

Amarin Reports Third Quarter 2012 Financial Results and Provides Update on Operations

Conference Call Set for 4:30 p.m. EST Today

BEDMINSTER, N.J. and DUBLIN, Ireland, Nov. 8, 2012 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced financial results for the quarter ended September 30, 2012 and provided an update on company operations.

Amarin noted the following highlights of progress made since the quarter ended June 30, 2012:

- FDA approval of VascepaTM (icosapent ethyl) capsules as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG≥500 mg/dL) hypertriglyceridemia
- Eight patents either issued or allowed with the United States Patent and Trademark Office, in addition to over 30 other U.S. patent applications pending
- Receipt of Intention to Grant letter for a European patent related to the MARINE Phase 3 trial findings
- While evaluating three paths to commercialization (an acquisition of Amarin, a strategic collaboration, or selfcommercialization, the latter of which could include third-party support), continued preparedness for early Q1 2013 Vascepa launch, including inventory purchases, managed care outreach and management expansion
- Publication of ANCHOR Phase 3 trial results in The American Journal of Cardiology
- Publication of additional MARINE Phase 3 trial results in the Journal of Clinical Lipidology
- Presentation of Vascepa Phase 3 clinical data at the American Heart Association Scientific Sessions
- Regulatory approval of Catalent as second drug product encapsulator
- REDUCE-IT cardiovascular outcomes study enrollment progress on track, which continues to support the projected Prescription Drug User Fee Act (PDUFA) action date for the ANCHOR indication before the end of 2013
- Cash balance of \$215.1 million at September 30, 2012

"Our recent regulatory affairs and intellectual property progress has been significant, including our first U.S. marketing approval of Vascepa and an increase in U.S. patents granted or allowed to 8 and more than 30 additional applications being prosecuted," stated Joseph Zakrzewski, Amarin's Chairman and Chief Executive Officer. "In parallel, whether Amarin launches through a third party or on its own, commercial preparations for Vascepa have advanced and we remain confident, based on market feedback, that Vascepa will be well received when launched in early Q1 2013. We are very pleased with the approved label for our initial launch and believe that Vascepa has the potential to redefine lipid management."

Operational update

Vascepa regulatory update

On July 26, 2012, the U.S. Food and Drug Administration (FDA) approved Vascepa (icosapent ethyl) capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG > 500mg/dL) hypertriglyceridemia. The only reported adverse reaction with an incidence > 2% and greater than placebo in Vascepa treated patients was arthralgia (2.3% for Vascepa, 1.0% for placebo). The approved label shows that Vascepa, compared to placebo, reduces TG's, Apo B, non-HDL-C, total cholesterol and VLDL-C without increasing LDL-C.

Amarin expects to file sNDAs for two additional active pharmaceutical ingredient (API) suppliers before the end of 2012 and for a third API supplier in the first quarter of 2013. This brings to four, the total number of API suppliers for Vascepa and is part of Amarin's strategy to mitigate risk through multiple suppliers.

Amarin's sNDA has been prepared for the patient population studied in the ANCHOR Phase 3 trial. Consistent with prior guidance, Amarin plans to file this sNDA once its cardiovascular outcomes study, REDUCE-IT, is substantially underway. As previously discussed in Amarin's second quarter 2012 results conference call, based on continued REDUCE-IT progress Amarin anticipates submitting this sNDA to the FDA no later than the end of February 2013 resulting in an anticipated PDUFA action date for the ANCHOR sNDA before the end of 2013.

Vascepa exclusivity update

Amarin continues to make significant progress in its effort to expand the patent protection for Vascepa in the United States and

now has 8 patents either issued or allowed and over 30 additional patent applications being prosecuted. Amarin is also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States, including the application for Amarin's MARINE method of use patent in Europe for which Amarin previously announced receipt of an Intention to Grant letter. Amarin's goal is to protect the commercial potential of Vascepa to beyond 2030 through patent protection, regulatory exclusivity and trade secrets and by taking advantage of manufacturing barriers to entry.

