Amarin Reports Year-End and Q4 2010 Results

- AMR101 for Elevated Triglyceride Levels Advancing Towards Multi-Billion Dollar Market Opportunities-
- Conference Call Set for 8 am EDT Tomorrow, March 17 -

DUBLIN and MYSTIC, Conn., March 16, 2011 /PRNewswire/ -- Amarin Corporation plc (Nasdaq: AMRN), a clinical-stage biopharmaceutical company focused on cardiovascular disease, today reported financial results for the fiscal year and fourth quarter ended December 31, 2010. The Company also provided an update on its progress with the Phase 3 development program of its lead product candidate, AMR101 for the treatment of elevated triglyceride levels, which are associated with the increased risk of developing cardiac disease as well as being a component of certain other metabolic disorders, such as diabetes and obesity.

As reported by Amarin, key accomplishments since the Company's last quarterly financial report of September 30, 2010, include:

- Primary endpoints met in Phase 3 MARINE trial with AMR101 at both 4g and 2g doses
- Strengthened balance sheet with additional $98.7M cash
- Completed last patient visit for the Phase 3 ANCHOR trial
- Strengthened management team with focus on commercial —readiness of AMR101 through the addition of an accomplished Chief Commercial Officer
- On-track with the existing MARINE trial data for a New Drug Application (NDA) submission for AMR101 in Q3, 2011

"2010 was a year of great progress for Amarin. We accomplished our goal of advancing AMR101 toward commercial status with the release of positive MARINE trial results in the last quarter," stated Joseph Zakrzewski, Executive Chairman and Chief Executive Officer of Amarin. "Among prescription Omega-3 based drugs, AMR101 has the potential to be best-in-class for treating patients with very high triglycerides and the first-in-class for treating patients with high triglycerides with mixed dyslipidemia. Our focus is to become the leader in the market for triglyceride-lowering drugs by providing clinicians and patients a new generation of prescription Omega-3 therapies that offer a superior efficacy and safety for individuals who also suffer from other cardiovascular risk factors, including elevated non-HDL cholesterol levels."

Year End and Q4 2010 Financial Update

Amarin's cash and cash equivalents balance as of December 31, 2010, was $31.4 million. This balance was augmented by the successful public offering in January 2011 of 13.8 million ADSs (American Depository Shares, each representing one ordinary share) at a price of $7.60 per ADS, resulting in approximately $98.7 million in net cash proceeds to Amarin. During the three months ended December 31, 2010, net cash outflows were approximately $9 million, including approximately $6 million paid in connection with Amarin's two Phase III clinical trials. Cash outflows for operating activities for fiscal year 2010 were approximately $33.9 million, as compared to cash outflows for fiscal year 2009 of approximately $28.4 million.

Amarin Corporation plc was previously classified as a "foreign private issuer" for U.S. Securities and Exchange Commission (SEC) reporting purposes, reporting its annual financial results in accordance with International Financial Reporting Standards ("IFRS") on Form 20-F. Beginning January 1, 2011, the Company is no longer classified as a foreign private issuer and, as such, has transitioned to U.S. Generally Accepted Accounting Principles (U.S. GAAP). Amarin has filed its Annual Report on Form 10-K for the year ended December 31, 2010. All historical financial information contained therein has been presented in accordance with U.S. GAAP.

As a result of the change to U.S. GAAP, the Company identified differences between IFRS and U.S. GAAP, in particular, the accounting treatment for warrants. In connection with its October 2009 private placement, the Company issued warrants that contain a provision whereby the exercise price of the warrants could increase (not decrease) under certain circumstances. Under U.S. GAAP, this pricing variability feature requires the warrants to be classified as a derivative liability and, therefore, the Company reported a warrant derivative liability of $230 million at December 31, 2010. This warrant derivative liability represents a non-cash item and is required to be recorded at fair value at each reporting period. Changes in fair value from period to period are included in the net loss. Upon exercise of the warrants, the fair value of the warrants exercised is reclassified from liabilities to equity.

Amarin had approximately 125.5 million ADSs outstanding at March 1, 2011, which includes the 13.8 million ADSs issued in the January equity offering.

Clinical Trials Update

In November 2010, Amarin announced that AMR101, the Company's lead product candidate for the treatment of patients with very high triglycerides (≥500 mg/dL), met the primary endpoints, and multiple other endpoints in the Phase 3 MARINE study. Highly significant reductions in triglycerides were achieved with both the 4 gram and 2 gram doses of AMR101.

In addition to achieving these key endpoints, the results of this trial exceeded the Company's expectations by demonstrating:

- No statistically significant increase in LDL-cholesterol ("bad cholesterol") at either dose
- Triglyceride lowering that was better in the predefined subset of patients on statin therapy
- Encouraging results regarding pre-specified markers of inflammation
- Safety profile similar to placebo.

The endpoints for this trial were established under a Special Protocol Assessment agreement (SPA) with the U.S. Food and Drug Administration (FDA).

In contrast to previous studies of Omega-3 fatty acids and fibrate treatments of patients with very high triglyceride levels, AMR101 is the first such triglyceride-lowering therapy shown to reduce triglycerides without significantly increasing LDL-cholesterol levels.

Amarin's second Phase 3 trial, ANCHOR, is a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal trial evaluating the efficacy and safety of 2 grams and 4 grams of AMR101 in patients with mixed dyslipidemia and high triglyceride levels (200 mg/dL to less than 500 mg/dL) who are also on statin therapy. Patients in this trial are characterized as having high triglyceride levels with mixed dyslipidemia (two or more lipid disorders) and are at high risk for the development of cardiovascular disease.

