



## Amarin Reports Fourth Quarter and Year-End 2011 Financial Results and Provides Update on Operations

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

BEDMINSTER, N.J. and DUBLIN, Ireland, Feb. 29, 2012 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a late-stage biopharmaceutical company focused on cardiovascular disease, today announced financial results for the quarter and year ended December 31, 2011 and provided an update on company operations.

Key Amarin accomplishments since the quarter ended September 30, 2011 include:

- Acceptance of AMR101 New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) and FDA assignment of Prescription Drug User Fee Act (PDUFA) date of July 26, 2012
- Strengthened balance sheet through successful completion of a \$150M exchangeable note offering
- Commenced patient enrollment and dosing in the REDUCE-IT cardiovascular outcomes study
- Broadened management team with the addition of a General Counsel and a President of R&D

"In 2011, Amarin made important progress toward the development of, and commercial preparedness for, our lead product candidate, AMR101," said Joseph Zakrzewski, Chairman and Chief Executive Officer of Amarin. "In 2012 we are working vigorously to build on this progress and maximize the value of AMR101 as we advance toward the PDUFA date."

### Financial update

Amarin reported cash and cash equivalents of \$116.6 million at December 31, 2011. This cash balance was augmented by proceeds from the successful issuance in January 2012 of \$150 million in exchangeable 3.5% senior notes.

During the three months ended December 31, 2011, cash outflows from operating activities were approximately \$9.3 million. The majority of fourth quarter 2011 cash outflows related to research and development activities, including \$1.1 million paid to clinical research organizations in connection with Amarin's AMR101 clinical trial activities. In addition, marketing costs also contributed to the company's fourth quarter spending, including \$1.4 million paid for market research activities.

Cash used for operating activities during the year ended December 31, 2011 was approximately \$39.4 million, compared to approximately \$33.9 million in 2010.

Under U.S. Generally Accepted Accounting Principles (GAAP), Amarin reported net income of \$18.3 million in the fourth quarter of 2011, or basic income per share of \$0.14 and diluted income per share of \$0.12, including \$3.3 million in share-based compensation expense, \$1.1 million in warrant compensation income, and a \$30.7 million gain on the change in the fair value of derivative. In the fourth quarter of 2010, GAAP net loss was \$187.8 million, or basic and diluted loss per share of \$1.82, including \$3.2 million in share-based compensation expense, \$4.9 million in warrant compensation expense, and \$171.8 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 was \$10.2 million for the fourth quarter of 2011, or non-GAAP adjusted basic and diluted loss per share of \$0.08, compared to non-GAAP adjusted net loss of \$8.0 million, or non-GAAP adjusted basic and diluted earnings per share of \$0.08 for the same period in 2010.

In accordance with GAAP, the fair value of the derivative related to warrants issued in conjunction with Amarin's 2009 equity financing was recorded at the time of issuance as a non-cash liability. This liability is re-measured quarterly 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 a derivative liability, the maximum number of ordinary shares issuable upon exercise of these warrants remains fixed and the derivative liability does not represent a cash obligation to Amarin. Excluding this non-cash derivative liability, Amarin's liabilities reported as of December 31, 2011 totaled approximately \$9.2 million, primarily consisting of accrued expenses, accounts payable from operating activities, lease obligations and other long-term liabilities.

As of December 31, 2011, Amarin had approximately 135.8 million ADSs outstanding as well as approximately 21.1 million and 11.9 million equivalent shares underlying warrants and stock options, respectively, at average exercise prices of \$1.48 and

\$5.33, respectively. In addition, the \$150 million of exchangeable senior notes issued in January 2012 are exchangeable prior to October 15, 2031 into an aggregate of 17.0 million ADSs (based on an initial exchange price of approximately \$8.81 per ADS), subject to certain specified conditions. The notes accrue interest at an annual rate of 3.5%, payable semiannually in arrears on January 15 and July 15, beginning July 15, 2012. The notes will mature on January 15, 2032, unless earlier repurchased or redeemed by the company or exchanged by the holders.

