Amarin Reports Third Quarter 2023 Financial Results

November 1, 2023

-- Company Reported Total Net Revenues of $66 Million in the Third Quarter 2023 --

-- Delivered Positive Cash Flow of $8 Million in the Quarter, Marking Fifth Consecutive Quarter of Cash Positive Operations[1]; Quarter-Ending Cash Position of $321 Million --

-- Company Continues to Deliver Significant U.S. Profit Through Extended Lifecycle and Market Leadership of Branded VASCEPA® --

-- Early Launch Progress in European Countries Driven by New Leadership --

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

DUBLIN, Ireland and BRIDGEWATER, N.J., Nov. 01, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced financial results for the quarter ended September 30, 2023 and provided an update on company operations.

“As we focus on demonstrating results that will drive shareholder value, there are reasons to be optimistic about the future of Amarin,” said Patrick Holt, President & CEO of Amarin. “We have a strong balance sheet, with $321 million in cash, including five consecutive quarters of positive cash flow and no debt, proving that we can manage our cash effectively. In the US, we continue to extend the lifecycle and retain market leadership with branded VASCEPA® which provides meaningful profit and cash flow for the overall business. We have more work to do to accelerate revenues in Europe, but I am encouraged by the impact of new leadership and our team, delivering early results in recently launched countries. We have also seen early progress made by partners in the rest of the world, particularly our opportunity in China.”

“For our team moving forward, our path forward is simple -- to maximize the number of patients on our product, which will accelerate operational momentum and drive shareholder value,” said Holt.

Europe

Amarin has continued to make progress with both commercial and pricing and reimbursement efforts in Europe.

Amarin has early launches of VAZKEPA underway in several European countries, including the UK (England, Wales & Scotland), Spain and the Netherlands, with initial positive progress driven by launch efforts being implemented under new leadership.

In addition to these launch activities, the team in Europe is continuing to advance various Health Technology Assessment (HTA) processes and pricing & reimbursement discussions in all markets where Amarin has submitted market access dossiers. In July and August 2023, Amarin announced the following positive pricing and reimbursement milestones:

- The Spanish Drug Pricing Committee recommended the national reimbursement of VAZKEPA® (icosapent ethyl) to reduce the risk of cardiovascular (CV) events in patients with high cardiovascular risk.
- The Dutch Ministry of Health approved VAZKEPA for national reimbursement in the Netherlands.
- The Scottish Medicines Consortium (SMC) accepted VAZKEPA for reimbursement.

Although Italy's AIFA issued a negative reimbursement decision for VAZKEPA in that country, Amarin has finalized a new path forward to seek access to VAZKEPA for Italian patients by the end of 2024. In France, Amarin continues to progress its access strategy for VAZKEPA with the national health authorities. The Company does not expect this process to conclude in 2024. In Germany, Amarin is exploring new options to re-enter the market, and the Company will update investors in the coming quarters.

United States

U.S. product net revenue was $62.4 million in the third quarter of 2023, a decline of $2.2 million versus the second quarter of 2023, a decrease of 3% sequentially. The Company maintains approximately 57% market share of IPE (icosapent ethyl) prescriptions despite generic competition as the U.S. commercial organization continues an efficient support of branded VASCEPA.

During the third quarter of 2023, Amarin maintained its existing access for VASCEPA in exclusive accounts, representing approximately 43% of all Commercial and Part D lives on a weighted average basis.

The U.S. business continues to be profitable and support our global operations. Amarin continues to actively monitor key performance indicators in the U.S. market and is prepared to execute multiple strategies to support the business moving forward.

Rest of World

In China, Amarin's partner Edding Pharm launched VASCEPA in October to treat adult patients with severe hypertriglyceridemia (≥ 500 mg/dL). Edding also announced that it has submitted its regulatory filing with the National Medical Products Administration (NMPA) for the Company's new indication marketing application for VASCEPA to potentially treat cardiovascular risk reduction (CVRR). The Company is now awaiting the agency's acceptance of that filing.

