

AMARIN CORP PLC\UK  
Form 10-Q  
November 08, 2012  
[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, 2012

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)

<b>England and Wales</b> (State or Other Jurisdiction of  Incorporation or Organization)	<b>Not applicable</b> (I.R.S. Employer  Identification No.)
<b>2 Pembroke House, Upper Pembroke Street 28-32</b> (Address of Principal Executive Offices) <b>Registrant's telephone number, including area code: +353 (0) 1 6699 020</b>	<b>Dublin 2, Ireland</b> (Zip Code)

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

149,769,550 shares held as American Depositary Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 365,080 ordinary shares, were outstanding as of November 1, 2012.

**Table of Contents**

**INDEX TO FORM 10-Q**

	<b>Page</b>
<b><u>PART I Financial Information</u></b>	
Item 1. Financial Statements:	
<u>Condensed Consolidated Balance Sheets at September 30, 2012 and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011</u>	4
<u>Condensed Consolidated Statement of Changes in Equity (Deficit) at September 30, 2012 and September 30, 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	23
<b><u>PART II Other Information</u></b>	
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 6. <u>Exhibits</u>	43
<u>SIGNATURE</u>	44

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

	September 30, 2012	December 31, 2011
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 215,110	\$ 116,602
Inventory	8,989	
Deferred tax asset	533	533
Other current assets	4,110	1,837
<b>Total current assets</b>	<b>228,742</b>	<b>118,972</b>
Property, plant and equipment, net	796	432
Deferred tax asset	9,788	4,734
Other long term assets	15,672	2,241
<b>TOTAL ASSETS</b>	<b>\$ 254,998</b>	<b>\$ 126,379</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 13,696	\$ 4,419
Accrued expenses and other liabilities	18,816	4,033
<b>Total current liabilities</b>	<b>32,512</b>	<b>8,452</b>
Long-Term Liabilities:		
Warrant derivative liability	90,963	123,125
Long term debt	130,783	
Other long-term liabilities	702	764
<b>Total liabilities</b>	<b>254,960</b>	<b>132,341</b>
Commitments and contingencies (Note 5)		
Stockholders Equity (Deficit):		
Common stock, £0.50 par, unlimited authorized; 149,921,422 issued, 149,901,343 outstanding at September 30, 2012; 135,832,542 issued, 135,812,463 outstanding at December 31, 2011	124,244	113,321
Additional paid-in capital	613,087	449,393
Treasury stock; 20,079 shares at September 30, 2012 and December 31, 2011	(217)	(217)
Accumulated deficit	(737,076)	(568,459)
<b>Total stockholders equity (deficit)</b>	<b>38</b>	<b>(5,962)</b>

<b>TOTAL LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>	\$ 254,998	\$ 126,379
------------------------------------------------------------	------------	------------

See notes to condensed consolidated financial statements.

**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

	Three months ended September 30, 2012		Nine months ended September 30, 2011	
	2012	2011	2012	2011
Revenues		\$	\$	\$
Operating Expenses:				
Research and development	20,913	6,013	39,735	15,651
Marketing, general and administrative	13,397	3,433	41,059	16,185
Total operating expenses	34,310	9,446	80,794	31,836
Operating loss	(34,310)	(9,446)	(80,794)	(31,836)
Gain (loss) on change in fair value of derivative liability	16,454	106,614	(68,686)	(53,403)
Interest (expense) income, net	(4,570)	3	(12,838)	97
Other (expense) income, net	(427)	(59)	(411)	30
(Loss) income from operations before taxes	(22,853)	97,112	(162,729)	(85,112)
Provision for income taxes	(3,573)	(767)	(5,888)	(2,352)
Net (loss) income	(26,426)	\$ 96,345	\$ (168,617)	\$ (87,464)
(Loss) income per share:				
Basic	(0.18)	\$ 0.72	\$ (1.19)	\$ (0.68)
Diluted	(0.18)	\$ 0.62	\$ (1.19)	\$ (0.68)
Weighted average shares:				
Basic	149,200	133,238	141,947	128,377
Diluted	149,200	155,975	141,947	128,377

See notes to condensed consolidated financial statements.





**Table of Contents**

## AMARIN CORPORATION PLC

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (168,617)	\$ (87,464)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	123	48
Stock-based compensation	13,344	6,022
Stock-based compensation warrants	3,037	1,004
Shares issued for services	24	57
Excess tax benefit from stock-based awards	(10,106)	(1,571)
Accrued interest payable	1,094	
Expense for commitment fee	0	1,000
Amortization of debt discount and debt issuance costs	9,365	
Amortization of Laxdale milestone	108	
Loss on change in fair value of derivative liability	68,686	53,403
Changes in assets and liabilities:		
Other current assets	(2,273)	(1,543)
Inventory	(8,989)	
Other non-current assets	(17,355)	288
Change in lease liability	(55)	(39)
Accounts payable and other liabilities	33,075	932
Net cash used in operating activities	(78,539)	(27,863)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of equipment	(477)	(33)
Purchase of long term investment	(1,238)	(1,650)
Net cash used in investing activities	(1,715)	(1,683)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of transaction costs		98,654
Proceeds from exercise of stock options, net of transaction costs	7,834	5,073
Proceeds from exercise of warrants, net of transaction costs	16,526	18,661
Excess tax benefit from stock-based awards	10,106	1,571
Proceeds from issuance of exchangeable debt, net of transaction costs	144,316	
Payments under capital leases	(20)	
Net cash provided by financing activities	178,762	123,959
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>98,508</b>	<b>94,413</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>116,602</b>	<b>31,442</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 215,110</b>	<b>\$ 125,855</b>

Supplemental disclosure of cash flow information:

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

Cash paid during the year for:			
Interest	\$	2,713	\$
Income taxes	\$	697	\$ 581
Non-cash transactions:			
Transfer from derivative liability to equity, fair value of warrants exercised	\$	103,885	\$ 129,458

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 Global Market. 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 biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health. On July 26, 2012, the Company received FDA approval to market and sell its lead product Vascepa™ (icosapent ethyl) capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG  $\geq$ 500mg/dL) hypertriglyceridemia. Triglycerides are fats in the blood. Amarin is also developing Vascepa for the treatment of patients with high triglyceride levels who are also on statin therapy for elevated LDL-C levels, or what the Company refers to as mixed dyslipidemia.

**Basis of Presentation**

The accompanying consolidated financial statements of the Company and subsidiaries have been prepared on a basis which 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. Prior to 2004, the Company was in the business of selling a previous biopharmaceutical compound, which has since been discontinued. The Company's current focus is on the commercialization and development of Vascepa, which received approval from the FDA on July 26, 2012. 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.

At September 30, 2012, the Company had cash and cash equivalents of \$215.1 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.

On January 9, 2012, Amarin, through its wholly-owned subsidiary Corsicanto Limited, a private limited company incorporated under the laws of Ireland, completed a private placement of \$150.0 million in aggregate principal amount of its 3.5% exchangeable senior notes due 2032 resulting in net proceeds to the Company of \$144.3 million. The notes are the senior unsecured obligations of Corsicanto Limited and are guaranteed by Amarin. In July 2012 Amarin made its initial interest payment on the notes in the aggregate amount of \$2.7 million.

The Company believes its cash and cash equivalents will be sufficient to fund its operations for at least the next twelve months, including advancement of the REDUCE-IT cardiovascular outcomes study, continuing the commercial preparation for and launch of Vascepa, working capital and other general corporate activities.

**(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.

**Inventory**

The Company states inventories at the lower of cost or market. Cost is determined based on actual cost. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected market value due to obsolescence or quantities in excess of expected demand, the Company will record a reserve for the difference between cost and market value. The Company received FDA approval on July 26, 2012 and began capitalizing inventory purchases after that date. At September 30, 2012, the Company had approximately \$9.0 million in inventory, which consisted primarily of raw materials.

**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.

**Table of Contents****Marketing, General and Administrative Costs**

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

**Income Taxes**

During 2008, the Company arranged with United Kingdom tax authorities to migrate the tax residence of its parent company, Amarin Corporation plc, from the United Kingdom to Ireland. As part of this migration of tax residency, Amarin surrendered certain tax loss carryforwards accumulated prior to the time of such migration. The Company remains registered in the United Kingdom.

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 (Loss) Income per Share**

Basic net (loss) income per share is determined by dividing net (loss) income by the weighted average shares of common stock outstanding during the period. Diluted net (loss) income per share is determined by dividing net (loss) income 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 (loss) income per share (in thousands except share amounts):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net (loss) income	\$ (26,426)	\$ 96,345	\$ (168,617)	\$ (87,464)
Weighted average shares outstanding	149,200	133,238	141,947	128,377
Dilutive effect of employee stock options and warrants (1)	0	22,737	0	0
Diluted weighted average shares outstanding	149,200	155,975	141,947	128,377
Basic (loss) income per share	\$ (0.18)	\$ 0.72	\$ (1.19)	\$ (0.68)
Diluted (loss) income per share	\$ (0.18)	\$ 0.62	\$ (1.19)	\$ (0.68)

- (1) Potentially dilutive securities representing approximately 38.4 million and 3.2 million shares of common stock for the three month periods ended September 30, 2012 and September 30, 2011, respectively, and approximately 38.4 million and 31.9 million shares of common stock for the nine months ended September 30, 2012 and September 30, 2011, 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, apart from that described under Marketing, General, and Administrative Costs with respect to certain warrant-related expenses, is measured at the grant date, based on the then-fair value of the award, and is recognized as compensation cost over the requisite service period. Compensation expense is reduced for awards not expected to vest.

### **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 derecognized 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.

### **Debt Instruments**

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the statement of operations as interest expense at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares.

Our exchangeable notes contain a conversion option which is classified as equity. The fair value of the liability component of the debt instrument was deducted from the initial proceeds to determine the proceeds to be allocated to the conversion option. The embedded conversion option is indexed to the Company's stock and treated as equity on the balance sheet. The conversion option is evaluated on a quarterly basis to determine if it still meets the criteria to be equity classified. The excess principal amount of the debt over the carrying value of the liability is amortized over its estimated life.

### **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).

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

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.

**Table of Contents**

The following table presents information about the Company's liability as of September 30, 2012 and December 31, 2011 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 millions</i>	<b>Total</b>	<b>September 30, 2012</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents	\$ 37.1	\$ 37.1	\$	\$
<b>Liability:</b>				
Warrant derivative liability	\$ 91.0	\$	\$	\$ 91.0

<i>In millions</i>	<b>Total</b>	<b>December 31, 2011</b>		
		<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Asset:</b>				
Cash equivalents	\$ 39.0	\$ 39.0	\$	\$
<b>Liability:</b>				
Warrant derivative liability	\$ 123.1	\$	\$	\$ 123.1

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

At December 31, 2011, the fair value of the warrant derivative liability was determined to be \$123.1 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.36%, (ii) remaining term of 2.8 years, (iii) no dividend yield (iv) volatility of 118%, and (v) the stock price on the date of measurement.

At September 30, 2012, the fair value of the warrant derivative liability was determined to be \$91.0 million using the Black-Scholes option valuation model applying the following assumptions: (i) risk-free rate of 0.23%, (ii) remaining term of 2.0 years, (iii) no dividend yield (iv) volatility of 97%, and (v) the stock price on the date of measurement. The \$32.2 million decrease in the fair value of the warrant liability during the nine months ended September 30, 2012 was recognized as: (i) a \$103.9 million transfer from warrant liability to additional paid-in capital for the fair value of warrants exercised during the nine months ended September 30, 2012, (ii) a \$68.7 million loss on change in fair value of the remaining derivative liability and (iii) \$3.0 million in compensation expense for change in fair value of warrants issued to former employees, both amounts are included in the consolidated statement of operations for the nine months ended September 30, 2012. The change in the fair value of the warrant derivative liability is as follows (in thousands):

	<b>Three months ended September 30</b>	<b>Nine months ended September 30</b>
<b>Balance at June 30, 2011 &amp; December 31, 2010, respectively</b>	<b>\$ 285,984</b>	<b>\$ 230,069</b>
(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)

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

<b>Balance at September 30, 2011</b>	<b>\$ 155,018</b>	<b>\$ 155,018</b>
	<b>Three months ended September 30</b>	<b>Nine months ended September 30</b>
<b>Balance at June 30, 2012 &amp; December 31, 2011, respectively</b>	<b>\$ 120,214</b>	<b>\$ 123,125</b>
(Gain) loss on change in fair value of derivative liability	(16,454)	68,686
Compensation (income) expense for change in fair value of warrants issued to former employees	(1,194)	3,037
Transfers to equity	(11,603)	(103,885)
<b>Balance at September 30, 2012</b>	<b>\$ 90,963</b>	<b>\$ 90,963</b>

**Table of Contents**

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 of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of our common stock (\$13.84 based on the \$12.58 market price of our stock at September 28, 2012) on which the September 30, 2012 valuation was based, the value would have increased by \$10.1 million. Such increase would have been reflected as additional loss on revaluation of the warrant liability in our statement of operations. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value asset measurement.

