EX-99.1 2 a05-3807 1ex99d1.htm EX-99.1

Exhibit 99.1



Contact: Rick Stewart Chief Executive Officer Amarin Corporation plc Phone +44 (0) 207 907 2442 investor.relations@amarincorp.com

Alan Cooke Chief Financial Officer Amarin Corporation plc Phone +44 (0) 207 907 2442

AMARIN REPORTS FOURTH QUARTER AND FULL YEAR 2004 RESULTS

LONDON, **United Kingdom**, **February 17**, **2005** – Amarin Corporation plc (NASDAQSC: AMRN) today reported financial results for the quarter and full year ended December 31, 2004.

For the quarter ended December 31, 2004, Amarin reported a net loss, including discontinued activities, of \$4.8 million or 13 cents per American Depositary Share (ADS), compared with a net loss of \$2.8 million or 15 cents per ADS in the quarter ended December 31, 2003.

For the year ended December 31, 2004, Amarin reported net income, including discontinued activities, of \$4.7 million or 21 cents per ADS, compared with a net loss of \$19.3 million or \$1.13 per ADS in the year ended December 31, 2003.

2004 - KEY HIGHLIGHTS

- Sale of U.S. Operations on February 25, Amarin's U.S. sales and marketing operations were sold to Valeant Pharmaceutical International, Inc ("Valeant") for \$38 million in cash and \$8 million in contingent milestones;
- Settlement of debt obligations on February 25, Amarin settled its debt obligations with Elan Corporation, plc ("Elan") from the proceeds received from the sale of its U.S. operations to Valeant and by issuing a \$5 million 5-year loan note;
- *Valeant dispute settlement* on September 28, Amarin signed an agreement with Valeant settling an outstanding dispute between the companies whereby \$6 million of the \$8 million in contingent milestones due to Amarin from Valeant were waived. The remaining \$2 million of milestones became non-contingent and was paid by Valeant to Amarin on December 1;
- Significant investment by Amarin chairman on October 6, Amarin's non-executive chairman, Mr. Thomas Lynch, acquired Elan's entire debt and equity interests held in Amarin, including 4,653,819 ADSs and the previously noted \$5 million 5-year loan note:
- Equity financing on October 7, a private placement of 13,474,945 ordinary shares raising gross proceeds for Amarin of \$12.75 million was completed with a group of new and existing investors and management;
- Total debt reduced to \$2 million and maturity extended to 2009 on October 7, Mr. Lynch agreed to convert \$3 million of the \$5 million loan notes into 2,717,391 ordinary shares with an option to convert the remaining \$2 million at the offering price of any future equity financing. Amarin's total debt was thus reduced to, and is currently at, \$2 million with a maturity in 2009, if not previously converted;
- Laxdale acquisition on October 8, Amarin completed the acquisition of Laxdale Limited ("Laxdale"), the Company's neuroscience research and development partner based in Stirling, Scotland. The acquisition provides Amarin with a promising late stage neuroscience pipeline for central nervous system disorders.

Rick Stewart, chief executive officer of Amarin, commented "2004 has been a year of significant transformation. The company is now a highly focused R&D based neuroscience company. This was achieved through the execution of a series of significant transactions

https://www.sec.gov/Archives/edgar/data/897448/000110465905007516/a05-3807_1ex99d1.htm

which included the sale of Amarin's U.S. sales and marketing operations, the settlement of our outstanding debt obligations to Elan and the acquisition of our R&D development partner, Laxdale. In addition, our non-executive chairman, Thomas Lynch, became Amarin's largest shareholder, with an equity stake now of approximately 20%, through acquiring all Elan's remaining debt and equity interests in Amarin. Finally, in October, we raised \$12.75 million in a private placement and at the beginning of 2005, added two prominent business leaders, Simon Kukes and Michael Walsh, to our board."

Mr. Stewart continued "Amarin's continuing focus is clear. We are progressing the clinical development of Miraxion, our exciting lead product for Huntington's disease and treatment-unresponsive depression. We look forward to commencing two large phase III trials in Huntington's disease by mid-year and partnering our phase II treatment-unresponsive depression programme later in 2005."

ACQUISITION OF LAXDALE

The acquisition of Laxdale, Amarin's research and development partner, was completed in October 2004 and represents an important step towards achieving Amarin's goal of becoming a leader in the development and commercialization of novel drugs for the treatment of central nervous system ("CNS") disorders. The acquisition broadens Amarin's development pipeline to include North American, E.U. and Japanese rights to Miraxion for all CNS disorders, including Huntington's disease and treatment-unresponsive depression. In addition, it provides Amarin with an extensive portfolio of intellectual property in the area of CNS.

