Amarin Reports Third Quarter 2011 Results

Conference Call Set for 8:00 am EST November 8

BEDMINSTER, N.J., and DUBLIN, Ireland, Nov. 7, 2011 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a clinical-stage biopharmaceutical company focused on cardiovascular disease, today reported financial and operating results for the quarter ended September 30, 2011 (Q3 2011). Highlights since the Company's last quarterly report included:

- Submitted a New Drug Application (NDA) for AMR101 for the reduction in triglycerides in patients with very high triglycerides (>500 mg/dL), including efficacy and safety data from both Phase 3 MARINE and ANCHOR pivotal studies
- Agreement reached with FDA on Special Protocol Assessment (SPA) for the REDUCE-IT cardiovascular outcomes study
- U.S. patent applications for AMR101 increased to16 applications across 11 patent families
- Published MARINE Phase 3 clinical trial results in *The American Journal of Cardiology*
- Accepted for oral presentation from each of its two pivotal Phase 3 studies, the MARINE trial and the ANCHOR trial, at the American Heart Association's Scientific Sessions 2011
- Cash balance at end of third quarter was $125.9 million

Q3 2011 Financial Update

Amarin's cash and cash equivalents as of September 30, 2011 totaled approximately $125.9 million compared to $131.4 million as of June 30, 2011. During Q3 2011, $9.3 million in cash was used in operating activities, partially offset by the receipt of $3.8 million in net proceeds from the exercise of 2.5 million warrants for the purchase of the Company's American Depositary Shares (ADSs), each representing one ordinary share, as compared to $8.4 million in cash outflows for the same period of 2010. The increase in cash outflows for operations of $0.9 million versus the prior year period was due primarily to higher costs for personnel and commercial preparation activities.

At September 30, 2011, there were 135,445,501 outstanding shares held as ADSs and an additional 315,237 ordinary shares. Also outstanding at September 30, 2011 were warrants to purchase 21,139,090 ADSs and stock options to purchase 10,778,763 ADSs.

Under U.S. Generally Accepted Accounting Principles (GAAP), the Company reported net income for Q3 2011 of $96.3 million, or basic income per share of $0.72 and diluted income per share of $0.62, including $2.7 million in share-based compensation expense and $3.4 million in warrant compensation income, and a $106.6 million gain on the change in the fair value of derivative. For the same period in 2010, GAAP net loss was $11.2 million, or basic and diluted loss per share of $0.11, including $0.8 million in share-based compensation expense, $0.04 million in warrant compensation expense, and $1.4 million loss on the change in the fair value of derivative.

Excluding non-cash gains or losses for share-based compensation, warrant compensation and change in value of derivative, non-GAAP adjusted net loss for Q3 2011 was $11.0 million, or non-GAAP adjusted basic and diluted loss per share of $0.08, compared to non-GAAP adjusted net loss of $9.0 million, or non-GAAP adjusted basic and diluted earnings per share of $0.09 for the same period in 2010.

In accordance with GAAP, the fair value of the derivative related to warrants issued in conjunction with the Company's 2009 equity financing was recorded at the time of issuance as a non-cash liability and this liability is re-measured at the end of each reporting period. Changes in fair value from period to period are recorded as gains or losses. Upon exercise of the warrants, the fair value of the warrants exercised is reclassified from liabilities to equity. Although these warrants are accounted for as derivatives, the number of warrants issuable remains fixed and the derivative liability is not an obligation on the cash of the Company. Excluding this non-cash derivative liability, the Company's liabilities reported as of September 30, 2011 totaled approximately $7.0 million, primarily consisting of accrued expenses, accounts payable from operating activities, lease obligations and long-term liabilities.

Regulatory Update — NDA Submitted for Very High Triglycerides Indication

In September 2011, Amarin submitted an NDA to the FDA requesting approval to market and sell AMR101 for the indication studied in the Phase 3 MARINE trial - reduction in triglycerides in patients with very high triglycerides (>500 mg/dL). The NDA includes data from the Company's AMR101 development program, including safety and efficacy data from both the Phase 3 MARINE and ANCHOR pivotal studies.

Clinical Update - REDUCE-IT Outcomes Study

In August 2011, Amarin reached agreement with the FDA on a SPA (Special Protocol Assessment) agreement for the design of a cardiovascular outcomes study titled REDUCE-IT (Reduction of Cardiovascular Events with EPA - Intervention Trial). REDUCE-IT is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of AMR101 in reducing the first major cardiovascular event in an at-risk patient population on background statin therapy. The control arm of the study will be patients on optimized statin therapy. The active arm of the study will be patients on optimized statin therapy plus AMR101. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. The Company is beginning to recruit clinical trial sites for REDUCE-IT and aims to achieve approximately 50% patient enrollment before the end of 2012.

Once REDUCE-IT is substantially underway, the Company believes that it will have met all of the requirements to request approval of AMR101 for treating the mixed dyslipidemia patient population studied in the ANCHOR trial. AMR101 is positioned to be the first drug in its class approved for treatment of this indication.

