

AMARIN CORP PLC\UK  
Form 10-Q  
May 10, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2011

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-21392

**Amarin Corporation plc**

*(Exact Name of Registrant as Specified in its Charter)*

**England and Wales**  
*(State or Other Jurisdiction of Incorporation or Organization)*

**Not applicable**  
*(I.R.S. Employer Identification No.)*

**1<sup>st</sup> Floor, Block 3, The Oval Shelbourne Road, Ballsbridge**  
*(Address of Principal Executive Offices)*

**Dublin 4, Ireland**  
*(Zip Code)*

**Registrant's telephone number, including area code: +353 (0) 1 6699 020**

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-Q

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

127,221,591 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 269,296 ordinary shares, were outstanding as of May 3, 2011.

**Table of Contents**

**INDEX TO FORM 10-Q**

	<b>Page</b>
<b><u>PART I Financial Information</u></b>	
Item 1. Financial Statements:	
<u>Condensed Consolidated Balance Sheets at March 31, 2011 and December 31, 2010</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three months ended March 31, 2011 and 2010</u>	2
<u>Condensed Consolidated Statement of Changes in Equity at March 31, 2011 and March 31, 2010</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2011 and 2010</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	15
Item 4. <u>Controls and Procedures</u>	15
<b><u>PART II Other Information</u></b>	
Item 1A. <u>Risk Factors</u>	16
Item 6. <u>Exhibits</u>	18
<b><u>SIGNATURES</u></b>	19
<u>EX-10.1</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

**Table of Contents****PART I****AMARIN CORPORATION PLC****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 129,482	\$ 31,442
Other current assets	1,085	1,671
Total current assets	130,567	33,113
Property, plant and equipment, net	73	88
Deferred tax asset	2,166	2,166
<b>TOTAL ASSETS</b>	<b>\$ 132,806</b>	<b>\$ 35,367</b>
<b>LIABILITIES AND STOCKHOLDERS (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 1,513	\$ 4,449
Accrued expenses and other liabilities	2,407	3,128
Total current liabilities	3,920	7,577
Long-Term Liabilities:		
Warrant derivative liability	174,819	230,069
Lease obligations and other long-term liabilities	516	88
Total liabilities	179,255	237,734
Commitments and contingencies (Note 4)		
Stockholders (Deficit):		
Common stock, £0.50 par, unlimited authorized; 126,209,529 issued, 126,189,450 outstanding at March 31, 2011; 106,856,731 issued, 106,836,652 outstanding at December 31, 2010	105,621	90,465
Additional paid-in capital	329,186	206,718
Treasury stock; 20,079 shares at March 31, 2011 and December 31, 2010	(217)	(217)
Accumulated deficit	(481,039)	(499,333)
Total stockholders (deficit)	(46,449)	(202,367)
<b>TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT)</b>	<b>\$ 132,806</b>	<b>\$ 35,367</b>

See notes to condensed consolidated financial statements.



**Table of Contents****AMARIN CORPORATION PLC****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)****(In thousands, except share and per share amounts)**

	<b>Three months ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Revenues	\$	\$
Operating Expenses:		
Research and development	4,449	5,152
Marketing, general and administrative	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	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

See notes to condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(In thousands, except share amounts)

	<b>Common Shares</b>	<b>Common Stock</b>	<b>Additional Paid-in Capital</b>	<b>Treasury shares</b>	<b>Retained earnings</b>	<b>Total</b>
<b>At December 31, 2010</b>	<b>106,856,731</b>	<b>\$ 90,465</b>	<b>\$ 206,718</b>	<b>\$ (217)</b>	<b>\$ (499,333)</b>	<b>\$ (202,367)</b>
Warrants exercised	4,557,364	3,641	2,813	-	-	6,454
Transfer of fair value of warrants exercised from liabilities to equity	-	-	29,229	-	-	29,229
Shares issued in January financing	13,800,000	10,723	87,948	-	-	98,671
Stock options exercised	994,749	792	932	-	-	1,724
Share issued for services	685	-	6	-	-	6
Share based compensation	-	-	1,540	-	-	1,540
Income for the period	-	-	-	-	18,294	18,294
<b>At March 31, 2011</b>	<b>126,209,529</b>	<b>\$ 105,621</b>	<b>\$ 329,186</b>	<b>\$ (217)</b>	<b>\$ (481,039)</b>	<b>\$ (46,449)</b>
	<b>Common Shares</b>	<b>Common Stock</b>	<b>Additional Paid-in Capital</b>	<b>Treasury shares</b>	<b>Retained earnings</b>	<b>Total</b>
<b>At December 31, 2009</b>	<b>98,801,982</b>	<b>\$ 84,219</b>	<b>\$ 172,339</b>	<b>\$ (217)</b>	<b>\$ (249,744)</b>	<b>\$ 6,597</b>
Share based compensation	-	-	645	-	-	645
Loss for the period	-	-	-	-	(9,211)	(9,211)

At March 31, 2010

98,801,982    \$ 84,219    \$ 172,984    \$ (217)    \$ (258,955)    \$ (1,969)

See notes to condensed consolidated financial statements.



**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 18,294	\$ (9,211)
Adjustments to reconcile income (loss) to net cash used in operating activities:		
Depreciation and amortization	15	17
Stock-based compensation	1,540	645
Stock-based compensation warrants	(679)	54
Shares issued for services	6	
(Gain) loss on changes in fair value of derivative liability	(25,342)	2,112
Changes in assets and liabilities:		
Other current assets	586	1,134
Change in lease liability	(12)	(524)
Accounts payable and other liabilities	(3,217)	(1,972)
Net cash used in operating activities	(8,809)	(7,745)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of equipment		(18)
Net cash used in investing activities		(18)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of transaction costs	98,671	
Proceeds from exercise of stock options, net of transaction costs	1,724	
Proceeds from exercise of warrants, net of transaction costs	6,454	
Payments under capital leases		(2)
Net cash provided by (used in) financing activities	106,849	(2)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	98,040	(7,765)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	31,442	52,258
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 129,482	\$ 44,493
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$	\$
Income taxes	\$ 265	\$ 17
Non-cash transactions:		
Transfer from derivative liability to equity, fair value of warrants exercised	\$ 29,229	\$

See notes to condensed consolidated financial statements.