**Segment and Geographical Information**

For the three and nine months ended September 30, 2012 and 2011, 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 had 10,224,339 warrants to purchase common shares outstanding at September 30, 2012 at a weighted-average exercise price of \$1.43, as summarized in the following table:

<b>Issue Date</b>	<b>Amount</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
4/27/07	17,500	\$ 17.90	1/17/2014
12/5/07	287,513	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	7,487,388	1.50	10/15/14
10/16/09	627,050	1.50	10/15/14
	<b>10,224,339</b>	<b>\$ 1.43</b>	

**October 2009 Warrants**

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

The warrants issued in connection with the October 2009 financing contain a pricing variability feature which provides 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 exceeds 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, 2011 was determined to be approximately \$123.1 million using the Black-Scholes option pricing model.

Although the warrants contain a pricing variability feature, the number of common shares issuable under the warrants remains fixed. Therefore, as of September 30, 2012 the maximum number of common shares issuable as a result of the October 2009 private placement is 8.1 million. During the three and nine months ended September 30, 2012, approximately 1.0 million, and 10.6 million of the October 2009 warrants were exercised, respectively, resulting in gross proceeds to the Company of approximately \$1.6 million and \$15.9 million, respectively. 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. 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, 2012 and 2011, the fair value of the exercised warrants of \$103.9 million and \$129.5 million, respectively, 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, 2012 for the remaining warrants was determined to be approximately \$91.0 million. The Company recognized a gain on change in fair value of derivative liability of \$68.7 million and warrant compensation income of \$3.0 million for the nine month period ended September 30, 2012. The Company recognized a loss on change in fair value of derivative liability of \$53.4 million and warrant compensation expense of \$1.0 million for the nine month period ended September 30, 2011.

---

**Table of Contents****(4) Debt****Exchangeable Senior Notes**

In January 2012, the Company issued \$150.0 million in principal amount of 3.5% exchangeable senior notes due 2032 (the "Notes"). The Notes were issued by Corsicanto Limited, an Irish limited company acquired by Amarin in January 2012. Corsicanto Limited is a wholly-owned subsidiary of Amarin. The general, unsecured, senior obligations are guaranteed by Amarin. Net proceeds to the Company, after payment of underwriting fees and expenses, were approximately \$144.3 million.

The Notes have a stated interest rate of 3.5% per year, payable semiannually in arrears on January 15 and July 15 of each year beginning on July 15, 2012, and ending upon the Notes' maturity on January 15, 2032. The Notes are subject to repurchase by the Company at the option of the holders on each of January 19, 2017, January 19, 2022, and January 19, 2027, at a price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date. The Notes are exchangeable under certain circumstances into cash, ADSs, or a combination of cash and ADSs, at the Company's election, with an initial exchange rate of 113.4752 ADSs per \$1,000 principal amount of Notes. It is the Company's current intention to settle these obligations in cash. If the Company elected physical settlement, the Notes would initially be exchangeable into 17,021,280 ADSs. Based on the closing price of the Company's stock at September 30, 2012, the value of the shares if converted on that date would exceed the principal amount of the Notes by \$64.1 million.

Additional covenants include: (i) limitations on future indebtedness under certain circumstances, (ii) the timely filing of documents and reports pursuant to Section 13 or 15(d) of the Exchange Act with both the SEC and the Trustee, and (iii) maintaining the tradability of the Notes. The Company is required to use commercially reasonable efforts to procure and maintain the listing of the Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or other recognized stock exchange as defined in the Note Indenture) prior to July 15, 2012. If the Notes are not freely tradable, as a result of restrictions pursuant to U.S. securities law or the terms of the Indenture or the Notes, the Company shall pay additional interest on the Notes at the rate of 0.50% per annum of the principal amount of Notes outstanding for each day during such period for which the Company's failure to file has occurred and is continuing or for which the Notes are not freely tradable. On April 24, 2012 the Notes were admitted to the Global Exchange Market of the Irish Stock Exchange.

The Company may not redeem the Notes prior to January 19, 2017, other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts becoming due with respect to payments and/or deliveries on the Notes. On or after January 19, 2017 and prior to the maturity date, the Company may redeem for cash all or part of the Notes at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the Notes. If the Company undergoes a fundamental change, holders may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The Notes are the Company's senior unsecured obligations and rank senior in right of payment to the Company's future indebtedness that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to future secured indebtedness to the extent of the value of the assets securing such indebtedness.

The Notes are exchangeable under certain circumstances, and the proceeds allocated to this conversion option were determined to be \$23.8 million and were deducted from the initial fair value of the \$150.0 million debt obligation. The conversion option will not be subsequently remeasured as long as it continues to meet conditions for equity classification. The Notes fall under Level 3 of the fair value hierarchy. The Company determined the fair value of the liability component of the Notes to be \$126.2 million, and the excess of the principal amount of the liability component over the liability is the amount allocated to the conversion option and also results in a discount on the debt. The discount created from allocating proceeds to the conversion option will be amortized to interest expense using the effective interest method over the Notes' estimated remaining life, which was calculated to be a period of twenty-four months. The effective interest rate of the Notes is 13.5%. As of September 30, 2012, the unamortized discount created from the allocation of the proceeds to the conversion option was \$16.0 million.

The Company also recorded a debt discount to reflect the value of the underwriter's discounts and offering costs. A portion of the debt discount from underwriters discounts and offering costs was allocated to the equity and liability components of the Notes in proportion to the proceeds allocated to each component. The portion of the debt discount from underwriters discounts and offering costs allocated to the liability component is being amortized as interest expense over the estimated remaining life of the Notes of twenty-four months. As of September 30, 2012, the unamortized debt discount was \$3.2 million and was recorded as a direct reduction of debt on the balance sheet. The carrying value of the Notes, net of the unamortized discount, was \$130.8 million. During the three and nine months ended September 30, 2012, the Company recognized interest expense of \$4.7 million and \$13.2 million related to the Notes, respectively, of which \$2.8 million and \$7.8 million represent amortization of the debt discount created upon allocation of proceeds to the conversion option, respectively, \$1.3 million and \$3.8 million represent contractual coupon interest, respectively, and \$0.6 million and \$1.6 million represent the amortization of the discount from the underwriter's discounts and offering costs, respectively. At September 30, 2012, the Company had accrued interest of \$1.1 million, which has been included in other current liabilities.



---

**Table of Contents**

In July 2012, the first interest payment of \$2.7 million was paid as scheduled.

**(5) Commitments and Contingencies****Royalty and Milestone Obligations**

As of September 30, 2012, 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 Japan-based supplier Nisshin Pharma required a one-time non-refundable payment of \$0.5 million to the supplier upon the first marketing approval of Vascepa in the United States, which was received from the FDA in July 2012. This milestone payment was made in cash in August 2012. Subsequent to FDA approval of Vascepa, the supply agreement provides for minimum supply purchase obligations on behalf of the Company, which remaining aggregate minimum purchase obligations are approximately \$27.7 million through 2014 as of September 30, 2012. In preparation for the commercialization of Vascepa, the Company may purchase more than this minimum amount.

The Company signed two additional agreements in 2011 for the supply of API materials for Vascepa. In July 2012, the Company agreed to terms with a fourth API supplier, which terms are subject to certain contingencies that the Company anticipate will be satisfied in 2012. These agreements provide access to additional API supply that is incremental to supply from Nisshin Pharma, the Company's existing Japan-based API supplier. These agreements include requirements for the suppliers to qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company anticipates incurring certain costs associated with the qualification of product produced by these suppliers as described below. In each case, following qualification of the supplier for the manufacture of API for commercial sale, these agreements include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements. Since these suppliers have not yet been qualified for the manufacture of API for commercial sale as of September 30, 2012, no liability has been recorded for these minimum purchase obligations. The 2011 supply agreements also include (i) development fees up to a maximum of \$0.5 million (ii) 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 the supplier does not successfully develop and qualify the API by a certain date and (iii) a raw material purchase commitment of \$1.1 million. Under these agreements, the Company made payments of \$3.4 million during the third quarter of 2012. The agreement with the fourth API supplier provides for, upon satisfaction of all contingencies, development fees of up to \$2.3 million and a commitment of up to \$15.0 million, which will be credited against future API material purchases.

Concurrent with its entry into one of the two agreements entered into in 2011 for the supply of API materials for Vascepa, Amarin agreed to make a noncontrolling minority share equity investment in the supplier of up to \$3.3 million. The Company invested \$1.7 million under this agreement in July 2011 and an additional \$0.8 million in May 2012. The Company invested an additional \$0.4 million under this agreement, as amended in July 2012, and anticipates making the remaining \$0.4 million investment before the end of 2012. These amounts have been included in other long term assets and accounted for under the cost method at September 30, 2012.

Under the 2009 Lorazepam sale agreement with Elan Pharma International Ltd, Elan did not assume any obligations under a related development agreement with Neurostat Pharmaceuticals Inc. and, as a result, Amarin retained a potential obligation to make a \$0.2 million milestone payment to Neurostat, contingent upon the drug being tested by Elan in an efficacy study.

Under the 2004 share repurchase agreement with Laxdale Limited, in connection with commercialization of Vascepa 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 \$161.6 million at September 30, 2012); 0.5% for net sales between £100 million (approximately \$161.6 million at September 30, 2012) and £500 million (approximately \$808.2 million at September 30, 2012); and 0.25% for sales in excess of £500 million (approximately \$808.2 million at September 30, 2012). These

royalty obligations terminate on December 31, 2012.

Also under the 2004 share repurchase agreement with Laxdale Limited, upon receipt of marketing approval in the U.S. and/or Europe for the first indication for Vascepa (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 \$12.1 million at September 30, 2012) for each of the two potential marketing approvals (i.e. £15 million maximum, or approximately \$24.2 million at September 30, 2012). In addition, upon receipt of a marketing approval in the U.S. or Europe for a further indication of Vascepa (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 \$8.1 million at September 30, 2012) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.2 million at September 30, 2012). Upon the approval of Vascepa by the FDA on July 26, 2012, the Company capitalized the Laxdale milestone (\$11.6 million on July 26, 2012) as a component of other long term assets and recorded an accrued liability payable to the former shareholders of Laxdale. The Laxdale milestone will be amortized over its estimated useful life and the Company recognized amortization expense of \$0.1 million during the three months ended September 30, 2012. The Company recognized \$0.5 million in unrealized exchange rate losses on the liability as of September 30, 2012. The Company anticipates paying the liability in cash to the former shareholders of Laxdale before the end of 2012.

**Table of Contents**

Other than the \$12.1 million payable to the former Laxdale shareholders and approximately \$0.7 million of liability for uncertain tax positions recorded in long-term liabilities at September 30, 2012, the Company had no provision for any of the other obligations noted above, since the amounts are either not probable or estimable at September 30, 2012.

**(6) Equity****Common stock**

During the three and nine months ended September 30, 2012, the Company issued 622,266 and 3,107,913 shares, respectively, as a result of the exercise of stock options, resulting in gross proceeds of \$1.2 million and \$7.9 million, respectively, and net proceeds of \$1.2 million and \$7.8 million. In addition, during the three and nine months ended September 30, 2012, the Company issued 1,068,654, and 10,881,276 shares, respectively, as a result of the exercise of warrants, resulting in gross proceeds of \$1.6 million and \$16.6 million respectively, and net proceeds of \$1.6 million and \$16.5 million.

On February 1, 2012, the Company granted 584,400 restricted stock units ( RSU s ) to several employees under the Amarin Corporation plc 2011 Stock Incentive Plan. These RSUs vest upon the achievement of certain regulatory and time-based milestones and expire on February 1, 2015 if none of the milestones are achieved by such date. The RSUs will become fully vested upon a change of control of the Company. Upon vesting of each RSU, the participant shall be entitled to a payment equal to the fair market value of one share of Amarin common stock. The payment shall be paid to the participant in cash, or at the sole discretion of the Remuneration Committee in shares or a combination of cash or shares. The fair value of the RSUs were determined on the date of grant, and compensation expense related to the RSUs is recognized once the related milestone is deemed probable. The Company recorded expense of \$0.3 million and \$1.2 million during the three and nine months ended September 30, 2012 related to the vesting of the RSUs, respectively. In connection with FDA approval of Vascepa in July 2012, an aggregate of 97,398 of our shares were issued under these RSUs.

**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, 2011 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 biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. On July 26, 2012, we received approval from the U.S. Food and Drug Administration, or FDA, to market and sell our lead product Vascepa (icosapent ethyl) capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (TG  $\geq$ 500mg/dL) hypertriglyceridemia, which we sometimes refer to as the MARINE indication. Triglycerides are fats in the blood. We are also developing Vascepa for the treatment of patients with high (TG  $\geq$  200 mg/dL and <500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication.

Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. We estimate that over 40 million adults in the United States have elevated triglyceride levels (TG  $\geq$  200mg/dL) and approximately 4.0 million people in the United

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

States have severely high (TG  $\geq$ 500mg/dL) triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein, or HDL-C (often referred to as "good" cholesterol),

## Table of Contents

and elevated levels of LDL-C (often referred to as "bad" cholesterol). The effect of Vascepa on cardiovascular mortality and morbidity in patients with hypertriglyceridemia has not been determined. The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

The potential efficacy and safety of Vascepa was studied in two Phase 3 clinical trials, the MARINE trial and the ANCHOR trial. These trials showed favorable clinical results in their respective patient populations in reducing triglyceride levels without a statistically significant increase in LDL-C levels, and in the 4 gram Vascepa ANCHOR results, with a statistically significant decrease in LDL-C levels. These trials also showed favorable results, particularly with the 4 gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (Apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In each of these trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

In July 2012, we received approval from the FDA to market Vascepa in the MARINE indication. We plan to separately seek approval to market Vascepa for use in the treatment of patients in the ANCHOR population. Like the MARINE indication, the ANCHOR indication is supported by a 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 3 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 addressed 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. Moreover, any change to a study protocol can invalidate an SPA. There can be no assurance that the FDA will ultimately consider our SPA for the ANCHOR indication to be binding. If the FDA does not consider the SPA to be binding or makes a determination that we did not follow the SPA appropriately, the agency could assert that additional studies or data are required to support a regulatory submission.

To obtain FDA marketing approval for the use of Vascepa in the ANCHOR population, based on communications with the FDA, we believe that we must be substantially underway with a cardiovascular outcomes study at the time of the submission of a supplemental NDA, or sNDA, to the FDA seeking approval of the ANCHOR indication. Based on our current estimates, we anticipate that our cardiovascular outcomes study will be substantially underway in time to support an sNDA filing prior to the end of February 2013 which, assuming a ten-month FDA review period, we expect to result in the FDA assigning a Prescription Drug User Fee Act, or PDUFA, date of not later than the end of 2013. Based upon feedback from the FDA and consistent with the SPA for the ANCHOR trial, we do not believe the final results of an outcomes study are required for FDA approval of Vascepa for the ANCHOR indication.

In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial), that is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. The REDUCE-IT study is also the subject of an SPA with the FDA. If successful, we believe the results of this study could lead to a broadening of the market potential for Vascepa beyond the approved MARINE and proposed ANCHOR indications. We currently estimate that the duration of the REDUCE-IT trial, which duration is estimated based on prediction of the rate of occurrence of cardiac events, to be approximately six years.

### *Manufacturing and Supply*

The approval of Vascepa in July 2012 included the approval of one API manufacturer, Nisshin Pharma, Inc., and one API encapsulator, Banner Pharmacaps Europe BV. Nisshin and Banner are the API manufacturer and API encapsulator, respectively, with which we have had the longest working relationships. Their facilities were inspected by regulatory authorities as part of the process that led to the FDA's July 2012 approval of Vascepa, and we believe that the facilities are qualified to support our commercial launch of Vascepa. We have defined with the FDA our plan and specifications for qualifying additional API manufacturers. In October 2012, a second API encapsulator, Catalent Pharma Solutions LLC, was qualified to encapsulate API for Vascepa. We intend to submit an sNDA for the use of additional suppliers after these suppliers successfully complete the qualification process.

Our goal in expanding our supply chain is to provide greater capacity to meet anticipated demand, enable supply diversification and flexibility and introduce cost competition. After conducting an extensive global search for manufacturers capable of producing Vascepa API to our technical specifications, in 2011 we entered into limited exclusivity, long-term agreements with two additional API suppliers, Chemport and BASF (formerly Equateq Limited). In each case, following FDA qualification of the supplier for the manufacture of API for commercial sale and other milestones relating to manufacturing capacity, these agreements include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements. We recently agreed to terms with a fourth API supplier, which terms are subject to contingencies that we anticipate will be satisfied in 2012. Certain of our API supply agreements contain provisions under which the cost of supply to us decreases as we purchase increased product volume.

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

The agreements with each of our API suppliers contemplate phased capacity expansion aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa. Accordingly, our current supplier, Nisshin Pharma, and our other potential suppliers are currently working to expand and qualify their production capabilities to meet regulatory requirements to manufacture the API for Vascepa. These API suppliers are self-funding these expansion and qualification plans with contributions from Amarin. There can be no assurance that additional suppliers will fully-fund the capital costs of our engagement or that they will successfully qualify with the FDA.

---

## **Table of Contents**

We intend to purchase increasing amounts of API in preparation for the commercial launch of Vascepa. Our supply agreement with Nisshin contains minimum purchase commitments for metric tons of API, and we may purchase more than the minimum requirement. We anticipate receipt of the majority of this API during 2012, in advance of our planned commercial launch of Vascepa. We also plan to encapsulate and package such API as part of our commercial launch plans. During 2013, we intend to further increase our purchases of API and finished capsules of Vascepa. These purchases are generally made on the basis of rolling twelve-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. We may elect to make certain of these purchases prior to sNDA approval of our added suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, the supply of product for our launch may be delayed.

Our strategy is to expand capacity and to mitigate risk by having multiple API suppliers. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. While we anticipate purchasing qualified API from multiple suppliers for our first year of commercial sales of Vascepa, if no additional API supplier is approved by the FDA, our API supply will be limited to the API we purchase from Nisshin. We believe that our overall API manufacturing plan provides a pathway to the production of API in sufficient quantities to meet anticipated demand, subject to API supplier capacity expansion, qualification and regulatory approval. There can be no assurance that these expansion plans will be successful. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. During the period commencing October 1, 2012 through the expected launch of Vascepa in early 2013, we estimate cash outflow of \$20 to \$30 million to build inventory levels of API and Vascepa capsules in advance of the commercial launch of Vascepa. Our purchase of supply may be insufficient to meet, or exceed, actual demand for Vascepa.

### *Commercialization Strategy*

We anticipate commercial launch of Vascepa in the first quarter of 2013, and we continue to consider three potential paths for the marketing and sale of the product: strategic collaboration, acquisition and self-commercialization, the latter of which could include a third-party collaboration. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we may have discussions regarding such opportunities 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, we cannot estimate the timing of any such potential strategic transaction and no assurance can be given that we will enter into any such strategic transaction.

Until such time when we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to launch, market and sell Vascepa on our own. These efforts include, but are not limited to, advancing the introduction of Vascepa to managed care plans to gain formulary access, building up inventory levels, hiring key personnel and coordinating other pre-launch marketing activities.

The U.S. market is currently our primary focus for the initial commercial launch of Vascepa. Opportunities to market and sell Vascepa outside of the United States are also under evaluation.

### *January 2012 Financing and Financial Position*

On January 9, 2012, Amarin, through its wholly-owned subsidiary Corsicanto Limited, a private limited company incorporated under the laws of Ireland, completed a private placement of \$150.0 million in aggregate principal amount of its 3.5% exchangeable senior notes due 2032. The notes are the senior unsecured obligations of Corsicanto Limited and are guaranteed by Amarin. The notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2012. In July 2012 Amarin made its initial interest payments on the notes in the aggregate amount of \$2.7 million. The notes mature on January 15, 2032, unless earlier repurchased, redeemed or exchanged. On or after January 19, 2017, we may elect to redeem for cash all or a portion of the notes for the principal amount of the notes plus accrued and unpaid interest. On each of January 19, 2017, January 19, 2022 and January 19, 2027, the holders of the notes may require that we repurchase in cash the principal amount of the notes plus accrued and unpaid interest. At any time prior to January 15, 2032, upon certain circumstances, which circumstances include our issuing a notice of redemption to the note holders, the price of Amarin shares trading above 130% of the exchange price, or certain other events defined in the note agreement, the holders of the notes may elect to convert the notes. The exchange rate for conversion is 113.4752 ADSs per \$1,000 principal amount of the notes (equivalent to an initial exchange price of approximately \$8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if we pay cash dividends. Upon exchange, the notes may be settled, at Amarin's election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs. It is the Company's current intention to settle these obligations in cash.



## **Table of Contents**

As of September 30, 2012, our cash balance was \$215.1 million, including net proceeds of approximately \$144.3 million, after deducting underwriting commissions and expenses, associated with the issuance of \$150.0 million in principal amount of our 3.5% exchangeable senior notes in January 2012. We believe that we have sufficient financial resources to fund our operations at least for the next twelve months, including advancement of the REDUCE-IT cardiovascular outcomes study, and continuing the commercial preparations for and launch of Vascepa on each of the three potential paths we are considering for commercialization. Unless we enter into a strategic collaboration in support of a commercial launch, we will likely need to raise additional capital to support these efforts on our own.

### **Financial Operations Overview**

*Revenue.* We recorded no revenue in 2012 or 2011.

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

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

*Interest and Other Income (Expense), Net.* Interest expense consists of interest incurred under lease obligations, the amortization of the conversion option related to the Company's exchangeable debt, the amortization of the debt discount and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other income, net, consists primarily of foreign exchange gains and losses.

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

As a result of the issuance in January 2012 of our 3.5% exchangeable senior notes, we have included a Debt Issuance policy under our critical accounting policies at September 30, 2012. Other than this new Debt Issuance policy, at September 30, 2012, there have been no other changes in our critical accounting policies, judgments, and estimates as described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the SEC on February 29, 2012.

### **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, 2012 versus September 30, 2011***

*Revenue.* We recorded no revenue in 2012 or 2011.

*Research and Development Expense.* Research and development expense for the three months ended September 30, 2012 was \$20.9 million, versus \$6.0 million in the prior year period, an increase of \$14.9 million. Research and development expenses for the three months ended September 30, 2012 and 2011 are summarized in the table below:

**Three Months Ended  
September 30**

(in thousands)

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

	2012	2011
Research and development expenses, excluding non-cash expense (1)	\$ 19,943	\$ 5,607
Non-cash stock based compensation expense (2)	970	406
	\$ 20,913	\$ 6,013

- (1) Research and development expense, excluding non-cash charges, for the three months ended September 30, 2012 was \$19.9 million, versus \$5.6 million in the prior year period, an increase of \$14.3 million or 255%. The increase in research and development expense was due to increased costs in 2012 for our Vascepa cardiovascular program, primarily costs associated with the purchase of raw materials and vendor qualification, and increased clinical costs for the REDUCE-IT cardiovascular outcomes study. Prior to FDA approval of Vascepa on July 26, 2012, all supply purchases of Vascepa were expensed to research and development. After FDA approval, supply purchases

**Table of Contents**

of Vascepa were capitalized as a component of inventory, with the exception of clinical trial material which continues to be expensed to research and development. During the three months ended September 30, 2012, pre-approval supply purchases and vendor qualification costs were approximately \$5.7 million. During the three months ended September 30, 2012, expenses incurred for the REDUCE-IT study were approximately \$8.3 million.

- (2) Stock based compensation expense included within research and development was \$1.0 million and \$0.4 million for the three months ended September 30, 2012 and 2011, respectively.

Although clinical costs for the MARINE and ANCHOR trials have decreased as a result of their completion in 2011, we expect these cost reductions to be offset in 2012 by costs for the REDUCE-IT cardiovascular outcomes study for which dosing of initial patients commenced in December 2011 and for which the rate of patient enrollment has been increasing. Increases in research and development costs during the first half of 2012 also relate to the purchase of commercial supply of Vascepa, which supply we have included as a component of research and development expense for accounting purposes prior to FDA approval in July 2012. Purchases of commercial supply of Vascepa after FDA approval have been capitalized as a component of inventory.

*Marketing, General and Administrative Expense.* Marketing, general and administrative expense for the three months ended September 30, 2012 was \$13.4 million, versus \$3.4 million in the prior year period, an increase of \$10.0 million. Marketing, general and administrative expenses for the three months ended September 30, 2012 and 2011 are summarized in the table below:

	<b>Three Months Ended September 30</b>	
	<b>(in thousands)</b>	
	<b>2012</b>	<b>2011</b>
Marketing, general and administrative expenses, excluding non-cash expenses (1)	\$ 10,926	\$ 4,529
Non-cash stock based compensation expense (2)	3,665	2,256
Non-cash warrant related compensation expense (income) (3)	(1,194)	(3,352)
	<b>\$ 13,397</b>	<b>\$ 3,433</b>

- (1) Marketing, general and administrative expense, excluding non-cash compensation charges for stock compensation and warrants, for the three months ended September 30, 2012 was \$10.9 million, versus \$4.5 million in the prior year period, an increase of \$6.4 million, or 142%. The increase was primarily due to cost increases in 2012 for marketing research activities and medical education (approximately \$5.3 million) as well as from higher staffing levels and related travel (approximately \$1.6 million), higher facility costs and other general and administrative costs incurred in order to prepare for the commercialization of Vascepa.
- (2) Stock based compensation expense for the three months ended September 30, 2012 was \$3.7 million, versus \$2.3 million in the prior year period. This increase of \$1.4 million primarily reflects an increase in the number of awards outstanding during the period ending September 30, 2012 versus the prior period, and also in the fair value of new option awards granted to attract and retain qualified employees.
- (3) Warrant related compensation income for the three months ended September 30, 2012 was \$1.2 million, versus \$3.4 million in the prior year period. Warrant related compensation income for the period ended September 30, 2012 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former employees of Amarin, net of warrants exercised. The decrease in the fair value of the warrants for the three months ended September 30, 2012 is due primarily to a decrease in our stock price between June 30, 2012 and September 30, 2012. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses.

