 million in the corresponding period of 2022, a decrease of 10%. This decrease was driven by a decline in volume and net selling price due to the impact of generic competition in the U.S. In Europe revenue was $0.4 million in the first quarter of 2023.

Amarin recognized licensing and royalty revenue of approximately $1.3 million and $0.6 million during the three months ended March 31, 2023, and 2022, respectively, from VASCEPA-related commercial sales from our partners in Canada, the China region and the Middle East, as well as an upfront licensing fee from our partner in Australia and New Zealand.

Cost of goods sold for the three months ended March 31, 2023, was $38.0 million, compared to $22.2 million in the corresponding period of 2022. Amarin's overall gross margin on net product revenue for the three months ended March 31, 2023 was 55%, compared with 76% for the corresponding period of 2022. During the three months ended March 31, 2023, Amarin amended a supplier agreement resulting in a charge of $12.3 million. Excluding the impact of this item, gross margin was 70% for the three months ended March 31, 2023. The remaining decrease in gross margin is primarily a result of a decrease in net selling price.

Selling, general and administrative expenses for the three months ended March 31, 2023, was $59.6 million, compared to $90.6 million in the corresponding period of the prior year. This decrease was primarily due to the implementation of our ongoing cost reduction plan.

Research and development expenses for the three months ended March 31, 2023, were $5.7 million, compared to $10.1 million in the corresponding period of the prior year. This decrease was primarily driven by the implementation of our ongoing cost reduction plan.

Under U.S. GAAP, Amarin reported a net loss of $16.5 million for the three months ended March 31, 2023, or basic and diluted loss per share of $0.04. For the three months ended March 31, 2022, Amarin reported a net loss of $31.6 million, or basic and diluted loss per share of $0.08. Non-GAAP adjusted net income was $7.6 million for the first quarter ended March 31, 2023, or non-GAAP adjusted basic and diluted earnings per share of $0.02, compared with non-GAAP adjusted net loss of $25.5 million for the three months ended March 31, 2022, or non-GAAP adjusted basic and diluted loss per share of $0.06. As of March 31, 2023, Amarin reported aggregate cash and investments of $304.9 million.

2023 Financial Outlook

Amarin continues to make progress on reducing operating expenses and managing its cash position. The Company is now lowering operating expense guidance for the full year 2023 to the range of $270 million to $285 million from $290 to $305 million, reflecting additional identified cost savings along with timing of reimbursements. With the recent stable U.S. business revenues and recent cash preservation initiatives, Amarin reiterates its belief that current cash and investments and other assets are adequate to support continued operations, including European launch activities.

Conference Call and Webcast Information

Amarin will host a conference call on May 3, 2023, at 8:00 a.m. ET to discuss this information. The conference call can be accessed on the investor relations section of the company's website at 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 368360. A replay of the call will be made available for a period of two weeks following the conference call. To listen to a replay of the call, dial 877-481-4010 from within the United States and 919-882-2331 from outside of the United States, and reference conference ID 47933. 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 (loss) was derived by taking GAAP net loss and adjusting it for non-cash stock-based compensation expense, restructuring expense and other one-time expenses. 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. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk for patients worldwide. Amarin has offices in Bridgewater, New Jersey in the United States,

Dublin in Ireland, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world.

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 (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over twenty 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 VAZKEPA.

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 (≥ 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 should be monitored for bleeding.