Amarin expects the FDA to make a determination to award Vascepa either three-years of marketing exclusivity or five-years of marketing exclusivity. A marketing exclusivity determination may help to clarify the ultimate path for Vascepa commercialization among Amarin's three previously-disclosed potential paths: an acquisition of Amarin, a strategic collaboration, or self-commercialization, the latter of which could include third-party support.

Commercialization update

As Amarin continues to pursue in parallel three potential paths for the marketing and sale of Vascepa and, as previously guided, Amarin is beginning to build inventory of Vascepa capsules in preparation for commercial launch of Vascepa early in the first quarter of 2013. Amarin is also taking other steps to prepare for launch, including increased managed care outreach, increased activity at trade shows and other venues and selectively adding management personnel.

Investor presentations

Amarin expects to participate in the following upcoming investor conferences: Lazard 9th Annual Healthcare Conference in New York City, November 13, 2012, 3:00 pm ET (a live audio webcast of the presentation will be available at:

http://wsw.com/webcast/lz13/amrn/); 31st Annual JP Morgan Healthcare Conference in San Francisco, January 7-10, 2013; and CITI's 2013 Global Healthcare Conference in New York City, February 25-27, 2013.

Financial update

Amarin reported cash and cash equivalents of \$215.1 million at September 30, 2012, the end of its third quarter, representing a decrease of approximately \$35.2 million from the company's cash balance at the end of its second quarter. Included in these cash outflows were payments to clinical research organizations in connection with Amarin's Vascepa clinical trial activities as well as various costs associated with commercial readiness and expanded patent prosecution. Amarin's cash outflows during this period were partially offset by \$2.8 million in proceeds from the exercise of warrants and stock options.

Under U.S. Generally Accepted Accounting Principles (GAAP), Amarin reported a net loss for the three months ended September 30, 2012 of \$26.4 million, or basic and diluted loss per share of \$0.18, including \$4.6 million in share-based compensation expense, \$1.2 million in warrant compensation income, and a \$16.5 million gain on the change in the fair value of non-cash financial derivative. For the same period in 2011, GAAP net income was \$96.3 million, or basic and diluted income per share of \$0.72 and \$0.62, respectively, including \$2.7 million in share-based compensation expense, \$3.4 million in warrant compensation income, and a \$106.6 million gain on the change in the fair value of non-cash financial derivative.

Excluding non-cash losses for share-based, warrant-based compensation and change in value of derivative, non-GAAP adjusted net loss was \$39.4 million for the third quarter of 2012 (basic and diluted loss per share of \$0.26) compared to a non-GAAP adjusted net loss of \$11.0 million (basic and diluted loss per share of \$0.08) for the same period in the prior year.

Conference call and webcast information

Amarin will host a conference call at 4:30 p.m. EST today, November 8, 2012. To participate in the call, please dial (877) 407-8033 within the United States or (201) 689-8033 from outside the United States. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial (877) 660-6853 (inside the U.S.) or (201) 612-7415 (outside the U.S.). A replay of the call will also be available through Amarin's website shortly after the call. For both dial-in numbers please use account number 286 and conference ID 402385. The conference call can also be heard live through the investor relations section of Amarin's website at <u>www.amarincorp.com</u>.

Use of non-GAAP adjusted financial information

Included in this press release and the conference call referenced above are non-GAAP adjusted financial information as defined by SEC 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, are included in this press release after the condensed consolidated financial statements.

Non-GAAP adjusted net loss was derived by taking GAAP net loss and adjusting it with non-cash gains or losses for share-

based, warrant-based compensation, and change in value of derivative. Amarin's management believes that these non-GAAP adjusted measures provide investors with a better understanding of the company's historical results from its core business operations by excluding them.