Commercial Opportunity

The Company believes that AMR101 represents a major commercial opportunity as it is estimated approximately 4 million people with very high triglyceride levels (>500mg/dL-the triglyceride range studied in the MARINE trial) and approximately 36 million people with high triglyceride levels (>200 and <500mg/dL - the triglyceride range studied in the ANCHOR trial and a potential first in class prescription medicine for this indication). Clinical treatment guidelines include recommendations for triglyceride reductions in each of these groups and the Company believes that each group represents a multi-billion dollar market opportunity. In the top seven world markets it is estimated that the number of people with elevated triglyceride levels is at least two times that of the U.S. alone.

"In the third quarter, Amarin continued to make significant progress and, as demonstrated with the NDA submission, to do so in a timely manner," stated Joseph Zakrzewski, Chairman and Chief Executive Officer of Amarin. "We are advancing our business plan to maximize the value of AMR101 and believe there is a large unmet need for new therapies that target the broader set of lipids, including triglycerides and that AMR101 has the potential to redefine lipid management therapy."

Intellectual Property Update

Amarin is aggressively pursuing a patent strategy to bolster the proprietary position of AMR101. The Company has filed and is actively prosecuting numerous patents. Amarin has filed 16 pending U.S. patent applications belonging to 11 U.S. patent families that collectively include numerous independent claims and dependent claims. Several of Amarin's patent applications contain claims based upon the unexpected findings observed in the MARINE and ANCHOR Phase 3 clinical trials. Some of the U.S. applications were filed under the PTO's new process for prioritized examination, which could enable these applications to reach final disposition within twelve months. If granted, the Company believes that some of these resulting U.S. patents would expire in 2030 and beyond.

Securing a patent is a complex process in which an active exchange with the patent office is common and there can be no assurance that patents will be granted in the form initially filed, or at all. Our policy is to not comment on the nature of our active and ongoing discussions with the respective patent offices or to comment on the interim status of individual patent applications.

Based in part on the unexpected findings we observed in our MARINE and ANCHOR Phase 3 clinical trials, we continue to believe that our arguments for patentability are strong and we will continue to vigorously prosecute our multiple patent applications to the fullest extent.

Anticipated Presentations

As part of the Company's overall program for communicating further details of its clinical results, the following are upcoming:

- Presentation of clinical trial results in peer-reviewed forums:
    - ANCHOR results oral presentation at the annual meeting of the American Heart Association in Orlando, Florida, November 16 (the first oral presentation of these results);
    - MARINE results oral presentation at the annual meeting of the American Heart Association in Orlando, Florida, November 15 (including data results from of our MARINE trial which have not been previously presented);
- Publication of clinical trial results:
    - ANCHOR results publication: multiple publications anticipated commencing after peer-review presentation of

results

In addition, Amarin is scheduled to present at various upcoming investor conferences, including the Lazard Capital Markets 8th Annual Healthcare Conference (New York, November 15), the CITI 2011 Annual Small & Mid Cap Conference (November 15, Las Vegas), Leerink Swann Mayflower Management Access Days (Boston, November 21-22), and the JP Morgan Healthcare Conference (San Francisco, January 9-12, 2012).

Conference Call and Webcast Information

Amarin will host a conference call at 8:00 am EST (12 pm UTC/GMT) on November 8, 2011 to discuss its Q3 financial results and operational priorities. To participate in the call, please dial (877) 407-0778 within the U.S. or (201) 689-8565 from outside the U.S. 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 via the Company's website shortly after the call. For both dial-in numbers please use account number 286 and conference ID 382190. The conference call can also be heard live via the investor relations section of the Company's website at www.amarincorp.com.

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 compensation, warrant compensation, and change in value of derivative. The Company'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.

The non-GAAP adjusted financial information is not meant to be considered in isolation or as a substitute for GAAP financials. The non-GAAP adjusted financial information provided by the Company may also differ from non-GAAP adjusted information provided by other companies.

About AMR101

AMR101 is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure EPA (icosapent ethyl), that Amarin is developing for the treatment of patients with very high triglyceride levels (>500 mg/dL) and as a potentially first-in-class therapy for patients with high triglyceride levels (>200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels (which we refer to as mixed dyslipidemia). Triglycerides are fats in the blood. Significant scientific and clinical evidence support the efficacy and safety of ethyl-EPA in reducing triglyceride levels and other important lipid and inflammation biomarkers, including Apo-B, non-HDL-C, Total-Cholesterol, VLDL-C, Lp-PLA2, and hs-CRP without increasing LDL-C. AMR101 demonstrated a safety profile comparable to placebo in two completed Phase 3 clinical trials.

