

AMARIN CORP PLC\UK
Form 10-Q
November 08, 2011
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 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

Not applicable
(I.R.S. Employer

Incorporation or Organization)

Identification No.)

2 Pembroke House, Upper Pembroke Street 28-32
(Address of Principal Executive Offices)

Dublin 2, Ireland
(Zip Code)

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

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 ☐ (Do not check if smaller reporting company) 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 ☒

135,502,062 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 315,480 ordinary shares, were outstanding as of November 3, 2011.

Table of Contents

INDEX TO FORM 10-Q

	Page
<u>PART I Financial Information</u>	
Item 1.	
<u>Financial Statements:</u>	
<u>Condensed Consolidated Balance Sheets at September 30, 2011 and December 31, 2010</u>	1
<u>Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2011 and 2010</u>	2
<u>Condensed Consolidated Statement of Changes in Stockholders' Deficit at September 30, 2011 and 2010</u>	3
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2011 and 2010</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2.	10
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	
Item 3.	17
<u>Quantitative and Qualitative Disclosures about Market Risk</u>	
Item 4.	17
<u>Controls and Procedures</u>	
<u>PART II Other Information</u>	
Item 1.	18
<u>Legal Proceedings</u>	
Item 1A.	18
<u>Risk Factors</u>	
Item 6.	21
<u>Exhibits</u>	
<u>SIGNATURES</u>	22

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****AMARIN CORPORATION PLC****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share amounts)**

	September 30, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 125,855	\$ 31,442
Other current assets	2,214	1,671
Total current assets	128,069	33,113
Property, plant and equipment, net	73	88
Other non-current assets	3,528	2,166
TOTAL ASSETS	\$ 131,670	\$ 35,367
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	\$ 3,836	\$ 4,449
Accrued expenses and other liabilities	2,592	3,128
Total current liabilities	6,428	7,577
Long-Term Liabilities:		
Warrant derivative liability	155,018	230,069
Lease obligations and other long-term liabilities	559	88
Total liabilities	162,005	237,734
Commitments and contingencies (Note 4)		
Stockholders' Deficit:		
Common stock, £0.50 par, unlimited authorized; 135,780,817 issued, 135,760,738 outstanding at September 30, 2011; 106,856,731 issued, 106,836,652 outstanding at December 31, 2010	113,280	90,465
Additional paid-in capital	443,399	206,718
Treasury stock; 20,079 shares at September 30, 2011 and December 31, 2010	(217)	(217)
Accumulated deficit	(586,797)	(499,333)
Total stockholders' deficit	(30,335)	(202,367)

TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT	\$	131,670	\$	35,367
---	-----------	----------------	-----------	---------------

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 per share amounts)**

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Revenues	\$	\$	\$	\$
Operating Expenses:				
Research and development	6,013	7,642	15,651	20,565
Marketing, general and administrative	3,433	2,134	16,185	7,205
Total operating expenses	9,446	9,776	31,836	27,770
Operating loss	(9,446)	(9,776)	(31,836)	(27,770)
Gain (loss) on change in fair value of derivative liability	106,614	(1,370)	(53,403)	(33,402)
Interest income, net	3	30	97	15
Other (expense) income, net	(59)	15	30	(478)
Income (loss) from operations before taxes	97,112	(11,101)	(85,112)	(61,635)
Provision for income taxes	(767)	(108)	(2,352)	(142)
Net and comprehensive income (loss)	\$ 96,345	\$ (11,209)	\$ (87,464)	\$ (61,777)
Income (loss) per share:				
Basic	\$ 0.72	\$ (0.11)	\$ (0.68)	\$ (0.62)
Diluted	\$ 0.62	\$ (0.11)	\$ (0.68)	\$ (0.62)
Weighted average shares:				
Basic	133,238	100,150	128,377	99,284
Diluted	155,975	100,150	128,377	99,284

See notes to condensed consolidated financial statements.

Table of Contents

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury shares	Retained earnings	Total
At January 1, 2011	106,856,731	\$ 90,465	\$ 206,718	\$ (217)	\$ (499,333)	\$ (202,367)
Warrants exercised	12,855,642	10,263	8,398			18,661
Transfer of fair value of warrants exercised from liabilities to equity			129,458			129,458
Stock issued in January financing	13,800,000	10,723	87,931			98,654
Stock options exercised	2,255,721	1,819	3,254			5,073
Tax benefits from stock-based compensation			1,571			1,571
Stock issued for services	12,723	10	47			57
Stock-based compensation			6,022			6,022
Loss for the period					(87,464)	(87,464)

At September 30, 2011 **135,780,817** **\$ 113,280** **\$ 443,399** **\$ (217)** **\$ (586,797)** **\$ (30,335)**

	Common Shares	Common Stock	Additional Paid-in Capital	Treasury shares	Retained earnings	Total
At January 1, 2010	98,801,982	\$ 84,219	\$ 172,339	\$ (217)	\$ (249,744)	\$ 6,597
Warrants exercised	2,507,674	1,898	1,669			3,567
Transfer of fair value of warrants exercised from liabilities to equity			4,637			4,637
Stock options exercised	31,666	24	5			29
Stock-based compensation			2,010			2,010
Loss for the period					(61,777)	(61,777)

At September 30, 2010 **101,341,322** **\$ 86,141** **\$ 180,660** **\$ (217)** **\$ (311,521)** **\$ (44,937)**

See notes to condensed consolidated financial statements.