While management believes that this non-GAAP adjusted financial measure provides useful supplemental information to investors regarding the underlying performance of the company's business operations, investors are reminded to consider this non-GAAP measure 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 Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and

the potential therapeutic benefits of polyunsaturated fatty acids. VascepaTM (icosapent ethyl), Amarin's first FDA approved product, is a patented, ultra pure omega-3 fatty acid product comprising not less than 96% EPA. For more information about Vascepa visit <u>www.vascepa.com</u>. For more information about Amarin visit <u>www.amarincorp.com</u>.

The Amarin Corporation plc logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=13817

Forward-looking statements

This press release contains forward-looking statements, including statements about the timing of a commercial launch of Vascepa, preparations for commercial launch, including among other things plans to purchase commercial supply, the potential additional indications for which FDA marketing approval of Vascepa may be sought and the timing of planned regulatory filings and decisions, the potential for an acquisition of Amarin or a strategic collaboration with a third party for the commercialization of Vascepa, the timing and outcome of FDA's review determination of whether Vascepa should be granted new chemical entity or new product marketing exclusivity, the status of patent applications currently under review by the United States Patent and Trademark Office, the coverage and expected expiration dates of those patent applications and issued patents and the ability of Amarin to protect the commercial potential of Vascepa. In particular there can be no assurance that Vascepa will be awarded five-year new chemical entity or three-year new product marketing exclusivity and the FDA may take longer than expected to reach any such determination. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with the commercial success of new pharmaceutical products, such as Vascepa; Amarin's ability to negotiate and execute a successful acquisition of Amarin or a strategic collaboration with a third party for the commercialization of Vascepa; Amarin's lack of experience with commercializing pharmaceutical products; risks associated with preparations associated with a commercial launch; the risk that FDA may not grant new chemical entity or new product marketing exclusivity to Vascepa; the risk that FDA may not reach a determination with respect to these matters on the timetable that we expect; the risk that patent applications may not result in issued patents, and that issued patents may not prevent competitors from competing with Vascepa; the risk that competitors may challenge the validity, enforceability or both the validity and enforceability of our patents or seek to design products around our issued patent claims and gain marketing approval for generic versions of Vascepa or branded competitive products based on new clinical studies; and the risk that trade secrets may not be maintained and that circumstances that create manufacturing barriers to entry may not last. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in the "Risk Factors" section of 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 except as required by law.

Amarin's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials. This press release is intended for communication with investors. Nothing in this press release should be construed as marketing the use of such product candidates.

CONSOLIDATED BALANCE SHEET DATA

(U.S. GAAP)

September 30, 2012 December 31, 2011

(in thousands)

Current Assets		
Cash and cash equivalents	\$ 215,110	\$ 116,602
Inventory	8,989	
Deferred tax asset	533	533
Other current assets	4,110	1,837
Total Current Assets	\$ 228,742	\$ 118,972
Property, plant and equipment, net	796	432
Deferred tax asset	9,788	4,734
Other long term assets	15,672	2,241
Total Assets	\$ 254,998	\$ 126,379

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

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Current Liabilities:		
Accounts payable	\$ 13,696	\$ 4,419
Accrued expenses and other liabilities	18,816	4,033
Total current liabilities	\$ 32,512	\$ 8,452
Long-Term Liabilities		
Warrant derivative liability	90,963	123,125
Long term debt	130,783	
Other long-term liabilities	702	764
Total liabilities	\$ 254,960	\$ 132,341
Stockholders' Equity (Deficit)		
Common Stock	124,244	113,321
Additional paid-in capital	613,087	449,393
Treasury Stock	(217)	(217)
Accumulated deficit	(737,076)	(568,459)
Total stockholders' equity (deficit)	\$ 38	\$ (5,962)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 254,998	\$ 126,379

CONSOLIDATED STATEMENTS OF OPERATIONS DATA

(U.S. GAAP)

