Amarin Reports First Quarter 2011 Results

-Successful Phase 3 Clinical Program for AMR101 Positions Company for NDA Filing in Q3- - Conference Call Set for 8:00 am EDT Today, May 10 -

DUBLIN and MYSTIC, Conn., May 10, 2011 /PRNewswire/ -- Amarin Corporation plc (NASDAQ: AMRN), a clinical-stage biopharmaceutical company focused on cardiovascular disease, today reported financial results for the quarter ended March 31, 2011 (Q1 2011). The Company also provided an update on its business progress related to the development program of AMR101, its lead product candidate. AMR101 is being developed as a next generation lipid modification drug with an initial clinical focus on the treatment of elevated triglyceride levels, which is associated with the increased risk of developing cardiovascular disease as well as being a component of certain other metabolic disorders, such as diabetes and obesity.

Q1 2011 Financial Update

Amarin's cash and cash equivalents as of March 31, 2011 totaled $129.5 million. This cash balance includes $98.7 million in net cash proceeds received by Amarin in a January 2011 public offering of 13.8 million ADSs (American Depository Shares, each representing one ordinary share) at a price of $7.60 per ADS. Additionally, during the three months ended March 31, 2011, the Company issued 994,749 ADSs as a result of the exercise of stock options and 4,557,364 ADSs as a result of the exercise of warrants, resulting in net proceeds to the Company of $1.7 million and $6.5 million, respectively.

Amarin had approximately 126.2 million ADSs, 29.4 million warrants and 10.4 million stock options outstanding at March 31, 2011.

During the three months ended March 31, 2011, net cash outflows from operating activities were $8.8 million compared to $7.8 million for the same period in 2010. During Q1 2011, the Company's total operating expenses were $7.2 million compared to $7.4 million in the same period of the prior year. This reduction was a result of lower research and development costs, reflecting the timing of clinical trial costs, partially offset by higher net non-cash charges for stock and warrant related compensation expense and to higher costs in preparation for the commercialization of AMR101.

The Company reported net income of $18.2 million, or $0.12 per share income on a diluted share basis, during Q1 2011 compared to a net loss of $9.2 million, or $0.09 per share loss on a diluted share basis, in the same period of the prior year. The Company's net income in Q1 2011 reflects a non-cash gain of $25.3 million from a change in the fair value of warrant derivative liability. In accordance with U.S. generally accepted accounting principles (U.S. GAAP), the fair value of the derivative related to warrants issued in conjunction with the Company's 2009 equity financing was recorded as a non-cash liability, and this liability is re-measured at 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. Excluding this non-cash derivative liability, the Company's liabilities reported as of March 31, 2011 totaled approximately $4.4 million primarily consisting of accrued expenses and accounts payable from operating activities.

Clinical Trials Update

In April, Amarin reported that its ANCHOR clinical trial, a pivotal Phase 3 trial, met all primary and secondary endpoints with statistically significant reductions in triglyceride levels compared to placebo at both 4-gram and 2-gram daily doses. In this trial, AMR101 was evaluated for the treatment of patients with high triglycerides (≥200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels (we refer to these patients as having mixed dyslipidemia). The positive results achieved in this trial were on top of background statin therapy at LDL-C goal. Notably, AMR101 in this trial demonstrated a decrease in LDL-C which was statistically significant and superior compared to placebo in the AMR101 4 gram/day dose group. These positive ANCHOR trial results follow Amarin's announcement in November 2010 that AMR101 was successful in meeting the primary endpoint and numerous other pre-specified endpoints in the MARINE clinical trial with no statistically significant increase in LDL-C compared to placebo. The Company believes that, in addition to other positive findings, the decrease in LDL-C reported in the ANCHOR study and the lack of LDL-C increase in the MARINE study favorably differentiates AMR101 from other therapies for treating the populations studied in the ANCHOR and MARINE trials. In the MARINE trial, AMR101 was evaluated for the treatment of very high triglycerides (≥500 mg/dL). Both the MARINE and ANCHOR trials were conducted under SPA agreements with the FDA. Safety results from both of these trials were comparable to placebo.

New Drug Application (NDA)

Amarin currently plans to submit an NDA to the FDA in the third quarter of 2011, requesting approval to market and sell

AMR101 for the indication studied in the MARINE trial for patients with very high triglycerides (>500 mg/dL). The Company is evaluating its strategy for submitting the ANCHOR trial results for regulatory review. Currently, the Company believes that it will most likely add the ANCHOR trial safety and efficacy results to the MARINE results NDA. In pursuing this approach, the Company will pursue initial NDA approval for the indication studied in the MARINE trial with the ANCHOR results possibly referenced in the initial label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In order to secure an indication based on the ANCHOR trial results, a supplemental NDA for the ANCHOR trial results will likely be submitted upon substantial enrollment of patients in an outcomes study, the design of which is near completion.