Table of Contents

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (87,464)	\$ (61,777)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	48	49
Expense for commitment fee	1,000	
Stock-based compensation	6,022	2,010
Stock-based compensation warrants	1,004	858
Stock issued for services	57	
Excess tax benefit from stock-based awards	(1,571)	
Loss on changes in fair value of derivative liability	53,403	33,402
Changes in assets and liabilities:		
Other assets	(1,255)	1,253
Change in lease liability	(39)	(537)
Accounts payable, accrued expenses, and other liabilities	932	404
Net cash used in operating activities	(27,863)	(24,338)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of long term investment	(1,650)	
Purchases of equipment	(33)	(24)
Net cash used in investing activities	(1,683)	(24)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of transaction costs	98,654	
Proceeds from exercise of stock options, net of transaction costs	5,073	29
Proceeds from exercise of warrants, net of transaction costs	18,661	3,567
Excess tax benefit from stock-based awards	1,571	
Payments under capital leases		(9)
Net cash provided by financing activities	123,959	3,587
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	94,413	(20,775)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	31,442	52,258
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 125,855	\$ 31,483
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	\$	\$

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

Income taxes	\$	581	\$	65
--------------	----	-----	----	----

Non-cash transactions:

Transfer from derivative liability to equity, fair value of warrants exercised	\$	129,458	\$	4,637
--	----	---------	----	-------

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 and 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 September 30, 2011, the Company had cash and cash equivalents of \$125.9 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 commercial preparation of AMR101 and the initiation of a clinical outcomes study. 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.

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

Unless the Company enters into a strategic collaboration to provide additional capital in connection with the launch, marketing and sale of AMR101, the Company will need to raise additional funds on its own to support these efforts. Additional financing may not be available when the Company needs it or may not be available on terms that are favorable to it. If adequate funds are not available to the Company on a timely basis, or at all, the Company may be required to delay the establishment of sales and marketing capabilities or terminate or delay the clinical outcomes study.

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.

Marketing, General and Administrative Costs

Warrant related expense from non-cash changes in fair value of the warrant derivative liability associated with warrants issued in October 2009 to former employees of Amarin is recorded as compensation expense and classified as part of marketing, general and administrative costs, net of warrants exercised.

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:

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 96,345	\$ (11,209)	\$ (87,464)	\$ (61,777)
Weighted average shares outstanding	133,238	100,150	128,377	99,284
Dilutive effect of employee stock options and warrants	22,737	0	0	0
Diluted weighted average shares outstanding	155,975	100,150	128,377	99,284

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

Basic income (loss) per share	\$	0.72	\$	(0.11)	\$	(0.68)	\$	(0.62)
Diluted income (loss) per share	\$	0.62	\$	(0.11)	\$	(0.68)	\$	(0.62)

Potentially dilutive securities representing approximately 3.2 million and 51.0 million shares of common stock for the three month periods ended September 30, 2011 and September 30, 2010, respectively, and approximately 31.9 million and 51.0 million shares of common stock for the nine months ended September 30, 2011 and September 30, 2010, respectively were excluded from the computation of diluted earnings per share for these periods because their effect would have been anti-dilutive.

Table of Contents**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.

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 September 30, 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>		September 30, 2011		
	Total	Level 1	Level 2	Level 3
Liability:				
Warrant derivative liability	\$ 155,018	\$	\$	\$ 155,018

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

<i>In thousands</i>	Total	December 31, 2010		Level 3
		Level 1	Level 2	
Liability:				
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 September 30, 2011, the fair value of the warrant derivative liability was determined to be \$155.0 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.42%, (ii) remaining term of 3.0 years, (iii) no dividend yield, (iv) volatility of 118%, and (v) the stock price on the date of measurement. The \$75.1 million decrease in the fair value of the warrant liability during the nine months ended September 30, 2011 was recognized as: (i) a \$129.5 million transfer from warrant liability to additional paid-in capital for the fair value of warrants exercised during the nine months ended September 30, 2011, (ii) a \$53.4 million loss on the change in fair value of the remaining derivative liability and (iii) \$1.0 million in compensation expense for the change in fair value of warrants issued to former employees. The change in the fair value of the warrant derivative liability is as follows (in thousands):

	Three months ended September 30	Nine months ended September 30
Balance at June 30, 2010 & December 31, 2009	\$ 72,422	\$ 41,520
Loss on change in fair value of derivative liability	1,370	33,402
Compensation expense for change in fair value of warrants issued to former employees	36	858
Transfers to equity	(2,685)	(4,637)
Balance at September 30, 2010	\$ 71,143	\$ 71,143

	Three months ended September 30	Nine months ended September 30
Balance at June 30, 2011 & December 31, 2010	\$ 285,984	\$ 230,069
(Gain) loss on change in fair value of derivative liability	(106,614)	53,403
Compensation (income) expense for change in fair value of warrants issued to former employees	(3,352)	1,004
Transfers to equity	(21,000)	(129,458)
Balance at September 30, 2011	\$ 155,018	\$ 155,018

Segment and Geographical Information

For the three and nine months ended September 30, 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 21,139,090 warrants to purchase common shares outstanding at September 30, 2011 at a weighted-average exercise price of \$1.48, as summarized in the following table:

Issue Date	Amount	Exercise Price	Expiration Date
4/27/07	17,500	17.90	1/17/2014
6/1/07	55,737	7.20	5/31/12
12/5/07	539,027	1.17	12/3/12
7/31/09	138,888	1.00	7/30/14
7/31/09	1,666,000	1.00	7/30/14
10/16/09	18,074,888	1.50	10/15/14
10/16/09	647,050	1.50	10/15/14
	21,139,090	\$ 1.48	

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

Table of Contents

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 September 30, 2011 the maximum number of common shares issuable as a result of the October 2009 private placement is 18.7 million. During the three and nine months ended September 30, 2011, approximately 2.5 million and 12.1 million of the October 2009 warrants were exercised, respectively, resulting in gross proceeds to the Company of approximately \$3.8 million and \$18.1 million, respectively. During the three and nine months ended September 30, 2010, approximately 1.3 million and 2.2 million warrants were exercised, respectively, resulting in gross proceeds of the Company of approximately \$1.9 million and \$3.3 million, respectively. Upon exercise, the fair value of the warrants exercised is remeasured and reclassified from warrant liability to additional paid-in capital. During the nine months ended September 30, 2011, \$129.5 million of fair value for 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 September 30, 2011 for the remaining warrants was determined to be approximately \$155.0 million. The Company recognized a loss on change in fair value of derivative liability of \$53.4 million and compensation expense of \$1.0 million for the nine month period ended September 30, 2011.

(4) Commitments and Contingencies

Litigation

The Company is, from time to time, subject to legal proceedings, claims, and litigation arising in the normal course of business. At September 30, 2011, there were no asserted claims against the Company which, in the opinion of management, would have a material effect on the consolidated financial statements.

Royalty and Milestone Obligations

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

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 Company signed agreements in the second quarter of 2011 for the supply of materials for AMR101 with two new API suppliers, Equateq and Chemport. These agreements provide access to additional API supply that is incremental to supply from its existing Japan-based API supplier. These agreements include requirements for the suppliers to qualify their materials and facilities. The Company anticipates incurring certain costs associated with the qualification of product produced by these suppliers. Following FDA approvals of AMR101, both agreements include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements. Because the Company has not yet obtained FDA approval for AMR101, no liability has been recorded. The 2011 supply agreement with Equateq also includes (i) a one-time commitment fee of \$1.0 million, (ii) development fees up to a maximum of \$0.5 million, and (iii) material commitments of up to \$5.0 million for initial raw materials, which will be credited against future API purchases, and is refundable to Amarin if Equateq fails to successfully develop and qualify the API by a certain date. The \$1.0 million commitment fee paid to Equateq in May 2011 is refundable if

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

Equateq fails to satisfy certain capital sufficiency requirements. The 2011 supply agreement with Chemport includes, prior to a marketing approval, a raw material purchase commitment of \$1.1 million. No payments have been made under this agreement as of September 30, 2011;

Concurrent with the agreement with Chemport for commercial supply, Amarin agreed to make a minority share equity investment in Chemport of up to \$3.3 million. In July 2011, the Company paid to Chemport \$1.7 million under this agreement, which has been included in other long term assets at September 30, 2011.

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 by Elan and (ii) a \$0.2 million payment if the drug is tested by Elan in an efficacy study. During the third quarter of 2011, the Company was notified that the first milestone was completed. The milestone payable of \$0.2 million has been included in accounts payable at September 30, 2011, and was paid in October 2011.

Table of Contents

Under the 2004 share repurchase agreement with Laxdale Limited, in connection with commercialization of AMR101 for cardiovascular indications, prior to the end of 2012 the Company is required to pay potential royalties to a former employee of Laxdale of 1% on net sales up to £100 million (approximately \$156 million at September 30, 2011); 0.5% for net sales between £100 million (approximately \$156 million at September 30, 2011) and £500 million (approximately \$781 million at September 30, 2011); and 0.25% for sales in excess of £500 million (approximately \$781 million at September 30, 2011).

In addition, under this same agreement with Laxdale Limited, 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), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale Limited (at the sole option of each of the sellers) of £7.5 million (approximately \$11.7 million at September 30, 2011) for each of the two potential marketing approvals (i.e. £15 million maximum, or approximately \$23.4 million at September 30, 2011). 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 (approximately \$7.8 million at September 30, 2011) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$15.6 million at September 30, 2011).

Other than \$0.2 million for the Neurostat milestone payable to Neurostat noted above, the Company has no provision for any of the obligations noted above since the amounts are either not probable or estimable at September 30, 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 proceeds of \$98.7 million, net of \$6.2 million in transaction costs.

During the three and nine months ended September 30, 2011, the Company issued 91,074 and 2,255,721 shares, respectively, as a result of the exercise of stock options, resulting in net proceeds of \$0.1 million and \$5.1 million, respectively. In addition, during the three and nine months ended September 30, 2011, the Company issued 2,525,000 and 12,855,642 shares, respectively, as a result of the exercise of warrants, resulting in net proceeds of \$3.7 million and \$18.7 million, respectively.