Unaudited

	Three Months Ended Sept 30 (in thousands, except share and per share amounts)		Nine Months Ended Sept 30 (in thousands, except share and per share amounts)	
	2012	2011	2012	2011
Revenues	\$	\$	\$	\$
OPERATING EXPENSES:				
Research and development(1)	20,913	6,013	39,735	15,651
Marketing, general and administrative(1)	13,397	3,433	41,059	16,185
Total operating expenses	34,310	9,446	80,794	31,836
Operating loss	(34,310)	(9,446)	(80,794)	(31,836)

Gain (Loss) on change in fair value of derivative liability (2)	16,454	106,614	(68,686)	(53,403)
Interest income (expense), net	(4,570)	3	(12,838)	97
Other income (expense), net	(427)	(59)	(411)	30
Income (Loss) from operations before taxes	(22,853)	97,112	(162,729)	(85,112)
Provision for income taxes	(3,573)	(767)	(5,888)	(2,352)
Net and comprehensive income (loss)	\$ (26,426)	\$ 96,345	\$ (168,617)	\$ (87,464)
(Loss) income per share:				
Basic	\$ (0.18)	\$ 0.72	\$ (1.19)	\$ (0.68)
Diluted	\$ (0.18)	\$ 0.62	\$ (1.19)	\$ (0.68)
Weighted average shares:				
Basic	149,200	133,238	141,947	128,377
Diluted	149,200	155,975	141,947	128,377

(1) A substantial portion of the Amarin's marketing, general and administrative costs represents non-cash warrant based compensation to former officers. Excluding non-cash stock and warrant based compensation, research and development expenses were \$19,943 and \$5,607 for the three months ending September 30, 2012 and 2011, respectively, and marketing, general and administrative expenses were \$10,926 and \$4,529, respectively, for the same periods.

(2) Non-cash charges result from changes in the fair value of the warrant derivative liability. This liability is revalued at each reporting period and, upon exercise of warrants, is reclassified at fair value from liability to stockholders' equity. These warrants are valued using the Black-Scholes option pricing model, they are classified for accounting purposes as financial derivatives because, under certain circumstances, the exercise price of the warrants could increase.

The following is a reconciliation of the non-GAAP financial measures used by Amarin to describe its financial results determined in accordance with United States generally accepted accounting principles (GAAP). An explanation of these measures is also included under the heading "Use of Non-GAAP Adjusted Financial Information" above.

RECONCILIATION OF NON-GAAP LIABILITIES

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Unaudited

	September 30, 2012	December 31, 2011	
	(in thousands)		
Current Liabilities:			
Accounts payable	\$ 13,696	\$ 4,419	
Accrued expenses and other liabilities	18,816	4,033	
Total current liabilities	\$ 32,512	\$ 8,452	
Long-Term Liabilities			
Warrant derivative liability	90,963	123,125	
Long term debt	130,783		
Other long-term liabilities	702	764	
Total liabilities — GAAP	\$ 254,960	\$ 132,341	
Warrant derivative liability	(90,963)	(123,125)	
Total liabilities — non GAAP	\$ 163,997	\$ 9,216	

	Three Months En	Three Months Ended Sept 30		Nine Months Ended Sept 30		
	(in thousands, except share and per share amounts)		(in thousands, except share and per share amounts)			
	2012	2011	2012	2011		
Net income (loss) for EPS ¹ — GAAP	\$ (26,426)	\$ 96,345	\$ (168,617)	\$ (87,464)		
Share based compensation expense	4,635	2,662	13,344	6,022		

Warrant compensation (income) expense	(1,194)	(3,352)	3,037	1,004
(Gain) loss on change in fair value of derivative	(16,454)	(106,614)	68,686	53,403
Adjusted net income (loss) for ${\sf EPS}^1$ — non GAAP	(39,439)	(10,959)	(83,550)	(27,035)
¹ Basic and diluted				
Loss per share:				
Basic and diluted — non GAAP	\$ (0.26)	\$ (0.08)	\$ (0.59)	\$ (0.21)
Weighted average shares:				
Basic and diluted	149,200	133,238	141,947	128,377
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