We expect marketing, general and administrative costs in 2012 to increase as we prepare for the commercialization of Vascepa in early 2013, including costs for market research, hiring key personnel, sales force preparation and development of management information systems. Unless we enter into a strategic collaboration in support of a commercial launch, we currently anticipate that we would hire the majority of the anticipated number of sales representatives near the end of 2012.

*Gain (loss) on Change in Fair Value of Derivative Liability.* Gain (loss) on change in fair value of derivative liability for the three months ended September 30, 2012 was a gain of \$16.5 million versus a gain of \$106.6 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 June 30, 2012 was \$120.2 million and we recognized a \$16.5 million gain on change in fair value of derivative liability for the three months ended September 30, 2012 for these warrants. The fair value of the warrant derivative liability at June 30, 2011 was \$286.0 million and we recognized

**Table of Contents**

a \$106.6 million gain on change in fair value of derivative liability for the three months ended September 30, 2011. The warrant derivative liability is decreased when warrants are exercised and the derivative liability associated with such exercised warrants is reclassified to stockholders equity. The fair value of the warrant derivative liability also decreases or increases due to decreases or increases in the price of our common stock during the reporting period as well as to changes in other variables in the Black-Scholes option valuation model used to calculate such non-cash derivative liability.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances. Interest expense includes the amortization of the exchange option related to our exchangeable debt, the amortization of the debt discount and debt obligation coupon interest. During the three months ended September 30, 2012, we recognized interest expense of \$4.7 million, of which \$2.8 million represents amortization of the debt discount, \$1.3 million represents contractual coupon interest, \$0.6 million represents the amortization of the discount from underwriter discounts and offering costs.

*Other Income (Expense), net.* Other income primarily includes unrealized loss due to the fluctuation in the exchange rate of the Laxdale accrual in the amount of \$0.5 million. Also included are gains and losses on foreign exchange transactions.

**Comparison of Nine Months Ended September 30, 2012 versus September 30, 2011**

*Revenue.* We recorded no revenue in 2012 or 2011.

*Research and Development Expense.* Research and development expense for the nine months ended September 30, 2012 was \$39.7 million, versus \$15.7 million in the prior year period, an increase of \$24.0 million. Research and development expenses for the nine months ended September 30, 2012 and 2011 are summarized in the table below:

	<b>Nine Months Ended September 30</b>	
	<b>(in thousands)</b>	
	<b>2012</b>	<b>2011</b>
Research and development expenses, excluding non-cash expense (1)	\$ 36,830	\$ 14,751
Non-cash stock based compensation expense (2)	2,905	900
	<b>\$ 39,735</b>	<b>\$ 15,651</b>

- (1) Research and development expense, excluding non-cash charges, for the nine months ended September 30, 2012 was \$36.8 million, versus \$14.8 million in the prior year period, an increase of \$22.0 million, or 148%. The increase in research and development expense was due to increased costs in 2012 for our Vascepa cardiovascular program, primarily costs associated with the purchase of raw materials and vendor qualification, and increased clinical costs for the REDUCE-IT cardiovascular outcomes study. Prior to FDA approval of Vascepa on July 26, 2012, all supply purchases of Vascepa were expensed to research and development. After FDA approval, supply purchases of Vascepa were capitalized, with the exception of clinical trial material which continues to be expensed to research and development. During the nine months ended September 30, 2012, pre-approval supply purchases and vendor qualification costs were approximately \$11.0 million. During the nine months ended September 30, 2012, expenses incurred for the REDUCE-IT study were approximately \$13.4 million.
- (2) Stock based compensation expense included within research and development was \$2.9 million and \$0.9 million for the nine months ended September 30, 2012 and 2011, respectively.

Although clinical costs for the MARINE and ANCHOR trials have decreased as a result of their completion in 2011, we expect these cost reductions to be offset in 2012 by costs for the REDUCE-IT cardiovascular outcomes study for which dosing of initial patients commenced in December 2011 and for which the rate of patient enrollment has been increasing. Increases in research and development costs during the first half of 2012 also relate to the purchase of commercial supply of Vascepa, which supply we have included as a component of research and development expense for accounting purposes prior to NDA approval. Purchases of commercial supply of Vascepa after FDA approval have been capitalized as a component of inventory.

## 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, 2012 was \$41.1 million, versus \$16.2 million in the prior year period, an increase of \$24.9 million, or 154%. Marketing, general and administrative expenses for the nine months ended September 30, 2012 and 2011 are summarized in the table below:

	<b>Nine Months Ended September 30</b>	
	<b>(in thousands)</b>	
	<b>2012</b>	<b>2011</b>
Marketing, general and administrative expenses, excluding non-cash expenses (1)	\$ 27,583	\$ 10,059
Non-cash stock based compensation expense (2)	10,439	5,122
Non-cash warrant related compensation expense (3)	3,037	1,004
	<b>\$ 41,059</b>	<b>\$ 16,185</b>

**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, 2012 was \$27.6 million, versus \$10.1 million in the prior year period, an increase of \$17.5 million, or 173%. The increase was primarily due to cost increases in 2012 for marketing research activities and medical education program development (approximately \$11.5 million) as well as from higher staffing and related travel (approximately \$3.4 million), higher facility costs and other general and administrative costs incurred in order to prepare for the commercialization of Vascepa.
- (2) Stock based compensation expense for the nine months ended September 30, 2012 was \$10.4 million, versus \$5.1 million in the prior year period, an increase of \$5.3 million primarily reflecting an increase in the number of awards outstanding during the period ending September 30, 2012 versus the prior period, and also in the fair value of new option awards granted to attract and retain qualified employees.
- (3) Warrant related compensation expense for the nine months ended September 30, 2012 was expense of \$3.0 million, versus expense of \$1.0 million in the prior year period. Warrant related compensation expense for the period ended September 30, 2012 reflects a non-cash change in fair value of the warrant derivative liability associated with warrants issued in October 2009 to three former employees of Amarin, net of warrants exercised. The increase in the fair value of the warrants for the nine months ended September 30, 2012 is due primarily to an increase in our stock price between December 31, 2011 and September 30, 2012. We anticipate that the value of this warrant derivative liability may increase or decrease from period to period based upon changes in the price of our common stock. Such non-cash changes in valuation could be significant as the history of our stock price has been volatile. The gain or loss resulting from such non-cash changes in valuation could have a material impact on our reported net income or loss from period to period. In particular, if the price of our stock increases, the change in valuation of this warrant derivative liability will add to our history of operating losses. We expect marketing, general and administrative costs in 2012 to increase as we prepare for the commercialization of Vascepa in early 2013, including costs for market research, hiring key personnel, sales force preparation and development of management information systems. Unless we enter into a strategic collaboration in support of a commercial launch, we currently anticipate that we would hire the majority of the anticipated number of sales representatives near the end of 2012.

*(Loss) Gain on Change in Fair Value of Derivative Liability.* (Loss) gain on change in fair value of derivative liability for the nine months ended September 30, 2012 was a loss of \$68.7 million versus a loss of \$53.4 million in the prior year period. (Loss) gain on change in fair value of derivative liability is related to the change in fair value of warrants issued in conjunction with the October 2009 private placement. In October 2009 we issued 36.1 million warrants at an exercise price of \$1.50 and recorded a \$48.3 million warrant derivative liability, representing the fair value of the warrants issued. As these warrants have been classified as a derivative liability, they are revalued at each reporting period, with changes in fair value recognized in the statement of operations. The fair value of the warrant derivative liability at December 31, 2011 was \$123.1 million and we recognized a \$68.7 million loss on change in fair value of derivative liability for the period ended September 30, 2012 for these warrants. 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 period ended September 30, 2011. The warrant derivative liability is decreased when warrants are exercised and the derivative liability associated with such exercised warrants is reclassified to stockholders equity. The fair value of the warrant derivative liability also decreases or increases due to decreases or increases in the price of our common stock during the reporting period as well as to changes in other variables in the Black-Scholes option valuation model used to calculate such non-cash derivative liability.

*Interest Income (Expense), net.* Interest income includes interest earned on cash balances. Interest expense includes the amortization of the conversion option related to our exchangeable debt, the amortization of the debt discount and debt obligation coupon interest. During the nine months ended September 30, 2012, we recognized interest expense of \$13.2 million, of which \$7.8 million represents amortization of the debt discount, \$3.8 million represents contractual coupon interest, \$1.6 million represents the amortization of the discount from underwriters discounts and offering costs.

*Other Income (Expense), net.* Other income primarily includes unrealized loss due to the fluctuation in the exchange rate of the Laxdale accrual in the amount of \$0.5 million. Also included are gains and losses on foreign exchange transactions.

**Liquidity and Capital Resources**

Our sources of liquidity as of September 30, 2012 include cash and cash equivalents of \$215.1 million. In January 2012 we completed a convertible debt offering from which we received approximately \$144.3 million in net proceeds. Our projected uses of cash include the continued funding of the REDUCE-IT study, continued commercial preparation for and launch of Vascepa, working capital and other general corporate activities. Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table (in millions):

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
Cash (used in) provided by continuing operations:		
Operating activities	\$ (78.5)	\$ (27.8)
Investing activities	(1.7)	(1.7)
Financing activities	178.7	123.9
Increase in cash and cash equivalents	\$ 98.5	\$ 94.4

---

**Table of Contents**

We had no debt obligations at December 31, 2011.

On January 9, 2012, Amarin, through our wholly-owned subsidiary Corsicanto Limited, a private limited company incorporated under the laws of Ireland, completed a private placement of \$150.0 in aggregate principal amount of its 3.5% exchangeable senior notes due 2032. The proceeds received by Amarin from the January 2012 debt offering were approximately \$144.3 million, net of fees and transaction costs. These notes were issued pursuant to an indenture dated as of January 9, 2012, by and among Corsicanto Limited, Amarin Corporation plc as guarantor, and Wells Fargo Bank, National Association, as trustee. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. The notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2012. The notes mature on January 15, 2032, unless earlier repurchased, redeemed or exchanged. On or after January 19, 2017, we may elect to redeem for cash all or a portion of the notes for the principal amount of the notes plus accrued and unpaid interest. On each of January 19, 2017, January 19, 2022 and January 19, 2027, the holders of the notes may require that we repurchase in cash the principal amount of the notes plus accrued and unpaid interest. At any time prior to January 15, 2032, upon certain circumstances, which circumstances include our issuing a notice of redemption to the note holders, the price of Amarin shares trading above 130% of the exchange price, or certain other events defined in the note agreement, the holders of the notes may elect to convert the notes. The exchange rate for conversion is 113.4752 ADSs per \$1,000 principal amount of the notes (equivalent to an initial exchange price of approximately \$8.8125 per ADS), subject to adjustment in certain circumstances, including adjustment if we pay cash dividends. Upon exchange, the notes may be settled, at Amarin's election, subject to certain conditions, in cash, ADSs or a combination of cash and ADSs. It is the Company's current intention to settle these obligations in cash.

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 associated with this transaction.

We believe that our cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months, including advancement of the REDUCE-IT cardiovascular outcomes study, continuing commercial preparations for and launch of Vascepa, working capital and other general corporate activities.

Our future capital requirements will depend on, and could be affected materially by, numerous forward-looking factors, including:

the terms, timing and receipt of payments, if any, from any strategic collaboration we may enter into to support the marketing and sale of Vascepa;

the cost and timing of establishing marketing and sales capabilities if we do not enter into a strategic collaboration to market and sell Vascepa;

the rate of progress and cost of our ongoing REDUCE-IT outcomes trial, the need, if any, to conduct additional clinical trials and other development activities for the regulatory approval of Vascepa in additional indications in the United States and internationally;

the decisions by regulatory authorities regarding regulatory exclusivity with respect to our approved applications, in particular as it relates to Vascepa;

the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the success of the commercial launch of Vascepa.

We may seek to raise additional funds to:

purchase commercial supply of Vascepa;

facilitate our efforts to establish marketing and sales capabilities to market and sell Vascepa in the United States;

further develop Vascepa to meet the requirements for regulatory approval of Vascepa for additional indications in the United States and internationally; and

develop internally, acquire or in-license new products, technologies or businesses or to otherwise fund our operations.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. There can be no assurance that funding, if needed, will be available on attractive terms, or at all. Furthermore, any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Similarly, financing obtained through future collaborations may require us to forego certain commercialization rights to our drug candidates in certain jurisdictions. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to successfully pursue our business strategy.

**Table of Contents****Contractual Obligations**

The following table summarizes our contractual obligations at September 30, 2012 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	2012	2013 to 2014	2015 to 2016	After 2016
<b>Contractual Obligations:</b>					
Purchase obligations (1)	\$ 27.7	\$ 19.8	\$ 7.9	\$ 0	\$ 0
Operating lease obligations (2)	1.0	0.2	0.8	0	0
Interest payment obligations (3)	7.9	0	7.9	0	0
<b>Total contractual cash obligations</b>	<b>\$ 36.6</b>	<b>\$ 20.0</b>	<b>\$ 16.6</b>	<b>\$ 0</b>	<b>\$ 0</b>

(1) Represents minimum purchase obligations under our supply agreement with Nisshin as of September 30, 2012. We paid \$10.8 million during the nine months ended September 30, 2012 and as of September 30, 2012 had additional purchase obligations of \$27.7 million. In preparation for the commercialization of Vascepa we may purchase more than the minimum amount.