---

**Table of Contents**

**AMARIN CORPORATION PLC**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

For purposes of this Quarterly Report on Form 10-Q, our ordinary shares may also be referred to as common shares or common stock.

**(1) Nature of Business, Basis of Presentation**

**Nature of Business**

Amarin Corporation plc, Amarin or the Company, is a public limited company with its primary stock market listing in the United States on the NASDAQ Capital Market (AMRN). Amarin was originally incorporated in England as a private limited company on March 1, 1989 under the Companies Act 1985, and re-registered in England as a public limited company on March 19, 1993.

Amarin is a clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease. The Company is currently focusing its efforts on AMR101 (icosapent ethyl), a prescription-only omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA).

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of the Company and subsidiaries are unaudited and have been prepared on a basis that assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ) have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. These financial statements should be read in conjunction with the audited financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. The Company's current focus is on the development and commercialization of AMR101, which is still under development and not available for sale. However, the Company is not considered a development stage business, as the release and sale of the previous product represented the exit of the Company from the development stage.

The notes and accompanying condensed consolidated financial statements are unaudited. The information furnished reflects all adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods. Such adjustments consisted only of normal recurring items. The interim periods are not necessarily indicative of the results expected for the full year or any future period.

The preparation of these condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reporting period. Actual results could differ from those estimates.

At March 31, 2011, the Company had cash and cash equivalents of \$129.5 million. The Company's consolidated balance sheet also includes a significant derivative liability (see footnote 3 warrants and derivative liability) reflecting the fair value of outstanding warrants to purchase shares of the Company's common stock. This liability can only be settled in shares of the Company's stock and, as such, would only result in cash inflows upon the exercise of the warrants not a cash outflow. Accordingly, this warrant derivative liability presents neither a short nor long-term claim on the liquid assets of the Company.

In January 2011, the Company completed an offering of 13.8 million American Depositary Shares (ADSs), with each ADS representing one share of the Company's common stock. The shares were sold at a price of \$7.60 per share, and resulted in net proceeds of \$98.7 million.

The Company believes its cash will be sufficient to fund its projected operations for the next twelve months which contemplates not only working capital and general corporate needs but also the filing of a New Drug Application (NDA) and commercial preparation of AMR101 as further described below. This is based on management's current operational plans and does not assume any cash inflows from strategic collaborations, warrant exercises or from equity or debt financings which may occur in future periods. If the Company elects to commercialize AMR101 alone, rather than through a partner, or decides to commence a cardiovascular outcomes study, additional funds will be needed to complete such activities.



**Table of Contents****(2) Significant Accounting Policies****Cash and Cash Equivalents**

Cash and cash equivalents consist of cash, deposits held at call with banks, and short term highly liquid instruments with remaining maturities at the date of purchase of 90 days or less.

**Research and Development Costs**

The Company charges research and development costs to operations as incurred. Research and development expenses are comprised of costs incurred by the Company in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in its drug candidates; and infrastructure costs, including facilities costs and depreciation expense.

**Income Taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carryforwards and other attributes using enacted rates expected to be in effect when those differences reverse. Valuation allowances are provided against deferred tax assets that are not more likely than not to be realized.

The Company provides reserves for potential payments of tax to various tax authorities or does not recognize tax benefits related to uncertain tax positions and other issues. Tax benefits for uncertain tax positions are based on a determination of whether a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized, assuming that the matter in question will be decided based on its technical merits. The Company's policy is to record interest and penalties in the provision for income taxes.

**Net Income (Loss) per Share**

Basic net income (loss) per share is determined by dividing net income (loss) by the weighted average shares of common stock outstanding during the period. Diluted net income (loss) per share is determined by dividing net income (loss) by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options and warrants calculated using the treasury stock method and convertible notes using the if-converted method. In periods with reported net operating losses, all common stock options and warrants are deemed anti dilutive such that basic net loss per share and diluted net loss per share are equal.

The following table presents the calculation of both basic and diluted net income (loss) per share:

	<b>Three Months Ended</b>	
	<b>(In thousands, except per share amounts)</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Net income (loss)	\$ 18,294	\$ (9,211)
Weighted average shares outstanding	123,426	98,782
Dilutive effect of employee stock options and warrants	28,074	
Diluted weighted average shares outstanding	151,500	98,782
Basic income (loss) per share	\$ 0.15	\$ (0.09)
Diluted income (loss) per share	\$ 0.12	\$ (0.09)

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-Q

Potentially dilutive securities representing approximately 1.1 million and 44.2 million shares of common stock for the three month periods ended March 31, 2011 and March 31, 2010, respectively, were excluded from the computation of diluted earnings per share for these periods because their effect would have been anti-dilutive.

### **Stock-Based Compensation**

Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as compensation cost over the requisite service period.

**Table of Contents****Derivative Instruments**

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. The warrants are valued using a Black-Scholes option pricing model or a Monte Carlo simulation depending on the nature of instrument.

If the terms of warrants that initially require the warrants to be classified as derivative financial liabilities lapse, the derivative financial liability is reclassified out of financial liabilities into equity at its fair value on that date. At settlement date, if the instruments are settled in shares the carrying value of the warrants are derecognised and transferred to equity at their fair value at that date. The cash proceeds received from exercises of warrants are recorded in common stock and additional paid-in capital.

**Foreign Currency**

All subsidiaries use the United States dollar as the functional currency. Monetary assets and liabilities denominated in a foreign currency are remeasured into United States dollars at year-end exchange rates. Non-monetary assets and liabilities carried in a foreign currency are remeasured into United States dollars using rates of exchange prevailing when such assets or liabilities were obtained or incurred, and expenses are generally remeasured using rates of exchange prevailing when such expenses are incurred. Gains and losses from the remeasurement are included in other income, net in the consolidated financial statements of operations. For transactions settled during the period, gains and losses are included in other income, net in the consolidated statements of operations. Foreign exchange gains (and losses) have not been significant in the periods presented.