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, should, would and 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

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

executive management were changed, and our research and development activities, as well as certain executive functions, were consolidated 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 (³ 500

Table of Contents

mg/dL). The MARINE 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 229 patients with fasting triglyceride levels ≥ 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.

Patients enrolled in the MARINE trial were given the option to be treated with AMR101 for a period of up to 40-weeks after their last dose in the pivotal trial. The results from this 40-week open label non-placebo controlled extension period are not part of the MARINE trial primary endpoints.

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 (≥ 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.

In addition to achieving the primary endpoints of the MARINE and ANCHOR trials, AMR101, particularly at the 4 gram dose, demonstrated significant reductions in various secondary and exploratory efficacy endpoints for other lipid and inflammatory biomarkers which we believe are important as they potentially represent additional predictors of cardiovascular risk. These biomarkers include total cholesterol; non-HDL-cholesterol; VLDL-cholesterol; Apo B (Apolipoprotein B), a sensitive index of residual cardiovascular risk which is generally considered to be a better predictor than LDL-C; Lp-PLA2 (Lipoprotein-phospholipase A2), an enzyme found in blood and atherosclerotic plaque and high levels of which have been implicated in the development and progression of atherosclerosis; and high sensitivity C-reactive protein (hsCRP), an important marker of vascular inflammation.

The MARINE and ANCHOR trials were conducted under separate Special Protocol Assessment, or SPA, 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.

On September 26, 2011 we submitted a New Drug Application (NDA) to the FDA seeking approval to market and sell AMR101 in the United States for the indication studied in the MARINE trial (for the treatment of patients with very high triglycerides). Also included in our NDA submission were the safety and efficacy results of the ANCHOR trial. The FDA has 60 days after receipt of the NDA to preliminarily review the NDA and determine if the application is sufficiently complete to permit a substantive review and if it meets the threshold for filing.

In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, our SPA with the FDA for the ANCHOR trial requires that we have a cardiovascular outcomes study substantially underway at the time of the NDA submission. In accordance with this SPA, the final results of an outcomes study are not required for FDA approval of indication studied in the ANCHOR trial. In accordance with our SPA for the MARINE trial an outcomes study is not required for the indication studied in such trial.

In August 2011, we reached agreement with the FDA on a SPA for the design of the cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). REDUCE-IT, is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of AMR101 in reducing first major cardiovascular events in an at-risk patient population. The control arm of the study will be patients on optimized statin therapy. The active arm of the study will be patients on optimized statin therapy plus AMR101. All subjects enrolled in the study will have elevated triglyceride levels (fasting TG levels of ≥ 3

135 mg/dL and < 500 mg/dL) and either coronary heart disease or risk factors for coronary heart disease. This study will be conducted internationally. Based on the results of REDUCE-IT, we may seek additional indications for AMR101 beyond the indication studied in the ANCHOR trial such as prevention of cardiac events, although there can be no assurance as to whether the results of the study will support to any such indication. In September 2011 we engaged a clinical research organization to begin initial trial and clinical site preparation. We will seek to have REDUCE-IT at least 50% enrolled by the end of 2012, and project the study to cost between \$100 and \$125 million over the anticipated six year study period, of which we anticipate not more than \$25 million being paid before the end of 2012. We will require additional funds to complete REDUCE-IT.

In accordance with our SPA for the ANCHOR trial, we currently intend to file a supplemental NDA (sNDA) seeking approval of the indication studied in the ANCHOR trial once we have a cardiovascular outcomes study substantially underway. The sNDA cannot be filed until after both

Table of Contents

the initially submitted NDA for the indication studied in the MARINE trial is approved and the cardiovascular outcomes study is substantially underway. However, as part of our interaction with the FDA regarding our NDA for the indication studied in the MARINE trial, we may explore whether there is an opportunity for the indication studied in the ANCHOR trial to be considered in conjunction with the FDA's review of the indication studied in the MARINE trial. However, there can be no assurance that the FDA will approve such an approach.

We have filed and are prosecuting numerous patent applications in the U.S. and internationally. In the U.S. we have filed patent applications which seek to expand to eleven the number of patent families protecting the proprietary position of AMR101. For certain of these patent families, we have filed multiple patent applications. Collectively the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims based upon unexpected and positive findings from the MARINE and ANCHOR trials. If granted, we believe that many of these resulting patents would expire in 2030. However, no assurance can be given that any of our patent applications will be granted or, if they grant, that they will prevent competitors from competing with AMR101. Securing additional patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the U.S. and internationally are at varying stages of examination, the timing of which is outside our control. Many of our patent applications are unlikely to be examined by the U.S. Patent Office or other international patent offices during 2011. In addition, we may elect to submit, or patent office's may require, additional evidence to support certain of the claims we are pursuing. Providing such additional evidence could result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent portfolio will provide to us.

In order to commercialize AMR101, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. With the assistance of financial advisors, we have held discussions about collaboration and other strategic opportunities with larger pharmaceutical companies in the past, and may continue to hold such discussions in the future. These strategic opportunities may include licensing or similar transactions, joint ventures, partnerships, strategic alliances, business associations, or a sale of the company. However, no assurance can be given that we will enter into any such strategic transaction.