About Amarin

Amarin Corporation plc is a clinical-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. The Company's lead product candidate is AMR101 (icosapent ethyl). Amarin reported positive, statistically significant top-line results for both of its two pivotal Phase 3 clinical trials, the MARINE trial (investigation of AMR101 as a treatment for patients with very high triglycerides [>500 mg/dL]), as reported in November 2010, and the ANCHOR trial (investigation of AMR101 for the treatment of patients on statin therapy with high triglycerides [>200 and <500mg/dL] with mixed dyslipidemia), as reported in April 2011. Both the MARINE and ANCHOR trials were conducted under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA). Amarin also has next-generation lipid candidates under evaluation for preclinical development. In September 2011, Amarin submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the marketing and sale of AMR101 for treatment of the patient population studied in the MARINE trial. Amarin plans to separately seek approval for the population studied in the ANCHOR trial after its REDUCE-IT cardiovascular outcomes trial is substantially underway. In August 2011, an SPA agreement with the FDA was reached for the REDUCE-IT cardiovascular outcomes study. The Company aims to achieve approximately 50% patient enrollment in this study before the end of 2012.

Disclosure Notice

This press release contains forward-looking statements, including statements about the efficacy and safety of the Company's

product candidates, clinical trial results, the timing of initiating, enrolling and completing a planned cardiovascular outcomes study, the timing of data publication and presentation, clinical importance of AMR101, regulatory submissions and approvals, patent approvals, the commercial opportunity and competitive positioning for AMR101and the ability of Company to achieve current operating priorities. 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 are the following: anticipated operating losses and the likely need for additional capital to fund future operations and the planned cardiovascular outcomes study; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; risks associated with qualifying new contract manufacturers prior to commercial launch; the risk that SPAs are not a guarantee that FDA will accept an NDA or approve a product candidate upon submission; the risk that historical clinical trial enrollment and randomization rates may not be predictive of future results; risks associated with our intellectual property including the risk that our issued patents may not prevent third parties from developing competitive products or from infringing our intellectual property and the risk that our patent applications may not issue; dependence on third-party manufacturers, suppliers and collaborators; significant competition; loss of key personnel; and uncertainties associated with market acceptance and adequacy of reimbursement, technological change and government regulation. A further list and description of these risks, uncertainties and other matters can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and 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. The Company 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. The Company's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials. Nothing in this press release should be construed as marketing the use of such product candidates.

CONSOLIDATED BALANCE SHEET DATA

(U.S. GAAP)

Unaudited

	September 30, 2011	December 31, 2010
	(in thousands)	
ASSETS		
Cash and cash equivalents	$ 125,855	$ 31,442
Total Assets	$ 131,670	$ 35,367
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities (excluding warrant derivative liability)	$ 6,987	$ 7,665
Total shareholders' (deficit) equity	$(30,335)	$ (202,367)

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)	
	2011	2010	2011	2010
Revenues	$ --	$ --	$ --	$ --
OPERATING EXPENSES:				
Research and development(1)	6,013	7,642	15,651	20,565
Marketing, general and administrative(1)	3,433	2,134	16,185	7,205
Total operating expenses	9,446	9,776	31,836	27,770
Operating loss	(9,446)	(9,776)	(31,836)	(27,770)
Gain (loss) on change in fair value of derivative liability(2)	106,614	(1,370)	(53,403)	(33,402)

Interest income (expense), net	3	30	97	15
Other income (expense), net	(59)	15	30	(478)
Income (loss) from operations before taxes	97,112	(11,101)	(85,112)	(61,635)
Provision for income taxes	(767)	(108)	(2,352)	(142)
Net and comprehensive income (loss)	$ 96,345	$ (11,209)	$ (87,464)	$ (61,777)
Income (loss) per share:				
Basic	$ 0.72	$ (0.11)	$ (0.68)	$ (0.62)
Diluted	0.62	(0.11)	(0.68)	(0.62)
Weighted average shares:				
Basic	133,238	100,150	128,377	99,284
Diluted	155,975	100,150	128,377	99,284

(1) A substantial portion of the Company's marketing, general and administrative costs represents non-cash warrant based compensation to former employees. Excluding non-cash stock and warrant based compensation, research and development expenses were $5,607 and $7,350 for the three months ended September 30, 2011 and 2010, respectively and marketing, general and administrative expenses were $4,529 and $1,631, 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 the Company to describe the Company's financial results determined in accordance with United States generally accepted accounting principles (GAAP).

RECONCILIATION OF NON-GAAP NET INCOME / (LOSS)

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)**	
	2011	**2010**	**2011**	**2010**
Net income/(loss) for EPS[1] — GAAP	$ 96,345	$ (11,209)	$ (87,464)	$ (61,777)
Share based compensation expense	(2,662)	(759)	(6,022)	(2,010)
Warrant compensation income (expense)	3,352	(36)	(1,004)	(858)
Gain/(loss) on change in fair value of derivative	106,614	(1,370)	(53,403)	(33,402)
Adjusted net loss for EPS[1] — non GAAP	(10,959)	(9,044)	(27,035)	(25,507)
[1] basic and diluted				
Loss per share:				
Basic and diluted — non GAAP	$ (0.08)	$ (0.09)	$ (0.21)	$ (0.26)
Weighted average shares:				
Basic and diluted	133,238	100,150	128,377	99,284

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