**Fair Value of Financial Instruments**

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following table presents information about the Company's liability as of March 31, 2011 and December 31, 2010 that is measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

<i>In thousands</i>	<b>Total</b>	<b>March 31, 2011</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Liability:</b>				
Warrant derivative liability	\$ 174,819	\$	\$	\$ 174,819

  

<i>In thousands</i>	<b>Total</b>	<b>December 31, 2010</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Liability:</b>				
Warrant derivative liability	\$ 230,069	\$	\$	\$ 230,069

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature.



**Table of Contents**

At December 31, 2010, the fair value of the warrant derivative liability was determined to be \$230.1 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 1.52%, (ii) remaining term of 3.8 years, (iii) no dividend yield (iv) volatility of 117%, and (v) the stock price on the date of measurement.

At March 31, 2011, the fair value of the warrant derivative liability was determined to be \$174.8 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 1.77%, (ii) remaining term of 3.5 years, (iii) no dividend yield (iv) volatility of 113%, and (v) the stock price on the date of measurement. The \$55.2 million decrease in the fair value of the warrant liability during the three months ended March 31, 2011 was recognized as: (i) a \$29.2 million transfer from warrant liability to additional paid-in capital for the fair value of warrants exercised during the three months ended March 31, 2011, (ii) a \$25.3 million gain on change in fair value of the remaining derivative liability and (iii) \$0.7 million compensation income for change in fair value of warrants issued to former employees, both amounts are included in the consolidated statement of operations for the three months ended March 31, 2011. The change in the fair value of the warrant derivative liability is as follows (in thousands):

	October 2009 Warrants
<b>Balance at December 31, 2009</b>	<b>\$ 41,520</b>
Loss on change in fair value of derivative liability	2,112
Compensation expense for change in fair value of warrants issued to former employees	54
Transfers to equity	
<b>Balance at March 31, 2010</b>	<b>\$ 43,686</b>
	October 2009 Warrants
<b>Balance at December 31, 2010</b>	<b>\$ 230,069</b>
Gain on change in fair value of derivative liability	(25,342)
Compensation income for change in fair value of warrants issued to former employees	(679)
Transfers to equity	(29,229)
<b>Balance at March 31, 2011</b>	<b>\$ 174,819</b>

**Segment and Geographical Information**

For the three months ended March 31, 2011 and 2010, the Company has reported its business as a single reporting segment. The Company's chief decision maker, who is the Chief Executive Officer, regularly evaluates the Company on a consolidated basis.

**Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by FASB and are adopted by the Company as of the specified effective date. The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

**(3) Warrants and Derivative Liability**

The Company has 29,437,368 warrants to purchase common shares outstanding at March 31, 2011 at a weighted-average exercise price of \$1.48, as summarized in the following table:

<b>Issue Date</b>	<b>Amount</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
4/27/07	17,500	17.90	1/17/2014
6/1/07	57,400	7.20	5/31/12
6/21/07	1,000	3.60	11/28/12
12/5/07	647,132	1.17	12/3/12
6/4/09	55,555	1.00	6/3/14
7/31/09	138,888	1.00	7/30/14
7/31/09	1,666,000	1.00	7/30/14
10/16/09	26,149,888	1.50	10/15/14
10/16/09	704,005	1.50	10/15/14
	<b>29,437,368</b>	<b>\$ 1.48</b>	

## **Table of Contents**

### **October 2009 Warrants**

On October 16, 2009, the Company completed a \$70.0 million private placement with both existing and new investors resulting in \$62.3 million in net proceeds and an additional \$3.6 million from bridge notes converted in conjunction with the private placement. In consideration for the \$62.3 million in net cash proceeds Amarin issued 66.4 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$1.00 and (ii) a warrant with a five year term to purchase 0.5 of an ADS at an exercise price of \$1.50 per ADS. In consideration for the conversion of \$3.6 million of convertible bridge notes, Amarin issued 4.0 million units, each unit consisting of (i) one ADS (representing one ordinary share) at a purchase price of \$0.90 and (ii) a warrant with a five year term to purchase 0.5 of an ADS at an exercise price of \$1.50 per ADS. The total number of warrants issued in conjunction with the financing was 35.2 million.

The warrants issued in connection with the October 2009 financing contained a pricing variability feature which provided for an increase to the exercise price if the exchange rate between the U.S. dollar and British pound adjusts such that the warrants could be issued at a price less than the £0.5 par value of the common stock that is, if the exchange rate exceeded U.S. \$3.00 per £1.0 sterling. Due to the potential variable nature of the exercise price, the warrants are not considered to be indexed to the Company's common stock. Accordingly, the warrants do not qualify for the exception to classify the warrants within equity and are classified as a derivative liability. The fair value of this warrant derivative liability is remeasured at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrants at December 31, 2010 was determined to be approximately \$230.1 million using the Black-Scholes option pricing model.

Although the warrants contain a pricing variability feature, the number of warrants issuable remains fixed. Therefore, as of March 31, 2011 the maximum number of common shares issuable as a result of the October 2009 private placement is 26.9 million. During the three months ended March 31, 2011, approximately 3.9 million of the October 2009 warrants were exercised, resulting in gross proceeds to the Company of approximately \$5.9 million. No warrants were exercised in the three months ended March 31, 2010. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in capital. The \$29.2 million fair value of the exercised warrants was transferred from warrant liability to additional paid in capital with the change in the fair value on the exercise date recognized in the statement of operations. The fair value of the warrant liability at March 31, 2011 for the remaining warrants was determined to be approximately \$174.8 million. The Company recognized a gain on change in fair value of derivative liability of \$25.3 million and compensation income of \$0.7 million for the three month period ended March 31, 2011.