Until such time as we complete any such strategic transaction, if ever, we are continuing to develop plans to launch, market and sell AMR101 on our own. This includes making preparations for securing a sufficient commercial supply of AMR101 and expanding sales and marketing capabilities. In order to secure a sufficient commercial supply of AMR101, we have completed agreements for the supply of materials for AMR101 to provide for raw materials that are incremental to our existing Japan-based API supplier. Each agreement contemplates a phased capacity expansion plan aimed at creating sufficient capacity to meet anticipated demand for API material for AMR101 following FDA approval. These API suppliers are self-funding these expansion plans with contributions from Amarin. We are also considering adding a fourth API supplier. These agreements include requirements for the qualification of the suppliers' material and facilities with the FDA prior to the commercial sale of any such material. We will make no purchase commitments until such time as these qualification events have been completed.

Opportunities to market and sell AMR101 outside of the United States are also under evaluation.

Unless we enter into a strategic collaboration in connection with the launch, marketing and sale of AMR101 to provide us with additional capital, we will need to raise additional capital on our own to support these efforts. We will also need additional capital to complete our REDUCE-IT cardiovascular outcomes trial. Additional financing may not be available when we need it or may not be available on terms that are acceptable to us. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay the establishment of sales and marketing capabilities or terminate or delay our planned cardiovascular outcomes study. If we seek to raise additional funds, we may do so through the sale of additional equity, debt or convertible securities. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. The terms of any financings may be dilutive to, or otherwise adversely affect, holders of our outstanding securities. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

As of September 30, 2011, our cash balance was \$125.9 million.

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

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

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 non-cash warrant related compensation expense attributable to October 2009 warrants issued to former employees, salaries and other related costs for current 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.

Table of Contents**Critical Accounting Policies and Significant Judgments and Estimates**

There have been no changes in our critical accounting policies and significant 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 September 30, 2011 versus September 30, 2010***

Revenue. We recorded no revenue in 2011 or 2010.

Research and Development Expense. Research and development expense for the three months ended September 30, 2011 was \$6.0 million, versus \$7.6 million in the prior year period, a decrease of \$1.6 million, or 21.0%. Research and development expenses for the three months ended September 30, 2011 and 2010 are summarized in the table below:

	Three Months Ended September 30	
	2011	2010
Research and development expenses, excluding non-cash expense (1)	\$ 5,607	\$ 7,350
Non-cash stock based compensation expense	406	292
	\$ 6,013	\$ 7,642

- (1) Research and development expense, excluding non-cash charges, for the three months ended September 30, 2011 was \$5.6 million, versus \$7.4 million in the prior year period, a decrease of \$1.8 million, or 24.3%. 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 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. We estimate to incur approximately \$2.0 million in additional CRO expenses to complete these studies.

Our estimate of remaining costs to be incurred to complete the MARINE and ANCHOR studies are significantly lower than the costs we included for these studies during 2010. However, we anticipate the decline in research and development expenditures for those two trials to be offset by an increase in clinical costs associated with our planned REDUCE-IT cardiovascular outcomes study. We currently estimate that cumulative costs incurred through a CRO for REDUCE-IT will not exceed \$25 million by the end of 2012.

Marketing, General and Administrative Expense. Marketing, general and administrative expense for the three months ended September 30, 2011 was \$3.4 million, versus \$2.1 million in the prior year period, an increase of \$1.3 million, or 61.9%. Marketing, general and administrative expenses for the three months ended September 30, 2011 and 2010 are summarized in the table below:

**Three Months Ended
September 30**

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

	2011	2010
Marketing, general and administrative expenses, excluding non-cash expense (1)	\$ 4,529	\$ 1,631
Non-cash stock based compensation expense (2)	2,256	467
Non-cash warrant related compensation (income) expense (3)	(3,352)	36
	\$ 3,433	\$ 2,134

- (1) Marketing, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended September 30, 2011 was \$4.5 million, versus \$1.6 million in the prior year period, an increase of \$2.9 million, or 181.25%. The increase was primarily due to higher staffing and marketing related expenses in 2011 to prepare for the commercialization of AMR101.
- (2) Stock based compensation expense for the three months ended September 30, 2011 was \$2.3 million, versus \$0.5 million in the prior year period, an increase of \$1.8 million reflecting an increase in expense associated with option awards granted in 2010 and 2011 to attract and retain qualified employees.
- (3) Warrant related compensation income for the three months ended September 30, 2011 was \$3.4 million, versus expense of \$0.04 million in the prior year period. Warrant related compensation income for the three months ended September 30, 2011 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to former employees of Amarin, net of

Table of Contents

warrants exercised. The decrease in the fair value of the warrants for the three months ended September 30, 2011 is due primarily to a decrease in our stock price between June 30, 2011 and September 30, 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, excluding non-cash warrant related compensation expense the value of which we cannot reasonably estimate, 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 on change in fair value of derivative liability for the three months ended September 30, 2011 was a gain of \$106.6 million versus a loss of \$(1.4) million in the prior year period. Gain/(loss) 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 July 1, 2011 was \$286.0 million and we recognized a \$106.6 million gain on the change in fair value of derivative liability during the three months ended September 30, 2011 for these warrants. The fair value of the warrant derivative liability at July 1, 2010 was \$72.4 million and we recognized a \$(1.4) million loss on the change in fair value of derivative liability during the three months ended September 30, 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.

Comparison of Nine Months Ended September 30, 2011 versus September 30, 2010

Revenue. We recorded no revenue in 2011 or 2010.