Program	Indication	Status	Partners
Lipophilic Platform			
Miraxion	Huntington's disease	Phase III	Scil Biomedical GmbH (Germany, Austria, France, Benelux)
			Juste S.A.Q.F. (Spain, Portugal)
Miraxion	Treatment-unresponsive depression	Phase II	Link Pharmaceuticals Ltd (UK, Ireland) Japan – partner not disclosed
Combinatorial Lipid Platform			
Various	CNS disorders	Pre-clinical	_
In-licensed			
LAX-201	Major Depression in Women	Phase II	_
LAX-202	Multiple Sclerosis Fatigue	Phase II	_

Amarin is preparing to commence two phase III trials with Miraxion in Huntington's disease late in the second quarter of this year. Amarin intends to utilize the data from these trials to support an application for marketing approval to the U.S. and E.U. regulatory authorities. In Europe, prior to its acquisition by Amarin, Laxdale submitted a marketing approval application based upon the initial phase III study. Amarin has decided to voluntarily withdraw that application and plans to re-submit when data from the two planned phase III trials is available. Miraxion has been granted Fast Track designation by the U.S. Food and Drug Administration and has Orphan Drug status in the U.S. and E.U.

Amarin has partnered the marketing rights to Miraxion for Huntington's disease in the major European markets and will receive a significant double-digit royalty on sales, if approved, in these markets. Amarin intends to directly market Miraxion for Huntington's disease in the U.S.

Miraxion is also in phase II clinical development for treatment-unresponsive depression. Amarin intends to progress development of this indication by seeking a development and marketing partner for the U.S. and E.U. markets. Amarin has partnered its intellectual property for this indication in the Japanese market.

While Miraxion is Amarin's core asset and near-term value driver, Amarin has two other products in the phase II stage of development and a preclinical programme utilizing its combinatorial lipid technology from which additional next generation phospholipid-based

products may emerge.

FINANCIAL RESULTS - INCOME STATEMENT

For the fourth quarter, Amarin reported a net loss, including discontinued activities, of \$4.8 million, compared with a net loss of \$2.8 million in the fourth quarter of 2003. For the full year 2004, Amarin reported net income, including discontinued activities, of \$4.7 million, compared with a net loss of \$19.3 million in 2003.

The results for the quarter and year ended December 31, 2004 are analyzed between continuing and discontinued activities and are set out in detail in the three pages of financial tables attached. Amarin's results include the results of Laxdale from October 8, 2004, being the closing date of the acquisition.

Continuing Activities

For continuing activities, the operating loss for the fourth quarter increased to \$5.0 million from \$0.9 million in the fourth quarter of 2003. Similarly, the operating loss from continuing activities for the full year 2004 increased to \$9.6 million from \$6.2 million in 2003. The increase for both periods is primarily due to:

- the inclusion of Laxdale's operating expenses in the fourth quarter of \$2.2 million for the first time;
- the inclusion of the previously announced non-recurring payment of \$0.9 million to Scarista Limited on October 8, 2004; and
- the high level of professional fees incurred due to the significant amount of corporate activity in the periods.

The results for continuing activities for the quarter and year ended December 31, 2003 represent Amarin's head office operating expenses, including business and corporate development activities.

Discontinued activities

For the quarter ended December 31, 2004, the loss before interest for discontinued activities was \$0.7 million representing year end finalization of the loss on disposal of our U.S. operations and of the gain on the settlement with Elan. This compares with a loss before interest for discontinued activities for the comparative quarter ended December 31, 2003 of \$9.1 million.

For the year ended December 31, 2004, Amarin earned a profit before interest of \$21.1 million on discontinued activities compared with a loss of \$19.5 million for the same period in 2003. The results on discontinued activities for 2004 reflect:

- (1) the results of Amarin's former U.S. business for the period from January 1, 2004 to February 25, 2004, being the date upon which the business was sold to Valeant:
- (2) an exceptional loss of \$3.1 million on disposal of the majority of its U.S. operations and certain products to Valeant;
- (3) an exceptional gain of \$0.75 million, representing receipt of the final installments of the sale proceeds the disposal of Amarin's Swedish drug delivery business to Watson in October 2003;
- (4) an exceptional gain of \$24.6 million on the settlement of debt obligations to Elan;
- (5) the costs incurred by Amarin relating to the completion of safety studies on Zelapar (the rights to which are owned by Valeant). Following the sale of the majority of Amarin's U.S. operations to Valeant in the first quarter of 2004, Amarin remained responsible for the cost of undertaking safety studies on Zelapar and was liable for up to \$2.5 million of development costs. That obligation has been fulfilled and Amarin will not incur any more costs relating to the development of Zelapar; and
- (6) the settlement of an outstanding dispute with Valeant. As previously announced, Amarin settled its outstanding dispute with Valeant in September 2004. The main terms of the settlement agreement are set out in our press release on November 11, 2004 announcing the results for the third quarter.