## **(4) Commitments and Contingencies**

### **Royalty and Milestone Obligations**

The Company is party to certain milestone and royalty obligations under several product development agreements, as follows:

An agreement in respect of certain patents and other intellectual property rights relating to a formulation of the compound Apomorphine, no longer in development;

The 2010 supply agreement with the Company's existing Japan-based supplier: (i) a one-time non refundable payment of \$0.5 million is due to the supplier upon the first marketing approval of AMR101 in the United States (ii) the Company is subject to minimum supply purchase commitments; and (iii) if the Company is not successful in obtaining NDA approval for AMR101, a penalty equal to the facility expansion costs incurred by the supplier to meet the supply demands, not to exceed \$5.0 million, less any profits paid to the supplier for purchased materials under the existing agreement;

The 2009 Lorazepam sale agreement with Elan, whereunder Elan did not assume any obligations under a related Neurostat development agreement and, as a result, Amarin retained a potential obligation to make two milestone payments to Neurostat, contingent upon future events: (i) a \$0.2 million payment if the drug is administered to human subjects and (ii) a \$0.2 million payment if the drug is tested in an efficacy study; and

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-Q

In connection with commercialization of AMR101, prior to the end of 2012 we are required to pay potential royalties of 1% on net sales up to £100 million (\$160 million at March 31, 2011); 0.5% for net sales between £100 million (\$160

## **Table of Contents**

million) and £500 million (\$802 million); and 0.25% for sales in excess of £500 million. In addition, upon receipt of marketing approval in the U.S. and/or Europe for the first indication for AMR101 (or first indication of any product containing Amarin Neuroscience intellectual property acquired from Laxdale Limited in 2004), Amarin must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £7.5 million (\$12 million) for each of the two potential marketing approvals (i.e. £15 million maximum, or \$24 million). In addition, upon receipt of a marketing approval in the U.S. or Europe for a further indication of AMR101 (or further indication of any other product using Amarin Neuroscience intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (\$8 million) for each of the two potential market approvals (i.e. £10 million maximum, or \$16 million).

The Company has no provision for any of these obligations since the amounts are either not probable or estimable at March 31, 2011.

### **(5) Equity**

#### **Common stock**

In January 2011, Amarin sold 13.8 million common shares to both existing and new investors at a price of \$7.60 per share, resulting in net proceeds of \$98.7 million.

During the three months ended March 31, 2011, the Company issued 994,749 shares as a result of the exercise of stock options, resulting in net proceeds of \$1.7 million. In addition the Company issued 4,557,364 shares as a result of the exercise of warrants, resulting in net proceeds of \$6.5 million.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part I, Item 1A under the heading Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and below under Part II, Item 1A, Risk Factors.*

*Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.*

### **Overview**

We are a clinical-stage biopharmaceutical company focused on developing improved treatments for cardiovascular disease. We are currently focusing our efforts on AMR101, a semi-synthetic omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA). On October 16, 2009, we completed a private placement resulting in gross proceeds of \$70.0 million. These proceeds were used primarily to fund the MARINE and ANCHOR studies for AMR101. In connection with this private placement, a significant portion of our board of directors and executive management were changed, and our research and development activities, as well as certain executive functions, were consolidated from multiple offices to our research and development headquarters in the United States. In connection with these changes, we re-focused our efforts on developing improved treatments for cardiovascular disease and ceased development of all product candidates outside of our cardiovascular disease focus.

In November 2010, we reported positive top-line results from the MARINE trial, the first to complete of our two concurrently run Phase 3 clinical trials of AMR101. In the MARINE trial, AMR101 was investigated as a treatment for patients with very high triglycerides (≥500 mg/dL). The MARINE trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal



**Table of Contents**

study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in 229 patients with fasting triglyceride levels  $\geq 500$  mg/dL. Patients with this level of triglycerides are characterized as having very high triglyceride levels, as outlined in the National Cholesterol Education Program (NCEP) Expert Panel (Adult Treatment Panel III, 2002), or the NCEP Guidelines. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. Reported top-line results of this study included announcement that AMR101 met the primary endpoint at both the 4 gram and 2 gram doses. In addition to achieving the primary endpoint of the trial, no statistically significant increase in low-density lipoprotein cholesterol, or LDL-C, was observed in this trial at either dose. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo.

In April 2011, we reported positive top-line results from the ANCHOR trial, the second of our two Phase 3 clinical trials of AMR101. In the ANCHOR trial, AMR101 was investigated as a treatment for patients with high triglycerides ( $\geq 200$  and  $< 500$  mg/dL) who are also receiving statin therapy. The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in 702 patients with high triglycerides who were on optimized statin therapy. Patients in this trial are characterized as having high triglyceride levels, as outlined in the NCEP Guidelines, with mixed dyslipidemia (two or more lipid disorders). The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. No prescription omega-3 based drug is currently approved in the U.S. for treating high triglyceride levels in statin-treated patients who have mixed dyslipidemia. Reported top-line results of this study included an announcement that AMR101 met the study's primary endpoint at both the 4 gram and 2 gram doses. In addition, AMR101 met each of the secondary endpoints in the trial, including at both doses the key secondary endpoint of LDL-C non-inferiority to statin therapy alone. Additionally, we observed in the trial a safety profile for AMR101 similar to placebo.

The MARINE and ANCHOR trials were conducted under separate SPAs with the FDA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the MARINE and ANCHOR trials adequately address the objectives necessary to support a regulatory submission. An SPA is generally binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing begins. Although we are not aware of any such issue, there is no assurance that the FDA will ultimately consider either of our SPAs to be binding. Moreover, any change to a study protocol can invalidate an SPA. If the FDA does not consider either of the SPAs to be binding, the agency could assert that additional studies or data are required to support a regulatory submission.

We currently expect to submit a New Drug Application, or 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 the treatment of patients with very high triglycerides) in the United States. We may elect to add the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, we currently expect that the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results supporting either a separate and additional indication (for the treatment of patients with high triglycerides who have mixed dyslipidemia) or referenced in the Other Clinical Experience section of the 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 obtain a separate indication for AMR101 based on the ANCHOR trial results, our SPA with the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA submission. The final results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial. We are in the late stages of designing an outcomes study to support the indication studied in the ANCHOR trial. Such outcomes study may also seek additional indications for AMR101 beyond the indication studied in the ANCHOR trial, such as an indication for prevention of cardiac events, although there can be no assurance as to whether any such outcomes study we may conduct will be designed support to any such indication. If we commence an outcomes study in 2011, we will seek to have it substantially enrolled by the end of 2012. We have begun to solicit proposals from CROs to support us in the conduct of such a study. The decision on whether to commence such study will include evaluation of feedback from potential strategic marketing partners and evaluation of various financial considerations, including the costs and timing of payments for such study and the financing of such costs over multiple years.