Research and Development Expense. Research and development expense for the nine months ended September 30, 2011 was \$15.7 million, versus \$20.6 million in the prior year period, a decrease of \$4.9 million, or 23.8%. Research and development expenses for the nine months ended September 30, 2011 and 2010 are summarized in the table below:

	Nine Months Ended September 30	
	2011	2010
Research and development expenses, excluding non-cash expense (1)	\$ 14,751	\$ 19,559
Non-cash stock based compensation expense	900	1,006
	\$ 15,651	\$ 20,565

- (1) Research and development expense, excluding non-cash charges, for the nine months ended September 30, 2011 was \$14.8 million, versus \$19.6 million in the prior year period, a decrease of \$4.8 million, or 24.5%. 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 the CRO we engaged in late 2009 to help manage the two trials. We began enrolling patients in these trials in early 2010 and completed enrollment in both trials during the second half of 2010. We estimate to incur approximately \$2.0 million in additional expense through this CRO to complete these studies.

Our estimate of remaining costs to be incurred to complete the MARINE and ANCHOR studies are significantly lower than the costs we included for these studies during 2010. However, we anticipate the decline in research and development expenditures for those two trials to be offset by an increase in clinical costs associated with our planned cardiovascular outcomes study. We currently estimate that cumulative costs incurred through a CRO for REDUCE-IT will not exceed \$25 million by the end of 2012.

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

Marketing, General and Administrative Expense. Marketing, general and administrative expense for the nine months ended September 30, 2011 was \$16.2 million, versus \$7.2 million in the prior year period, an increase of \$9.0 million, or 125%. Marketing, general and administrative expenses for the nine months ended September 30, 2011 and 2010 are summarized in the table below:

	Nine Months Ended September 30	
	2011	2010
Marketing, general and administrative expenses, excluding non-cash expense (1)	\$ 10,059	\$ 5,343
Non-cash stock based compensation expense (2)	5,122	1,004
Non-cash warrant related compensation expense (3)	1,004	858
	\$ 16,185	\$ 7,205

Table of Contents

- (1) Marketing, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the nine months ended September 30, 2011 was \$10.1 million, versus \$5.3 million in the prior year period, an increase of \$4.8 million, or 90.6%. The increase was primarily due to higher staffing and marketing related expenses in 2011 to prepare for the commercialization of AMR101.
- (2) Stock based compensation expense for the nine months ended September 30, 2011 was \$5.1 million, versus \$1.0 million in the prior year period, an increase of \$4.1 million, reflecting an increase in expense associated with option awards granted in 2010 and 2011 to attract and retain qualified employees.
- (3) Warrant related compensation expense for the nine months ended September 30, 2011 was \$1.0 million, versus \$0.9 million in the prior year period. Warrant related compensation expense reflects the non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to former employees of Amarin, net of warrants exercised. The decrease in the fair value of the warrants for the nine months ended September 30, 2011 is due primarily to an increase in our stock price between December 31, 2010 and September 30, 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, excluding non-cash warrant related compensation expense the value of which we cannot reasonably estimate, to increase as we prepare for the commercialization of AMR101, including costs for market research, sales force preparation and inventory management.

Loss on Change in Fair Value of Derivative Liability. Loss on change in fair value of derivative liability for the nine months ended September 30, 2011 was \$53.4 million versus \$33.4 million in the prior year period. Loss 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 \$53.4 million loss on change in fair value of derivative liability for the nine months period ended September 30, 2011 for these warrants. The fair value of the warrant derivative liability at December 31, 2009 was \$41.5 million and we recognized a \$33.4 million loss on change in fair value of derivative liability for the nine months period ended September 30, 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.

Liquidity and Capital Resources

Our sources of liquidity at September 30, 2011 include cash and cash equivalents of \$125.9 million. Our projected uses of cash include commencement of the REDUCE-IT cardiovascular outcomes study, 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):

	Nine Months Ended September 30,	
	2011	2010
Cash (used in) provided by continuing operations:		
Operating activities	\$ (27.8)	\$ (24.4)
Investing activities	(1.7)	
Financing activities	123.9	3.6
Increase (decrease) in cash and cash equivalents	\$ 94.4	\$ (20.8)

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

We had no debt obligations at September 30, 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, commencement of a cardiovascular outcomes study 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, 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.

Table of Contents**Contractual Obligations**

The following table summarizes our contractual obligations at September 30, 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

	Total	2011	2012 to 2013	2014 to 2015	After 2015
Contractual Obligations:					
Purchase obligations (1)	\$ 13.4	\$ 0.8	\$ 12.6	\$	\$
Operating lease obligations (2)	1.5	0.6	0.7	0.2	
Total contractual cash obligations	\$ 14.9	\$ 1.4	\$ 13.3	\$ 0.2	\$

- (1) Represents minimum purchase obligations with our Japan-based supplier. We purchased \$1.2 million of materials during the nine months ended September 30, 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.

- (2) Represents operating lease costs, primarily consisting of leases for facilities in Dublin, Ireland, Mystic, CT and Bedminster, NJ. We do not enter into financial instruments for trading or speculative purposes.