## **Operational update**

On January 3, 2012, Amarin provided an overview of the company's progress during 2011 in a letter to shareholders. Below is a summary of progress made in 2011 and update on key Amarin operational priorities:

### ***Regulatory progress during 2011***

In September 2011, Amarin submitted an NDA to the FDA requesting approval of AMR101 for use in the treatment of patients with very high triglycerides ( $\geq 500$  mg/dL), the patient population studied in Amarin's MARINE Phase 3 trial, or what the company refers to as the MARINE indication. The NDA included efficacy and safety data from both the MARINE and ANCHOR Phase 3 trials of AMR101. In November 2011, Amarin announced that the NDA for AMR101 was accepted for filing by the FDA, and that the FDA assigned a PDUFA date of July 26, 2012. The PDUFA date is the goal date for the FDA to complete its review of the NDA.

The company is currently supporting FDA's review of the NDA. As part of this review, and as previously announced, the company was informed in February 2012 that the FDA does not intend to hold an advisory committee meeting in connection with its review.

Amarin currently plans to file a supplemental NDA (sNDA) for the use of AMR101 in the treatment of patients with high triglyceride levels ( $\geq 200$  and  $< 500$  mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels (which the company refers to as mixed dyslipidemia), or what the company refers to as the ANCHOR indication. This population was studied in Amarin's ANCHOR Phase 3 trial. The sNDA cannot be submitted until after both the initially submitted NDA for the MARINE indication is approved and Amarin's cardiovascular outcomes study, REDUCE-IT, is substantially underway in the determination of the FDA. Each of the MARINE, ANCHOR and REDUCE-IT studies is the subject of a Special Protocol Assessment (SPA) agreement with the FDA.

### ***REDUCE-IT clinical trial update***

Amarin's REDUCE-IT study is designed to evaluate the efficacy of AMR101 in reducing major cardiovascular events in an at-risk patient population on statin therapy. The REDUCE-IT clinical trial is estimated to be completed in six years and is anticipated to include approximately 8,000 patients. Amarin is being supported in the management of this trial by a global clinical research organization through which it is estimated that Amarin will incur costs of approximately \$25 million in 2012 and \$125 million to complete the study. In December 2011, Amarin announced that the first patient was dosed in this study. As planned, the majority of current REDUCE-IT activities are focused on clinical site training and activation. Amarin anticipates that the study will include several hundred clinical sites world-wide.

### ***AMR101 exclusivity program update***

Amarin is continuing to execute on its plan to protect the proprietary position of AMR101 in its intended indications. Amarin's plan consists of seeking robust patent protection and regulatory exclusivity, maintaining trade secrets and taking advantage of manufacturing barriers to entry, with the goal of protecting the commercial potential of AMR101 until at least 2030. Amarin had previously disclosed that it is prosecuting a total 16 U.S. patent applications across 11 patent families. The actual number of patent applications and patent families has since grown due to the splitting of previously filed applications among multiple continuations and the filing of new applications seeking to cover what the company believes is additional patentable subject matter based on AMR101 clinical results.

## **Amarin's 2012 operational priorities**

Amarin's 2012 operational priorities include the following:

- NDA approval for the MARINE indication, which we expect to occur in the second half of 2012
- Commercial readiness to launch AMR101 through a strategic partner or by Amarin likely with third-party resources
- Patent protection potentially extending AMR101's proprietary position to 2030
- REDUCE-IT cardiovascular outcomes study substantially underway by year-end
- sNDA submission for the mixed dyslipidemia indication studied in the ANCHOR trial
- Publication of data from the ANCHOR trial in a prominent peer-reviewed journal
- Announcement of a fourth active pharmaceutical ingredient supplier

- Potential commencement of pharmacokinetic study of a combination product comprised of AMR101 and a leading statin

## Conference call and webcast information

Amarin will host a conference call at 4:30 p.m. EST (8:30 p.m. UTC/GMT) today, February 29, 2012. To participate in the call, please dial (877) 407-0778 within the United States or (201) 689-8565 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 388370. The conference call can also be heard live through the investor relations section of Amarin's website at [www.amarincorp.com](http://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.