In order to commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We plan to consider collaboration opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. We are in discussions with pharmaceutical companies regarding such a collaboration, although there can be no assurance that these discussions will result in any such transaction. Accordingly, we are also developing plans to launch, market and sell AMR101 on our own. If we do not enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101, we will need to raise additional capital to support these efforts.

In addition, as described above, we may commence an outcomes study to support the filing of an NDA for the clinical indication evaluated in the ANCHOR trial, whether or not we ultimately enter into a collaboration agreement with a strategic partner. The cost of an outcomes study would be considerable, and we will require additional funds to prepare for and complete these activities.

## Edgar Filing: AMARIN CORP PLC\UK - Form 10-Q

Opportunities to market and sell AMR101 outside of the United States are also under evaluation. If we do not enter into a strategic collaboration in connection with these opportunities, we will need to raise additional capital to support these efforts.

If we seek to raise additional funds, we may do so through the sale of additional equity, debt or convertible securities. The terms of any financings may be dilutive to, or otherwise adversely affect, holders of our outstanding securities. There can be no assurance that additional financing will be available in amounts or on terms acceptable to us, if at all.

As of March 31, 2011, our cash balance was \$129.5 million, including net proceeds of approximately \$98.7 million, after deducting underwriting commissions and expenses payable by us, associated with our sale in January 2011 of 13.8 million shares of our common shares, par value £0.50 per share.



## **Table of Contents**

### **Financial Operations Overview**

*Revenue.* We recorded no revenue in 2011 or 2010.

*Research and Development Expense.* Research and development expense consists primarily of fees paid to professional service providers in conjunction with independent monitoring of our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, fees paid to independent researchers, costs of contract manufacturing, services expenses incurred in developing and testing products and product candidates, salaries and related expenses for personnel, including stock-based compensation expense, costs of materials, depreciation, rent, utilities and other facilities costs. In addition, research and development expenses include the cost to support current development efforts, including patent costs and milestone payments. We expense research and development costs as incurred.

*Marketing, General and Administrative Expense.* Marketing, general and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expense, in our executive, business development, marketing, finance and information technology functions. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

*Interest and Other Income (Expense), Net.* Interest expense consists of interest incurred under lease obligations. Interest income consists of interest earned on our cash and cash equivalents. Other income, net, consists primarily of foreign exchange gains and losses.

### **Critical Accounting Policies and Significant Judgments and Estimates**

There have been no changes in our significant accounting policies, judgments, and estimates as described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC on March 16, 2011.

### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by FASB and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

### **Results of Operations**

#### ***Comparison of Three Months Ended March 31, 2011 versus March 31, 2010***

*Revenue.* We recorded no revenue in 2011 or 2010.

*Research and Development Expense.* Research and development expense for the three months ended March 31, 2011 was \$4.4 million, versus \$5.2 million in the prior year period, a decrease of \$0.8 million, or 15.4%. Research and development expenses for the three months ended March 31, 2011 and 2010 are summarized in the table below:

	<b>Three Months Ended</b>	
	<b>March, 31</b>	
	<b>2011</b>	<b>2010</b>
Research and development expenses, excluding non-cash expense (1)	\$ 4,149	\$ 4,780
Non-cash stock based compensation expense (2)	300	372
	<b>\$ 4,449</b>	<b>\$ 5,152</b>

- (1) Research and development expense, excluding non-cash charges, for the three months ended March 31, 2011 was \$4.1 million, versus \$4.8 million in the prior year period, a decrease of \$0.7 million, or 14.6%. The decrease in research and development expense was primarily

due to lower costs in 2011 for our AMR101 cardiovascular program, primarily costs associated with our two Phase III clinical trials incurred through Medpace, the clinical research organization (CRO) we engaged in late 2009 to help manage the two trials. We began enrolling patients in these trials in early 2010 and announced the completion of enrollment in both trials during the second half of 2010 with top-line results announced in November 2010 and April 2011 for the MARINE and ANCHOR trials, respectively.

- (2) Stock based compensation expense included within research and development was \$0.3 million and \$0.4 million for the three months ended March 31, 2011 and 2010, respectively.

**Table of Contents**

We expect research and development expenses associated with the MARINE and ANCHOR studies to decrease during 2011 as those trials near completion. However, if we elect to conduct an outcomes study, which decision will follow upon finalization of an outcome study design and funding, the anticipated decline in research and development expenditures could be substantially offset by costs associated with the outcomes study.

*Marketing, General and Administrative Expense.* Marketing, general and administrative expense for the three months ended March 31, 2011 was \$2.7 million, versus \$2.3 million in the prior year period, an increase of \$0.4 million, or 17.4%. Marketing, general and administrative expenses for the three months ended March 31, 2011 and 2010 are summarized in the table below:

	Three Months Ended	
	March, 31	
	2011	2010
Marketing, general and administrative expenses, excluding non-cash expenses (1)	\$ 2,165	\$ 1,926
Non-cash stock based compensation expense (2)	1,240	273
Non-cash warrant related compensation (income) expense (3)	(679)	54
	\$ 2,726	\$ 2,253

- (1) Marketing, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended March 31, 2011 was \$2.2 million, versus \$1.9 million in the prior year period, an increase of \$0.3 million, or 15.8%. The increase was primarily due to higher staffing in 2011 to prepare for the commercialization of AMR101.
- (2) Stock based compensation expense for the three months ended March 31, 2011 was \$1.2 million, versus \$0.3 million in the prior year period, an increase of \$0.9 million reflecting an increase in option awards for the year ended December 31, 2010 to attract and retain qualified employees.
- (3) Warrant related compensation (income) expense for the three months ended March 31, 2011 was income of \$0.7 million, versus expense of \$0.1 million in the prior year period. Warrant related compensation expense for the period ended March 31, 2011 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former employees of Amarin, net of warrants exercised. The increase in the fair value of the warrants for the three months ended March 31, 2011 is due primarily to a decrease in our stock price between December 31, 2010 and March 31, 2011. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.