The above table also does not reflect potential material purchases under new agreements signed in the second quarter of 2011 for the supply of materials for AMR101 with two new API suppliers, Equateq and Chemport. These agreements provide access to additional API supply that is incremental to supply from our existing Japan-based API supplier. Each agreement contemplates a phased capacity expansion plan aimed at creating sufficient capacity to meet anticipated demand for API material for AMR101 following FDA approval. These API suppliers are self-funding these expansion plans with contributions from Amarin. These agreements include requirements for the suppliers to qualify their materials and facilities. We anticipate incurring certain costs associated with the qualification of product produced by these suppliers. Following FDA approval of AMR101 both agreements include annual purchase levels enabling Amarin to maintain supply exclusivity with each respective supplier, and to prevent potential termination of the agreements. Because we have not yet obtained FDA approval for AMR101, these amounts are excluded from the above table. The 2011 supply agreement with Equateq also includes (i) a one-time commitment fee of \$1.0 million (paid in May 2011), (ii) development fees up to a maximum of \$0.5 million, and (iii) material commitments of up to \$5.0 million for initial raw materials, which will be credited against future API purchases, and is refundable to Amarin if Equateq does not successfully develop and qualify the API by a certain date. The \$1.0 million commitment fee paid to Equateq in May 2011 is refundable if Equateq fails to satisfy certain capital sufficiency requirements. The 2011 supply agreement with Chemport includes, prior to a marketing approval, a raw material purchase commitment of \$1.1 million. No payments have been made under this agreement as of September 30, 2011.

Table of Contents

Concurrent with the agreement with Chemport for commercial supply, we agreed to make a minority share equity investment in Chemport of up to \$3.3 million. In July 2011, we paid to Chemport \$1.7 million under this agreement, which has been included in other long term assets at September 30, 2011.

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 to a former employee of Laxdale of 1% on net sales up to £100 million (approximately \$156 million at September 30, 2011); 0.5% for net sales between £100 million (approximately \$156 million at September 30, 2011) and £500 million (approximately \$781 million at September 30, 2011); and 0.25% for sales in excess of £500 million (approximately \$781 million at September 30, 2011). In addition, under this same agreement with Laxdale Limited, 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), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £7.5 million (approximately \$11.7 million at September 30, 2011) for each of the two potential marketing approvals (i.e. £15 million maximum, or approximately \$23.4 million at September 30, 2011). 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), we must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately \$7.8 million at September 30, 2011) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$15.6 million at September 30, 2011).

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.

Off-Balance Sheet Arrangements

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

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 18.7 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 (\$10.12 based on the \$9.20 market price of our stock at September 30, 2011) on which the September 30, 2011 valuation was based, the value would have increased by \$16.8 million. Such increase would have been reflected as a reduction in the gain on revaluation of the warrant liability in our statement of operations.

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 Exchange Act of 1934, as amended (the Exchange Act) 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 September 30, 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 Exchange Act. 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 September 30, 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.

Table of Contents

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 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) under the Exchange Act, 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 third quarter of 2011: non-ordinary course transactions are considered and evaluated by senior finance management; we continue 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.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of September 30, 2011, that, in the opinion of management, might have a material adverse effect on our financial position, results of operations or cash flows.

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.

There can be no assurance that the FDA will accept the NDA we submitted to the FDA in September 2011, nor can there be any assurance that the NDA will be approved.

On September 26, 2011 we submitted an NDA to the FDA seeking approval to market and sell AMR101 in the United States for the indication studied in the MARINE trial (for the treatment of patients with very high triglycerides). After submission of an NDA, the FDA may refuse to file the application, deny approval of the application and/or require additional testing or data. In the event the FDA takes any such action, such actions would have a material adverse effect on our operations and financial condition.

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 September 30, 2011, we had cash and cash equivalents of approximately \$125.9 million. We believe that our current resources 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 commercial preparation of AMR101 and the initiation of the REDUCE-IT cardiovascular outcomes study. 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 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. We will also need additional capital to complete our REDUCE-IT cardiovascular outcomes trial.

Table of Contents

If we seek to raise additional funds, we may do so through the sale of additional equity, debt, convertible securities or a combination of these securities. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. 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. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us. 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 the advancement of the REDUCE-IT cardiovascular outcomes trial, 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.

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. Until such time as we complete any such strategic transaction, if ever, we are continuing to develop plans to launch, market and sell AMR101 on our own. This includes making preparations for securing a sufficient commercial supply of AMR101 and expanding sales and marketing capabilities and 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.

We may experience delays in the initiation of our cardiovascular outcomes study, or such outcomes study may take longer and cost more than we expect. The FDA may not approve our request to consider the indication studied in the ANCHOR trial in conjunction with the FDA's review of the indication studied in the MARINE trial.

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 cardiovascular outcomes study substantially underway at the time of the NDA submission. In August 2011, we reached an agreement with the FDA on an SPA for the design of the cardiovascular outcomes study of AMR101, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial). REDUCE-IT, is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of AMR101 in reducing first major cardiovascular events in an at-risk patient population. The control arm of the study will be patients on optimized statin therapy. The active arm of the study will be patients on optimized statin therapy plus AMR101. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. This study will be conducted internationally. Based on the results of REDUCE-IT, we may seek additional indications for AMR101 beyond the indication studied in the ANCHOR trial such as prevention of cardiac events, although there can be no assurance as to whether the results of REDUCE-IT will support any such indication.