We also anticipate incurring certain costs associated with the qualification of product produced by Nisshin. 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, Bedminster, NJ, and Groton, CT.

(3) Represents interest payments due under the terms of our 3.5% exchangeable senior notes ( notes ) due 2032, assuming they remain outstanding for 24 months and have not been exchanged for ADRs. The above table does not reflect the repayment of the \$150.0 million notes as they may be exchanged for ADRs.

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

The above table also does not reflect potential material purchases under the API supply agreements signed during 2011 with two additional API suppliers, or an additional supplier signed in July 2012. These agreements provide access to additional API supply that is incremental to supply from Nisshin Pharma, our existing API supplier. Each of these API agreements contemplates a phased capacity expansion plan aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa following commercial launch. 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. These agreements include annual purchase levels enabling Amarin to maintain supply exclusivity with each respective supplier, and to prevent potential termination of the agreements. These minimum purchase levels do not contractually begin until the applicable supplemental NDA, or sNDA, for the supplier is approved by the FDA, if ever, and upon the achievement of manufacturing capacity expansion. Accordingly, these amounts are excluded from the above table. The two supply agreements entered into in 2011 also include (i) development fees up to a maximum of \$0.5 million, (ii) material commitments of up to \$5.0 million for initial raw materials, which will be credited against future API purchases, and is refundable to us if a supplier does not successfully develop and qualify the API by a certain date and (iii) a raw material purchase commitment of \$1.1 million. The agreement with the fourth API supplier, when all contingencies are eliminated by the supplier, provides for development fees of up to \$2.3 million and a commitment of up to \$15.0 million, which will be credited against future API material purchases. During the period commencing October 1, 2012 through the expected launch of Vascepa in early 2013, we estimate that we may spend \$20 to \$30 million to build inventory levels of API and Vascepa capsules, including the contractual purchase obligations for this period described above plus potential additional purchases of API that we may elect to purchase.

Concurrent with our supply agreements with one of the two agreements entered into in 2011 for the supply of API materials for Vascepa, we agreed to make a minority share equity investment in the supplier of up to \$3.3 million. In July 2011, we paid to the supplier \$1.7 million, which

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

has been included in other long term assets at December 31, 2011 and September 30, 2012. Under this agreement, we paid an additional \$0.8 million in April 2012, which has also been included in other long term assets at September 30, 2012. We invested an additional \$0.4 million under this agreement, as amended in July 2012, and anticipate making the remaining \$0.4 million investment before the end of 2012.

Under our 2004 share repurchase agreement with Laxdale Limited, in connection with any commercialization of Vascepa 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 \$161.6 million at September 30, 2012); 0.5% for net sales between £100 million (approximately \$161.6 million at September 30, 2012) and £500 million (approximately \$808.2 million at September 30, 2012); and 0.25% for sales in excess of £500 million (approximately \$808.2 million at September 30, 2012). These royalty obligations terminate on December 31, 2012.

## **Table of Contents**

Under this same agreement with Laxdale Limited, upon receipt of marketing approval in the United States and/or Europe for the first indication for Vascepa (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 \$12.1 million at September 30, 2012) for each of the two potential marketing approvals (i.e., £15 million maximum, or approximately \$24.2 million at September 30, 2012). In addition, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (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 \$8.1 million at September 30, 2012) for each of the two potential market approvals (i.e. £10 million maximum, or approximately \$16.2 million at September 30, 2012). Upon FDA approval of Vascepa for commercial marketing in the United States in July 2012, we accrued the liability associated with the former shareholders of Laxdale Limited, which is expected to be paid in the fourth quarter of 2012.

In addition to the obligations in the table above, we have approximately \$0.7 million of liability for uncertain tax positions that have been recorded in long-term liabilities at December 31, 2011 and September 30, 2012. 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 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.

At September 30, 2012, we record as a liability the fair value of warrants to purchase 8.1 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 (\$13.84 based on the \$12.58 market price of our stock at September 28, 2012) on which the September 30, 2012 valuation was based, the value would have increased by \$10.1 million. Such increase would have been reflected as additional loss 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, 2012 (the Evaluation Date), 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 the Evaluation Date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the third quarter of 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than described below.

**Table of Contents****PART II****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 legal or arbitration proceedings and claims cannot be predicted with certainty, as of September 30, 2012, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position or profitability. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material legal or arbitration in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

**Item 1A. Risk Factors**

*This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product and product candidates, regulatory filings, approvals and determinations related to marketing exclusivity, commercialization activities, the likelihood of a strategic collaboration, the potential clinical benefits and market potential of our product and product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.*

*Those risk factors below denoted with a \* are newly added or have been materially updated from our Annual Report on 10-K filed with the SEC on February 29, 2012.*

**Risks Related to our Financial Position and Capital Requirements**

***We have a history of losses and anticipate that we will incur continued losses at least until we successfully commercialize Vascepa.***

We have not been profitable in any of the last five fiscal years. For the fiscal years ended December 31, 2011, 2010, and 2009, we reported losses of approximately \$69.1 million, \$249.6 million, and \$30.6 million, respectively. Our net loss for the three and nine months ended September 30, 2012 was \$26.4 million and \$168.6 million, respectively, and we had an accumulated deficit at September 30, 2012 of \$737.1 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and from non-cash losses on changes in the fair value of warrant derivative liabilities. We expect to incur additional and increasing operating losses at least until we successfully commercialize Vascepa. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital. We expect our research and development expenses to be substantial for both 2012 and 2013 in connection with our proposed clinical outcomes study for Vascepa and other activities. In addition, we may incur significant sales, marketing, in-licensing and outsourced manufacturing expenses as we attempt to commercialize Vascepa. Our shift in focus from research and development to commercialization, and the changes in operating costs relating to that shift, will also require us to make changes to our accounting results and procedures, which may have an adverse effect on our reported revenue or profit, if any.

As a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant and increasing operating losses at least until we successfully commercialize Vascepa. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses.

***We have not generated any revenue from Vascepa and may never be profitable.\****

Our ability to become profitable depends upon our ability to generate revenue. Despite gaining FDA marketing approval for Vascepa for use in the MARINE indication, we may not be able to generate sufficient revenue to attain profitability. Our ability to generate profits on sales of Vascepa is subject to our ability to manufacture commercial quantities of Vascepa through third parties at acceptable cost levels and establish sales and marketing capabilities or identify and enter into one or more strategic collaborations to effectively market and sell Vascepa.

Even though Vascepa has been approved by the FDA for marketing and commercial sale for the MARINE indication, it may not gain market acceptance or achieve commercial success and it may never be approved for the ANCHOR indication. In addition, we anticipate incurring significant costs associated with commercializing Vascepa. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient product revenues, we will not become profitable and may be unable to continue operations without continued funding.

*Our ability to generate increased revenue depends, in part, on obtaining additional regulatory approvals for Vascepa.\**

The costs of developing and obtaining regulatory approvals for pharmaceutical products can be substantial. While we are permitted to begin commercializing Vascepa for use in the MARINE indication in the United States, our ability to commercialize Vascepa in the ANCHOR

---

## **Table of Contents**

indication and outside of the United States is dependent upon receiving additional regulatory approvals. Further, our ability to file a supplemental new drug application, or sNDA, with the FDA for the use of Vascepa in the ANCHOR indication is dependent on our ability to reach substantial enrollment in our REDUCE-IT cardiovascular outcomes study. Enrollment in the REDUCE-IT cardiovascular outcomes study may take longer than we expect, in which case we may be delayed in our ability to file an sNDA for the use of Vascepa in the ANCHOR indication. Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize products successfully. For example, if the approval process for the ANCHOR indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Additionally, the terms of any approvals, including the approval received by the FDA in July 2012 for the MARINE indication, may not have the scope or breadth needed for us to commercialize Vascepa successfully.

### ***Our historical financial results do not form an accurate basis for assessing our current business.\****

As a consequence of the approval of our NDA for Vascepa in the MARINE indication, our historical financial results do not form an accurate basis upon which investors should base their assessment of our business and prospects. In addition, we expect that our costs will increase substantially as we begin to commercialize Vascepa in the MARINE indication and seek to obtain additional regulatory approval of Vascepa in the ANCHOR indication, including the continuation of the REDUCE-IT cardiovascular outcomes study. Accordingly, our historical financial results reflect a substantially different business from that currently being conducted and from that expected in the future. In addition, we have a limited history of obtaining regulatory approval for, and no demonstrated ability to successfully commercialize, a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

### ***We will require substantial additional resources to fund our operations. 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, 2012, we had cash and cash equivalents of approximately \$215.1 million. We believe that our current resources will be sufficient to fund our projected operations for at least the next twelve months, which projected operations contemplate not only working capital and general corporate needs but also continuing the commercial preparation of Vascepa and the REDUCE-IT cardiovascular outcomes study, working capital and other general corporate activities. However, in order to successfully commercialize Vascepa, we must either successfully 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 Vascepa. Although from time to time 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 currently working to launch, market and sell Vascepa 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 Vascepa, we will likely need to raise additional capital to fully support these efforts. We will also need additional capital to fully complete our REDUCE-IT cardiovascular outcomes trial.

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 Vascepa and the terms of any such collaboration;

the continued cost associated with the REDUCE-IT cardiovascular outcomes study to support the filing of an sNDA for the clinical indication evaluated in the ANCHOR trial;

the time and costs involved in obtaining additional regulatory approvals for Vascepa;

the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the costs associated with commercializing Vascepa for the MARINE indication in the United States and for additional indications in the United States and in jurisdictions in which we receive regulatory approval, if any, including the cost and timing of developing sales and marketing capabilities, or the cost and timing of securing commercial supply of Vascepa and the timing of entering into strategic collaboration with others relating to the commercialization of Vascepa, if at all.

If adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, and we do not enter into a collaboration agreement to help support the commercialization of Vascepa, our commercialization efforts for Vascepa may suffer materially, or we may need to delay the advancement of the REDUCE-IT cardiovascular outcomes trial.

*Continued negative economic conditions would likely have a negative impact on our ability to obtain financing on acceptable terms.*

While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our current operations or expand development programs for Vascepa, or that there will not be a further deterioration in financial markets and confidence in economies. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies.

---

## **Table of Contents**

### ***Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights.\****

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder.

As of September 30, 2012, there were warrants outstanding for the purchase of up to 10,224,339 American Depository Shares, or ADSs, each representing one of our ordinary shares, with a weighted average exercise price of \$1.43 per share. We may issue additional warrants to purchase ADSs or ordinary shares in connection with any future financing we may conduct. In addition, on January 9, 2012, we issued \$150 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, or the notes. The notes are exchangeable under certain circumstances into cash, our ADS, or a combination of cash and ADS, at our election, with a current exchange rate of 113.4752 ADS per \$1,000 principal amount of notes. Although we intend to settle these notes in cash, if we elected physical settlement, the notes would initially be exchangeable into 17,021,280 ADS.

Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. 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, Vascepa or product candidates, or grant licenses on terms that are not favorable to us.

### ***Potential business combinations or other strategic transactions may disrupt our business or divert management's attention.***

On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party, exclusive licenses of Vascepa or other strategic transactions or collaborations with third parties. The consummation and performance of any such future transactions or collaborations will involve risks, such as:

diversion of managerial resources from day-to-day operations;

exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;

misjudgment with respect to the value;

higher than expected transaction costs; or

an inability to successfully consummate any such transaction or collaboration.

As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders. If we are unsuccessful in consummating any such transaction or collaboration, we may be required to reevaluate our business only after we have incurred substantial expenses and devoted significant management time and resources.

### **Risks Related to the Development and Commercialization of Vascepa**

#### ***We are dependent upon the success of Vascepa, which only recently obtained FDA approval in the MARINE indication.\****

If commercialization efforts for Vascepa in the MARINE indication or, if approved, the ANCHOR indication, are not successful, or if adequate demand for Vascepa is not generated, our business will be materially and adversely affected. Even if we are able to develop additional products from our research and development efforts, the development time cycle for products typically takes several years. This restricts our ability to respond to adverse business conditions for Vascepa. If we are not successful in developing any future product or products, or if there is not adequate demand for Vascepa or the market for such product develops less rapidly than we anticipate, we may not have the ability to effectively shift our resources to the development of alternative products. As a result, the limited range of products we develop could constrain our ability to

generate revenues and achieve profitability.

***Vascepa may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.\****

Even though Vascepa has received marketing approval for the MARINE indication in July 2012, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of Vascepa for the MARINE indication and any future approved indications will depend on a number of factors, including:

efficacy and potential advantages compared to alternative treatments;

the ability to offer Vascepa for sale at competitive prices;

---

**Table of Contents**

convenience and ease of administration compared to alternative treatments;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the strength of marketing and distribution support;

sufficient third-party coverage or reimbursement; and

the prevalence and severity of any side effects.