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 AMR101

AMR101 (icosapent ethyl) is an ultra pure omega-3 fatty acid, comprising not less than 96% EPA (icosapent ethyl), that Amarin is developing as a treatment for patients with very high triglyceride levels ( $\geq 500$  mg/dL), and for patients with high triglyceride levels ( $\geq 200$  and  $< 500$  mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels (which we refer to as mixed dyslipidemia). The efficacy and safety of AMR101 were studied in two Phase 3 clinical trials, the MARINE trial, which studied patients with very high triglyceride levels, and the ANCHOR trial, which studied patients with high triglyceride levels who were also on statin therapy for elevated LDL-C levels. These two Phase 3 clinical trials showed favorable results in triglyceride reduction compared to placebo in the studied patient populations. Reduction in triglyceride levels was achieved without a statistically significant increase in LDL-C levels, and in the 4 gram AMR101 ANCHOR results, with a statistically significant decrease in LDL-C levels. These trials also showed favorable results, particularly with the 4 gram dose of AMR101, in other important lipid and inflammation biomarkers, including Apo-B, non-HDL-C, Total-Cholesterol, VLDL-C, Lp-PLA2, and hs-CRP. In these trials, AMR101 exhibited a safety profile comparable to placebo. In December 2011, Amarin commenced patient dosing in a cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA — Intervention Trial), that is designed to evaluate the efficacy of AMR101 in reducing major cardiovascular events in an at-risk patient population on statin therapy.

## About Amarin

Amarin Corporation plc is a late-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. Amarin has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the use of its lead product candidate, AMR101, in the treatment of patients with very high triglyceride levels (the population studied in Amarin's MARINE trial), and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of July 26, 2012. Amarin plans to separately seek approval for use of AMR101 in the treatment of patients with high triglyceride levels who are also on statin therapy for elevated LDL-C levels, the population studied in the ANCHOR trial, if the FDA approves the MARINE indication and after the REDUCE-IT cardiovascular outcomes trial is substantially underway. Each of the MARINE, ANCHOR and REDUCE-IT studies is the subject of a Special Protocol Assessment (SPA) agreement with the FDA. Amarin also has next-generation lipid candidates under evaluation in preclinical development.

## Forward looking statements

This press release contains forward-looking statements, including statements about the timing of FDA decisions regarding AMR101, the efficacy, safety and therapeutic benefits of AMR101, Amarin plans to seek approval for its product candidates, prepare for commercialization of its product candidates, obtain patent protection and regulatory exclusivity for its product candidates, maintain trade secrets, take advantage of manufacturing barriers to entry, enroll patients in its cardiovascular outcomes study and expects costs related thereto, publish data from its studies, announce a fourth active pharmaceutical ingredient supplier and commence a pharmacokinetic study of a combination product of AMR101 and a leading statin. 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 research and development, clinical trials and related regulatory approvals; the risk that SPAs are not a guarantee that FDA will approve a product candidate upon submission; the risk that FDA may not complete its review of the NDA by the PDUFA goal date or grant new chemical entity regulatory exclusivity to AMR101; the risk that historical clinical trial enrollment and randomization rates may not be predictive of future results and related cost may increase beyond expectations; the risk that patent applications may not result in issued patents, trade secrets may not be maintained and that circumstances that create manufacturing barriers to entry may not last; the risk that publications of scientific data may not accept proposals to publish AMR101 data; and risks associated with securing a fourth supplier of active pharmaceutical ingredient for AMR101. A further 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 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. 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.

Amarin'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)

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
	(in thousands)	
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 116,602	\$ 31,442
Deferred tax asset	533	608
Other current assets	<u>1,837</u>	<u>1,063</u>
Total Current Assets	\$ 118,972	\$ 33,113
Property, plant and equipment, net	432	88
Deferred tax asset	4,734	2,166
Other long term assets	<u>2,241</u>	<u>--</u>
Total Assets	<u>\$ 126,379</u>	<u>\$ 35,367</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 4,419	\$ 4,449
Accrued expenses and other liabilities	<u>4,033</u>	<u>3,128</u>
Total current liabilities	\$ 8,452	\$ 7,577
Long-Term Liabilities		
Warrant derivative liability	123,125	230,069
Lease obligations and other long-term liabilities	<u>764</u>	<u>88</u>
Total liabilities	\$ 132,341	\$ 237,734
Stockholders' Deficit		
Common Stock	113,321	90,465

Additional paid-in capital	449,393	206,718
Treasury Stock	(217)	(217)
Accumulated deficit	<u>(568,459)</u>	<u>(499,333)</u>
Total stockholders' deficit	\$ (5,962)	\$ (202,367)
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Total Liabilities and Stockholders' Deficit	<u>\$ 126,379</u>	<u>\$ 35,367</u>

**CONSOLIDATED STATEMENTS OF OPERATIONS DATA**

(U.S. GAAP)