We expect marketing, general and administrative costs in 2011 to increase as we prepare for the commercialization of AMR101, including costs for market research, sales force preparation and inventory management.

*Gain (loss) on Change in Fair Value of Derivative Liability.* Gain (loss) on change in fair value of derivative liability for the three months ended March 31, 2011 a gain of \$25.3 million versus a loss of \$2.1 million in the prior year period. (Loss) gain on change in fair value of derivative liability is related to the change in fair value of warrants issued in conjunction with the October 2009 private placement. In October 2009 we issued 36.1 million warrants at an exercise price of \$1.50 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2010 was \$230.1 million and we recognized a \$25.3 million gain on change in fair value of derivative liability for the period ended March 31, 2011 for these warrants. The fair value of the warrant derivative liability at December 31, 2009 was \$41.5 million and we recognized a \$2.1 million loss on change in fair value of derivative liability for the period ended March 31, 2010. The decrease or increase in the fair value of the warrant derivative liability is due primarily to the decrease or increase in the price of our common stock on the date of valuation.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances.

*Other Income, net.* Other income primarily includes gains and losses on foreign exchange transactions.



**Table of Contents****Liquidity and Capital Resources**

Our sources of liquidity as of March 31, 2011 include cash and cash equivalents of \$129.5 million. Our projected uses of cash include the completion of our two Phase III clinical trials for AMR101, including final analysis of results of the ANCHOR study and completion of the patient-optional open-label extension period of the MARINE study (results from which are not needed for the NDA submission), the submission of an NDA, commercial preparation of AMR101, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Cash (used in) provided by continuing operations:		
Operating activities	\$ (8.8)	\$ (7.8)
Investing activities		
Financing activities	106.8	
Increase (decrease) in cash and cash equivalents	\$ 98.0	\$ (7.8)

We had no debt obligations at March 31, 2011 or December 31, 2010.

In January 2011, we sold 13.8 million shares of our common shares, par value £0.50 per share, at a price of \$7.60 per share, resulting in net proceeds of approximately \$98.7 million after deducting underwriting commissions and expenses payable by us associated with this transaction.

We believe that our cash will be sufficient to fund our projected operations for the next twelve months which contemplates not only working capital and general corporate needs but also, the filing of an NDA and commercial preparations for AMR101. This is based on our current operational plans and activities at normal levels and does not assume any cash inflows from partnerships, warrant exercises or other dilutive or non-dilutive financings in the longer-term. If we elect to commercialize AMR101 ourselves, rather than through a collaborator, or decide to commence an outcome study, we will need additional funds to complete such activities. The sale of any equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all.

**Contractual Obligations**

The following table summarizes our contractual obligations at March 31, 2011 and the effects such obligations are expected to have on our liquidity and cash flows in future periods (in millions):

**Payments Due by Period**

	<b>Total</b>	<b>2011</b>	<b>2012 to 2013</b>	<b>2014 to 2015</b>	<b>After 2015</b>
Contractual Obligations:					
Purchase obligations (1)	\$ 13.4	\$ 0.8	\$ 12.6	\$	\$
Operating lease obligations	0.6	0.4	0.2		
Total contractual cash obligations	\$ 14.0	\$ 1.2	\$ 12.8	\$	\$

- (1) Represents minimum purchase obligations under a supplier agreement with a Japan-based supplier. We paid \$0.8 million during the three months ended March 31, 2011 and have additional purchase obligations of \$12.6 million in 2012. Not included in this obligation is a non-refundable milestone payment of \$0.5 million payable upon the first marketing approval of AMR101 in the United States. Additional future minimum purchases will be required, subject to an NDA approval, and in preparation for

commercialization of AMR101 we may purchase more than the minimum amount.

In addition, provided the supplier has expanded its manufacturing capacity in accordance with the agreement, the supplier may terminate the agreement in the event that (i) Amarin does not receive marketing approval for AMR101 in the United States on or before December 31, 2014 or (ii) in the event that Amarin abandons development of AMR101 for hypertriglyceridemia in the United States. In either case, Amarin will be required to reimburse the supplier for certain costs incurred by the supplier in connection with its manufacturing expansion, less the amount of profit received as a result of purchases of ethyl-EPA by Amarin, not to exceed \$5.0 million.

We anticipate incurring certain costs associated with the qualification of product produced by this Japan-based supplier. In an effort to further expand production capacity at this supplier or through the addition of supplemental suppliers, we may make capital commitments to support their expansion, particularly if such commitments further reduce the cost to us of the manufactured product.

We do not enter into financial instruments for trading or speculative purposes.

In addition to the obligations in the table above, we have approximately \$0.5 million of gross liability for uncertain tax positions that have been recorded as liabilities at December 31, 2010. We are not able to reasonably estimate in which future periods these amounts will ultimately be settled.

The above table does not reflect our contract with Medpace for the conduct of our two registration trials for AMR101. We paid \$3.7 million to Medpace during the three months ended March 31, 2011 and anticipate paying an additional \$5.3 million to Medpace in 2011 prior to the completion of this project.

Under our 2004 share repurchase agreement with Laxdale Limited, in connection with commercialization of AMR101 for cardiovascular indications, prior to the end of 2012 we are required to pay potential royalties of 1% royalty on net sales up to £100 million (\$160 million); 0.5% for net sales between £100 million (\$160 million) and £500 million; and 0.25% for sales in excess of £500 million (\$802 million). In addition, upon receipt of marketing approval in the United States and/or Europe for the first indication for AMR101 (or any product containing Amarin Neuroscience intellectual property acquired from Laxdale Limited in 2004), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £7.5 million (\$12 million) for each of the two potential market approvals (i.e. £15 million maximum, or \$24 million). In addition, upon receipt of a marketing approval in the United States or Europe for any other product using Amarin Neuroscience intellectual property or for a different indication of a previously approved product, we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (\$8 million) for each of the two potential market approvals (i.e. £10 million maximum, or \$16 million).

#### **Off-Balance Sheet Arrangements**

We do not have any special purpose entities or other off-balance sheet arrangements.