***We may not be able to compete effectively against our competitors' pharmaceutical products.***

The pharmaceutical industry is highly competitive. In attempting to achieve the widespread commercialization of Vascepa, we will face competition to the extent other pharmaceutical companies have on the market or are able to develop products for the treatment of similar indications. Potential competitors in this market include companies with greater experience in commercializing pharmaceutical products, resources and name recognition than we have. Furthermore, to the extent we are able to acquire or develop additional marketable products in the future, such products will compete with a variety of other products within the United States or elsewhere, possibly including established drugs and major brand names. Competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our future products. Products based on new technologies or new drugs could render our products obsolete or uneconomical.

The success of Vascepa and any of our future products will also depend in large part on the willingness of physicians to prescribe these products to their patients. Vascepa will, and our future products may, compete against products that have achieved broad recognition and acceptance among medical professionals. In order to achieve an acceptable level of prescriptions for Vascepa or any future product, we must be able to meet the needs of both the medical community and end users with respect to cost, efficacy and other factors.

Our potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and Abbott Laboratories, which currently markets Tricor and Trilipix for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the United States market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. We expect Apotex to compete against us as well. Other companies are also seeking to introduce generic versions of Lovaza. These competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) which is being developed by Omthera Pharmaceuticals, which announced initial top-line data from its first Phase 3 clinical trial in April 2012 and its second in November 2012, and Trygg Pharma, which has completed a Phase 3 study of an omega-3 based drug candidate for hypertriglyceridemia, but to our knowledge Trygg has not yet announced results from that study. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2011 the enrollment of its Phase 2 clinical trial to assess the safety and efficacy of its omega-3 prescription drug candidate for the treatment of hypertriglyceridemia. We believe Resolvix Pharmaceuticals and Catabasis Pharmaceuticals are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids but, to our knowledge, neither has initiated a Phase 2 clinical trial of its product. In addition, we are aware that Essentials, Inc is developing a controlled release diazoxide product for the treatment of hypertriglyceridemia. Essentials, Inc. has reported that they have completed five Phase 1 clinical studies and two Phase 2 clinical studies with this product.

Vascepa will also face competition from dietary supplement companies marketing naturally occurring omega-3 fatty acids as nutritional supplements.

***Vascepa is a prescription-only omega-3 fatty acid. Omega-3 fatty acids are also marketed by other companies as non-prescription dietary supplements. As a result, Vascepa would be subject to non-prescription competition and consumer substitution.***

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

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. To the extent the price of Vascepa is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements through that lack of coverage by insurers or otherwise, physicians may recommend these commercial alternatives instead of writing prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa.

---

## **Table of Contents**

***To maximize the commercial potential of Vascepa we must either develop a sales, marketing and distribution infrastructure or find collaborative partners to help market and sell the product.\****

To commercialize Vascepa, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have such experience. We are actively exploring such collaboration opportunities with these parties for the launch, marketing and sale of Vascepa. Until such time when we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to launch, market and sell Vascepa on our own. 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.

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 continued development of Vascepa for approval for additional indications and reduce the scope of our sales or marketing activities, or increase our planned expenditures and undertake additional 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 may not be able to market and sell Vascepa effectively, and generate as much product revenue, as we could under collaboration.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market Vascepa, we may not be successful in commercializing Vascepa on our own.***

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. Until such time as we complete a strategic transaction with a third party to market and sell Vascepa, if ever, we are continuing to execute on our plans to launch, market and sell Vascepa on our own. This includes making preparations for securing sufficient commercial supply of Vascepa, expanding sales and marketing capabilities building a substantial commercialization infrastructure to compete with larger companies that have larger and more established marketing and sales capabilities. We have only limited sales and marketing capabilities and infrastructure and as a company we have no experience in the sale, marketing or distribution of pharmaceutical products. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. Our effort to develop a sales and marketing organization may not be successful, and thus we may not be able to effectively market or sell Vascepa. For example, recruiting and training a sales force is expensive and time consuming and could delay our ability to become profitable. If the widespread commercialization of Vascepa for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market Vascepa or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with

third parties, we will not be successful in commercializing Vascepa.

***There can be no assurance that Vascepa will be approved for indications other than the MARINE indication.***

The FDA granted marketing approval for the use of Vascepa in the MARINE indication on July 26, 2012. Despite this approval, the FDA may deny approval of subsequent applications with respect to other indications and require additional testing or data. If the FDA takes any such action, such actions would have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

***Our SPAs with the FDA are not guarantees of FDA approval of Vascepa for the subject indications.***

A Special Protocol Assessment, or SPA, is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. The ANCHOR trial was, and the REDUCE-IT trial is, being conducted under an SPA

---

**Table of Contents**

with the FDA. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the ANCHOR trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. An SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. Even though we have received regulatory approval of Vascepa for the MARINE indication, there is no assurance that the FDA will not identify a scientific issue and deem either or both of the ANCHOR or REDUCE-IT SPAs no longer binding. Moreover, any change to a study protocol after agreement with the FDA is reached can invalidate an SPA. While we amended the protocol for the ANCHOR trial after the initial SPA evaluation was completed, we obtained the FDA's evaluation of, and agreement to, the amendment. If, for example, the FDA does not consider the applicable SPA to be binding during its review of our regulatory approval applications, or if the FDA determines that we did not follow the SPAs appropriately, the agency could assert that additional studies or data are required to support approval of the application.

***The commercial value to us of the MARINE and ANCHOR indications may be smaller than we anticipate.***

There can be no assurance as to the adequacy for commercial success of the scope and breadth of the MARINE indication or, if approved, the ANCHOR indication. Even if we obtain marketing approval for additional indications, 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. Also, with regard to the MARINE indication and any other indications for which we may gain approval, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential for our product candidate would suffer.

***Our products will be subject to extensive post-approval government regulation.***

Once a product candidate receives FDA marketing approval, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations enforced by the FDA and other regulatory bodies, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the approved application. Application holders must also submit advertising and other promotional material to regulatory authorities and report on ongoing clinical trials.

With respect to sales and marketing activities, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's current good manufacturing practice requirements, or cGMPs. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we or our potential partners comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We or our potential partners must also compete against other products in qualifying for coverage and reimbursement under applicable third party payment and insurance programs.

***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 fines and other 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. Even though we receive marketing approval for Vascepa for the MARINE indication only, physicians may nevertheless prescribe Vascepa 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 government fines and other related liability. For example, 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.

---

**Table of Contents**

In addition, incentives exist under applicable law that encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. Such lawsuits, whether with or without merit, are typically time consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

***Our cardiovascular outcomes study, REDUCE-IT, may take longer than we anticipate to be determined by the FDA to be substantially underway, which could delay FDA review and approval of the ANCHOR indication and cost more than we expect.***

Based on our communications with the FDA, in order to obtain FDA marketing approval of a separate indication for the use of Vascepa in the treatment of patients with high triglyceride levels who are also on statin therapy for elevated LDL-cholesterol levels (which we refer to as mixed dyslipidemia), or the ANCHOR indication, we believe that, in addition to achieving marketing approval for the MARINE indication as occurred in July 2012, we must have a cardiovascular outcomes study substantially underway at the time of the supplemental NDA, or sNDA, submission. In August 2011, we reached an agreement with the FDA on an SPA for the design of the REDUCE-IT cardiovascular outcomes study of Vascepa, and we began dosing patients in December 2011. In the event we experience delays in initiating or achieving substantial enrollment for REDUCE-IT or the FDA requires that we enroll more patients, our filing of an sNDA seeking approval of the ANCHOR indication will be delayed. In addition, to the extent that we experience delays or need to take actions to prevent delays in the REDUCE-IT cardiovascular outcomes study, the cost of this study will increase. The cost of this study is based on estimates and is not capped. We currently intend to file an sNDA seeking approval of the indication studied in the ANCHOR trial after we believe the REDUCE-IT study will be determined to be substantially underway by the FDA.

***The REDUCE-IT cardiovascular outcomes trial may fail to achieve its clinical endpoints, and the long-term clinical results of Vascepa 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 Vascepa on lipids and no outcomes study has been conducted evaluating Vascepa. Outcomes studies of certain other lipid modifying therapies have failed to achieve the endpoints of such studies.

For example, in September 2012, researchers published in the *Journal of the American Medical Association*, or *JAMA*, the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations, which meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. We believe the results of the *JAMA* meta-analysis may not be directly applicable to the use of Vascepa over time. For instance, nineteen of the twenty studies included in the *JAMA* meta-analysis involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. Vascepa is comprised of not less than 96% pure ethyl-EPA and contains no DHA, and has been approved by the FDA for use in patients with severe hypertriglyceridemia at the 4 grams per day dose. The only other outcomes study involving the use of a highly-pure formulation of EPA containing no DHA, called the Japan EPA Lipid Intervention Study, suggested that use of this formulation, called Epadel in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone.

Although we believe the results of the *JAMA* meta-analysis and other studies are not directly applicable to the potential long-term clinical experience with Vascepa, 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 Vascepa in REDUCE-IT or any other study of Vascepa 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 12-week clinical results it could prevent us from expanding the label of any approved product or even call into question the efficacy of any approved product.

***We may not be successful in developing or marketing future products if we cannot meet the extensive regulatory requirements of the FDA and other regulatory agencies for quality, safety and efficacy.***

The success of our research and development efforts is dependent in part upon our ability, and the ability of our partners or potential partners, to meet regulatory requirements in the jurisdictions where we or our partners or potential partners ultimately intend to sell such products once approved. The development, manufacture and marketing of pharmaceutical products are subject to extensive regulation by governmental authorities in the United States, the European Union, Japan and elsewhere. In the United States, the FDA generally requires pre-clinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before its introduction into the market. Regulatory authorities in other jurisdictions impose similar requirements. The process of obtaining regulatory approvals is lengthy and expensive and the issuance of such approvals is uncertain. The commencement and rate of completion of clinical trials and the timing of obtaining marketing approval from regulatory authorities may be delayed by many factors, including:

the lack of efficacy during clinical trials;

the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices for use in clinical trials;

---

**Table of Contents**

slower than expected rates of patient recruitment;

the inability to observe patients adequately after treatment;

changes in regulatory requirements for clinical or preclinical studies;

the emergence of unforeseen safety issues in clinical or preclinical studies;

delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site;

unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy; and

government or regulatory delays or clinical holds requiring suspension or termination of a trial.

Even if we obtain positive results from early stage pre-clinical or clinical trials, we may not achieve the same success in future trials. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer. For example, the efficacy results of our Vascepa Phase 3 clinical trials for the treatment of Huntington's disease were negative. As a result, we stopped development of that product candidate, revised our clinical strategy and shifted our focus to develop Vascepa for use in the treatment of cardiovascular disease.

Any approvals that are obtained may be limited in scope, may require additional post-approval studies or may require the addition of labeling statements focusing on product safety that could affect the commercial potential for our product candidates. Any of these or similar circumstances could adversely affect our ability to earn revenues from the sale of such products. Even in circumstances where products are approved by a regulatory body for sale, the regulatory or legal requirements may change over time, or new safety or efficacy information may be identified concerning a product, which may lead to the withdrawal of a product from the market or similar use restrictions. The discovery of previously unknown problems with a product or in connection with the manufacturer of products may result in restrictions on that product or manufacturer, including withdrawal of the product from the market, which would have a negative impact on our potential revenue stream.

***Legislative or regulatory reform of the health care system in the United States and foreign jurisdictions may affect our ability to profitably sell Vascepa.***

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, PPACA establishes:

An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;

A new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period; and

A new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by PPACA and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

---

## **Table of Contents**

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 6 to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of Vascepa to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

*As we evolve from a company primarily involved in research and development to a company also focused on commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.*

Although certain of our employees have commercialization experience, as a company we currently have no sales, marketing or distribution capabilities. Accordingly, as we prepare for the commercial launch of Vascepa, we are expanding our organization, including marketing and sales capabilities and exploring contracting with third parties to provide these capabilities for us, all of which are expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of Vascepa. If we are not successful in commercializing Vascepa, our future product revenue will suffer and we may incur significant additional losses.

As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize Vascepa and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

### **Risks Related to our Reliance on Third Parties**

*Our supply of product for commercial supply and clinical trials is dependent upon relationships with third party manufacturers and key suppliers.\**

We have no in-house manufacturing capacity and rely on contract manufacturers for our clinical and commercial product supply. We cannot assure you that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with our third party manufacturers. Moreover, if any manufacturer should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all.

Any manufacturing problem, natural disaster affecting manufacturing facilities, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and result in lost sales. If our suppliers were unable to supply us with adequate supply of ethyl-EPA it would have a material adverse effect on our ability to continue to commercialize Vascepa.

We currently purchase all of our supply of the bulk compound (ethyl-EPA), which constitutes the only active pharmaceutical ingredient, or API, of Vascepa, from a single supplier, Nisshin Pharma, or Nisshin, located in Japan. Nisshin currently obtains its supply of the key raw material to manufacture API from another third party single source of supply. While we have contractual freedom to source the API for Vascepa elsewhere and have entered into supply agreements with additional suppliers who rely on other third party suppliers of the key raw material to manufacture the API for Vascepa, Nisshin is the only supplier approved with our NDA to the FDA.