FULL U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Forward-Looking Statements
This press release contains forward-looking statements, within the meaning of U.S. securities laws, including, but not limited to, expectations regarding Amarin's financial performance, metrics, and initiatives, including its 2023 revenues, operating expenses, supply purchases, negotiations and settlements, product prescriptions and managed care coverage, continued savings from cost-cutting initiatives that is currently exceeding initial targets, and Amarin's overall ability to continue to deliver stable revenues and cash position from its U.S. business; beliefs about the timing and outcome of international commercial partnerships, regulatory filings, reviews, recommendations, approvals, and related reimbursement decisions and commercial launches of VASCEPA/VAZKEPA outside of the U.S.; beliefs that Amarin's current resources are sufficient to fund projected operations; and beliefs about the overall world-wide market potential and success of VASCEPA/VAZKEPA generally. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. A list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including Amarin's annual report on Form 10-K for the year ended December 31, 2022. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward-looking statements, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

Availability of Other Information About Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website (www.amarincorp.com), the investor relations website (investor.amarincorp.com), including but not limited to investor presentations and investor FAQs, U.S. 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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-Tables to Follow-

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

	March 31, 2023	December 31, 2022
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 191,412	$ 217,666
Restricted cash	523	523
Short-term investments	112,959	91,695
Accounts receivable, net	133,236	130,990
Inventory	225,813	228,732
Prepaid and other current assets	19,878	19,492
Total current assets	683,821	689,098
Property, plant and equipment, net	187	874
Long-term investments	544	1,275
Long-term inventory	143,730	163,620
Operating lease right-of-use asset	9,190	9,074
Other long-term assets	1,638	458
Intangible asset, net	21,078	21,780
TOTAL ASSETS	$ 860,188	$ 886,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 58,779	$ 64,602
Accrued expenses and other current liabilities	183,264	192,678
Current deferred revenue	2,199	2,199
Total current liabilities	244,242	259,479
Long-Term Liabilities:		
Long-term deferred revenue	12,702	13,147
Long-term operating lease liability	9,841	10,015
Other long-term liabilities	8,610	8,205
Total liabilities	275,395	290,846
Stockholders' Equity:		
Common stock	301,285	299,002

Additional paid-in capital	1,890,496	1,885,352
Treasury stock	(63,277)	(61,770)
Accumulated deficit	(1,543,711)	(1,527,251)
Total stockholders' equity	584,793	595,333
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 860,188	$ 886,179

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

	Three months ended March 31, (in thousands, except per share amounts)	
	2023	**2022**
Product revenue, net	$ 84,654	$ 93,986
Licensing and royalty revenue	1,321	644
Total revenue, net	85,975	94,630
Less: Cost of goods sold	25,794	22,239
Less: Cost of goods sold - restructuring inventory	12,254	—
Gross margin	47,927	72,391
Operating expenses:		
Selling, general and administrative (1)	59,587	90,647
Research and development (1)	5,681	10,051
Total operating expenses	65,268	100,698
Operating loss	(17,341)	(28,307)
Interest income, net	2,221	203
Other income (expense), net	624	(246)
Loss from operations before taxes	(14,496)	(28,350)
Income tax provision	(1,964)	(3,213)
Net loss	$ (16,460)	$ (31,563)
Loss per share:		
Basic	$ (0.04)	$ (0.08)
Diluted	$ (0.04)	$ (0.08)
Weighted average shares:		
Basic	406,177	397,805
Diluted	406,177	397,805

(1) - Excluding non-cash stock-based compensation, selling, general and administrative expenses were $55,244 and $86,018 for the three months ended March 31, 2023 and 2022, respectively, and research and development expenses were $4,468 and $8,602, respectively, for the same periods.

RECONCILIATION OF NON-GAAP NET INCOME (LOSS)
Unaudited

	Three months ended March 31, (in thousands, except per share amounts)	
	2023	**2022**
Net loss for EPS[1] - GAAP	(16,460)	(31,563)

Non-cash stock-based compensation expense	5,557	6,078
Restructuring inventory	12,254	—
Advisor fees	6,270	—
Adjusted net income (loss) for EPS[1] - non-GAAP	$ 7,621	$ (25,485)

[1]basic and diluted

Earnings (loss) per share:		
Basic - non-GAAP	$ 0.02	$ (0.06)
Diluted - non-GAAP	$ 0.02	$ (0.06)
Weighted average shares:		
Basic	406,177	397,805
Diluted	408,932	397,805