A non-cash deferred tax accounting charge of \$7.5 million on the exceptional gain on the settlement of debt obligations to Elan is included in the tax charge for the year ended December 31, 2004. This offsets a deferred tax credit of an equivalent amount included in the income statement of the fourth quarter of 2003.

The results for discontinued activities for the fourth quarter and year ended December 31, 2003 reflect the results of Amarin's disposed U.S. operations and Swedish drug delivery business, the gain on the disposal of the Swedish drug delivery business, impairment charges on intangible assets related to the disposed U.S. operations and a non-cash deferred tax credit related to the settlement of debt obligations with Elan. The U.S. operations and Swedish drug delivery business were disposed in February 2004 and October 2003 respectively.

Preference share dividend

During the period from 1999 to 2003, Amarin accrued a dividend of \$0.6 million on its issued and outstanding preference shares. In February 2003, the last of the preference shares were converted into ordinary shares. On conversion the preferential shareholders gave up their preferential rights including any rights to an accrued dividend in exchange for the new ordinary shares allotted. Following the settlement of debt obligations in 2004, there is no longer a need to maintain an accrual for a preference dividend. As a result, it has been written back to the income statement.

FINANCIAL RESULTS - BALANCE SHEET

Intangible fixed asset - Miraxion

Miraxion has an intangible carrying value of \$10.3 million, an increase of \$6.8 million from \$3.5 million at September 30, 2004. The increase in the carrying value arises out of the acquisition accounting for Laxdale.

Debt and cash

At December 31, 2004, Amarin had total debt of \$2.0 million with a cash maturity in 2009. This is reduced from debt of \$35.4 million due on demand at December 31, 2003. The \$35.4 million of debt was settled in the first quarter as referred to above (see Income Statement - discontinued activities) following the sale of Amarin's U.S. operations in the first quarter of 2004. On September 29, 2004, Amarin's non-executive chairman, Mr. Thomas Lynch, signed an agreement with Elan to acquire its remaining debt and equity

interests in Amarin, including the remaining \$5 million of loan notes owed by Amarin to Elan. On October 7, Mr. Lynch agreed to convert \$3 million of the \$5 million of loan notes into 2,717,391 ordinary shares with an option to convert the remaining \$2 million at the offering price of any future equity financing.

At December 31, 2004 Amarin had cash of \$11.0 million compared to \$2.1 million at December 31, 2003. On October 7, 2004, Amarin raised gross proceeds of \$12.75 million through the completion of a private placement of 13,474,945 ordinary shares. Amarin is forecast to have sufficient cash to fund the group's operating activities, including the planned phase III trials for Miraxion in Huntington's disease, through the end of the summer of 2005.

Amarin's financing strategy will depend on the timing of clinical trial expenditure on its development pipeline and on the level of revenue generated from its licensing and partnering activities.

CORPORATE STRATEGY

Amarin's strategy is to directly commercialize its neurology pipeline in the U.S. and to partner it for geographic markets outside the U.S. For indications outside neurology, such as, treatment-unresponsive depression, Amarin will partner its pipeline globally.

Amarin also intends to acquire and in-license neurology products that Amarin can develop and market directly in the U.S. Amarin's goal is to capitalize on its strong reputation in neuroscience and to become a leader in the development and commercialization of novel drugs that address unmet medical needs.

About Amarin Corporation

Amarin Corporation plc is a neuroscience company focused on the development and commercialisation of novel drugs for the treatment of central nervous system disorders. Miraxion, Amarin's lead development compound, is in phase III development for Huntington's disease and in phase II development for treatment-unresponsive depression.

For press releases and other corporate information, visit our website at http://www.amarincorp.com.

Statements in this press release that are not historical facts are forward-looking statements that involve risks and uncertainties which may cause the Company's actual results in future periods to be materially different from any performance suggested herein. Such risks and uncertainties include, without limitation, the inherent uncertainty of pharmaceutical research, product development and commercialisation, the impact of competitive products and patents, as well as other risks and uncertainties detailed from time to time in periodic reports. For more information, please refer to Amarin Corporation's Annual Report for 2003 on Form 20-F and its Form 6-Ks as filed with the U.S. Securities and Exchange Commission. The Company assumes no obligation to update information on its expectations.