**Table of Contents****Shelf Registration Statement**

On March 29, 2011, we filed with the SEC a universal shelf registration statement on Form S-3 (Registration No. 333-173132), which provides for the offer, from time to time, of an indeterminate and unlimited amount of: ordinary shares, which may be represented by American Depositary Shares; preference shares, which may be represented by American Depositary Shares; senior or subordinated debt securities; warrants to purchase any of these securities; and any combination of these securities, individually or as units. In addition, if we identify any security holder(s) in a prospectus supplement, they may also offer identified securities under this registration statement although we will not receive any of the proceeds from the sale of securities by any of these selling security holders. This universal shelf registration statement was automatically effective upon its filing. The addition of any newly issued equity securities into the market may be dilutive to existing stockholders and new issuances by us or sales by our selling security holders could have an adverse effect on the price of our securities.

**Item 3. *Quantitative and Qualitative Disclosures about Market Risk***

We are exposed to market risks, which include changes in interest rates, changes in credit worthiness and liquidity of our marketable securities. We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts.

We record as a liability the fair value of warrants to purchase 26.9 million shares of our common stock issued to investors. The fair value of this warrant liability is determined using the Black-Scholes option valuation model and is therefore sensitive to changes in the market price and volatility of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of our common stock (\$8.03 based on the \$7.30 market price of our stock at March 31, 2011) on which the March 31, 2011 valuation was based, the value would have increased by \$19.1 million. Such increase would have been reflected as additional loss on revaluation of the warrant liability in our statement of operations. Subsequent to March 31, 2011, the price of our common shares increased more than 10% which, if sustained on subsequent measurement periods will result in a greater increase in the value of the derivative liability and a greater additional loss than reflected in this hypothetical example.

**Item 4. *Controls and Procedures*****Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of March 31, 2011, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2011, our disclosure controls and procedures were not effective at the reasonable assurance level, due to a material weakness in internal control over financial reporting described below.

**Changes in Internal Control over Financial Reporting**

During the quarter ended March 31, 2011, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as described below.

As previously described in Item 9A *Controls and Procedures* in our Annual Report on Form 10-K filed for the year ended December 31, 2010, our management identified a material weakness in internal control over financial reporting as of December 31, 2009 and which persisted on December 31, 2010. Specifically, our management concluded there was a deficiency in the company's internal control over financial reporting relating to the technical expertise and review over the accounting for complex, non-routine transactions that could result in a material misstatement of the consolidated financial statements that would not be prevented or detected on a timely basis. In response to this material weakness, our management, with the input, oversight, and support of the Audit Committee, identified and took the following steps beginning during the second half of 2010 and all of which efforts continued into the first quarter of 2011: non ordinary course transactions are considered and evaluated by senior finance management; we continued to prepare accounting position papers for all complex transactions; and, where



appropriate, management seeks the advice of outside consultants on accounting matters related to the application of U.S. GAAP to complex, non-ordinary course transactions and in other instances as warranted. In addition, as a result of the relocation of the accounting functions from Dublin, Ireland to our Mystic, CT offices, in the quarter ended March 31, 2011, we hired new accounting personnel, continued to implement new controls over financial reporting, continued to implement new accounting software, and continued to use the assistance of outside professionals to ensure that data and reports can be relied upon for the purpose of accurately and timely recording transactions in accordance with U.S. GAAP.

## **Table of Contents**

### **PART II**

#### **Item 1A. Risk Factors**

*Investment in our securities involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2010, which was filed with the SEC on March 16, 2011, contains numerous risk factors relating to our business and operations, our intellectual property, clinical trials, regulatory matters, our dependence on third parties, our industry and our common stock.*

*The following risk factors are either new or have changed materially from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2010. You should carefully review the risks involved and those described in our Annual Report on Form 10-K and in other reports we file with the Securities and Exchange Commission in evaluating our business.*

***We will require substantial additional resources to fund our operations and to develop our product candidates. If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business.***

We currently operate with limited resources. At March 31, 2011, we had a cash and cash equivalents balance of approximately \$129.5 million. Based upon current business activities and existing cash resources, we believe our current resources are sufficient to enable us to file an NDA requesting approval to market and sell AMR101 for the indication evaluated in the MARINE trial (for the treatment of patients with very high triglycerides) and to prepare for the commercialization of, but potentially not to commercialize, AMR101 for this indication in the United States.

In order to commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We plan to consider collaboration opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. Although we are in discussions with pharmaceutical companies regarding such a collaboration, there can be no assurance that these discussions will result in any such transaction. Accordingly, we are also developing plans to launch, market and sell AMR101 in the United States on our own. If we do not enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101, we will need to raise additional capital to support these efforts.

In addition, we may elect to add the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, we currently expect that the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results supporting either a separate and additional indication (for the treatment of patients with high triglycerides who have mixed dyslipidemia) or referenced in the Other Clinical Experience section of the 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 obtain a separate indication for AMR101 based on the ANCHOR trial results, our SPA with the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA submission. Under the terms of our SPA, the final results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial. We are in the late stages of designing an outcomes study to support the indication studied in the ANCHOR trial. Such outcomes study may also seek additional indications for AMR101 beyond the indication studied in the ANCHOR trial, such as an indication for prevention of cardiac events, although there can be no assurance as to whether any such outcomes study we may conduct will be designed support to any such indication.

We anticipate being ready to commence an outcomes study in 2011 and we have begun to solicit proposals from CROs to support us in the conduct of such a study. The decision on whether to commence such study will include evaluation of feedback from potential strategic marketing partners and evaluation of various financial considerations, including the costs and timing of payments for such study and the financing of such costs over multiple years. The cost of an outcomes study would be considerable, and we will require additional funds to complete these activities.

If we seek to raise additional funds, we may do so through the sale of additional equity, debt or convertible securities. The terms of any financings may be dilutive to, or otherwise adversely affect, holders of our outstanding securities. There can be no assurance that additional financing will be available in amounts or on terms acceptable to us, if at all. Any inability to obtain additional funds when needed would have a material adverse effect on our business and on our ability to operate on an ongoing basis.