We intend to purchase increasing amounts of API in preparation for the commercial launch of Vascepa. Our strategy is to expand manufacturing capacity and to partially mitigate the risk of reliance on too few suppliers by having multiple API suppliers beyond Nisshin. Expanding manufacturing capacity and qualifying such capacity is difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers are limited and costs associated with projected expansion and qualification can be significant. The resources of our suppliers vary. For example, Chemport, which is one of the API suppliers that we see to qualify, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources, including the \$3.3 million that we invested in Chemport as part of our agreement with them. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA, our API supply will be limited to the API we purchase from

Nisshin. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for Vascepa.

**Table of Contents**

We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements.

We currently rely on two suppliers, Banner and Catalent, for the encapsulation of API for all capsules of Vascepa. While we have contractual freedom to source the API encapsulation for Vascepa elsewhere, Banner and Catalent are the only encapsulators approved by the FDA for encapsulation of API for Vascepa. There can be no guarantee that additional other suppliers with which we have contracted to encapsulate API will be qualified to manufacture the product to our specifications or that these and any future suppliers will have the manufacturing capacity to meeting anticipated demand for Vascepa. We cannot assure you that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements.

***We have no experience with the commercial sale of Vascepa and thus our purchase of API and encapsulation of API in anticipation of expected demand may not be correct. We may purchase too much or not enough supply to satisfy actual demand, which could have a material adverse effect on our financial results and financial condition.\****

Our agreements with our suppliers typically include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling twelve-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. We have no experience with the commercial sale of Vascepa, and as such expectations regarding expected demand may be wrong. We may not purchase sufficient quantities of Vascepa to meet actual demand or our purchase of supply may exceed actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

***The manufacture and packaging of pharmaceutical products such as Vascepa are subject to FDA requirements and those of similar foreign regulatory bodies. If we or our third party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.***

The manufacture and packaging of pharmaceutical products, such as Vascepa, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these current good manufacturing practices regulations who are both capable of manufacturing Vascepa and willing to do so. Failure by us or our third party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. For example, our NDA approved by the FDA had only one supplier of API for Vascepa, Nisshin, and Nisshin has plans to expand its capacity to supply API to us by further expanding their current facility. If we are not able to manufacture Vascepa to required specifications through Nisshin, we may be delayed in successfully launching the product and our anticipated future revenues and financial results may be materially adversely affected.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's current good manufacturing practices, or cGMPs. Any new facility may be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay or prevent the launch of a product. For example, we plan to file a supplemental NDA to add new manufacturing facilities from other third party suppliers to manufacture API for Vascepa. If these third parties cannot establish, to the satisfaction of the FDA, that they are in substantial compliance with cGMPs, and that the products manufactured at the new site meet FDA requirements, we may not be able to manufacture API from that site, our supply of API for Vascepa may be delayed, and our anticipated future revenues and financial results may be materially adversely affected.

Furthermore, the FDA and foreign regulatory agencies require that we be able to consistently produce the active pharmaceutical ingredient and the finished product in commercial quantities and of specified quality on a repeated basis, including proven product stability, and document our ability to do so. This requirement is referred to as process validation. We have not yet completed all of the steps and documentation necessary to validate processes and product stability for the API for Vascepa at any API contract supplier other than Nisshin. Each of our potential API suppliers uses a different method to manufacture API than that used by Nisshin, which has the potential to increase the risk to us that our manufacturers will not meet applicable regulatory requirements. This includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, the launch of Vascepa or commercial supply after launch may be delayed, or we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand.

The FDA and similar foreign regulatory bodies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to

regulatory, civil actions or penalties which could significantly and adversely affect our business.

---

## **Table of Contents**

During 2012, we are increasing our purchases of API and finished capsules of Vascepa to further expand purchase levels of supply. We may elect to make API purchases from certain of our suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases from other suppliers, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, our reaching profitability may be delayed.

***We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such clinical trials.***

Our reliance on third parties for clinical development activities reduces our control over these activities. However, if we sponsor clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

### **Risks Related to our Intellectual Property and Regulatory Exclusivity**

***We are dependent on patents, proprietary rights and confidentiality. Our patent portfolio directed to the formulation and uses of Vascepa is still evolving and some patent applications may not issue prior to commercial launch, if ever.\****

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and trade secret protection for new technologies, products and processes. Our ability to successfully implement our business plan will depend in large part on our ability to:

obtain, defend and maintain patent protection and market exclusivity for our current and future products;

preserve any trade secrets relating to our current and future products;

acquire patented or patentable products and technologies; and

operate without infringing the proprietary rights of third parties.

Our patent portfolio directed to the formulation and uses of Vascepa is still evolving and some patent applications may not issue prior to commercial launch, if ever. We currently have two issued U.S. patents directed to a pharmaceutical composition of Vascepa in a capsule that have terms that expire in 2020 and 2030, respectively, one issued U.S. patent covering highly pure EPA which expires in 2021, two additional U.S. patents covering the use of Vascepa that have terms that expire in 2030, and have received Notices of Allowance from the United States Patent and Trademark Office, or USPTO, for three additional patent applications that have terms that expire in 2030 and are related to the use of Vascepa and potentially competitive products. A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. A Notice of Allowance does not afford patent protection until the underlying patent is issued by the USPTO. No assurance can be given that our issued patents and our pending patents, if and when issued, will prevent competitors from competing with Vascepa.

We may be dependent in some cases upon third party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 go into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

Although we intend to make reasonable efforts to protect our current and future intellectual property rights and to ensure that any proprietary technology we acquire or develop does not infringe the rights of other parties, we may not be able to ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our current or future products or technologies. In addition, third parties may be able to obtain patents that prevent the sale of our current or future products or require us to obtain a license and pay significant fees or royalties in order to continue selling such products.

We may in the future discover the existence of products that infringe upon patents that we own or that have been licensed to us. If we were to initiate legal proceedings against a third party to stop such an infringement, such proceedings could be costly and time consuming, regardless of the outcome. No assurances can be given that we would prevail, and it is possible that, during such a proceeding, our patent rights could be held to be invalid, unenforceable or both. Although we intend to protect our trade secrets and proprietary know-how through confidentiality agreements with our manufacturers, employees and consultants, we may not be able to prevent parties subject to such confidentiality agreements from breaching these agreements or third parties from independently developing or learning of our trade secrets.

---

**Table of Contents**

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approvals. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, even if the opposition or challenge has little or no merit. Patent opposition proceedings and challenges are generally highly technical, time consuming and expensive to pursue. Were we to be subject to one or more patent oppositions or challenges, that effort could consume substantial time and resources, with no assurances of success, even when holding an issued patent.

***Our issued patents and our pending patents, if and when issued, may not prevent competitors from competing with Vascepa.\****

We plan to vigorously defend our rights under issued patents. Other drug companies may challenge the validity, enforceability or both of the our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of Vascepa or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. Any such competition could undermine sales, marketing and collaboration efforts for Vascepa, and thus reduce, perhaps materially, the revenue potential for Vascepa.

Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion.

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

We have filed and are prosecuting numerous families of patent applications in the United States and internationally with claims designed to protect the proprietary position of Vascepa. 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 what we believe are unexpected and favorable findings from the MARINE and ANCHOR trials. If granted, many of the resulting granted patents would expire in 2030 or beyond. However, no assurance can be given that any of our pending patent applications will be granted or, if they grant, that they will prevent competitors from competing with Vascepa.

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. The timing of the patent review process is independent of and has no effect on the timing of the FDA's review of our NDA or supplemental NDA submissions. We cannot predict the timing or results of any patent application. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Providing such additional evidence could prolong the patent office's review of our applications and result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

***If Vascepa is not granted new chemical entity exclusivity protection from the FDA our business may be materially harmed.\****

Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

The FDA typically publishes a determination on the marketing exclusivity of recently approved products in a cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, mid-month in the month following the drug's approval. Vascepa was approved by the FDA in July 2012, but we have not yet been informed of a determination by the FDA on our pending exclusivity request for Vascepa. Since prior to FDA approval of the Vascepa new drug application, we have had an active dialogue with the FDA related to our marketing exclusivity request for Vascepa, which requested NCE status for Vascepa. In recent months, we have repeatedly followed up with the FDA seeking a determination. While we continue to believe our arguments in support of an NCE determination for Vascepa are strong, the FDA may not agree with our arguments. Based on our discussions with the FDA, we do not know what determination the FDA will reach regarding the pending exclusivity request for Vascepa or when the FDA will make such determination. We have been informed by FDA that the FDA has drafted a proposed response letter to our exclusivity request, that such draft response letter has been circulated internally at the FDA for comment and the FDA has been considering the issue actively. However, we have not been informed of the content of the FDA's draft response and cannot, based on our communications with the FDA, make a reliable prediction as to when the FDA

will communicate a determination on the matter. Accordingly, we have not been informed as to what determination the FDA will make with respect to pending Vascepa marketing exclusivity request. There can be no assurance that Vascepa will be granted NCE exclusivity, or that the FDA will make a determination on the pending exclusivity request in a timely manner.

**Table of Contents**

NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or certain abbreviated new drug applications submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, Amarin may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the end of the five-year exclusivity period, and may also be afforded other extensions under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats to our commercialization of these compounds from other manufacturers, including the manufacturers of generic alternatives. Further, even if Vascepa is considered to be a NCE and we are able to gain five-year marketing exclusivity, another company could challenge that decision to seek to overturn FDA's determination. Another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Amendments, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

If Vascepa is not granted NCE marketing exclusivity, we expect it will be granted three years of new product exclusivity under the Hatch-Waxman Amendments. Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of Vascepa, a product candidate that the FDA views as having the same conditions of approval as Vascepa (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with Vascepa as the reference product, for a period of three years from the date of FDA approval, although the FDA may accept and commence review of such applications during the exclusivity period. Such three-year exclusivity grant would not prevent a company from challenging the validity of our patents at any time. In this case, Amarin may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the period that Amarin responds to a pending patent challenge, and may also be afforded other extensions under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

*Despite the use of confidentiality agreements and/or proprietary rights agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.*

We will also rely upon trade secrets and know-how to help protect our competitive position. We rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require certain of our academic collaborators, contractors and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information.

**Risks Related to our Business**

*Potential technological changes in our field of business create considerable uncertainty.*

We are engaged in the biopharmaceutical field, which is characterized by extensive research efforts and rapid technological progress. New developments in research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render some or all of our programs or product candidates uncompetitive or obsolete. Our business strategy is based in part upon new and unproven technologies to the development of therapeutics to improve cardiovascular health. We cannot assure you that unforeseen problems will not develop with these technologies or applications or that any commercially feasible products will ultimately be developed by us.

*We are subject to potential product liability.*

Following the commercial launch of Vascepa, we will be subject to the potential risk of product liability claims relating to the manufacturing and marketing of Vascepa. Any person who is injured as a result of using Vascepa may have a product liability claim against us without having to prove that we were at fault.

In addition, we could be subject to product liability claims by persons who took part in clinical trials involving our current or former development stage products. A successful claim brought against us could have a material adverse effect on our business. We cannot guarantee that a product liability claim will not be asserted against us in the future.

*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 Yisum Research Development Company of The Hebrew University of Jerusalem.

---

## **Table of Contents**

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 any future payment obligations payable by us 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 us. 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 several communications on behalf of the former shareholders of Ester asserting that we are in breach of its amended agreement due to the fact that the Yissum terminated its license and we 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.

***We will incur significant, increased costs as a result of provisions of the Sarbanes-Oxley Act of 2002, and our management will be required to devote substantial time to new compliance initiatives.***

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we perform system and process evaluation and testing of our internal controls over financial reporting and our independent registered public accounting firm reports on the effectiveness of our internal controls over financial reporting, as required by Section 404 of The Sarbanes-Oxley Act of 2002. Based on this evaluation and testing, our management identified a material weakness in internal control over financial reporting as of December 31, 2009 which persisted on December 31, 2010 and which was remediated as of December 31, 2011. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be new material weaknesses. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, the identification by us or our independent registered public accounting firm of deficiencies in our internal controls that are deemed to be additional material weaknesses could cause the market price of the ADSs to decline, and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

***We have previously identified a material weakness in our internal control over financial reporting in the past and cannot assure you that material weaknesses will not occur in the future.***

As part of the annual financial statement review under International Financial Reporting Standards for the period ended December 31, 2009, management concluded that as of December 31, 2009 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. Accordingly, management determined that this control deficiency constituted a material weakness. During 2010, we did not engage in any new non-routine transactions. Nevertheless, based on management's evaluation of our internal control over financial reporting as of December 31, 2010, management determined that this material weakness in our internal control over financial reporting remained. 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 to remediate the control deficiency: non-ordinary course transactions are now 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. Any future deficiencies could materially and adversely affect our ability to provide timely and accurate financial information, and the current and future deficiencies may impact investors' confidence in our internal controls and our company, which could cause our stock price to decline.