Amarin is in the second year of a three-year plan to submit and obtain regulatory approval in 20 or more additional countries and regions around the world to ensure that patients in the top 50 cardiometabolic markets worldwide can benefit from VASCEPA/VAZKEPA.

In the third quarter of 2023, Amarin signed an exclusive commercialization agreement with Lotus Pharmaceuticals to distribute and commercialize VAZKEPA across 10 countries in Southeast Asia and South Korea. Amarin also announced an exclusive marketing and commercial agreement with Neopharm for VAZKEPA in Israel.

Financial Update

Total net revenue for the three months ended September 30, 2023, was $66.1 million, compared to $89.9 million in the corresponding period of 2022, a decrease of 27%. Total net revenue in the quarter includes $64.9 million in net product revenue and approximately $1.2 million in licensing and royalty revenue.

Net product revenue for the three months ended September 30, 2023, was $64.9 million, compared to $89.2 million in the corresponding period of 2022, a decrease of 27%. This decrease was driven by generic competition resulting in lower volume, as well as increased net pricing pressure offset primarily by a one-time Medicaid rebate adjustment of $6.5 million, versus the third quarter of 2022. In Europe revenue was $0.8 million in the third quarter of 2023.

Amarin recognized licensing and royalty revenue of $1.2 million and $0.7 million during the three months ended September 30, 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 South Korea and ASEAN.

Cost of goods sold for the three months ended September 30, 2023, was $36.2 million, compared to $27.0 million in the corresponding period of 2022. Amarin's overall gross margin on net product revenue for the three months ended September 30, 2023 was 44%, compared with 70% for the corresponding period of 2022. As a result of amended supplier agreements Amarin recognized a charge of $12.7 million during the three months ended September 30, 2023. During the three months ended September 30, 2022, Amarin also amended a supplier agreement resulting in a charge of $3.1 million. Excluding the impact of these one-time items, gross margin was 64% and 73% for the three months ended September 30, 2023 and 2022, respectively.

Selling, general and administrative expenses for the three months ended September 30, 2023, was $45.5 million, compared to $58.7 million in the corresponding period of the prior year. This decrease was primarily due to the implementation of our previously announced cost reduction plan.

Research and development expenses for the three months ended September 30, 2023, were $5.1 million, compared to $5.8 million in the corresponding period of the prior year. This decrease was primarily driven by the implementation of our previously announced cost reduction plan.

Restructuring expense for the three months ended September 30, 2023 was $0.7 million compared to $3.5 million in the corresponding period of the prior year. The charge in the current year is due to the implementation of the Organizational Restructuring Plan which was approved during the second quarter of 2023 and announced on July 18, 2023, which resulted in a reduction of our entire U.S. sales field force, while maintaining our managed care and trade organization to support U.S. commercial efforts, as well as a reduction of approximately 30% of non-sales positions. The prior year charge was primarily the result of the discontinuation of the German operations as a result of not being able to reach a viable agreement on the reimbursement price for VAZKEPA in Germany.

Under U.S. GAAP, Amarin reported a net loss of $19.3 million for the three months ended September 30, 2023, or basic and diluted loss per share of $0.05. For the three months ended September 30, 2022, Amarin reported a net loss of $5.1 million, or basic and diluted loss per share of $0.01. Amarin reported aggregate cash and investments of $321 million as of September 30, 2023 compared to $306 million as of September 30, 2022.

2023 Financial Outlook

Amarin continues to make progress on reducing operating expenses and managing its cash position and on-track to deliver $40 million of annual savings based on the reduction in force announced in July 2023. With the 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 November 1, 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

877-545-0523 within the United States, 973-528-0016 from outside the United States, and referencing conference ID 991868. 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 49172. 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.

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.