The company believes that the treatment of high triglycerides in patients on statins represents a major commercial opportunity for AMR101 as a potential first-in-class prescription medicine for this indication, and a best-in-class prescription medicine for the treatment of very high triglycerides. It is estimated that more than 100 million people in the major markets of the world have high triglycerides including approximately 40 million people in the U.S. alone, the majority of whom have mixed dyslipidemia.

"With the highly successful results from the ANCHOR and MARINE Phase 3 trials in hand, we are rapidly advancing our business plan to maximize the value of AMR101 through commercial preparations that include regulatory, supply chain and sales and marketing initiatives," stated Joseph Zakrzewski, Executive Chairman and Chief Executive Officer of Amarin. "Above and beyond ANCHOR and MARINE, we believe that AMR101 has the potential to redefine lipid management therapy by targeting a wide variety of lipid biomarkers that are believed to contribute to cardiovascular disease."

Pending Milestones and Presentations

The following is a summary of milestones and other notable activities that the Company is seeking to achieve in 2011:

- NDA submission: Q3
- Presentation of clinical trial results in peer-reviewed forums:
  - MARINE results presentation: May 19-22 at the National Lipid Association's Annual Meeting in New York City with potential broader presentation at future forums
  - MARINE results oral presentation at the European Society of Cardiology (ESC) in Paris, in August
  - ANCHOR results presentation: at a forum to be announced once plans are confirmed
- Publication of clinical trial results:
  - MARINE results publication: multiple publications planned, commencing with *The American Journal of Cardiology* scheduled for publication in September
  - ANCHOR results publication: multiple publications being planned commencing after peer-review presentation of results
- Additional suppliers: two incremental API suppliers expected to be added prior to the end of 2011

Amarin is scheduled to present at various upcoming investor conferences, including Jefferies 2011 Global Healthcare Conference (New York City, June 6-9), the Canaccord Genuity Growth Conference (Boston, August 9-11) and the Wedbush 2011 Life Sciences Conference (New York City, August 17).

Conference Call and Webcast Information

Amarin will host a conference call at 8:00 am EDT (12 pm UTC/GMT) today, May 10, 2011 to discuss its Q1 financial results and operational priorities. We anticipate that the call will run for approximately 30 minutes. 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) 678-7415 (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 372416. 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) and as a potentially first-in-class therapy for patients with high triglyceride levels ($\geq$200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels (which we refer to as mixed dyslipidemia). 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 with expertise in lipid science focused on the treatment of

cardiovascular disease. The Company's lead product candidate is AMR101 (icosapent ethyl). The Company 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 on November 29, 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 on April 18, 2011. Both the MARINE and the 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.

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 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)
Unaudited

	March 31, 2011	December 31, 2010
	(in thousands)	
ASSETS		
Cash and cash equivalents	$ 129,482	$ 31,442
Total Assets	$ 132,806	$ 35,367
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities (excluding warrant derivative liability)	$ 4,436	$ 7,665
Total shareholders' (deficit) equity	$ (46,449)	$ (202,367)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA

(U.S. GAAP)
Unaudited

	Three Months Ended March 31 (in thousands, except share and per share amounts)	
	2011	**2010**
Revenues	$ -----	$ -----
OPERATING EXPENSES:		
Research and development(1)	4,449	5,152
Marketing, general and administrative(1)	2,726	2,253
Total operating expenses	7,175	7,405
Operating loss	(7,175)	(7,405)
Gain (loss) on change in fair value of derivative liability(2)	25,342	(2,112)
Interest income (expense), net	1	(14)
Other income, net	77	337
Income (loss) from operations before taxes	18,245	(9,194)
Benefit (provision) for income taxes	(49)	(17)
Net and comprehensive income (loss)	$ 18,294	$ (9,211)
Income (loss) per share:		
Basic	$ 0.15	$ (0.09)
Diluted	0.12	(0.09)
Weighted average shares:		
Basic	123,426	98,782
Diluted	151,500	98,782

1. Excluding non-cash stock and warrant based compensation, research and development expenses were $4,149 and $4,780 for the three months ended March 31, 2011 and 2010, respectively and marketing, general and administrative expenses were $2,165 and $1,926, respectively, for the same periods
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

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