Currently, no Omega-3 based therapy is approved by FDA for treating this patient population. The company believes that the treatment of high triglycerides represents a major commercial opportunity for AMR101 as a potential first-in-class prescription medicine, because it is estimated that more than 40 million patients in the U.S. alone have high triglycerides. The primary endpoint in this trial is statistically significant triglyceride reduction from baseline compared to placebo. A secondary endpoint is LDL-C non-inferiority as compared with placebo. As with the MARINE trial, the ANCHOR trial is being conducted under an SPA agreement with FDA. The Company and its contract research organization (CRO), including all of its employees, officers and directors, currently are blinded to the efficacy results of this trial. The Company expects to report top-line results of this trial in the second quarter of this year.

New Drug Application (NDA)

Amarin expects to file an NDA with FDA in third quarter of this year. The Company is evaluating whether it will file the NDA based on the MARINE data alone with a separate filing for ANCHOR efficacy results or whether it will include the ANCHOR efficacy results in the initial NDA submission. As previously stated, the MARINE data alone is sufficient for the Company's filing of an NDA for the very high triglyceride indication (≥500 mg/dL).

Business Update

In preparation for commercialization of AMR101, Amarin appointed Paul Huff as Chief Commercial Officer in January 2011. Mr. Huff brings extensive experience in commercializing cardiovascular drugs, including his tenure at Reliant Pharmaceuticals where he participated in the commercialization of Lovaza, and at Kos Pharmaceuticals where he participated in the commercialization of Niaspan. In addition, Amarin added Stephen Schultz to its management team as Senior Director of Investor Relations and Communications.

Moving forward, Amarin's priorities for 2011 include:

- Presentation of the MARINE trial's complete data set at an appropriate scientific conference and securing various publications of the data
- Announcing the top-line data for the ANCHOR trial in the second quarter
- Filing an NDA for AMR101 in Q3, 2011
- Building a foundation for the commercialization of AMR101
- Establishing greater capacity and diversification in the AMR101 supply chain in preparation for the product's planned launch

Amarin is scheduled to present at several upcoming investor conferences, including Needham & Company's Heathcare Conference (New York City, April 5), BioCentury's "Future Leaders" Conference (New York City, April 15) and Deutsche Bank's Healthcare Conference (Boston, May 2-4).

Conference Call and Webcast Information

Amarin will host a conference call at 8 am EDT (12 pm UTC/GMT) tomorrow, March 17, 2011. 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 369151. The conference call can also be heard live via the investor relations section of the Company's website at www.amarincorp.com.

About AMR101

AMR101 is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA) that Amarin is developing as a potentially best-in-class prescription medicine for the treatment of patients with very high triglyceride levels (>500 mg/dL). AMR101 is also being evaluated 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. Significant scientific and clinical evidence support the efficacy and safety of ethyl-EPA in reducing triglyceride levels.

About Amarin

Amarin Corporation plc is a clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease. The Company's lead product candidate is AMR101, a semi-synthetic form of ethyl-EPA. In November, 2010, Amarin reported positive, statistically significant top-line results from the MARINE trial, the first of its Phase 3 clinical trials of AMR101. In the MARINE trial, AMR101 was investigated as a treatment for very high triglycerides (≥500 mg/dL). AMR101 is presently being investigated in a second Phase 3 clinical trial, the ANCHOR trial, for the treatment of patients with high triglyceride levels (≥200 and <500mg/dL) who are also on statin-therapy for elevated LDL-cholesterol levels. The MARINE trial was, and the ANCHOR trial currently is, conducted under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA).

Disclosure Notice

This press release contains forward-looking statements, including statements about the efficacy and safety of the Company's product candidates, timing and success of clinical trial results, data publication and presentation, NDA submission timing, commercialization of product candidates, establishing greater product supply capacity and adding suppliers and 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; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; 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 enrolment and randomization rates may not be predictive of future results; uncertainties relating to the timing of data collection and analysis for the ANCHOR and MARINE trials; 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. 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.

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CONSOLIDATED BALANCE SHEET DATA
(U.S. GAAP)

	December 31,	
	2010	2009
	(in thousands, except share and per share amounts)	
ASSETS		
Cash and cash equivalents	$ 31,442	$ 52,258
Total Assets	$ 35,367	$ 55,444
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities (excluding warrant derivative liability)	$ 7,665	$ 7,327
Total shareholders' (deficit) equity	$ (202,367)	$ 6,597

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

	Years Ended December 31,		
	2010	2009	2008
	(In thousands, except share and per share amounts)		
Revenues	$ -----	$ -----	$ -----
OPERATING EXPENSES:			
Research and development	28,014	20,892	7,899
General and administrative (1)	17,087	13,152	19,622
Total operating expenses	45,101	34,044	27,521
Operating loss	(45,101)	(34,044)	(27,521)
(Loss) gain on change in fair value of derivative liability (2)	(205,153)	5,137	9,289
Interest income (expense), net	34	(2,633)	(405)
Other income (expense), net	130	33	(900)
Loss from operations before taxes	(250,090)	(31,507)	(19,537)
(Provision for) benefit from income taxes	501	901	1,048
Net loss	$ (249,589)	$ (30,606)	$ (18,489)
Loss per basic and diluted share:	$ (2.49)	$ (0.72)	$ (0.84)
Weighted average shares:			
Basic and diluted	100,239	42,424	22,086

(1) Includes non-cash warrant-related compensation expense reflecting the change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to individuals who were employees of Amarin of that time and who are now former employees. Also included are restructuring, severance and lease exit costs associated with the 2009 decision to relocate certain activities to Mystic, CT. Excluding these costs, general and administrative expenses were $7,237 and $8,593 in 2010 and 2009 respectively.

(2) Non-cash charges resulting 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.

SOURCE Amarin Corporation plc