Unaudited

	Three Months Ended Dec 31 (in thousands, except share and per share amounts)		Twelve Months Ended Dec 31 (in thousands, except share and per share amounts)	
	2011	2010	2011	2010
Revenues	\$ --	\$ --	\$ --	\$ --
OPERATING EXPENSES:				
Research and development(1)	5,951	7,448	21,602	28,014
Marketing, general and administrative(1)	6,374	9,883	22,559	17,087
Total operating expenses	<u>12,325</u>	<u>17,331</u>	<u>44,161</u>	<u>45,101</u>
Operating loss	(12,325)	(17,331)	(44,161)	(45,101)
Gain (loss) on change in fair value of derivative liability (2)	30,734	(171,751)	(22,669)	(205,153)
Interest income (expense), net	133	19	230	34
Other income (expense), net	<u>(40)</u>	<u>607</u>	<u>(10)</u>	<u>130</u>
Income (loss) from operations before taxes	18,502	(188,456)	(66,610)	(250,090)
Provision for income taxes	<u>(164)</u>	<u>644</u>	<u>(2,516)</u>	<u>501</u>
Net and comprehensive income (loss)	<u>\$ 18,338</u>	<u>\$ (187,812)</u>	<u>\$ (69,126)</u>	<u>\$ (249,589)</u>
Income (loss) per share:				
Basic	\$ 0.14	\$ (1.82)	\$ (0.53)	\$ (2.49)
Diluted	\$ 0.12	\$ (1.82)	\$ (0.53)	\$ (2.49)
Weighted average shares:				
Basic	135,797	103,073	130,247	100,239
Diluted	156,630	103,073	130,247	100,239

(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 \$20,138 and \$26,480 for 2011 and 2010, respectively and marketing, general and administrative expenses were \$14,825 and \$7,237, 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**

Unaudited

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
	(in thousands)	
Current Liabilities:		
Accounts payable	\$ 4,419	\$ 4,449
Accrued expenses and other liabilities	<u>4,033</u>	<u>3,128</u>
Total current liabilities	\$ 8,452	\$ 7,577
Long-Term Liabilities		
Warrant derivative liability	123,125	230,069
Lease obligations and other long-term liabilities	<u>764</u>	<u>88</u>
Total liabilities — GAAP	\$ 132,341	\$ 237,734
Warrant derivative liability	<u>(123,125)</u>	<u>(230,069)</u>
Total liabilities — non GAAP	<u>\$ 9,216</u>	<u>\$ 7,665</u>

RECONCILIATION OF NON-GAAP NET INCOME / (LOSS)

Unaudited

	<u>Three Months Ended Dec 31,</u>		<u>Twelve Months Ended Dec 31,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
	(In thousands, except share and per share amounts)			
Net income/(loss) for EPS <sup>1</sup> — GAAP	\$ 18,338	\$ (187,812)	\$ (69,126)	\$ (249,589)
Share based compensation expense	(3,272)	(3,198)	(9,294)	(5,207)
Warrant compensation income (expense)	1,100	(4,855)	96	(5,713)
Gain/(loss) on change in fair value of derivative	<u>30,734</u>	<u>(171,751)</u>	<u>(22,669)</u>	<u>(205,153)</u>
Adjusted net loss for EPS <sup>1</sup> — non GAAP	\$ (10,224)	\$ (8,008)	\$ (37,529)	\$ (33,516)
Loss per share:				
Basic and diluted — non GAAP	\$ (0.08)	\$ (0.08)	\$ (0.29)	\$ (0.33)
Weighted average shares:				
Basic and diluted	135,797	103,073	130,247	100,239

(1) Basic and diluted

CONTACT: Investor Contact Information:

Stephen D. Schultz

Senior Director, Investor Relations and

Corporate Communications

Amarin Corporation

In U.S.: +1 (860) 572-4979 x292

[investor.relations@amarincorp.com](mailto:investor.relations@amarincorp.com)

Lee M. Stern

The Trout Group

In U.S.: +1 (646) 378-2922

[lstern@troutgroup.com](mailto:lstern@troutgroup.com)

Media Contact Information:

David Schull or Martina Schwarzkopf, Ph.D.

Russo Partners

In U.S.: +1 (212) 845-4271 or +1 (212) 845-4292 (office)

+1 (347) 591-8785 (mobile)

[david.schull@russopartnersllc.com](mailto:david.schull@russopartnersllc.com)

[martina.schwarzkopf@russopartnersllc.com](mailto:martina.schwarzkopf@russopartnersllc.com)

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