***A change in our tax residence could have a negative effect on our future profitability.***

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

Under current U.K. legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the U.K., is regarded as resident in the U.K. for taxation purposes. Under current Irish legislation, a company is regarded as resident for tax purposes in

## **Table of Contents**

Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Where a company is treated as tax resident under the domestic laws of both the U.K. and Ireland then the provisions of article 4(3) of the Double Tax Convention between the U.K. and Ireland provides that such enterprise shall be treated as resident only in the jurisdiction in which its place of effective management is situated. We have sought to conduct our affairs in such a way so as to be resident only in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland. Trading income of an Irish company is generally taxable at the Irish corporation tax rate of 12.5%. Non-trading income of an Irish company (e.g., interest income, rental income or other passive income), is taxable at a rate of 25%.

However, we cannot assure you that we are or will continue to be resident only in Ireland for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become resident in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets. Similarly, if the tax residency of any of our subsidiaries were to change from their current jurisdiction for any of the reasons listed above, we may be subject to a charge to local capital gains tax charge on the assets.

### ***The loss of key personnel could have an adverse effect on our business.\****

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. As a small company with a streamlined management structure, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, as our business plan progresses we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we evolve from a development stage company to a commercial stage company we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

### **Risks Related to Ownership of our ADSs and Common Shares**

#### ***The price of our ADSs and common shares may be volatile.***

The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In addition, the market prices of the securities of many pharmaceutical and medical technology companies have been especially volatile in the past, and this trend is expected to continue in the future.

As of November 1, 2012 we had 150,134,630 common shares outstanding. As of November 1, 2012 there were 149,769,550 shares held as ADSs and 365,080 held as common shares (which are not held in the form of ADSs). In our October 2009 private placement we issued 66.4 million ADSs and warrants to purchase an additional 33.2 million ADSs. There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. If any of our large investors, such as the participants in our October 2009 private placement, seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

The market price of our ADSs and common shares may also be affected by factors such as:

the status of our pending exclusivity request with the FDA for Vascepa and ongoing;

developments or disputes concerning ongoing patent prosecution efforts and any future patent or proprietary rights;

regulatory developments in the United States, the European Union or other countries;

actual or potential medical results relating to our products or our competitors' products;

interim failures or setbacks in product development;

innovation by us or our competitors;

currency exchange rate fluctuations; and

period-to-period variations in our results of operations.

***Actual or potential sales of our common shares by our employees, including members of our senior management team, pursuant to pre-arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.***

In accordance with the guidelines specified under Rule 10b5-1 of the Securities and Exchange Act of 1934 and our policies regarding stock transactions, a number of our directors and employees, including members of our senior management team, have adopted and may continue to adopt pre-arranged stock trading plans to sell a portion of our common stock. Generally, sales under such plans by members of our

---

## **Table of Contents**

senior management team and directors require public filings. Actual or potential sales of our ADSs by such persons could cause the price of our ADSs to fall or prevent it from increasing for numerous reasons. For example, a substantial amount of our ADSs becoming available (or being perceived to become available) for sale in the public market could cause the market price of our ADSs to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.

### ***Our existing indebtedness could adversely affect our financial condition.***

Our existing indebtedness, which we entered into in January 2012, consists of \$150.0 million in aggregate principal amount of 3.50% exchangeable senior notes due 2032, with provisions for the notes to be called on or after January 19, 2017. Our indebtedness and the related annual debt service requirements may adversely impact our business, operations and financial condition in the future. For example, they could:

increase our vulnerability to general adverse economic and industry conditions;

limit our ability to raise additional funds by borrowing or engaging in equity sales in order to fund future working capital, capital expenditures, research and development and other general corporate requirements;

require us to dedicate a substantial portion of our cash to service payments on our debt; or

limit our flexibility to react to changes in our business and the industry in which we operate or to pursue certain strategic opportunities that may present themselves.

### ***The accounting method for convertible debt securities that may be settled in cash, such as our notes, could have a material effect on our reported financial results.***

Under the FASB Accounting Standards Codification, or ASC, we may be required to separately account for the liability and equity components of the convertible debt instruments (such as the notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC on the accounting for our outstanding convertible notes may be that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheets and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the notes. As a result, we may be required to record non-cash interest expense as a result of the amortization of the discounted carrying value of the notes to their face amount over the term of the notes. We may be required to report higher interest expense in our financial results because ASC may require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results and the trading price of our ADSs.

Servicing our debt may require a significant amount of cash, and we may not have sufficient cash flow from our business to provide the funds sufficient to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the notes, and have a material adverse effect on the trading price of our ADSs.

We may be able to incur substantial additional debt in the future, subject to the restrictions contained in our future debt instruments, if any, which would intensify the risks discussed above.

***We may be a passive foreign investment company, or PFIC, which would result in adverse U.S. tax consequences to U.S. investors.***

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

Amarin Corporation plc and certain of our subsidiaries may be classified as passive foreign investment companies, or PFICs, for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. The application of these factors depends upon our financial results, which are beyond our ability to predict or control, and which may be subject to legal and factual uncertainties.

While we cannot provide any assurance that we are, are not, or will or will not be, a PFIC now or in the future, we believe it prudent to assume that the we were classified as a PFIC in 2011 and that we could be classified as such in 2012 or in future years.

If we are a PFIC, U.S. holders of notes, ordinary shares or ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Whether or not U.S. holders of our ADSs make a timely QEF election or mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect

---

**Table of Contents**

to the acquisition, ownership and disposition of Amarin ADSs and any distributions such U.S. Holders may receive. A QEF election and other elections that may mitigate the effect of our being classified as a PFIC are unavailable with respect to the notes. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to the notes, ordinary shares and ADSs.

***The conditional exchange feature of the notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional exchange feature of the notes is triggered, holders of notes will be entitled to exchange the notes at any time during specified periods at their option. If one or more holders elect to exchange their notes, unless we elect to satisfy its exchange obligation by delivering solely the ADSs (other than cash in lieu of any fractional ADS), we would be required to settle a portion or all of its exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to exchange their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***The fundamental change repurchase feature of the notes may delay or prevent an otherwise beneficial takeover attempt of us.***

The indenture governing the notes will require us to repurchase the notes for cash upon the occurrence of a fundamental change of Amarin and, in certain circumstances, to increase the exchange rate for a holder that exchanges its notes in connection with a make-whole fundamental change. A takeover of us may trigger the requirement that we purchase the notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us. Such additional costs may have the effect of delaying or preventing a takeover of us that would otherwise be beneficial to investors.

***We do not intend to pay cash dividends on the ordinary shares in the foreseeable future.***

We have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on the ordinary shares in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our Articles of Association, which requires that all dividends must be approved by our Board of Directors and, in some cases, our shareholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis.

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.***

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. The principal differences include the following:

Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings. Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depository bank.

Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.

Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution, including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

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

In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a squeeze out to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares/ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders representing 75% of the ordinary shares and a majority of the shareholders voting at the meeting for approval.

Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.

---

## **Table of Contents**

The quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

***We may in the future be subject to the UK Takeover Code which we do not believe is binding on our company at the present time. Nevertheless, the UK Takeover Code could apply to our company under certain circumstances in the future.\****

We may in the future be subject to the UK City Code on Takeovers and Mergers which we do not believe is binding on our company at the present time.

In the United Kingdom, takeover offers and certain other transactions in respect of certain public companies are regulated by the UK City Code on Takeovers and Mergers, or the Takeover Code, which is administered by the Takeover Panel. Currently, the Takeover Code applies to public companies which have their registered offices in the United Kingdom, the Channel Islands or the Isle of Man if their securities are admitted to trading on a regulated market in the United Kingdom or on a stock exchange in the Channel Islands or the Isle of Man. The Takeover Code also applies to public companies which have their registered office in the United Kingdom, the Channel Islands or the Isle of Man notwithstanding that their securities are not admitted to trading on one of the markets mentioned above, if the Takeover Panel considers that the company has its place of central management and control in the UK, the Channel Islands or the Isle of Man, or the so-called residency test. We do not believe that our company has its place of central management and control in the UK, the Channel Islands or the Isle of Man and we therefore do not believe that the Takeover Code currently applies to us.

In July 2012, the Takeover Panel published three public consultation papers setting out proposed amendments to the Takeover Code, which include a proposal to eliminate the residency test described above. If this proposal is adopted, we could become subject to the Takeover Code since our registered office is in the United Kingdom.

In summary, the Takeover Code sets out binding rules that provide a framework within which takeovers are required to be conducted and this approach differs from the typical U.S. approach which permits the incumbent board greater flexibility to act in a manner it believes is in the best interests of shareholders. The Takeover Code is designed principally to ensure that shareholders in an offeree company are treated fairly, that they are not denied an opportunity to decide on the merits of a takeover and that they are each afforded equivalent treatment by an offeror.

One of the rules of the Takeover Code requires that if an offeror (and persons acting in concert with it) were to acquire interests in our ordinary shares representing 30% or more of the voting rights of all our ordinary shares, the offeror (and, depending upon the circumstances, persons acting in concert with it) would be required (except with the consent of the Takeover Panel) to make a cash offer for the outstanding ordinary shares at a price not less than the highest price paid for any interest in the ordinary shares by the offeror (or persons acting in concert with it) during the 12 months prior to the announcement of that offer. A similar obligation to make such a mandatory offer would also arise on the acquisition of an interest in our ordinary shares by a person holding (together with persons acting in concert with it) an interest representing between 30% and 50% of the voting rights of all our ordinary shares.

If we become subject to the Takeover Code, we will be subject to greater controls in relation to the conduct of any takeover offer for our ordinary shares and this may affect the willingness of potential acquirers to proceed with a takeover offer that would otherwise be beneficial to investors. In addition, if we become subject to the Takeover Code, our board of directors would be less able to exercise its judgment over the conduct of any proposed takeover than it would if the Takeover Code did not apply.

***U.S. shareholders may not be able to enforce civil liabilities against us.***

We are incorporated under the laws of England and Wales, and our subsidiaries are incorporated in various jurisdictions, including foreign jurisdictions. A number of the officers and directors of each of our subsidiaries are non-residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our English solicitors that there is doubt as to the enforceability in England in original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal securities laws of the United States.

***Our directors, management and affiliated investment funds exercise significant control over our company, which will limit your ability to influence corporate matters.***

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

As of October 31, 2012 our executive officers, directors and affiliated investment funds collectively controlled approximately 10.23% of our outstanding ordinary shares, excluding any shares subject to ADSs that such persons may have the right to acquire upon exercise of outstanding options or warrants. As a result, these shareholders, if they act together, will be able to influence our management and affairs and all matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions.

## **Table of Contents**

In addition, we entered into an agreement with various participants in the October 2009 private placement under which investment funds affiliated with Orbimed Advisors LLC, Sofinnova Ventures and Abingworth LLP have the ability to designate persons for Amarin to nominate to its Board of Directors and the other participants have given these investment funds a proxy to vote their securities in favor of these nominees. We have a continuing obligation to nominate one (1) designee of investment funds affiliated with Sofinnova Ventures to its Board of Directors for so long as such funds beneficially own at least fifty percent (50%) of the ADSs they purchased in the October 2009 private placement. Dr. James I. Healy was designated by investment funds affiliated with Sofinnova Ventures pursuant to this arrangement. In addition, we have agreed to nominate one (1) designee of investment funds affiliated with Abingworth LLP to its Board of Directors for so long as such funds beneficially own at least five percent (5%) of our outstanding voting securities. Dr. Joseph Anderson was designated by investment funds affiliated with Abingworth LLP under this arrangement. This concentration of ownership and the above-described arrangement may have the effect of delaying or preventing a change in control of our company that other shareholders may desire and might negatively affect the market price of the ADSs.

***U.S. holders of the ADSs or ordinary shares may be subject to U.S. income taxation at ordinary income tax rates on undistributed earnings and profits.***

There is a risk that we will be classified as a controlled foreign corporation, or CFC, for U.S. federal income tax purposes. If we are classified as a CFC, any ADS holder or shareholder that is a U.S. person that owns directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares may be subject to U.S. income taxation at ordinary income tax rates on all or a portion of our undistributed earnings and profits attributable to subpart F income. Such 10% holder may also be taxable at ordinary income tax rates on any gain realized on a sale of ordinary shares or ADS, to the extent of our current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U.S. Holders of the ordinary shares or ADSs are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

**Table of Contents****Item 6. Exhibits**

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

Exhibit Number	Description
10.1	Second Amendment to API Commercial Supply Agreement by and between Amarin Pharmaceuticals Ireland Ltd. and Chemport Inc., dated July 19, 2012
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 Schema Document
101.CAL**	XBRL Calculation Linkbase Document
101.LAB**	XBRL Labels Linkbase Document
101.PRE**	XBRL Presentation Linkbase Document
101.DEF**	XBRL Definition Linkbase Document

\* Furnished herewith

\*\* 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.

Confidential treatment has been requested with respect to portions of this exhibit pursuant to an application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.

**Table of Contents**

**SIGNATURE**

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

AMARIN CORPORATION PLC

By: /s/ John F. Thero  
John F. Thero  
*President* (Principal Financial and Accounting  
Officer)

(On behalf of the Registrant)

Date: November 8, 2012