Our future capital requirements will depend on many factors, including:

whether or not we enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101;

whether or not we elect to commence an outcomes study to support the filing of an NDA for the clinical indication evaluated in the ANCHOR trial;

time and costs involved in obtaining regulatory approvals for AMR101;

number of additional product candidates we may pursue;

costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and

the costs associated with commercializing our product candidates if they receive regulatory approval, including the cost and timing of developing sales and marketing capabilities, or entering into strategic collaboration with others relating to the commercialization of our product candidates.

If we do not enter into a collaboration agreement as described above, or if adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, we may be required to terminate or delay our development efforts in support of our product candidates or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize AMR101 in the event we obtain regulatory approval for this product candidate.

## **Table of Contents**

***In order to commercialize any future product that is approved for marketing, we may need to find a collaborative partner to help with marketing and sales.***

In order to commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We plan to consider collaboration opportunities with larger pharmaceutical companies for the launch, marketing and sale of AMR101. If we do complete such a collaboration agreement, we will be reliant on one or more of these strategic partners to generate revenue on our behalf. In the event that we are not successful in finding a suitable partner, we may choose to commercialize AMR101 ourselves. This would require that we build a substantial commercialization infrastructure in order to compete with larger companies with established marketing and sales capabilities.

We may not be successful in finding a collaborative partner to help market and sell our products, or may be delayed in doing so, in which case we would not receive revenue or royalties on the timeframe and to the extent that we currently anticipate. We face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we cannot raise sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

For example, in October 2009, we announced our heightened strategic and operating focus on cardiovascular disease and our cessation of research and development of product candidates to treat central nervous system disorders. Subsequent to October 2009, we did not receive any acceptable offers to acquire, out-license or otherwise continue the development of any of these product candidates to treat central nervous system disorders.

***There can be no assurance that the FDA will accept an NDA for the indication studied in the MARINE trial if the NDA also seeks approval for the indication studied in the ANCHOR trial unless a clinical outcomes study is substantially underway at the time of the NDA submission. In the event that we elect to submit an NDA for the indication studied in the ANCHOR trial, and the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA submission, the submission of our NDA may be delayed.***

We currently expect 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 the treatment of patients with very high triglycerides) in the United States. However, we are also considering adding the ANCHOR trial results to the NDA we are preparing. If the ANCHOR results are added to the NDA, we currently expect that the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results supporting either a separate and additional indication (for the treatment of patients with high triglycerides who have mixed dyslipidemia) or referenced in the Other Clinical Experience section of the label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia.

There can be no assurance that the FDA would accept an NDA for the indication studied in the ANCHOR trial unless a clinical outcomes study is substantially underway at the time of the NDA submission as specified in our SPA with the FDA or allow for ANCHOR trial data to be included in the Other Clinical Experience section of the label. Although we are making preparations to commence an outcomes study and anticipate being ready to commence an outcomes study in 2011, we will not have a clinical outcomes study substantially underway in the third quarter of 2011. In the event that we elect to submit an NDA for the indication studied in the ANCHOR trial, and the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA submission, the filing of our NDA may be delayed.

There can be no assurance that, if we commence an outcomes study, we will be able to complete substantial enrolment in this study in 2012 or at all. In the event we experience delays in achieving substantial completion of enrolment for such an outcomes study, our filing of a supplemental NDA seeking approval of an indication based on the ANCHOR trial results will be delayed.



***Even if we obtain marketing approval for AMR101 in the United States, there can be no assurance as to the final indication approved by the FDA, and the actual number of patients with the condition included in such approved indication may be smaller than we anticipate.***

Whether we elect to submit an NDA to the FDA requesting approval to market and sell AMR101 for the indication studied in the MARINE trial alone or we elect to submit an NDA also requesting approval to market and sell AMR101 for the indication studied in the ANCHOR trial or we elect to submit an NDA requesting approval to market and sell AMR101 for the indication studied in the MARINE trial with the ANCHOR results referenced in the Other Clinical Experience section of the label, there can be no assurance as to the final indication approved by the FDA in the event that marketing approval is obtained. Even if marketing approval is obtained, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. Even if we obtain marketing approval, the FDA may impose restrictions on the product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials. If any such approved indication is more narrow than we anticipate, the market potential for our product candidate would suffer.

***The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for AMR101, physicians may nevertheless prescribe AMR101 to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

***We may become subject to product liability claims as a result of our prior sales and marketing activities related to Permax.***

Amarin was responsible for the sales and marketing of Permax® (pergolide mesylate), as an adjunctive treatment for Parkinson's disease, from May 2001 until February 2004. On May 17, 2001, Amarin acquired the U.S. sales and marketing rights to Permax from Elan Corporation, or Elan. An affiliate of Elan had previously obtained the licensing rights to Permax from Eli Lilly and Company in 1993. Eli Lilly originally obtained approval for Permax on December 30, 1988, and has been responsible for the manufacture and supply of Permax since that date. On February 25, 2004, Amarin sold its U.S. subsidiary, Amarin Pharmaceuticals, Inc., including the rights to Permax, to Valeant Pharmaceuticals.

On March 29, 2007, the FDA announced that the manufacturers of pergolide drug products would voluntarily remove these drug products, including Permax, from the market because of the risk of serious damage to patients' heart valves. Further information about the removal of Permax and other pergolide drug products is available on the FDA's website.

Six cases alleging claims related to cardiac valvulopathy and Permax were filed in April 2008 in the United States and currently remain pending. Eli Lilly, Valeant, Amarin Pharmaceuticals (sold to Valeant in 2004 as described above) and unidentified parties were named as defendants in these cases. Amarin was never named as a defendant or served with the complaints from these cases. We understand that, as of the date of this Quarterly Report on Form 10-Q, all of these cases have either settled or been dismissed.

---

**Table of Contents**

**Item 6. Exhibits**

The following exhibits are incorporated by reference or filed as part of this report.

<b>Exhibit Number</b>	<b>Description</b>
10.1	Paul Huff offer letter, dated January 28, 2011
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of President (Principal Financial Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer (Principal Executive Officer) and President (Principal Financial Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002

**Table of Contents**

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMARIN CORPORATION PLC

By:

/s/ John F. Thero

John F. Thero

*President* (Principal Financial Officer)

(On behalf of the Registrant)

Date: May 10, 2011