Table of Contents

In the event we experience delays in initiating or achieving substantial enrolment for REDUCE-IT, our filing of a supplemental NDA (sNDA) seeking approval of an indication based on the ANCHOR trial results will be delayed.

In accordance with our SPA for the ANCHOR trial, we currently intend to file a sNDA seeking approval of the indication studied in the ANCHOR trial once we have a cardiovascular outcomes study substantially underway. The sNDA cannot be filed until after both the initially submitted NDA is approved and the cardiovascular outcomes study is substantially underway. However, as part of our interaction with the FDA regarding our NDA for the indication studied in the MARINE trial, we may explore whether there is an opportunity for the indication studied in the ANCHOR trial to be considered in conjunction with the FDA's review of the indication studied in the MARINE trial once the REDUCE-IT trial is substantially underway. However, there can be no assurance that the FDA will approve such an approach. If the FDA requires additional enrollment, our ability to seek approval for the indication evaluated in the ANCHOR trial could be delayed.

The REDUCE-IT cardiovascular trial may fail to achieve its clinical endpoints, and the long-term clinical results of AMR101 may not be consistent with the clinical results we observed in our Phase 3 pivotal trials.

In accordance with the SPA for our MARINE and ANCHOR trials, efficacy was evaluated in these trials compared to placebo at twelve weeks. No placebo-controlled studies have been conducted regarding the long-term effect of AMR101 on lipids and no outcomes study has been conducted evaluating AMR101. Outcomes studies of certain other lipid modifying therapies have failed to achieve the endpoints of such studies. There can be no assurance that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved or that the lipid modifying effects of AMR101 in REDUCE-IT or any other study of AMR101 will not be subject to variation beyond twelve weeks. If the REDUCE-IT trial fails to achieve its clinical endpoints or if the results of these long-term studies are not consistent with the clinical results it could prevent us from expanding the label of any approved product.

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.

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 narrower 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.

We may become subject to liability in connection with the wind-down of our EN101 program.

In 2007, we purchased Ester Neurosciences Limited, an Israeli pharmaceutical company, and its lead product candidate, EN101, an AChE-R mRNA inhibitor for the treatment of myasthenia gravis, or MG, a debilitating neuromuscular disease. In connection with the acquisition, we assumed a license to certain intellectual property assets related to EN101 from the Yissum Research Development Company of The Hebrew University of Jerusalem.

In June 2009, in keeping with our decision to re-focus our efforts on developing improved treatments for cardiovascular disease and cease development of all product candidates outside of our cardiovascular disease focus, we amended the terms of our acquisition agreement with the original shareholders of Ester. Under the terms of this amendment, Amarin was released from all research and development diligence obligations contained in the original agreement and was authorized to seek a partner for EN101. The amendment agreement also provided that

Table of Contents

any future payment obligations payable by Amarin to the former shareholders of Ester would be made only out of income received from potential partners. In connection with this amendment agreement, in August 2009 we issued 1,315,789 ordinary shares to the former Ester shareholders. Under the terms of this amendment agreement, the former Ester shareholders have the option of reacquiring the original share capital of Ester if we are unable to successfully partner EN101.

Following our decision to cease development of EN101, Yissum terminated its license agreement with Amarin. In June 2011 Yissum announced that it had entered into a license agreement with BiolineRX Ltd for the development of EN101 in a different indication, Inflammatory Bowel Disease.

We have received correspondence on behalf of the former shareholders of Ester asserting that Amarin is in breach of its amended agreement due to the fact that the Yissum terminated its license and Amarin failed to return shares of Ester, and assets relating to EN101, to the shareholders, as was required under certain circumstances under the amended agreement. We do not believe these circumstances constitute a breach of the amended agreement, but there can be no assurance as to the outcome of this dispute.

There can be no assurance that any of our pending patent applications relating to AMR101 or its use will issue as patents.

We have filed and are prosecuting numerous patent applications in the U.S. and internationally. In the U.S. we have filed patent applications which seek to expand to eleven the number of patent families protecting the proprietary position of AMR101. For certain of these patent families, we have filed multiple patent applications. Collectively the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims that are based upon unexpected and positive findings from the MARINE and ANCHOR trials. If granted, many of these patents would expire in 2030. However, no assurance can be given that any of our patent applications will be granted or, if they grant, that they will prevent competitors from competing with AMR101. The patent applications we have filed in the U.S. and internationally are at varying stages of examination, the timing of which is outside our control. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

The process of obtaining a patent can be lengthy, during which patent claims may undergo substantial modification before allowance and could result in significantly reduced coverage for a product. There can be no assurance that the U.S. Patent Office or international patent offices will find the our arguments in support of patentability to be persuasive. The timing of the patent examination process is independent of and has no effect on the timing of the FDA's review of our NDA.

Item 6. Exhibits

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

Exhibit	
Number	
10.1	Stuart Sedlack offer letter, dated August 1, 2007.
10.2	Online Office Agreement dated as of September 30, 2011 by and between Amarin Corporation plc and Regus CME Ireland Ltd.
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.
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*

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

101.LAB XBRL Taxonomy Extension Label Linkbase Document*

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act and otherwise are not subject to liability under those sections.

Table of Contents

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, 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)

Date: November 8, 2011