Amarin Contact Information

Investor Inquiries:
Jordan Zwick
Amarin Corporation plc
IR@amarincorp.com

Media Inquiries:
Mark Marmur
Amarin Corporation plc
PR@amarincorp.com

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

	September 30, 2023	December 31, 2022
	(in thousands)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 270,814	$ 217,666
Restricted cash	524	523
Short-term investments	49,848	91,695
Accounts receivable, net	122,400	130,990
Inventory	254,461	228,732
Prepaid and other current assets	19,464	19,492
Total current assets	717,511	689,098
Property, plant and equipment, net	147	874
Long-term investments	—	1,275
Long-term inventory	91,792	163,620
Operating lease right-of-use asset	8,510	9,074
Other long-term assets	1,395	458
Intangible asset, net	19,676	21,780
TOTAL ASSETS	$ 839,031	$ 886,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 53,362	$ 64,602
Accrued expenses and other current liabilities	211,304	192,678
Current deferred revenue	2,025	2,199
Total current liabilities	266,691	259,479
Long-Term Liabilities:		
Long-term deferred revenue	2,949	13,147
Long-term operating lease liability	8,970	10,015
Other long-term liabilities	7,273	8,205
Total liabilities	285,883	290,846
Stockholders' Equity:		
Common stock	302,318	299,002
Additional paid-in capital	1,895,155	1,885,352
Treasury stock	(63,743)	(61,770)
Accumulated deficit	(1,580,582)	(1,527,251)
Total stockholders' equity	553,148	595,333
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 839,031	$ 886,179

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

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2023	2022	2023	2022
Product revenue, net	$ 64,903	$ 89,222	$ 214,744	$ 277,004
Licensing and royalty revenue	1,153	656	17,454	1,944
Total revenue, net	66,056	89,878	232,198	278,948
Less: Cost of goods sold	23,560	23,941	72,553	81,990
Less: Cost of goods sold - restructuring inventory	12,674	3,078	39,228	18,078
Gross margin	29,822	62,859	120,417	178,880
Operating expenses:				
Selling, general and administrative (1)	45,457	58,745	155,997	236,285
Research and development (1)	5,105	5,765	16,428	25,172
Restructuring	711	3,493	10,743	13,706
Total operating expenses	51,273	68,003	183,168	275,163
Operating loss	(21,451)	(5,144)	(62,751)	(96,283)
Interest income, net	3,216	750	8,438	1,241
Other (expense) income, net	(575)	511	3,092	(1,990)
Loss from operations before taxes	(18,810)	(3,883)	(51,221)	(97,032)
Provision for income taxes	(501)	(1,257)	(2,110)	(9,627)
Net loss	$ (19,311)	$ (5,140)	$ (53,331)	$ (106,659)
Loss per share:				
Basic	$ (0.05)	$ (0.01)	$ (0.13)	$ (0.27)
Diluted	$ (0.05)	$ (0.01)	$ (0.13)	$ (0.27)
Weighted average shares:				
Basic	408,417	404,614	407,489	399,944
Diluted	408,417	404,614	407,489	399,944

(1) - Excluding non-cash stock-based compensation, selling, general and administrative expenses were $41,807 and $54,358 for the three months ended September 30, 2023 and 2022, respectively, and research and development expenses were $4,113 and $5,138, respectively, for the same periods.

RECONCILIATION OF NON-GAAP NET INCOME (LOSS)
Unaudited

	Three months ended September 30, (in thousands, except per share amounts)		Nine months ended September 30, (in thousands, except per share amounts)	
	2023	2022	2023	2022
Net loss for EPS[1] - GAAP	(19,311)	(5,140)	(53,331)	(106,659)
Non-cash stock-based compensation expense	4,643	5,015	12,034	20,192
Restructuring inventory	12,674	3,078	39,228	18,078
Restructuring expense	711	3,493	10,743	13,706
Advisor fees	—	—	6,270	—
Adjusted net (loss) income for EPS[1] - non-GAAP	$ (1,283)	$ 6,446	$ 14,944	$ (54,683)

[1]basic and diluted

Earnings (loss) per share:				
Basic - non-GAAP	$ (0.00)	$ 0.02	$ 0.04	$ (0.14)
Diluted - non-GAAP	$ (0.00)	$ 0.02	$ 0.04	$ (0.14)

Weighted average shares:				
Basic	408,417	404,614	407,489	399,944
Diluted	408,417	405,541	417,117	399,944

[1] *Excludes one-time supply restructuring payment of $25 million in third quarter 2022 and one-time supply restructuring payment of $10 million in first quarter 2023.*